Attachment: 10-Q

Exhibit 10.1

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT, MARKED BY BRACKETS, WERE OMITTED BECAUSE THOSE PORTIONS ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL TO THE COMPANY IF PUBLICLY DISCLOSED.

BASE AGREEMENT

BETWEEN

ADVANCED TECHNOLOGY INTERNATIONAL (ATI)
315 SIGMA DRIVE

SUMMERVILLE, SC 29486

AND

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591

MEDICAL CBRN DEFENSE CONSORTIUM (MCDC) BASE AGREEMENT NO.: 2020-504

Authority: MCDC Other Transaction Agreement (OTA) No. W15QKN-16-9-1002 and 10 U.S.C. § 2371b, Section 815 of the 2016 National Defense Authorization Act (NDAA), Public Law (P.L.) 114-92.

This Agreement is entered into between the Advanced Technology International hereinafter referred to as the "Consortium Management Finn (CMF)," and Regeneron Pharmaceuticals. Inc, hereinafter referred to as "Project Agreement Holder." This Agreement constitutes the entire understanding and agreement between the parties with respect to the subject matter hereof and supersedes all prior representations and agreements. It shall not be varied except by an instrument in writing of subsequent date duly executed by an authorized representative of each of the parties. The validity, construction, scope and performance of this Agreement shall be governed by the laws of the state of South Carolina, excluding its choice of laws rules.

ADVANCED TECHNOLOGY INTERNATIONAL	REGENERON PHARMACEUTICALS, INC.
/s/	/s/ Robert Landry
(Signature)	(Signature)
_____	Robert Landry, Executive Vice President, Finance and Chief Financial Officer
(Name & Title)	(Name & Title)
July 6 2020	July 6 2020
(Date)	(Date)

Article I. SCOPE OF THE AGREEMENT

Section 1.01 Background

The U.S. Army Contracting Command-New Jersey (ACC-NJ) is entering into a Section 815 Prototype Other Transaction Agreement (OTA) with the Medical CBRN Defense Consortium, c/o Advanced Technology International 315 Sigma Drive, Summerville, SC 29486. The Joint Project Manager for Medical Countermeasure Systems (JPM-MCS) through the Joint Program Executive Office for Chemical and Biological Defense (JPEO- CBD) seeks to collaborate with the MCDC to carry out a coordinated research and development program. An OTA is being proposed with the purpose of conducting Research and Development into medical, pharmaceutical, and diagnostic technologies to enhance mission effectiveness of military personnel. The MCDC was formed in response to the Government's expressed interest to engage with an industry consortium comprised of traditional and nontraditional government contractors, small and large businesses, for-profit and not-for-profit entities, academic organizations and their affiliates for the purpose of entering into an OTA for prototype projects.

Under the OTA and associated awards, the Government, along with the non-government members from the MCDC, shall perform coordinated planning and research and development prototype efforts designed to encompass the areas contained within the scope of this OTA as listed in Article I, Section 1.03.

Section 1.02 Definitions

"Academic Research Institution" means accredited institutions (colleges, universities or other educational institutions) of higher learning in the U.S.

"Agreement" refers to the Base Agreement between the Medical CBRN Defense Consortium (MCDC) Consortium Management Firm (CMF) Advanced Technology International (ATI) and the Project Agreement Holder.

"Agreements Officer (AO)" is the U.S. Army Contracting Command – New Jersey's warranted Contracting Officer authorized to sign the final OTA for the Government.

"Agreements Officer Representative (AOR)" is the individual designated by the Government on a per project basis to monitor all technical aspects and assist in agreement administration of the specific project; the AOR shall only assist in agreement administration of the specific project to the extent delegated such administration authority in writing in the AOR delegation letter by the responsible Agreements Officer.

"Basket" is an electronic file containing proposals that have been submitted by MCDC Members in response to Requests for Prototype Proposals (RPP), reviewed by the Government, and favorably evaluated in accordance with the procedures outlined in Section 1.03 of this Article.

"Cash Contribution" means a MCDC member organization's financial resources expended to conduct a project awarded under this Agreement. The cash contribution can be derived from MCDC member organization funds or outside sources or may also come from non-federal contract or grant revenues or from profit or fee on a federal procurement contract. A MCDC member organization's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds can be utilized as a cash contribution provided those funds identified by the MCDC member organization are to be spent on the conduct of a project's Statement of Work. Prior IR&D will not be considered as part of the MCDC member organization's cash or in kind contributions nor will fee be considered on the Project Awards that include cost sharing. Cash contributions include the funds a MCDC member organization will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), subcontractor efforts expended on a project, and restocking the parts and material consumed under a project.

"Consortium Management Firm (CMF)" refers to the organization acting on behalf of the MCDC to execute and administer the efforts under the Other Transaction Agreement for this program as defined in the specific agreement

entered into between the MCDC and the CMF. The current CMF is Advanced Technology International (ATI). The MCDC reserves the right to replace the CMF at any time.

“Cost Share” means resources expended by the PAH on the proposed project SOW and subject to the direction of the AOR. There are two kinds of cost share: cash contribution and in-kind contribution. Cost Share may only be proposed and collected on cost-reimbursement type agreements.

“Contracting Activity” means an element of an agency designated by the agency head and delegated broad authority regarding acquisition functions. It also means elements or another agency designated by the director of a defense agency which has been delegated contracting authority through its agency charter.

“Date of Completion” is the date on which all work is completed or the date on which the period of performance ends.

“Development” means the systematic use, under whatever name, of scientific and technical knowledge in the design, development, test, or evaluation of an existing or potential new technology, product or service (or of an improvement in an existing technology, product or service) for the purpose of meeting specific performance requirements or objectives. Development includes the research functions of design engineering, prototyping, and engineering testing.

“Effective Date” means the date when this Agreement is signed and executed by the Agreements Officer for the Government.

“Government” means the US Government and its departments and agencies.

“Government Fiscal Year” means the period commencing on October 1 and ending September 30 of the following calendar year.

“In Kind Contribution” means the MCDC member organization’s nonfinancial resources expended by the MCDC member organization to conduct a project, such as wear and tear on in-place capital assets like machinery or the prorated value of space used for the conduct of a project, and the reasonable fair market value (appropriately prorated) of equipment, materials, and other property used in the conduct of the project.

“JPM-MCS” means the Joint Project Manager-Medical Countermeasure Systems Office created for the advanced development of medical countermeasures for chemical and biological defense. The JPM-MCS is also the program management office for this overall effort. The JPM-MCS includes an array of stakeholders involved in the development of prototype hardware, software, and system technologies.

“Milestone” means a scheduled event signifying the completion of a major deliverable or a set of related deliverables.

“Medical CBRN Defense Consortium” is the consortium formed by industry in response to the Government’s expressed interest to quickly provide the warfighter with safe and effective chemical, biological, radiological, and nuclear countermeasures. The MCDC is comprised of Traditional and Nontraditional Defense Contractors, including small and large (other than small) businesses, for profit, and not for profit entities, and academic research institutions. The MCDC was originally named the National Chemical and Biologic Defense Consortium.

“MCDC Executive Committee” is the Executive Committee, comprised of Traditional and Nontraditional Defense Contractors, including small and large businesses, for profit and not for profit entities, and academic research institutions.

“MCDC Members” means the Nontraditional and Traditional Defense Contractors, including small and large businesses, for profit and not for profit entities, and Academic Research Institutions that are members in good standing of the MCDC.

“Nontraditional Defense Contractor” with respect to applicable authority, means an entity that is not currently performing and has not performed, for at least the one-year period preceding the solicitation of sources by the Department of Defense for the procurement or transaction, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to section 1502 of title 41 and the regulations implementing such section.

“Other Transaction Agreement (OTA)” refers to the Section 815 Other Transaction Agreement between the Government and the MCDC by its Consortium Management Firm, Advanced Technology International, Agreement No. W15QKN-16-9-1002.

“Other Transactions for Prototype Projects” refers to this type of Other Transaction Agreement (OTA). Section 815 of Public Law 114-92 authorizes the use of OTAs, under the authority of 10 U.S.C. 2371(b), under certain circumstances for prototype projects directly relevant to enhancing the mission effectiveness of military personnel and supporting the platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. This type of OTA is treated by DoD as an acquisition instrument, commonly referred to as an “other transaction” for a prototype project or Section 815 “other transaction”.

“Parties” means the Consortium Management Firm, Advanced Technology International, and the Project Agreement Holder where collectively identified and “Party” where each entity is individually identified.

“Payable Milestone” means that once a milestone has been met (see definition of “milestone”), the Government can approve payment to the MCDC of a predetermined dollar amount in relation to performance of a particular project under the Other Transaction Agreement.

“Program Manager” means the Technical Administrator for the Program (located at the JPM-MCS) responsible for Government oversight of the MCDC OTA program.

“Project” refers to the scope of work being completed under a Project Agreement.

“Project Agreement (PA)” means that agreement between the MCDC, by its CMF, and the MCDC member entity whose proposal is evaluated and competitively selected by the Government for funding, establishing the scope of work, terms and conditions for the MCDC member entity performance and payment under the Government funded project. Project Agreements shall comply with all provisions contained within the OTA and any other supporting documents referenced therein. The Project Agreement is initiated by the CMF based on the Technical Direction Letter sent by the Government to the CMF.

“Project Agreement Holder (PAH)” means the MCDC member entity issued a Project Agreement by the CMF.

“Technical Direction Letter (TDL)” is a Government document to be issued to the CMF reflecting the Government's decision to select and fund all or part of a particular proposal submitted by a MCDC member or team of MCDC members through the RPP process conducted under this OTA. The TDL shall establish the scope of work, terms and conditions for performance and payment and include the MCDC member proposal selected for Government funding. Where a specific Government agency laboratory, test facility, center or other location will be used by the MCDC member entity in performance of the Project Agreement, it will be identified and the cost of such use, whether Government-contributed or MCDC member reimbursed, will be identified in the TDL.

“United States Army Contracting Command – New Jersey Contracting Activity” (ACC-NJ) means the contracting activity who is designated as the lead Government organization in charge of executing the Program.

“White Paper” means a document limited to a few pages prepared and submitted by a MCDC member(s) in response to a Government solicitation issued under the terms and conditions of the OTA that briefly describes and summarizes a technology idea or concept for an indicated research area in a Government-specified format. The White Papers are evaluated by the Government to determine whether submission of a full proposal on the summarized concept or idea might be warranted. To the extent that a MCDC member(s) desires to include

proprietary information in the white paper it shall be identified and marked in accordance with the terms for protection of information under Article VIII. Confidential Information.

Section 1.03 Scope

The Government in conjunction with the MCDC member entities shall perform a coordinated research and development program designed to support the DoD's medical, pharmaceutical, and diagnostic requirements as related to enhancing the mission effectiveness of military personnel. The mission of JPM-MCS is to provide the U.S. military forces and the nation safe, effective, and innovative medical solutions to counter Chemical Biological Radiological and Nuclear (CBRN) threats. Under the OTA and associated Project Agreements, the Government along with the Consortium member entities, shall perform coordinated planning and research and development prototype efforts in support of the JPM-MCS mission through the development of products in three (3) major Medical Countermeasure Systems (MCS) objective areas:

- Detection: Systems and devices to identify CBRN agents and assist in making medical decisions
- Prevention: Prophylaxis, pretreatment, and post-exposure prophylaxis
- Treatment: Therapeutics (post-exposure, post-symptomatic)

The Government will determine which endeavors to pursue and projects to fund. At any time throughout the term of the OTA, the Government may address the needs for the desired MCS objective areas or other related Government needs as they arise. The MCDC and the Government agree that other organizations and agencies within the U.S. Government may participate in the collaborative activities through a Memorandum of Agreement or other such arrangement. It is anticipated that these other organizations may include JPEO-CBD and DTRA.

Request for Prototype Proposal (RPP) Process:

Once the Government identifies a need under one of the MCS objective areas above, the Government will issue a Request for Prototype Proposal (RPP). The RPP will include a Request for White Papers (RWP) and/or a Request for Prototype Proposal (RPP) to the Consortium Management Firm (CMF). Due dates will be indicated for each. The CMF shall in turn issue a similar request to MCDC's member entities, for which the Government will review and evaluate all responses. The Government will be solely responsible for evaluation of the white papers and/or proposal submissions, as applicable. If the RPP includes a RWP, only members submitting white papers will be permitted to submit full proposal submissions. Based on the evaluation of the white papers, the Government will make a recommendation on whether the member should or should not submit a full proposal submission. Any member submitting a white paper, regardless of the Government's recommendation, may submit a proposal.

MCDC member white papers and proposals shall be submitted to the CMF in accordance with the RPP instructions which will include evaluation criteria and a Statement of Work (SOW) template on the due date indicated in the RPP. The CMF will review white paper and proposal submissions for completeness and format compliance. The CMF shall in turn prepare and transmit MCDC's member's white papers and proposals to the Government for evaluation. The Government will be responsible for technical evaluation and selection of the projects from the proposals submitted. The CMF will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government Agreement Officer will review this assessment and make the final determination regarding whether the negotiated project cost is fair and reasonable. All Project Agreements will be subject to discussions/negotiations and proposal updates, as appropriate, prior to execution.

Once all steps are complete, the Government will issue a Technical Direction Letter (TDL) to the CMF for the authorization and execution of the selected project to be performed by the selected MCDC's member entity(ies). Once the CMF receives notification of selection of a project for funding via TDL, the CMF will enter into a Project Agreement with the MCDC member.

A modification will be included with the TDL, which will include the funding for the negotiated and agreed-upon project. After receipt of the TDL and review and execution of the funding modification, the CMF shall enter into a Project Agreement (PA) with MCDC member whose project was selected. MCDC CMF shall administer the

Government-funded Project Agreements. The Government's designated Agreements Officer Representative (AOR) for the specific project will supervise the technical work performed by MCDC's member entity in execution of the

PA. The Government reserves the right to revise the terms and conditions of these projects in accordance with Article III, Section 3.04.

Placement in the Electronic "Basket File":

Qualifying proposals, not eligible for current funding, may be entered into an electronic basket and subject to award for up to thirty-six (36) months. The RPP will contain the available ratings and their definitions to be assigned to proposals as a result of the technical evaluation as well as which specific ratings will qualify a proposal for inclusion in the Basket. The Government reserves the right to determine which, if any, proposals are to be selected according to the published criteria.

Once in the Basket, a proposal may be identified for award by the Government based on Government need and availability of funding. The Government reserves the right to 1.) request that the MCDC member who submitted the identified proposal, scale or otherwise adjust the original proposal, and to 2.) fund all or part of the identified proposal. The MCDC member will have an opportunity to update their proposal, as applicable, if selected from the basket. The Government will review any updated information provided by the MCDC member and/or CMF. Upon the Government's decision to fund such a proposal from the Basket, the CMF will receive notification of the award decision through a TDL whereupon the CMF will enter into a Project Agreement with the indicated MCDC member as required.

A selected proposal will reside in the Basket for thirty-six (36) months from the date the corresponding RPP is closed unless funded or the submitting MCDC member requests in writing beforehand to have it removed.

SBIR Phase III Project Requests

It will be incumbent upon the MCDC member, on their own with some general support and guidance from the CMF, to find a Government Technical POC with both (1) available funding and (2) an interest in furthering technology developed under a current or prior SBIR project. Upon doing so, the Government Technical POC will coordinate the feasibility of placing the award under the OTA with the Government AO and OTA Program Manager and the following areas will be considered when making a determination for appropriateness of award under the OTA:

- How the proposed effort derives from, extends, or logically concludes efforts performed under prior SBIR funding agreements;
- How the proposed effort fits within the definition of a prototype effort related to medical, pharmaceutical, and diagnostic technologies to enhance mission effectiveness of military personnel in accordance with the statutory requirement;
- How the proposed effort fits within the overall scope of work and the goals and objectives of the OTA.

Should the Government AO and the OTA Program Manager determine it is appropriate to award the SBIR Phase III under the OTA, the Government AO will send a proposal request to the MCDC member through the CMF, as is standard for any Government request under the OTA. The CMF will provide a cost analysis summary to the Government Agreements Officer (AO) for consideration in the Government's award determination. The Government will evaluate the proposal, conduct any necessary negotiations through the CMF, and make an award determination. If the Government makes the determination to award to the MCDC member, the Government AO will issue a TDL letter to the CMF, resulting in the issuance of a Project Agreement between the CMF and MCDC member.

SBIR Phase III awards under this Agreement shall include the Data Rights provisions and Data Rights granted to the MCDC member contained within Article XI of this Agreement. All administrative, reporting, and other aspects of awards made for SBIR Phase III efforts under this Agreement will be in accordance with the terms and conditions of the OTA. MCDC Members must have been awarded and performed under a previous SBIR Phase I and/or Phase II contract in order to qualify for SBIR Phase III award under this Agreement.

Section 1.04 Goals/Objectives

The following goals/objectives will be pursued through the execution of the OTA:

- Accelerate the development of mission critical technologies in the areas of concern from applied research into advanced development.
- Deliver therapeutic MCM prototypes targeting viral, bacterial, and biological toxin targets of interest to the DOD. MCM prototypes are drug products that have completed all or part of the activities required to support FDA licensure. This may include meeting warfighter requirements of protection against an aerosolized route of exposure.
- Deliver enabling technologies that will support the development and regulatory review of MCM prototypes. The enabling technologies can include animal models of viral, bacterial or biological toxin disease and pathogenesis (multiple routes of exposure), assays, diagnostic technologies or other platform technologies applicable to development and regulatory review of MCM.
- Develop prototype candidates for the prophylaxis, treatment and diagnosis of Chemical threats. This will include diagnosis of, and prophylaxis and treatment for, exposure to traditional and emerging chemical nerve agent threats, as well as other emerging chemical threat agents other than nerve agents.
- Develop prototype candidates for the prophylaxis, treatment and diagnosis of Radiological and Nuclear threats. This will include prototype candidates for diagnosis of, and prophylaxis and treatment for Acute Radiation Syndrome.
- Develop soldier-carried autoinjector delivery devices for single drug administration. Develop soldier-carried autoinjector delivery devices for administration of two or more drugs.
- Develop vaccine-manufacturing platforms that offer early stage manufacturing flexibility and diversity using a deep knowledge of protein(s) expression in a biological system that is reproducible and scalable, and preferably with direct FDA experience. The goal is to manufacture and test identified protective molecule(s) and target molecule(s) (along with associated reagents and standards) in multiple scalable, flexible manufacturing platforms encompassing a diverse array of manufacturing systems (e.g., insect, mammalian, live viral, plant, *E.coli*, yeast, etc.) for use in appropriate animal model(s) and in Phase 1 trials.
- Pharmaceutical development will address the FDA Animal Rule, as appropriate.
- Utilize adjuvants and excipients supporting the ability to develop up to 300,000 equivalent doses within 60 days at clinical quality.
- Support a family of systems diagnostic approach that increases the speed, accuracy, and confidence of agent identification and disease diagnosis. Diagnostic areas include those for organisms that circulate freely and at relatively high numbers at or near the onset of symptoms, organisms that circulate in low numbers early in infection but then integrate with host cells, organisms that have significant genomic diversity from strain to strain, and non-BW agents such as toxins/chemical agents/radiological agents that do not replicate and require low quantities to cause illness.
- Support the Defense Biological Products Assurance Office (formally the Critical Reagents Program), the principal DoD resource of high quality, validated, and standardized biological reference materials, reagents, and assays, as necessary.
- DoD Advanced Development and Manufacturing Capabilities: To facilitate lessons learned and to ensure DoD MCM product development schedules are not impacted, the consortium will consider Advanced Development and Manufacturing (ADM) capability contractors for biologics manufacturing activities for monoclonal antibodies, vaccines, and recombinant proteins may utilize the DoD funded facility.
- Pursue collaborative research with non-traditional technology providers in a manner that enables effective transition of technologies to Government prototyping programs during any phase of life cycle support (affordability, manufacturability, sustainment, etc.).

Section 1.05 Reports

The MCDC member organizations conducting projects in accordance with this Agreement shall maintain records of the activities performed and funding expended under the projects and the results of any studies analyses, tests, and other investigations conducted. Based on the progress of the funded projects and other

information known to the AO or authorized designee, the MCS Program Office shall review the relevant projects throughout the period to determine if any changes to planning or budget are required. If such a change is expected which will cause a need to modify the OTA, the Technical Direction Letter or an individual Project Agreement may be modified to incorporate such changes. The AO is the only authorized representative of the Government who may make modifications to the OTA. PAHs shall submit the following reports to the CMF who will review and provide one cumulative report detailing status of all funded projects to the MCS Program Office.

a.) Project Agreement Quarterly Report. The report will have two major sections:

(i) Technical Status Report. The technical status report will detail technical progress to date and report on all problems, technical issues or major developments during the reporting period. Each of the topics described below shall be addressed for the effort performed:

(1) A comparison of actual accomplishments with the goals and objectives of the project established for the period.

(2) Reasons why established goals and objectives were not met, if appropriate.

(3) Other pertinent information including, when appropriate, analysis and explanation of cost variances.

(4) A cumulative chronological list of written publications in technical journals. Include those in press as well as manuscripts in preparation and planned for later submission. Indicate likely journals, authors, and titles.

(5) Papers presented at meetings, conferences, seminars, etc.

(ii) Business Status Report. The business status report shall provide summarized details of the resource status of the Project Agreement, including the status of the contributions by all participants. This report will include a quarterly accounting of current expenditures. Any major deviations from the agreed to project plans shall be explained with discussion of proposed actions to address the deviations. The report will also include an accounting of interest earned on Government Funds, if any. It is not expected that any interest will accrue under the Project Agreement(s), as milestone payments will be tracked and adjusted accordingly. In any event, the Government reserves the right to require interest amounts in excess of $250 per year to be remitted to the US Treasury.

b.) Annual Technical Report. Annual technical reports are required for projects whose periods of performance are greater than one year. The PAH's report will provide a concise and factual discussion of the significant accomplishments and progress during the year covered by the report.

c.) Final Technical Report.

(i) Final Technical Report (FTR). A Final Technical Report shall be submitted to the CMF within thirty (30) calendar days of the completion of the Project Agreement. This report will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the effort. Each of the topics described above shall be addressed as appropriate for the effort performed. Upon receipt, the AOR will review and provide any comments within 30 days. If necessary, the PAH will update the FTR within 30 days of receipt of AOR's comments. Once the CMF has informed PAH that the FTR has been approved by the AOR, the PAH shall forward a copy of the FTR to the Defense Technical Information Center, Attn. DTIC-O, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060-6218.

(ii) Format. The cover and title page shall be Standard Form (SF) 298, Report Documentation Page. Item 13 of the form should contain a 100 to 200 word abstract summarizing technical progress during the reporting

period. Style should be third person singular using past tense. Jargon, special symbols or notations, subscripts, mathematical symbols or foreign alphabet letters are not permitted. All pages should be prepared for acquisition and distribution by the Defense Technical Information Center (DTIC). All pages should be good quality for copying purposes. The report shall be prepared in accordance with American National Standards Institute (ANSI) document Z39.18-1987, "Scientific and Technical Reports: Organization, Preparation, and Production," which may be obtained from American National Standards Institute Incorporated, 1430 Broadway, New York, NY, 10018. The FTR front page shall be marked in a conspicuous place with a distribution statement to denote the extent of its availability for distribution, release, and disclosure without additional approvals or authorizations.

d.) Final Business Status Report. The final business status report shall provide summarized details of the resource status of the Project Agreement, including the status of the contributions by all participants. This report will include a final accounting of cumulative expenditures. If a project is terminated prior to the end of a quarter or a year and sufficient funding is available, the PAH, through the CMF, must submit a final technical and business status report in the same format as detailed herein.

Note: Deficiencies in regulatory reports must be adequately assessed by the Government, MCDC and the individual performer, or consortium as a whole, to come to resolution.

Article II. TERM

Section 2.01 The Term of this Agreement

The period of performance for this Agreement is from the effective date, which is the date of last signature, to April 7, 2036. If at any time funds expended exceed the amount obligated on a Project Agreement prior to the expiration of the term, the Parties have no obligation to continue performance and may elect to cease their efforts at that point. Provisions of this Agreement, which, by their express terms or by necessary implication, apply for periods of time other than specified in Article II herein, shall be given effect, notwithstanding this Article.

Section 2.02 Termination of this Agreement by Mutual Agreement

Except for the rights and obligations with respect to proprietary information and/or specific intellectual property agreements between or amongst the Government, the CMF and the MCDC member organizations, unless extended by mutual written agreement of the Parties, this Agreement shall automatically terminate by written agreement of the Parties. Unless otherwise directed by the AO through the CMF, individual Project Agreements pursuant to this Agreement shall also terminate upon the termination of this Agreement.

Section 2.03 Termination Provisions

Subject to a reasonable determination that the program, or a project funded under the program, will not produce beneficial results commensurate with the expenditure of resources, the Government may terminate performance of work under this OTA or a specific project, in whole or in part, if the AO determines that a termination is in the Government’s interest. The AO shall terminate by delivering to the MCDC through its CMF a Notice of Termination specifying the extent of termination and the effective date.

After receipt of a Notice of Termination, and except as directed by the CMF, the PAH shall immediately proceed with the following obligations, regardless of any delay in determining or adjusting any amounts due:

(1) Stop work and direct its subawardees to stop work as specified in the notice.

(2) Place no further subagreements or orders (referred to as orders in this clause) for materials, services, or facilities, except as necessary to complete the continued portion of the project.

(3) Terminate all orders to the extent they relate to the work terminated.

(4) Assign to the Government, as directed by the AO, all right, title, and interest of the PAH under the orders terminated, in which case the Government shall have the right to settle or to pay any termination settlement proposal arising out of those terminations.

(5) With approval or ratification to the extent required by the AO, the CMF may settle all outstanding liabilities and termination settlement proposals arising from the termination of orders; the approval or ratification will be final for purposes of this clause.

(6) Provide CMF, and/or obtain from the subawardees under the terminated portion of the Agreement a transfer of title to the following where applicable and deliver to the Government --

(i) The fabricated or unfabricated parts, work in process, completed work, supplies, and other material produced or acquired for the work terminated; and

(ii) The completed or partially completed plans, drawings, information, and other property that, if the order had been completed, would have been required to be furnished to the Government.

(7) Complete performance of any work not terminated, if applicable.

(8) Take any action that may be necessary, or that the AO may direct through the CMF, for the protection and preservation of the property related to this project that is in the possession of the PAH(s) or any subawardee and in which the Government has or may acquire an interest.

(9) Use commercially reasonable efforts to sell, as directed or authorized by the CMF, any property of the types referred to under Article II. Section 2.03 Termination Provisions, (6)(i) and (ii); provided, however, that the PAH:

(i) is not required to extend credit to any purchaser and

(ii) may arrange for the subawardee who was performing the terminated work to acquire the property under the conditions prescribed by, and at prices approved by, the CMF.

(iii) will in no event be required to continue with such efforts for more than three (3) months after notice by the CMF to sell or disposition such property.

(10) The PAH has no obligation to continue to cost share on the terminated project or terminated portion of the project.

The requirement for at least 1/3 cost share of the total project cost by the PAH is assessed prior to award. In the event that during the course of the performance of the Project Agreement any of the parties to the Project Agreement believe the cost sharing funds available will be insufficient, the PAH shall notify the CMF within twenty-five (25) days of the event that gave rise to the insufficient cost sharing funds. CMF will notify the Government within five (5) days of receiving such notice from the PAH. The Government will determine whether it is in its best interest to either renegotiate the scope and/or terms of the Project Agreement to meet the cost share requirement or terminate the Project Agreement in whole or in part.

The proceeds of any transfer or disposition of project property will be applied to reduce any payments to be made by the Government under that particular project, including credited to the price or cost of the work, or paid in any other manner directed by the CMF.

In the event of a termination of the Project Agreement, the Government shall have patent rights as described in Article X, Patent Rights, and rights in Data as described in Article XI, Data Rights. Failure of the PAH and Government to agree to an equitable adjustment shall be resolved pursuant to Article VII, Disputes.

Section 2.04 Termination Cost

The CMF will negotiate with the Government and PAH in good faith equitable reimbursement for work performed toward accomplishment of the task or tasks of individual projects. The Government will allow full credit for the Government share of the obligations properly incurred by a PAH prior to termination. Costs incurred by a PAH during a suspension or after termination of a project are not allowable unless the CMF expressly authorizes them in either the notices of suspension, termination, or subsequently. Other PAH's costs incurred during a suspension or after termination which are necessary and not reasonably avoidable are allowable if:

(a) The costs result from obligations which were properly incurred by the PAH before the effective date of the suspension or termination, are not in anticipation of it, and in the case of a termination, are non-cancellable; and

(b) The costs would be allowable if the project was not suspended or the award expired normally at the end of the funding period in which the termination takes effect.

Section 2.05 Close-out Procedure.

If the Government funds an individual Project Agreement and then subsequently terminates the agreement or the requirements of the agreement are met, the following closeout procedures apply:

(a) Definitions.

(i) "Closeout" – the process by which the Government and CMF determine that all applicable administrative actions and all required work have been completed by the PAH.

(ii) "Date of Completion" – the date on which all work is completed or the date on an amendment thereto on which the period of performance ends.

(iii) "Disallowed costs" – those charges that the Government or its representative determines to be unallowable, in accordance with the terms and conditions stated in this Agreement.

(b) Upon request, the Government shall make prompt payments to the PAH through the CMF for allowable reimbursable costs under the MCS Project Agreement being closed out.

(c) The PAH shall immediately refund any balance of unobligated (unencumbered) cash that the CMF has paid and that is not authorized to be retained by the PAH for use in the performance of the Project Agreement.

(d) The CMF shall obtain from the PAH within 90 calendar days after the date of completion of an MCS Project Agreement all financial, performance, and other reports required as a condition of the MCS Project Agreement. The CMF may grant extensions when requested by the PAH.

(e) When authorized, the CMF shall make a settlement for any upward or downward adjustments to the Government's share of costs after these reports are received based on final, actual expenditures in accordance with the Termination Costs provision of the Agreement.

(f) Quick close-out procedures similar to FAR 42.708 shall be followed.

(g) The PAH shall account for any property received from the Government.

Section 2.06 Stop Work

As directed by the AO, the CMF may, at any time, by written order to the PAH, require the PAH to stop all, or any part, of the work called for under this Agreement or any Project Agreement for a period of 90 days after the written order is delivered to the PAH, and for any further period to which the parties may agree. The order shall be

specifically identified as a stop-work order issued under this section. Upon receipt of the order, the PAH shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage. Within a period of 90 days after a stop-work is delivered to the PAH, or within any extension of that period to which the parties shall have agreed, the CMF shall either:

(a) Cancel the stop-work order; or

(b) Terminate the work covered by the Project Agreement as provided in Article II, Term and Termination.

If a stop work order issued under this clause is canceled, the PAH shall resume work. The CMF shall make an equitable adjustment in the delivery schedule or Project Agreement estimated cost/price, or both, and the Government's share of the Project Agreement shall be modified, in writing, accordingly, if—

(1) The stop-work order results in an increase in the time required for, or in the PAH's cost properly allocable to, the performance of any part of the Project Agreement; and

(2) The PAH asserts its right to the adjustment within 30 days after the end of the period of work stoppage; provided, that, if the Government decides the facts justify the action, the Government through the MCDC CMF may receive and act upon a proposal submitted at any time before final payment under the Project Agreement.

If a stop work order is not canceled and the work covered by the Project Agreement is terminated in accordance with Article II, the MCDC CMF shall work with the PAH to negotiate an equitable reimbursement in accordance with Article II. Section 2.03, Termination Provisions.

Article III. MANAGEMENT OF THE PROJECT

Section 3.01 The Medical CBRN Defense Consortium (MCDC)

The MCDC, as defined in the OTA, was formed to work with the Government and provide input in developing technologies to support the Department of Defense's (DoD) medical, pharmaceutical, and diagnostic requirements as related to enhancing the mission effectiveness of military personnel ultimately resulting in fully executed research and development prototype projects selected by the Government. Every Member in this MCDC is independent of the other, and there is no affiliation between the MCDC members within the definition of 13 C.F.R. 121.103 of the Federal Small Business Regulations and no such affiliation is intended either by the formation or implementation of the MCDC.

As appointed by the MCDC Executive Committee, the CMF has the authority to execute the Other Transaction Agreement (OTA) on behalf of the MCDC and has the responsibility for day to day overall administration of this Agreement, subject to the supervision of the MCDC Executive Committee.

Section 3.02 The following MCDC decisions are subject to the ACC-NJ approval:

1. Changes to the MCDC Articles of Collaboration if such changes substantially alter the relationship of the MCDC and the Government as originally agreed upon when the OTA was executed;
2. Changes to, or elimination of, any ACC-NJ funding allocation to any MCDC Member as technically and/or financially justified.

Section 3.03 Management and Project Structure

Technical and project management of the coordinated research program established under this Agreement shall be accomplished through the management structures and processes detailed in this Article.

The Government competitively selected the MCDC, organized by its Consortium Management Firm Advanced Technology International, a Section 501(c)(3) nonprofit organization. MCDC has entered into an agreement with Advanced Technology International authorizing Advanced Technology International to enter into this OTA as the

consortium manager, engage in overall day to day management of the MCDC under the guidance of and as designated by the MCDC Executive Committee, including technical, programmatic, reporting, financial, administrative and contractual matters and administer Project Agreements required for performance under this OTA.

As established by funded projects under the OTA, the Government Program Manager shall fully participate in the appropriate program technical meetings held by the MCDC. The AORs and Other Government personnel, as deemed appropriate, also may participate in the technical portion of these meetings.

Section 3.04 Modifications

As a result of scheduled meetings, end of program reviews, or at any time during the term of the OTA, research progress or results may indicate that a change in the OTA's scope, objectives or Term would be beneficial to program objectives. Recommendations for modifications, including justifications to support any changes to the OTA Scope, will be documented in a letter and submitted by the PAH to the CMF, who will then forward it to the Program Manager with a copy to the AO. This documentation letter will detail the technical, chronological, and financial impact of the proposed modification to the OTA. The Program Manager shall be responsible for the review and verification of any recommendations to revise or otherwise modify the OTA Scope or other proposed changes to the terms and conditions of the OTA and subsequently this Agreement.

With regard to projects the Government determines to fund as a result of the RPP process specified in the Agreement Scope, any PAH recommendations for modifications, including justifications to support any changes to the funded projects, will be documented in a letter and submitted by the CMF to the AO with a copy to the Government Agreements Officer Representative designated for the particular project. The AO shall be responsible for review of proposed changes and for all modifications to the terms and conditions of the project awards. The CMF shall modify the Project Agreement(s) in the event of any such modifications or changes to the project.

Management of Projects

(1) Performance of the work on each project is subject to the technical direction of the AOR designated in the Project Agreement. For the purposes of this clause, technical direction includes the following:

   a. Direction to the PAH, which shifts work emphasis between work areas or tasks, requires pursuit of certain lines of inquiry, fills in details or otherwise serves to accomplish the objectives described in the statement of work;
   b. Guidelines to the PAH that assist in the interpretation of drawings, specifications or technical portions of work description.
   c. Review and, where required by the Project Agreement, approval of technical reports, drawings, specifications, or technical information to be delivered by the PAH under the Project Agreement.

   The AOR shall monitor the PAH's performance with respect to compliance with the technical requirements of the Project Agreement.

(2) Technical direction must be within the general scope of work stated in the Project Agreement. Technical direction may not be used to
   a. Assign additional work under the Project Agreement;
   b. Increase or decrease the estimated Project Agreement cost, fee (if any), or the time required for the project performance;
   c. Change any of the terms, conditions or specifications of the Project Agreement; or
   d. Accept non-conforming work.

   As such, no verbal or written request, notice, authorization, direction or order received by the PAH shall be binding upon the MCDC, CMF or Government, or serve as the basis for a change in the Project Agreement cost or any other provision of the Project Agreement, unless issued (or confirmed) in writing by the MCDC CMF Contractual Representative designated in the Project Agreement.

(3) The PAH shall immediately notify the MCDC CMF Contractual Representative whenever a written change notification has been received from anyone other than the MCDC CMF Contractual Representative, which would affect any of the terms, conditions, cost, schedules, etc. of the Project Agreement, and the PAH is to perform no work or make any changes in response to any such notification or make any claim on the MCDC through its CMF or Government, unless the MCDC CMF Contractual Representative directs the PAH, in writing, to implement such change notification.

Article IV. AGREEMENT ADMINISTRATION

Administrative and contractual matters under this Agreement shall be referred to the following representatives of the parties:

MCDC: Advanced Technology International

Sr. Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Project Agreement Holder: _____
_____
_____
_____
_____
_____

Each party may change its representatives named in this Article by written notification to the other parties.

Agreements Officer Representative (AOR): AOR will be designated by the Government on a per project basis.

Article V. OBLIGATION AND PAYMENT

Section 5.01 Obligation:

Except as specified in Article VII: Disputes, the CMF's liability to make payments to the PAH is limited only to those funds obligated under the Project Agreement(s). The CMF may incrementally fund the Project Agreement(s). If modification becomes necessary in performance of projects, pursuant to Article V of this Agreement, the CMF and the PAH shall establish and execute a revised Schedule of Payable Milestones consistent with the current Project Agreement.

Section 5.02 Project Payments:

The detailed instructions for project payments will be included in the Technical Direction Letter to be issued by the CMF on a project by project basis.

Section 5.03 Accounting System Requirements:

Prior to the submission of invoices, the PAH shall have and maintain an established accounting system which complies with Generally Accepted Accounting Principles (GAAP) and the requirements of this Agreement. The PAH shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for Federal funds under this Agreement. Consistent with this stipulation, an acceptable accounting system will be one in which all cash receipts and disbursements are controlled and documented properly.

Section 5.04 Invoicing Instructions:

Project Payable Milestones: The PAH shall segregate and track all individual project costs separately and shall document the accomplishments of each Payable Milestone under each Project Agreement. A Payable Milestones report shall be detailed on a project basis and submitted with each request to the AOR or designee for approval.

Section 5.04 a. Payment Method Types

Project Agreements will be issued as either a fixed price milestone payment method or a cost reimbursement milestone payment method as described below.

(a) *Fixed Price Milestone Payment Method:* Payments shall be made in accordance with the Payable Milestone Schedule of each Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. The Payable Milestone Schedule may be revised as appropriate and deemed necessary by issuance of a bilateral modification to the Project Agreement. Quarterly reviews by the AOR and the CMF will assess the need for revisions to the Payable Milestone Schedule. An acceptable invoice for adjustable fixed price milestone payments is one that (on the invoice or on the Payable Milestone Report):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone; and

(iii) lists the milestone cost negotiated and contained in each Project Agreement

(b) *Cost Reimbursable Milestone Payment Method (with not to exceed ceiling):* Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Project Agreement. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. Per (ii) below, either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Task Assignment):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, and extended totals;

(iv) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(v) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

(c) *Cost Plus Fixed Fee Milestone Payment Method (with not to exceed ceiling):* Payment is contingent

upon satisfactory progress toward completion of milestones as delineated in Project Agreement. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. The PAH will normally fund any costs incurred above this maximum amount. Either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Agreement):

(i) contains the date of invoice and the Base t Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, fixed fee and extended totals;

(iv) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(v) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

(d) *Cost Reimbursable, Cost Sharing Milestone Payment Method (with not to exceed ceiling):* Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Project Agreement and acceptable cost share. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. Per (ii) below, either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Agreement):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a report of the cost share expended towards the accomplishment of the SOW tasks and/or milestones. This cost share report may be attached to the invoice if contractor practices make inclusion of such information on the invoice itself impractical. If the cost share report is separate from the invoice, it must be signed by an authorized representative. This cost share report must contain a breakout of the cost share by cost element similar to the level of detail required on the invoice and any in-kind contributions. The preferred method of reporting cost share is to provide an invoice for actual cost incurred with a value for the cost shared amount and the value to be reimbursed by the Government through the CMF;

(iv) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, and extended totals;

(v) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(vi) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

Section 5.04 b. Submission of Invoices

Invoices may be submitted no more frequently than monthly. The PAH shall submit invoices and any necessary supporting documentation via email to .

For Cost type Project Agreements, the PAH's final invoice (completion invoice) will be clearly indicated as such and shall indicate the cumulative amounts incurred and billed to completion, and a written certification of the total hours expended. Actual project costs incurred and cost share performance, if applicable, of each project shall be reported and reviewed each quarter.

Section 5.04 c. Payment Terms

Payment terms are NET 30 days after CMF's receipt of an acceptable invoice. An acceptable invoice is one that meets the conditions described in Article V Section 5.04a. Payment Method Types.

Section 5.05 Advance Payments:

On a per project basis, advance payments may be approved by the AO. If the AO has approved advance payments, there will be a requirement to establish a separate interest bearing account. The PAH sets up and maintains funds in a separate interest bearing account unless one of the following applies:

(1) The PAH receives less than $120,000 in Federal awards per year;

(2) The best reasonably available interest bearing account would not expect to earn interest in excess of $250 per year on such cash advances;

(3) The depository would require an average or minimum balance so high that it would not be feasible within the expected cash resources for the project; or

(4) The advance payments are made one time to reduce financing costs for large up-front expenditures and the fund will not remain in the PAH's account for any significant period of time.

Where a separate interest bearing account is set up, any interest earned should be remitted annually to the CMF. CMF shall forward the funds to the Government as directed by the AO. Interest payments shall be made payable to the U.S. Treasury.

Section 5.06 Limitation of Funds:

Except as set forth in Article VII, the Government's financial liability will not exceed the amount obligated for projects and available for payment.

Section 5.07 Financial Records and Reports:

The PAH shall maintain adequate records to account for Federal funds received under this Agreement and shall maintain adequate records to account for Project Agreement funding provided under this Agreement, should cost sharing procedures be implemented for funding a particular project. PAH's relevant financial records are available and subject to examination or audit on behalf of the ACC-NJ for a period not to exceed five (5) years after final payment of the PAH's project. The AO or designee shall have direct access to sufficient records and information of the PAH to ensure full accountability for all funding under this Agreement. Such audit, examination or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party. Any audit required during the course of the program may be conducted by the Government using Government auditors or, at the request of the PAH, by the requesting PAH's external CPA accounting firm at the expense of the requesting PAH.
AGREEMENT

Article VI. NONTRADITIONAL DEFENSE/COST SHARING

In accordance with provisions of 10 USC 2371b, Section 815 of the 2016 National Defense Authorization Act, P.L. 114-92, which provides the Department of Defense (DoD) authority to enter into transactions *other than* contracts, grants, or cooperative agreements, the Department of Defense (DoD) has the authority to make awards that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or the improvement of platforms, systems, components, or materials in use by the armed forces. Section 815 revised the definition for the term ‘nontraditional defense contractor’ as defined in Article I. Section 1.01, Definitions.

Each MCDC Member Organization must meet the definition of a Nontraditional Defense Contractor or have at least one Nontraditional Defense Contractor participating to a significant extent in the performance of an awarded Project Agreement. Examples of what might be considered a significant extent or significant contribution include, but may not be limited to supplying new key technologies or products, accomplishing a significant amount of the effort, or in some other way causing a material reduction in the cost or schedule or increase in the performance.

If significant Nontraditional Defense Contractor participation cannot be fulfilled, the Member Organization must provide at least one third cost share of the value of the Project Agreement awarded to the Member Organization. Proposals that fail to comply with this requirement will not be awarded under the OTA.

Cost Sharing is not required under this Other Transaction Agreement for projects that contain significant nontraditional defense contractor participation. Where both Parties agree, cost sharing may be considered on a per project basis under terms and conditions to be agreed to by the Parties and in accordance with the “Other Transactions” (OT) Guide For Prototype Projects dated January 2001. For traditional Government contractors without a significant nontraditional defense contractor teaming partner, a one third cost share of the project costs is required as described in the “Other Transaction” (OT) Guide For Prototype Projects dated January 2001. For traditional Government contractors with significant nontraditional defense contractor participation, cost sharing is not required for Projects under this OTA.

Throughout the period of performance of any Project Agreement, the Government AO and AOR will actively monitor Nontraditional Defense Contractor participation and/or cost sharing to ensure compliance with this provision in accordance with implementation guidance from HQDA and/or OSD. The PAH will be given the opportunity to become compliant with the guidance should they be found non-compliant. Failure to comply may result in termination.

Article VII. DISPUTES

Section 7.01 General

For the purposes of this Article, “Parties” means the CMF, the PAH and the Government where collectively identified and “Party” where each entity is individually identified. The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

Section 7.02 Dispute Resolution Procedures

Any disagreement, claim or dispute among the Parties concerning questions of fact or law arising from or in connection with this Agreement and whether or not involving an alleged breach of this Agreement, may be raised only under this Article.

Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding which arose more than three (3) months prior to the notification made under this article constitute the basis for relief under this article unless the ACC-NJ, Center Director for Emerging Technologies, in the interest of justice, waives this requirement.

Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party in writing documenting the relevant facts, identifying unresolved issues, specifying the clarification or remedy sought, and documenting the rationale as to why the clarification/remedy is appropriate. Within ten (10) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a decision by the ACC-NJ, Center Director for Emerging Technologies. The other Party shall submit a written position on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The ACC-NJ, Center Director for Emerging Technologies, will conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such position. Any such decision is final and binding, unless a Party shall, within thirty (30) calendar days request further review as provided by this article.

If requested within thirty (30) calendar days of the ACC-NJ, Center Director for Emerging Technologies’ decision, further review will be conducted by the Chair of the MCDC Executive Committee and the ACC-NJ Associate Director. In the event of a decision, or in absence of a decision within sixty (60) calendar days of referral to the Chair of the MCDC Executive Committee and the ACC-NJ, Associate Director (or such other period as agreed to by the parties), either party may pursue any right or remedy provided by law, including but not limited to the right to seek extraordinary relief under Public Law 85-804. Alternatively, the parties may agree to explore and establish an Alternate Disputes Resolution procedure to resolve this dispute.

Section 7.03 Limitation of Liability and Damages

In no event shall the liability of the MCDC PAH or any other entity performing research activities under a Project Agreement exceed the funding such entity has received for their performance of the specific Project Agreement under which the dispute arises.

No Party shall be liable to any other Party for consequential, punitive, special and incidental damages or other indirect damages, whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's willful misconduct; Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.

Article VIII. CONFIDENTIAL INFORMATION

Section 8.01 Definitions

(1) "Disclosing Party" means CMF, MCDC PAHs, or the Government who discloses Confidential Information as contemplated by the subsequent Paragraphs.
(2) "Receiving Party" means CMF, MCDC PAHs, or the Government who receives Confidential Information disclosed by a Disclosing Party.
(3) "Confidential Information" means information and materials of a Disclosing Party which are designated as confidential or as a Trade Secret in writing by such Disclosing Party, whether by letter or by use of an appropriate stamp or legend, prior to or at the same time any such information or materials are disclosed by such Disclosing Party to the Receiving Party. Notwithstanding the foregoing, materials and other information which are orally, visually, or electronically disclosed by a Disclosing Party, or are disclosed in writing without an appropriate letter, stamp, or legend, shall constitute Confidential Information or a Trade Secret if such Disclosing Party, within thirty (30) calendar days after such disclosure, delivers to the Receiving Party a written document or documents describing the material or information and indicating that it is confidential or a Trade Secret, provided that any disclosure of information by the Receiving Party prior to receipt of such notice shall not constitute a breach by the Receiving Party of its obligations under this Paragraph. "Confidential Information" includes any information and materials considered a Trade Secret by the PAH. "Trade Secret" means all forms and types of financial, business, scientific, technical, economic, or engineering or otherwise proprietary information, including, but not limited to, patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if -

(a) The owner thereof has taken reasonable measures to keep such information secret; and

(b) The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

Section 8.02 Exchange of Information:

Neither the Government nor MCDC on behalf of the MCDC member entities or PAHs nor the CMF shall be obligated to transfer Confidential Information independently developed by the Government or the MCDC member entities or PAHs or the CMF absent an express written agreement between the Parties involved in the exchange providing the terms and conditions for such disclosure.

Section 8.03 Authorized Disclosure:

The Receiving Party agrees, to the extent permitted by law, that Confidential Information shall remain the property of the Disclosing Party (no one shall disclose unless they have the right to do so), and that, unless otherwise agreed to by the Disclosing Party, Confidential Information shall not be disclosed, divulged, or otherwise communicated by it to third parties or used by it for any purposes other than in connection with specified project efforts and the licenses granted in Article X, Patent Rights, and Article XI, Data Rights, provided that the duty to protect such "Confidential Information" and "Trade Secrets" shall not extend to materials or information that:

(a) Are received or become available without restriction to the Receiving Party under a proper, separate agreement,

(b) Are not identified with a suitable notice or legend per Article VIII entitled "Confidential Information" herein,

(c) Are lawfully in possession of the Receiving Party without such restriction to the Receiving Party at the time of disclosure thereof as demonstrated by prior written records,

(d) Are or later become part of the public domain through no fault of the Receiving Party,

(e) Are received by the Receiving Party from a third party having no obligation of confidentiality to the Disclosing Party that made the disclosure,

(f) Are developed independently by the Receiving Party without use of Confidential Information as evidenced by written records,

(g) Are required by law or regulation to be disclosed; provided, however, that the Receiving Party has provided written notice to the Disclosing Party promptly so as to enable such Disclosing Party to seek a protective order or otherwise prevent disclosure of such information.

Section 8.04 Return of Proprietary Information:

Upon the request of the Disclosing Party, the Receiving Party shall promptly return all copies and other tangible manifestations of the Confidential Information disclosed. As used in this section, tangible manifestations include human readable media as well as magnetic and digital storage media.

Section 8.05 Term:

The obligations of the Receiving Party under this Article shall continue for a period of seven (7) years from conveyance of the Confidential Information.

Section 8.06 Flow Down

The PAH shall flow down the requirements of this Article VIII to their respective personnel, member entities, agents, subawardees (including employees) at all levels, receiving such Confidential Information under this OTA.

Article IX. PUBLICATION AND ACADEMIC RIGHTS

Section 9.01 Use of Information.

For the purposes of this Article, “Parties” means the PAH and the Government where collectively identified and “Party” where each entity is individually identified.

Subject to the provisions of Article VIII, Confidential Information, Article IX, Publication and Academic Rights, and Article XI Data Rights, the PAH and the Government shall have the right to publish or otherwise disclose information and/or data developed by the Government and/or the respective MCDC PAH under the Research Project. The PAH and the Government (and its employees) shall include an appropriate acknowledgement of the sponsorship of the Research Projects by the Government and the MCDC PAH in such publication or disclosure. The Parties shall have only the right to use, disclose, and exploit any such data and Confidential Information in accordance with the rights held by them pursuant to this Agreement. Notwithstanding the above, the Parties shall not be deemed authorized by this paragraph, alone, to disclose any Confidential Information of the Government or the PAH.

Section 9.02 Publication or Public Disclosure of Information

(a) Classified Project Agreements

If a release of Confidential Information or Trade Secrets is for a classified Project Agreement, the provisions of the DoD Security Agreement (DD Form 441) and the DoD Contract Security Classification Specification (DD Form 254) apply.

(b) Review or Approval of Technical Information for Public Release.

(1) At least 30 days prior to the scheduled release date PAH shall submit to the CMF a copy of the information to be released. In turn, CMF shall submit to the Government AOR a copy of the information to be released.

The Government AOR is hereby designated as the approval authority for the AO for such releases.

(2) Where the PAH is an Academic Research Institution performing fundamental research on campus. PAH shall provide papers and publications for provision to the CMF for provision to the Government AOR for review and comment 30 days prior to formal paper/publication submission. However, if that Academic Research Institution incorporates into its research results or publications artifacts produced by and provided to these institutions on behalf of other (non-educational institution) MCDC PAHs (or has authors listed on the paper who are not employees or students of the Academic Research Institution) then the procedures in Section 9.02(a) ABOVE must be followed.

(3) Parties to this Agreement are responsible for assuring that an acknowledgment of government support will appear in any publication of any material based on or developed under this OTA, using the following acknowledgement terms:

> "Effort sponsored by the U.S. Government under Other Transaction number W15QKN-16-9-1002 between the MCDC, and the Government**.** The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

(4) Parties to this Agreement are also responsible for assuring that every publication of material based on or developed under this project contains the following disclaimer:

> "The views and conclusions contained herein are those of the authors and should not be interpreted as necessarily representing the official policies or endorsements, either expressed or implied, of the U.S. Government.

The PAH shall flowdown these requirements to its subawardees, at all tiers.

(c) Notices. To avoid disclosure of Confidential Information or Trade Secrets belonging to an MCDC member entity or PAH and/or the Government and the loss of patent rights as a result of premature public disclosure of patentable information, the PAH that is proposing to publish or disclose such information shall provide advance notice to the MCDC, through its CMF, and identify such other parties as may have an interest in such Confidential Information. The CMF shall notify such parties at least [* * *] prior to any PAH's submission for publication or disclosure, together with any and all materials intended for publication or disclosure relating to technical reports, data, or information developed by the parties during the term of and pursuant to this Agreement. The Government must notify the MCDC, through its CMF, of any objection to disclosure within this [* * *] period, or else the PAH, shall be deemed authorized to make such disclosure.

(d) Filing of Patent Applications. During the course of any such [* * *] period, the PAH shall
provide notice to the CMF as to whether it desires that a patent application be filed on any invention disclosed in such materials. In the event that a PAH and/or the Government desires that such a patent be filed, the PAH or the Government proposing to publish or disclose such materials agrees to withhold publication and disclosure of such materials until the occurrence of the first of the following:

(1) Filing of a patent application covering such invention, or

(2) Written agreement, from the AO and the CMF (on behalf of the PAH to whom such Confidential Information belong) that no patentable invention is disclosed in such materials.

(3) Further, during the course of any such [* * *] period, the PAH shall notify the AO and the Government, through the CMF, if PAH believes any of its Confidential Information have been included in the proposed publication or disclosure and shall identify the specific Confidential Information or Trade Secrets that need to be removed from such proposed publication. The Government and the CMF on behalf of the PAH proposing the publication or disclosure of such materials agrees to remove from the proposed publication or disclosure all such Confidential Information so identified by the CMF.

Article X. PATENT RIGHTS

Section 10.01 Definitions

“Invention” means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

“Made” when used in relation to any invention means the conception or first actual reduction to practice of such invention.

“Practical application” means to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and in each case, under such conditions as to establish that the invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

“Subject Invention” means any invention of the MCDC’s PAH or its subcontractors of any tier conceived or first actually reduced to practice in the performance of work on a Project Agreement under this Agreement.

"Background Invention" means any invention, or improvement to any invention, other than a Subject Invention, made by a PAH (or their subcontractors of any tier) that was conceived, designed, developed, produced, and/or actually reduced to practice prior to performance of the Agreement or outside the scope of work performed under this Agreement.

Section 10.02 Allocation of Principal Rights

The PAH, or its subcontractor to the extent such is proper assignee of the invention, shall retain the entire right, title, and interest throughout the world to each Subject Invention consistent with the provisions of this Article, Executive Order 12591 and 35 U.S.C § 202. In the event that a PAH consists of more than one entity or person, those entities or persons may allocate such right, title interest between themselves or others as they may agree in writing. With respect to any Subject Invention in which the PAH retains title, the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. The PAH may elect to provide full or partial rights that it has retained to other parties. The Government shall have the right to use any products or processes used for test and evaluation (including materials for testing or assays) in any other project pursued on behalf of the U.S. Government.

Section 10.03 Invention Disclosure, Election of Title, and Filing of Patent Application

(1) The PAH shall disclose each Subject Invention to the CMF within [* * *] after the inventor discloses it in writing to his company personnel responsible for patent matters. The disclosure to the CMF shall be in the form of a written report and shall identify the Agreement under which the invention was made and the identity of the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, sale, or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure.

(2) If the PAH determines that it does not intend to retain title to any such invention, the PAH shall notify the CMF, in writing, within [* * *] of disclosure. However, in any case where publication, sale or public use has initiated the one (1) year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by the ACC-NJ through CMF to a date that is no more than [* * *] prior to the end of the project.

(3) The PAH shall file its initial patent application on a Subject Invention to which it elects to retain title within [* * *] after election of title or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use. The MCDC PAH may elect to file patent applications in additional countries (including the European Patent Office and the Patent Cooperation Treaty) within either [* * *] of the corresponding initial patent application or [* * *] from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

(4) After considering the position of the CMF on behalf of the PAH, a request for extension of the time for disclosure election, and filing under this Article IX, paragraph C, may be approved by ACC-NJ, which ACC-NJ approval shall not be unreasonably withheld.

Section 10.04 Conditions When the Government May Obtain Title

Upon written request to the CMF, the PAH shall convey to the Government title to any Subject Invention under any of the following conditions:

(1) If the PAH fails to disclose or elects not to retain title to the Subject Invention within the times specified in Section 10.03 of this Article X, Patent Rights; provided, that the Government may only request title within [* * *] after learning of the failure of the PAH to disclose or elect within the specified times.

(2) In those countries in which the PAH fails to file patent applications within the times specified in Section 10.03 of this Article X, Patent Rights; provided, that if the PAH has filed a patent application in a country after times specified in Section 10.03 of this Article X, Patent Rights, but prior to its receipt of the written request by the Government through the CMF, the PAH shall continue to retain title in that country; or

(3) In any country in which the PAH decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a Subject Invention.

Section 10.05 Minimum Rights to the MCDC PAH and Protection of the MCDC PAH's Right to File

The Parties agree that:

(1) The PAH shall retain a non-exclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title, except if the PAH fails to disclose the invention within the times specified in Section 10.03 of this Article X, Patent Rights. PAH's license extends to the domestic (including Canada) subsidiaries and affiliates, if any, of the PAH within the corporate structure of which the PAH is a party and includes the right to grant licenses of the same scope to the extent that PAH was legally obligated to do so at the time the Project Agreement was funded. The license is transferable only with the approval of the Government, except when transferred to the successor of that part of the business to which the invention pertains. Government approval for license transfer shall not be unreasonably withheld.

(2) The PAH domestic license may be revoked or modified by the Government to the extent necessary to achieve expeditious practical application of the Subject Invention pursuant to an application for an exclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. This license shall not be revoked in that field of use or the geographical areas in which the PAH has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the Government to the extent

the PAH, its licensees, or the subsidiaries or affiliates have failed to achieve practical application in that foreign country.

(3) Before revocation or modification of the license, the Government shall furnish the CMF, and the CMF shall forward to the PAH, a written notice of the Government's intention to revoke or modify the license, and the PAH shall be allowed [* * *] (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

Section 10.06 Action to Protect the Government's Interest

(1) The PAH shall execute or have executed and promptly deliver to CMF all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which the PAH elects to retain title, and (ii) convey title to the Government when requested under Section 10.04 of this Article X, Patent Rights, and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

(2) The PAH agrees to require, by written agreement, that its employees working on Project Agreements, other than clerical and non-technical employees, agree to disclose promptly in writing, to personnel identified as responsible for the administration of patent matters and in a format acceptable to the CMF, each Subject Invention made under this Agreement in order that the CMF on behalf of the PAH can comply with disclosure provisions of Section 10.03 of the Article X, Patent Rights, and to execute all papers necessary to file the patent applications on the Subject Invention and to establish the Government's rights in the Subject Invention. The PAH acknowledges and shall instruct its employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The PAH shall notify the CMF of any decision not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent, in any country, not less than [* * *] before the expiration of the response period required by the relevant patent office.

(4) The PAH shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with U.S. Government support under Agreement No. W15QKN-16-9-1002 awarded by the ACC-NJ to the MCDC. The Government has certain rights in the invention."

Section 10.07 Lower Tier Agreements

The PAH shall include the Article X, Patent Rights, suitably modified to identify the parties, in all lower tier agreements, regardless of tier, for experimental, development, or research work.

Section 10.08 Reporting on Utilization of Subject Inventions

The PAH shall submit, on request during the term of the Project Agreement, periodic reports no more frequently than annually on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the PAH or its licensees or assignees. Such reports shall include information regarding the status of development date of first commercial sale or use, gross royalties received by the PAH, and such other data and information as the agency may reasonably specify. The PAH also agrees to provide additional reports as may be requested by the Government, through CMF, in connection with any march-in proceedings undertaken by the Government in accordance with Section 10.10 of this Article X, Patent Rights. Consistent with 35 U.S.C. § 205, the Government agrees it shall not disclose such information to persons outside the Government without permission of the MCDC on behalf of the PAHs.

Section 10.09 Preference for American Industry

Notwithstanding any other provision of the Article X, Patent Rights, the PAH is not to grant to any person the exclusive right to use or sell any Subject Invention in the United States or Canada unless such person agrees that any product embodying the Subject Invention or produced through the use of the Subject Invention shall be manufactured substantially in the United States or Canada. However, in individual cases, the requirements for such an agreement may be waived by the Government upon a showing by the PAH that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

Section 10.10 March-in Rights

The PAH agrees that, with respect to any Subject Invention in which its PAH has retained title, the Government, through CMF, has the right to require the PAH to obtain and grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the PAH refuses such a request, the Government has the right to grant such a licensee itself if the Government determines that:

(1) Such action is necessary because the PAH or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the Subject Invention;

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the PAH, assignee, or their licensees;

(3) Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by the PAH, assignee, or licensees; or

(4) Such action is necessary because the Agreement required by Section 10.09 of this Article X, Patent Rights, has not been obtained or waived or because a licensee who has the exclusive right to use or sell any Subject Invention in the United States is in the breach of such Agreement.

Section 10.11 Opportunity to Cure

Certain provisions of this Article X, Patent Rights, provide that the Government may gain title or license to a Subject Invention by reason of the PAH’s action, or failure to act, within the times required by this Article X, Patent Rights. Prior to claiming such rights (including any rights under Article X, Section 10.10 March-In Rights), the Government will give written notice to MCDC, through its CMF, and CMF will convey such written notice to PAH, of the Government's intent, and afford the PAH a reasonable time to cure such action or failure to act. The length of the cure period will depend on the circumstances, but in no event will be more than 60 days. PAH may also use the cure period to show good cause why the claiming of such title or right would be inconsistent with the intent of this Agreement in light of the appropriate timing for introduction of the technology in question, the relative funding and participation of the parties in the development, and other factors.

Section 10.12 Background Information

In no event shall the provisions set forth in this Article X apply to any Background Inventions or Patents. The PAHs or their subcontractors shall retain the entire right, title, and interest throughout the world to each such Inventions and Patents that each party has brought through MCDC to the project issued under this Agreement and the Government shall not have any rights under this Agreement. Projects to be funded under this Agreement will list Background Inventions and Patents anticipated to be used on the project; such listing may be amended by the parties as appropriate to reflect changes in such plans.

Section 10.13 Survival Rights

Provisions of this Article X shall survive termination of this Agreement under Article II.

Notwithstanding the terms of this Article, differing rights in patents may be negotiated among the Parties to each individual project on a case-by-case basis.

Article XI. DATA RIGHTS

This is a Data Rights Clause specifically tailored for this OTA to address respective rights of the Government and MCDC on behalf of its actual or prospective MCDC PAHs to such Data as is owned, developed, to be developed or used by an actual or prospective MCDC member entity or PAH (1) as identified in a MCDC member entity(ies) proposal submitted to the Government through the CMF in response to a competitive Government OTA call for proposals, and (2) when such proposal is selected by the Government for funded performance and the Project Agreement is issued by the CMF to that MCDC member entity for performance of such Government OTA project.

Section 11.01 Definitions

(1) "Commercial Computer Software" as used in the Article is defined in DFARS 252-227-7014(a)(1) (Jun 1995).

(2) "Commercial Computer Software License" means the license terms under which commercial computer software and Data (as defined in this OTA) is sold or offered for sale, lease or license to the general public.

(3) "Computer Data Base" as used in this Agreement, means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.

(4) "Computer program" as used in this Agreement means a set of instructions, rules, or routines in a form that is capable of causing a computer to perform a specific operation or series of operations.

(5) "Computer software" as used in this Agreement means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated or recompiled. Computer software does not include computer data bases or computer software documentation.

(6) "Computer software documentation" means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

(7) "Data" as used in this Article of the Agreement, means computer software, computer software documentation, form, fit and function data, and technical data as defined in this Article.

(8) "Form, fit and function data" means technical data that describes the required overall physical, functional and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.

(9) "Government purpose rights" means the rights to use, modify, duplicate or disclose the "Data" licensed with such rights under this OTA within the Government for United States Government purposes only; and to release or disclose data outside the Government to any authorized persons pursuant to an executed non-disclosure agreement for such persons use, modification, or reproduction for United States Government purposes only. United States Government purposes include Foreign Military Sales purposes. Under this Agreement, the period of Government purpose rights shall be no less than ten (10) years and during such time the MCDC member entity or PAH developing or providing such Data to the Government with government purpose rights shall have the sole and exclusive right to use such Data for commercial purposes. In the event this Data is used to perform another project issued to that MCDC member entity or PAH under this OTA during this ten (10) year period, the period of

government purpose rights shall be extended an additional ten (10) years starting with the date of completion of performance of the additional project.

(10) “Limited rights” as used in this Article is as defined in DFARS 252.227-7013(a)(13) (Nov 1995).

(11) “Restricted rights” as used in this Article is as defined in DFARS 252.227-7014(a)(14) (Jun 1995).

(12) “Specially Negotiated License Rights” are those rights to Data that have been specifically negotiated between the Government and the MCDC on behalf of the member entity or PAH whose proposal is selected by the Government under a call for proposals issued under the OTA.

(13) “Technical data” means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

(14) “Unlimited rights” as used in this Article is as defined n DFARS 252.227-7013(a)(16).

Section 11.02 Data Categories

(1) Category A is the Data developed and paid for totally by private funds, or the PAH's (or its subcontractor's) IR&D funds and it is Data to which the PAH (or its subcontractor) retains all rights. Category A Data shall include, but not be limited to,

(a) Data as defined in this Article and any designs or other material provided by the PAH for a project under this Agreement which was not developed in the performance of work under that project, and for which the PAH retains all rights.

(b) Any initial Data or technical, marketing, or financial Data provided at the onset of the project by any of the MCDC member entities or PAHs. Such Data shall be marked “Category A” and any rights to be provided to the Government for such Data under a specific project shall be as identified in the proposal submitted to the Government and included into the Technical Direction Letter and CMF issued Project Agreements.

(2) Category B is any Data developed under this OTA with mixed funding, i.e. development was accomplished partially with costs charged to a PAH’s indirect cost pools and/or costs not allocated to a PAH’s Project Agreement under this OTA, and partially with Government funding under this OTA. Any Data developed outside of this OTA whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data.

(3) Category C is any Data developed exclusively with Government funds under this OTA. Research and Development performed was not accomplished exclusively or partially at private expense. Under this category,

(a) the Government will have Government Purpose Rights in Data developed exclusively with Government funds under a project funded by the Government under this OTA that is:

(i) Data pertaining to an item, component, or process which has been or will be developed exclusively with Government funds;

(ii) Studies, analyses, test data, or similar data produced for this contract, when the study, analysis, test, or similar work was specified as an element of performance;

(iii) Data created in the performance of the OTA that does not require the development, manufacture, construction, or production of items, components, or processes;

(iv) Form, fit, and function data;

(v) Data necessary for installation, operation, maintenance, or training purposes (other than detailed manufacturing or process data);

(vi) Corrections or changes to technical data furnished to the Contractor by the Government;

The Government can only order such Data as is developed under the OTA project where the order request is made within one (1) year following OTA project completion. In the event the Government orders such Data, it shall pay the PAH the reasonable costs for all efforts to deliver such requested Data, including but not limited to costs of locating such Data, formatting, reproducing, shipping, and associated administrative costs.

(b) The Government shall have unlimited rights in Data

(i) Otherwise publicly available or that has been released or disclosed by PAH without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the Data to another party or the sale or transfer of some or all of a business entity or its assets to another party;

(ii) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or

(iii) Data furnished to the Government, under this or any other Government contract or subcontract thereunder, with—

(1) Government Purpose Rights or limited rights and the restrictive condition(s) has/have expired; or

(2) Government purpose rights and the PAH's exclusive right to use such Data for commercial purposes under such contract or subcontract has expired.

(c) However, any Data developed outside of this OTA whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data.

(d) Further, the Government's rights to Commercial Computer Software and Data licensed under a Commercial Computer Software License under this OTA, and the treatment of Data relating thereto, shall be as set forth in the Commercial Computer Software License.

(4) The parties to this Agreement understand and agree that the CMF shall require PAHs stamp all documents in accordance with this Article and that the Freedom of Information Act (FOIA) and Trade Secrets Act (TSA) apply to Data.

Section 11.03 Allocation of Principal Rights

(1) The Government shall have no rights to Category A Data.

(2) The Government shall have immediate Government Purpose Rights to Category B or C Data upon delivery or project or Agreement completion (whichever is earlier), except that

(a) where the PAH whose Data it is, is a small business as defined under the Small Business Innovation research Program (SBIR) under 15 U.S.C. 638, and such data was developed under a project designated by the Government in the RPP as an SBIR program project, such PAH automatically shall be entitled to a delay in the start of the Government Purpose Rights period for at least five (5) years from project completion, or such longer period as may be negotiated among the Government and MCDC on behalf of the PAH, and

(b) The CMF, at the request of small business or an other than small business MCDC member entity or PAH, may request on such member entity's or PAH's behalf a delay of the start of Government Purpose Rights in Category B or C Data for a period not to exceed five (5) years from project or Agreement completion (whichever is earlier). Such requests will only be made in those cases where the CMF has provided information from the affected actual or prospective PAH demonstrating the need for this additional restriction on Government use and shall be submitted to the ACC-NJ AO for approval, which approval shall not be unreasonably withheld. In the event of any dispute regarding approval of this request, the parties agree to treat this as a dispute and shall follow the provisions of Article VII, Disputes.

(c) for Article XI.Section 11.02 3(c) Category C Data, the Government shall have only the rights established under prior agreements.

(d) for Article XI.Section 11.02 3(d) Category C Data, the Government shall only have the rights set forth in the Commercial Computer Software Data license agreement.

(3) Data that will be delivered, furnished, or otherwise provided to the Government as specified in a specific project award funded under this Agreement, in which the Government has previously obtained rights, shall be delivered, furnished, or provided with the pre-existing rights, unless (a) the parties have agreed otherwise, or (b) any restrictions on the Government’s rights to use, modify, reproduce, release, perform, display, or disclose the data have expired or no longer apply.

(4) Each proposal submitted by the MCDC member entities in response to a Government call for proposals under this OTA shall include a list of the Category A, B and C Data to be used or developed under the proposal if selected. Rights in such Data shall be as established under the terms of this Agreement, unless otherwise asserted in the proposal and agreed to by the Government. The Government AO will incorporate the list of Category A, B and C Data and the identified rights therefor in the award document.

Following issuance of a Technical Direction Letter and subsequent CMF issuance of the Project Agreement to the Government selected MCDC member entity (the PAH), the PAH shall update the list to identify any additional, previously unidentified, Data if such Data will be used or generated in the performance of the funded work. Rights in such Data shall be as established under the terms of this Agreement, unless otherwise asserted in a supplemental listing and agreed to by the Government.

Section 11.04 Marking of Data

Except for Data delivered with unlimited rights, Data to be delivered under this Agreement subject to restrictions on use, duplication or disclosure shall be marked with the following legend:

Use, duplication, or disclosure is subject to the restrictions as stated in the Agreement between the U.S. Government and the MCDC, Agreement No. W15QKN-16-9-1002, Project Title and the MCDC Project Agreement with [insert name of company] No.___.

It is not anticipated that any Category A Data will be delivered to the Government under this Agreement.

In the event commercial computer software and Data is licensed under a commercial computer software license under this OTA, a Special License rights marking legend shall be used as agreed to by the parties.

The Government shall have unlimited rights in all unmarked Data. In the event that a PAH learns of a release to the Government of its unmarked Data that should have contained a restricted legend, the CMF on behalf of the member

entity or PAH will have the opportunity to cure such omission going forward by providing written notice to the Government AO within three (3) months of the erroneous release.

Section 11.05 Copyright

The PAHs reserve the right to protect by copyright original works developed under this Agreement. All such copyrights will be in the name of the individual PAH. The PAH(s) hereby grant to the U.S. Government a non-exclusive, non-transferable, royalty-free, fully paid-up license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, for governmental purposes, any copyrighted materials developed under this agreement, and to authorize others to do so.

In the event Data is exchanged with a notice indicating that the Data is protected under copyright as a published, copyrighted work and it is also indicated on the Data that such Data existed prior to, or was produced outside of this Agreement, the Party receiving the Data and others acting on its behalf may reproduce, distribute, and prepare derivative works for the sole purpose of carrying out that Party's responsibilities under this Agreement with the written permission of the Copyright holder.

Copyrighted Data that existed or was produced outside of this Agreement and is unpublished - having only been provided under licensing agreement with restrictions on its use and disclosure - and is provided under this Agreement shall be marked as unpublished copyright in addition to the appropriate license rights legend restricting its use, and treated in accordance with such license rights legend markings restricting its use.

The PAHs are responsible for affixing appropriate markings indicating the rights of the Government on all Data delivered under this Agreement.

The Government agrees not to remove any copyright notices placed on Data and to include such notices on all reproductions of the Data.

Section 11.06 Data First Produced by the Government:

As to Data first produced by the Government in carrying out the Government's responsibilities under this OTA and which Data would embody trade secrets or would comprise commercial or financial information that is privileged or confidential if obtained from the CMF on behalf of any PAH, such Data will, to the extent permitted by law, be appropriately marked with a suitable notice or legend and maintained in confidence by the CMF and any PAH to whom disclosed for three (3) years after the development of the information, with the express understanding that during the aforesaid period such Data may be disclosed and used by the CMF or any PAH, including its respective employees or subcontractors of any tier, (under suitable protective conditions) by or on behalf of the Government for Government purposes only.

Section 11.07 Prior Technology

(1) Government Prior Technology: In the event it is necessary for the Government to furnish the CMF or any MCDC member entity or PAH, including their respective employees or their subcontractors of any tier, with Data which existed prior to, or was produced outside of this Agreement, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used only for the purpose of carrying out their responsibilities under this Agreement. Data protection will include proprietary markings and handling, and the signing of non-disclosure agreements by CMF, PAHs, PAH subcontractors of any tier and their respective employees to whom such Data is provided for use under the OTA. Upon completion of activities under this Agreement, such Data will be disposed of as requested by the Government.

(2) CMF and PAH Prior Technology: In the event it is necessary for the CMF or any PAH to furnish the Government with Data which existed prior to, or was produced outside of this Agreement, and such Data embodies trade secrets or comprises commercial or financial information which is privileged or confidential, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used by the Government and such Government Contractors or contract employees that the Government may hire on a temporary or periodic basis only for the purpose of carrying out the Government's responsibilities under this

Agreement. Data protection will include proprietary markings and handling, and the signing of nondisclosure agreements by such Government Contractors or contract employees. Neither the CMF nor any PAH shall be obligated to provide Data that existed prior to, or was developed outside of this Agreement to the Government. Upon completion of activities under this Agreement, such Data will be disposed of as requested by the CMF on behalf of itself or PAHs.

(3) Oral and Visual Information: If information which the PAH (including their subcontractors of any tier and their respective employees) considers to embody trade secrets or to comprise commercial or financial information which is privileged or confidential is expressly disclosed orally or visually directly to the Government and/or CMF, the exchange of such information must be memorialized in tangible, recorded form and marked with a suitable notice or legend, and furnished to the Government and/or CMF within ten (10) calendar days after such oral or visual disclosure, or the Government and/or CMF shall have no duty to limit or restrict, and shall not incur any liability for any disclosure and use of such information. Upon Government and/or CMF request, additional detailed information about the exchange will be provided subject to restrictions on use and disclosure.

(4) Disclaimer of Liability: Notwithstanding the above, neither the Government nor the CMF shall be restricted in, nor incur any liability for, the disclosure and use of:

(a) Data not identified with a suitable notice or legend as set forth in this Article; nor

(b) Information contained in any Data for which disclosure and use is restricted under Article VIII entitled “Confidential Information” above, if such information is or becomes generally known without breach of the above, is properly known to the Government or CMF or is generated by the Government or CMF independent of carrying out responsibilities under this Agreement, is rightfully received from a third party without restriction, or is included in Data which the PAH has furnished, or is required to furnish to the Government or CMF without restriction on disclosure and use.

(5) Marking of Data: Any Data delivered under this Agreement shall be marked with a suitable notice or legend.

Notwithstanding the Paragraphs in this Article, differing rights in Data may be negotiated among the Parties to each individual project on a case-by-case basis.

Section 11.08 Lower Tier Agreements

The PAH shall include this Article, suitably modified to identify the parties, in all subcontracts or lower tier agreements, regardless of tier, or experimental, developmental, or research work.

Section 11.09 Survival Rights

Provisions of this Article shall survive termination of this Agreement under Article II.

Notwithstanding the terms of this in this Article, differing rights in data may be negotiated among the Parties to each individual Technology Project Agreement on a case-by-case basis.

Article XII. EXPORT CONTROL

Export Control

(1) Information subject to Export Control Laws/International Traffic in Arms Regulation (ITAR):

Public Law 90-629, « Arms Export Control Act, » as amended (22 U.S.C. 2751 et. seq.) requires that all unclassified technical data with military application may not be exported lawfully without an approval, authorization, or license under EO 12470 or the Arms Export Control Act and that such data require an approval, authorization, or license under EO 12470 or the Arms Export Control Act. For purposes of making this determination, the Military Critical Technologies List (MCTL) shall be used as general

guidance. All documents determined to contain export controlled technical data will be marked with the following notice:

WARNING- this document contains technical data whose export is restricted by the Arms Export Control Act (Title 22, U.S.C., and Sec 2751, et seq.) or the Export Administration Act of 1979, as amended, Title 50, U.S.C., App. 2401 et seq. Violations of these export laws are subject to severe criminal penalties. Disseminate in accordance with provision of DOD Directive 5230.25.

(2) Flowdown.

The PAH shall include this Article, suitably modified, to identify all Parties, in all Project Agreements or lower tier agreements. This Article shall, in turn, be included in all sub-tier subcontracts or other forms of lower tier agreements, regardless of tier.

Article XIII. TITLE AND DISPOSITION OF PROPERTY

Section 13.01 Definitions

In this Article, "property" means any tangible personal property other than property actually consumed during the execution of work under this Agreement.

Section 13.02 Title to Property

No significant items of property are expected to be acquired under this Agreement by the PAH. Title to any item of property valued $10,000.00 or less that is acquired by the PAH pursuant to a Project Agreement with the MCDC, in performance of the project issued to the PAH under this OTA shall vest in the PAH upon acquisition with no further obligation of the Parties unless otherwise determined by the Government AO. Should any item of property with an acquisition value greater than $10,000.00 be required, the PAH through the CMF shall obtain prior written approval of the Government AO. Title to this property shall also vest in the MCDC member entity or PAH upon acquisition. That PAH shall be responsible for the maintenance, repair, protection, and preservation of all such property at its own expense. Property acquired pursuant to this clause shall not be considered as in exchange for services in performance of the project, but shall be considered a Government contribution to the project.

Section 13.03 Government Furnished Property

The Government may provide the PAH Government Furnished Property (GFP) to facilitate the performance of individual projects under this Other Transaction Agreement. Such GFP will be specifically identified to a particular project and incorporated into the applicable Project Agreement. The GFP shall be utilized only for the performance of that individual project unless a specific exception is made in writing by the Agreements Officer.

The PAH shall assume the risk of and be responsible for any loss or destruction of, or damage to, any Government Furnished Property while in its possession or control, with the exception of reasonable wear and tear or reasonable and proper consumption. All property shall be returned at the end of the Project Agreement in as good as condition as when received with the exception of said reasonable wear and tear or in accordance with the provisions of the Project Agreement regarding its use. The PAH shall obtain explicit written authorization for any transfer or disposition of Government Furnished Property.

Article XIV. CIVIL RIGHTS ACT

This Agreement and any resulting Project Agreement is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to nondiscrimination in Federally assisted programs. It is the responsibility of each PAH to assure the PAH has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act (Attachment 1).

Article XV. NO SMALL BUSINESS AFFILIATION

Reserved

Article XVI. ANTITRUST

In the MCDC Articles of Collaboration, members agree to comply with all applicable U.S. laws, including U.S. antitrust laws. The MCDC is recognized under the National Cooperative Research and Production Act of 1993 and the MCDC will be similarly filing under the Act.

Article XVII. SECURITY & OPSEC

All PAH shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting when applicable.

Covered Defense Information (CDI) will be identified at the Project Agreement level. The MCDC Member shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting, which includes implementing on its covered contractor information systems the security requirements specified by DFARS 252.204-7012. Nothing in this paragraph shall be interpreted to foreclose the MCDC Member's right to seek alternate means of complying with the security requirements in National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171 (as contemplated in DFARS 252.204-7008 (Compliance with Safeguarding Covered Defense Information Controls) (Oct 2016) and DFARS 252.204-7012 (Safeguarding Covered Defense Information and Cyber Incident Reporting (Oct 2016)).

Work performed by a PAH under a Project Agreement may involve access to Controlled Unclassified Information (CUI). All Controlled Unclassified Information (CUI) developed under this Agreement will be managed in accordance with DoD Manual 5200.01, Volume 4 dated February 24, 2012. Contractor personnel shall comply with applicable Technology Protection Plans (TPP), Interim Program Protection Plans (IPPP) and/or Program Protection Plans (PPP). If a project involves a Controlled Unclassified Information (CUI) effort, the below listed Department of Defense Directives, Federal Acquisition Regulation (FAR) and the Defense Federal Acquisition Regulation Supplement (DFARS), and ARDEC clauses will be incorporated into the Project Agreements by reference with the same force and effect as if they were given in full text.

(1) Each project Scope of Work will be provided by the Agreements Officer Representative (AOR) to the Joint Project Manager- Medical Countermeasure Systems Office for dissemination to the appropriate Fort Detrick COMSEC officer prior to award for review.
(2) Each project Scope of Work will be subject to Ft. Detrick policy and procedure according to DoD 5220.22-M, (National Industrial Security Program Operating Manual, NISPOM), as deemed applicable and appropriate during the security review process and prior to award. Additional COMSEC requirements may be required at other locations/facilities (based on service/command requirements).
(3) Specific applicable policies, instructions, and regulations will be identified in each project. Throughout the life of the Agreement, if any policy, instruction, or regulation is replaced or superseded, the replacement or superseding version shall apply. The following is a snapshot of key regulatory documents, policies, regulations, etc. that may be applicable at time of project award.
    a) DoDM 5200.01 DoD Information Security Program, 24 Feb 12
    b) DoD 5200.2-R Personnel Security Regulation, Jan 87
    c) DoDD 5220.22 National Industrial Security Program, 28 Feb 06
    d) DoDI 5200.01, Information Security Program and Protection of Sensitive Compartmented Information, 24 Feb 2012
    e) DoD 5400.7-R, DOD Freedom of Information Act, Sept 98
    f) DoDD 2000.12, Antiterrorism Program, 18 Aug 03
    g) FAR Clause 4.402, Safeguarding Classified Information Within Industry
    h) FAR Clause 52.204-2, Security Requirements, Aug 1996

(4) For all Project Agreements, the following statement shall be flowed to the MCDC member entities unless otherwise stated within the Project Agreements.

a) Classification guidance for requirement - “The security level for this agreement is UNCLASSIFIED.”

(5) Anti-Terrorism Level I Training. This provision is for PAH employees with an area of performance within an Army controlled installation, facility or area. All PAH employees requiring access to Army installations, facilities and controlled access areas shall complete AT Level I awareness training within sixty (60)-calendar-days after project start date or effective date of incorporation of this requirement into the project, whichever is applicable. PAH(s) shall submit certificates of completion for each affected employee and PAH employee, to the AOR or to the Agreements Officer, if an AOR is not assigned, within thirty (30)-calendar-days after completion of training by all employees or personnel. AT level I awareness training is available at the following website: https://atlevel1.dtic.mil/at.

(6) Access and General Protection/Security Policy and Procedures. This standard language text is for PAH employees with an area of performance within an Army controlled installation, facility or area. PAH employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The PAH also shall provide all information required for background checks to meet installation access requirements to be accomplished by installation Provost Marshal Office, Director of Emergency Services or Security Office. The PAH workforce must comply with all personal identity verification requirements as directed by DOD, HQDA and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in PAH security matters or processes.

(7) Anti-Terrorism Awareness Training for PAH Personnel Traveling Overseas. This standard language text requires U.S.-based PAH employees to make available and to receive Government provided area of responsibility (AOR) specific AT awareness training as directed by AR 525-13. Specific AOR training content is directed by the combatant commander with the unit Anti-terrorism Officer (ATO) being the local point of contact.

(8) iWATCH Training. This standard language is for PAH employees with an area of performance within an Army- controlled installation, facility or area. PAH(s) shall brief all employees on the local iWATCH program (training standards provided by the requiring activity ATO). This local developed training will be used to inform employees of the types of behavior to watch for and instruct employees to report suspicious activity to the AOR. This training shall be completed within sixty (60)-calendar-days of a Project Agreement award and within sixty (60)-calendar- days of new employees’ commencing performance with the results reported to the AOR NLT thirty (30)-calendar-days after Project Agreement award.

(9) Impact on PAH performance during increased FPCON during periods of increased threat. During FPCONs Charlie and Delta, services may be discontinued / postponed due to higher threat. Services will resume when FPCON level is reduced to Bravo or lower.

(10) Random Antiterrorism Measures Program (RAMP) participation. PAH personnel working on an installation are subject to participation in Installation RAMP security program (e.g. vehicle searches, wearing of ID badges, etc.).

(11) PAH Employees Who Require Access to Government Information Systems. All PAH employees with access to a government information system must be registered in the ATCTS (Army Training Certification Tracking System) at commencement of services, and must successfully complete the DOD Information Assurance Awareness prior to access to the IS and then annually thereafter.

(12) For projects that Require an OPSEC Standing Operating Procedure/Plan. The PAH shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer, per AR 530-1, Operations Security.

This plan will be submitted by MCDC on behalf of the PAH(s) to the AO for coordination of approvals. This SOP/Plan will include the Government's critical information, why it needs to be protected, where it is located, who is responsible for it and how to protect it. In addition, MCDC shall identify an individual who will be an OPSEC Coordinator. MCDC will ensure this individual becomes OPSEC Level II certified per AR 530-1.

(13) For projects that Require OPSEC Training. Per AR 530-1, Operations Security, new PAH employees assigned by the PAH(s) to perform under a MCDC Project Agreement must complete Level I OPSEC awareness training within thirty (30)-calendar-days of their reporting for duty. All PAH employees performing under an OPSEC-designated project must complete annual Level I OPSEC awareness training. Level I OPSEC awareness training is available at the following website: http://cdsetrain.dtic.mil/opsec/.

(14) For Information assurance (IA)/information technology (IT) training. All PAH employees must complete the DoD IA awareness training before issuance of network access and annually thereafter. All PAH(s) working IA/IT functions must comply with DoD and Army training requirements in DoDD 8570.01, DoD 8570.01-M and AR 25-2 within six (6) months of employment.

(15) For information assurance (IA)/information technology (IT) certification. Per DoD 8570.01-M , DFARS 252.239-7001 and AR 25-2, the PAH employees supporting IA/IT functions shall be appropriately certified upon Project Agreement award. The baseline certification as stipulated in DoD 8570.01-M must be completed upon Project Agreement award.

(16) For PAH personnel authorized to accompany the Force. DFARS Clause 252.225-7040, Contractor Personnel Authorized to Accompany U.S. Armed Forces Deployed Outside the United States. The clause shall be used in projects that authorize PAH personnel to accompany U.S. Armed Forces deployed outside the U.S. in contingency operations; humanitarian or peacekeeping operations; or other military operations or exercises, when designated by the combatant commander. The clause discusses the following AT/OPSEC related topics: required compliance with laws and regulations, pre-deployment requirements, required training (per combatant command guidance) and personnel data required.

(17) For projects requiring Performance or Delivery in a Foreign Country, DFARS Clause 252.225-7043, Antiterrorism/Force Protection for Defense Contractors Outside the U.S. The clause shall be used in projects that require performance or delivery in a foreign country. This clause applies to both contingencies and non-contingency support. The key AT requirement is for non-local national PAH personnel to comply with theater clearance requirements and allows the combatant commander to exercise oversight to ensure the PAH’s compliance with combatant commander and subordinate task force commander policies and directives.

(18) For projects requiring the PAH to obtain U.S. Government Common Access Cards, installation badges, and/or access passes, the PAH shall return all issued U.S. Government Common Access Cards, installation badges, and/or access passes to the AOR when the project is completed or when the PAH employee no longer requires access to the installation or facility.

(19) For projects that require access to Potential Critical Program Information (PCPI) / Critical Program Information (CPI):

a) The PAH shall comply with the associated Interim Program Protection Plan (IPPP) / Program Protection Plan (PPP) / or Technology Protection Plan (TPP). The PAH shall comply with DOD, DA and AMC technology protection requirements in DODI 5200.39, AR 70-1, DA PAM 70-3 and AMC- R-380-13.

(20) Work by the Consortium Management Firm (CMF) and Project Agreement Holder/Consortium Member (PAH) under Project Agreements may involve access to Controlled Unclassified Information (CUI) as well as information classified as "Confidential", "Secret", or "Top Secret". The CMF and the PAH and their employees who work on such Project Agreements shall comply with (1) the Security Agreement (DD Form 441), including the National Industrial Security Program Operation Manual (DOD 5220.22M), (2) any revisions to that manual that may be issued, and (3) the Agreement security classification specification (DD form 254) if included, and all security requirements including but not limited to OPSEC plans and those security requirements specific to the individual projects. During the course of this Agreement the Parties may determine that information developed by the PAH and/or the Government pursuant to this Agreement shall be treated as classified. Such information shall be classified in accordance with DOD 5220.22M.

a) Each project Scope of Work will be provided by the AOR to the AOR's local Security Office prior to award for review. For classified efforts that Security Office will provide the overall Security Classification Specification (DD Form 254). The PAH will be responsible for providing a copy of any Subcontract Security Classification Specification (DD Form 254) to lower tier awards.

b) If a Project Agreement involves a classified effort or a Controlled Unclassified Information (CUI) effort, Department of Defense Directives, Federal Acquisition Regulation (FAR) and the Defense Federal Acquisition Regulation Supplement (DFARS) clauses by reference, and local clauses will be incorporated with the same force and effect as if they were given in full text shall be incorporated into this agreement.

c) Specific applicable policies, instructions, and regulations will be identified in each Project Agreement. Throughout the life of the Project Agreement, if any policy, instruction, or regulation is replaced or superseded, the replacement or superseding version shall apply.

d) Agreement Structure

i) Research and Development under these Project Agreements will be in accordance with the Other Transaction Agreement (OTA) between the United States Army Contracting Command – New Jersey (ACC-NJ) and the MCDC in care of its Consortium Management Firm (CMF), Advanced Technology International (ATI).

ii) Within the Project Agreements, sharing of classified information will be on a need to know basis as directed in required Project Agreements.

iii) Upon Project Agreement completion or termination, the PAH must:

(1) Return ALL classified information received or generated under the Project Agreement;
(2) Destroy all of the classified information; or,

(3) Request retention for a specified period of time

Flowdown for OPSEC/Security Requirements:

MCDC shall include the aspects of this Article as they pertain to each project requirement. Each project will include specific OPSEC / Security requirements within each SOW and RPP. The requirements delineated within each project, in turn, shall be included in all sub-tier subcontracts or other forms of lower-tier agreements, regardless of tier.

Article XVIII. SAFETY

The PAH shall adhere to all local, state, and federal rules and regulations required in maintaining a safe and non-hazardous occupational environment throughout the duration of the project. At a minimum, the PAH shall provide the following reports and materials on an as needed basis:

Accident/Incident Report: The PAH shall report immediately any major accident/incident (including fire) resulting in any one or more of the following: causing one or more fatalities or one or more disabling injuries; damage of Government property exceeding $10,000; affecting program planning or production schedules; degrading the safety of equipment under a project, such as personnel injury or property damage may be involved; identifying a potential hazard requiring corrective action. The PAH shall prepare the report (DI-SAFT-81563) for each incident.

Material Safety Data Sheets (MSDS): The PAH shall prepare and maintain MSDS for all materials used and generated under this Agreement.

Environmental Requirements include the following:

Pollution Prevention: Consideration should be given to alternative materials and processes in order to eliminate, reduce, or minimize hazardous waste being generated. This is to be accomplished while minimizing item cost and risk to item performance.

Environmental Compliance: All activities must be in compliance with Federal, State, and local environmental laws and regulations, Executive orders, treaties, and agreements. The PAH shall evaluate the environmental consequences and identify the specific types and amounts of hazardous waste being generated during the conduct of efforts undertaken under this Agreement.

Hazardous Waste Report: The PAH shall evaluate the environmental consequences and identify the specific types and amounts of hazardous waste being generated during this Agreement. The PAH shall submit a Hazardous Waste Report IAW DI-MGMT-80899.

Disposal Instructions for Residual/Scrap Materials: The PAH shall dispose of all residual and scrap materials generated from this Agreement, including high explosives. The PAH shall specify the anticipated quantities, methods, and disposal costs.

Article XIX. REPRESENTATIONS AND WARRANTIES

Section 19.01 Representations and Warranties of All Parties

Each Party to this Agreement represents and warrants to the other Parties that (1) it is free to enter into this Agreement; (2) in so doing, it will not violate any other agreement to which it is a party; and (3) it has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement.

Section 19.02 Limitations

Except as expressly provided herein, no party to this Agreement makes any warranty, express or implied, either in fact or by operation of law, by statute or otherwise, relating to (1) any research conducted under this agreement, or (2) any invention conceived and/or reduced to practice under this agreement, or (3) any other intellectual property developed under this Agreement, and each party to this Agreement specifically disclaims any implied warranty of merchantability or warranty of fitness for a particular purpose.

Article XX. LIABILITY OF THE PARTIES

Section 20.01 Waiver of Liability

With regard to the activities undertaken pursuant to this Agreement, no Party shall make any claim against the others, employees of the others, the others' related entities (e.g., Government, contractors, subcontractors, etc.), or employees of the others' related entities for any injury to or death of its own employees or employees of its related entities, or for damage to or loss of its own property or that of its related entities, whether such injury, death, damage or loss arises through negligence or otherwise, except in the case of willful misconduct.

Section 20.02 Damages

The Parties shall not be liable to each other for consequential, punitive, special and incidental damages or other indirect damages, whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's willful misconduct; Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.

Section 20.03 Extension of Waiver of Liability

The PAH agrees to extend the waiver of liability as set forth above subawardees at any tier under an Project Agreement by requiring them, by contract or otherwise, to agree to waive all claims against the Parties to this Agreement.

Section 20.04 Applicability

Notwithstanding the other provisions of this article, this Waiver of Liability shall not be applicable to:

(1) Claims between the PAH and the CMF regarding a material breach, noncompliance, or nonpayment of funds;

(2) Claims for damage caused by willful misconduct; and

(3) Intellectual property claims.

Section 20.05 Limitation of Liability

In no case shall the CMF, or the PAH's financial liability exceed the amount obligated by the Government or committed as a Cash Contribution or In-kind Contribution by a MCDC member entity under a Project Agreement. Nothing in this Article shall be construed to create the basis of a claim or suit where none would otherwise exist.

Article XXI. GENERAL PROVISIONS

Section 21.01 Fees

The PAH will not be constrained from the payment of an appropriate fee or profit for the effort being conducted on a Project Agreement when cost share is not being contributed. The fees shall be specific to the individual Project Agreements and negotiated on project by project basis.

Section 21.02 Waiver

No waiver of any rights shall be effective unless assented to in writing by the party (Government, MCDC, CMF, or PAH) to be charged, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

Section 21.03 Section Headings

The headings and subheadings of the sections of this Agreement are intended for convenience of reference only and are not intended to be a part of, or to affect the meaning or interpretation of this Agreement.

Section 21.04 Severability

In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision; Provided that no such severability shall be effective if the result of such action materially changes the economic benefit of this Agreement to the Parties.

Section 21.05 Force Majeure

No failure or omission by the CMF or the MCDC PAH in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement or create any liability if the same shall arise from any cause or causes beyond the control of the Parties, including but not limited to, the following: acts of God; Acts or omissions of any Government; Any rules, regulations or orders issued by any Governmental authority or by any officer, department, and agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; and invasion and provided that such failure or omission resulting from one of the above causes is cured as soon as is practicable after the occurrence of one or more of the above mentioned causes.

Section 21.06 Regulatory Affairs

Development and production of medical products and processes fall under the purview of the Food and Drug Administration (FDA) and research on these products involving animal or human studies is regulated by other laws, directives, and regulations. Project Awards under this Agreement that involve work in support of or related to FDA regulatory approval will address contingencies for Government access to regulatory rights in the event of product development abandonment or failure. Efforts conducted under this OTA shall be done ethically and in accordance with all applicable laws, directives, and regulations.

The Government shall ensure performance includes regulatory expertise and guidance for candidate medical countermeasure development efforts:

(1) This includes allowing the government to discuss/negotiate in partnership with the consortium how to assume appropriate risk in regulatory strategies. The government will review, negotiate, and come to consensus with the PAH on product-specific risk-based decisions.

(2) PAHs will use all regulatory programs to accelerate the pace of candidate medical countermeasure development, including fast-track status, and as appropriate meeting requirements for priority review vouchers, applying for breakthrough therapy and accelerated approval as appropriate (see FDA Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics).

(3) PAH will provide FDA submissions to the government such as all documentation requested by FDA and all proposals to FDA.

(4) PAH will allow the government to monitor all FDA communications by listening to teleconferences and attending meetings.

(5) PAH will allow the government to attend regulatory site visits and audits, and actively participate in all third-party audits.

(6) PAH will comply with Quality Assurance according to negotiated standards with the government on reports, material for Interim Fielding Capability (such as Emergency Use Authorization or Expanded Access Protocols), product for trials, prototypes, etc.

(7) PAH will provide strategies to address contingencies that could arise from regulatory directives, and regulatory failures.

Section 21.07 Radioactive Materials

PAH shall ensure compliance with the provisions of Title 10 CFR 21. This regulation establishes procedures and requirements for implementation of Section 206 of the Energy Reorganization Act of 1974.

Section 21.08 Recombinant DNA

PAH shall ensure that all work involving the use of recombinant DNA will be in compliance with guidance provided at the following website: http://www4.od.nih.gov/oba (National Institutes of Health [NIH] Guidelines for Research Involving Recombinant DNA Molecules).

Section 21.09 Required Compliance for Use of Laboratory Animals

Notwithstanding any other provisions contained in this award or incorporated by reference herein, the PAH is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the US Army Medical Research and Materiel Command, Animal Care and Use Office,. The PAH shall receive written approval to begin research under the applicable protocol proposed for a Project Agreement from the US Army Medical Research and Materiel Command, Animal Care and Use Office under separate letter to the PAH and Principal Investigator. A copy of this approval will be provided to the ACC-NJ for the official file. Non-compliance with any provision of this clause may result in the termination of award. Information is provided at the following website http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_regulations. The PAH will conduct advanced development/pivotal studies including human safety studies, animal efficacy studies or clinical studies required for approval using validated endpoints, and other studies as deemed necessary by the FDA for licensure of the candidate product in adherence to current Good Laboratory Practice regulations, current Good Clinical Practice regulations, and all other applicable FDA regulations in the conduct of non-clinical and clinical studies as defined by FDA guidance (21 CFR Parts 210-211).

Section 21.10 Required Compliance for Use of Human Subjects

Research under this award involving the use of human subjects may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol in accordance with 45 CFR Part 46. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the funded institution and the Principal Investigator. A copy of this approval will be provided to ACC-NJ for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award. Information is provided at the following website: http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo.

Section 21.11 Required Compliance for use of Human Anatomical Substances

Research at funded institutions using human anatomical substances may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human anatomical substances under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the funded institution and the Principal Investigator. A copy of this approval will be provided to ACC-NJ, from the CMF, for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award. Information is provided at the following web site: http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo

Section 21.12 Compliance with current Good Manufacturing Processes (cGMP)

Manufacturing Standards as appropriate for the level of prototype Material used for clinical trials, pivotal non- clinical studies, consistency lots, and other uses as defined in regulatory plans should be compliant with current Good Manufacturing Processes (cGMP) as defined by FDA guidance (21 CFR Parts 210-211). If at any time during the life of the award, the PAH fails to comply with cGMP in the manufacturing, processing and packaging of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the PAH shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure.

Section 21.13 Registration with Select Agent Program

Where required, consortium members performing studies and tasks using select biological agent or toxins should be registered with the program with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied. Listings of select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

Section 21.14 Duty-Free Entry

(a) *Definitions*. As used in this clause –

(1) "Component," means any item supplied to the Government as part of an end product or of another component.
(2) "Customs territory of the United States" means the 50 States, the District of Columbia, and Puerto Rico.
(3) "Eligible product" means –
(i) "Designated country end product" as defined in the Trade Agreements clause;
(ii) "Free Trade Agreement country end product" other than a "Bahrainian end product" or a "Moroccan end product" as defined in the Buy American Act – Free Trade Agreements – Balance of Payments Program; or
(iii) "Canadian end product" as defined in Alternate I of the Buy American Act – Free Trade Agreements – Balance of Payments Program.
(4) "Qualifying country" and "qualifying country end product" have the meanings given in the Trade Agreements clause, the Buy American Act and Balance of Payments Program clause, or the Buy American Act—Free Trade Agreements—Balance of Payments Program.

(b) Except as provided in paragraph (i) of this clause, or unless supplies were imported into the customs territory of the United States before the date of a Project Agreement or the applicable subcontract, the price of this Agreement shall not include any amount for duty on-
(1) End items that are eligible products or qualifying country end products;
(2) Components (including, without limitation, raw materials and intermediate assemblies) produced or made in qualifying countries, that are to be incorporated in U.S – made end products to be delivered under an Project Agreement; or
(3) Other supplies for which the PAH estimates that duty will exceed $200 per shipment into the customs territory of the Unites States

(c) The PAH shall –
(1) Claim duty-free entry only for supplies that the PAH intends to deliver to the Government under an Project Agreement, either as end items or components of end items; and
(2) Pay duty on supplies, or any portion thereof, that are diverted to nongovernmental use, other than –
(i) Scrap or salvage; or
(ii) Competitive sale made, directed, or authorized by the Agreements Officer.

(d) Except as the PAH may otherwise agree, the Government will execute duty-free entry certificates and will afford such assistance as appropriate to obtain the duty-free entry of supplies –
(1) For which no duty is included in the Project Agreement price in accordance with paragraph (b) of this clause; and
(2) For which shipping documents bear the notation specified in paragraph (e) of this clause.

(e) For foreign supplies for which the Government will issue duty-free entry certificates in accordance with this clause, shipping documents submitted to Customs shall –
(1) Consign the shipments to the appropriate –
(i) Military department in care of the PAH, including the PAH's delivery address; or
(ii) Military installation; and

(2) Include the following information:

(i) Prime Agreement number and, if applicable, delivery order number.

(ii) Number of the subcontract for foreign supplies, if applicable.

(iii) Identification of the carrier.

(iv) (A) For direct shipments to a U.S. military installation, the notation: "UNITED STATES GOVERNMENT DEPARTMENT OF DEFENSE Duty-Free Entry to be claimed pursuant to Section XXII, Chapter 98, Subchapter VIII, Item 9808.00.30 of the Harmonized Tariff Schedule of the United States. Upon arrival of shipment at the appropriate port of entry, District Director of Customs, please release shipment under 19 CFR Part 142 and notify Commander, Defense Contract management Agency (DCMA) New York, ATTN: Customs Team, DCMAE-GNTF, 207 New York Avenue, Staten Island, New York, 10305-5013, for execution of Customs Form 7501, 7501A, or 7506 and any required duty-free entry certificates."

(B) If the shipment will be consigned to other than a military installation, e.g., a domestic contractor's plant, the shipping document notation shall be altered to include the name and address of the contractor, agent, or broker who will notify Commander, DCMA New York, for execution of the duty- free certificate. (If the shipment will be consigned to a contractor's plant and no duty-free entry certificate is required due to a trade agreement, the PAH shall claim duty-free entry under the applicable trade agreement and shall comply with the U.S. Customs Service requirements. No notification to Commander, DCMA New York, is required.)

(v) Gross weight in pounds (if freight is based on space tonnage, state cubic feet in addition to gross shipping weight.)

(vi) Estimated value in U.S. dollars.

(vii) Activity address number of the contract administration office administering the prime contract, e.g., for DCMA Dayton, S3605A.

(f) Preparation of customs forms.

(1)(i) Except for shipments consigned to a military installation, the PAH shall –

(A) Prepare any customs forms required for the entry of foreign supplies into the customs territory of the United States in connection with this Agreement; and

(B) Submit the completed customs forms to the District Director of Customs, with a copy to DCMA NY for execution of any required duty-free entry certificates.

(ii) Shipments consigned directly to a military installation will be released in accordance with sections 10.101 and 10.102 of the U.S. Customs regulations.

(2) For shipments containing both supplies that are to be accorded duty-free entry and supplies that are not, the PAH shall identify on the customs forms those items that are eligible for duty-free entry.

(g) The PAH shall –

(1) Prepare (if the PAH is a foreign supplier), or shall instruct the foreign supplier to prepare, a sufficient number of copies of the bill of lading (or other shipping document) so that at least two of the copies accompanying the shipment will be available for use by the District Director of Customs at the port of entry;

(2) Consign the shipment as specified in paragraph (e) of this clause; and

(3) Mark on the exterior of all packages –

(i) "UNITED STATES GOVERNMENT, DEPARTMENT OF DEFENSE"; and

(ii) The activity address number of the contract administration office administering the prime Agreement.

(h) The PAH through the MCDC CMF shall notify the ACO in writing of any purchase of eligible products of qualifying country supplies to be accorded duty-free entry, that are to be imported into the customs territory of the United States for delivery to the Government or for incorporation in end items to be delivered to the Government. The PAH through the MCDC CMF shall furnish the notice to the ACO immediately upon award to the supplier and shall include in the notice –

(1)The PAH's name, address, and Commercial and Government Entity (CAGE) code;

(2) Prime Agreement number and Project Agreement number;

(3) Total dollar value of the prime Agreement or Project Agreement number;

(4) Date of the last scheduled delivery under the prime Agreement or Project Agreement number;

(5) Foreign supplier's name and address;

(6) Number of the subcontract for foreign supplies;
(7) Total dollar value of the subcontract for foreign supplies;
(8) Date of the last scheduled delivery under the subcontract for foreign supplies;
(9) List of items purchased;
(10) An agreement that the PAH will pay duty on supplies, or any portion thereof, that are diverted to nongovernmental use other than –
(i) Scrap of salvage; or
(ii) Competitive sale made, directed, or authorized by the Agreements Officer;
(11) Country or origin; and
(12) Scheduled delivery date(s).

(i) This clause does not apply to purchases of eligible products or qualifying country supplies in connection with this Agreement if –
(1) The supplies are identical in nature to supplies purchased by the PAH or any subcontractor in connection with its commercial business; and
(2) It is not economical or feasible to account for such supplies so as to ensure that the amount of the supplies for which duty-free entry is claimed does not exceed the amount purchased in connection with this Agreement.

(j) The PAH shall –
(1) Insert the substance of this clause, including this paragraph (j), in all subcontracts for –
(i) Qualifying country components; or
(ii) Nonqualifying country components for which the PAH estimates that duty will exceed $200 per unit;
(2) Require subcontractors to include the number of this Agreement on all shipping documents submitted to Customs for supplies for which duty-free entry is claimed pursuant to this clause; and
(3) Include in applicable subcontracts –
(i) The name and address of the ACO for this Agreement;
(ii) The name, address, and activity address number of the contract administration office specified in this Agreement; and
(iii) The information required by paragraphs (h)(1), (2), and (3) of this clause.

Section 21.15 Follow-On Production

10 U.S.C. § 2371b, Section 815 authorizes the use of a follow-on production contract (FAR) or transaction (OTA). In order to be eligible for follow-on production, the following criteria is required: (1) the follow-on shall be awarded to the same participants named in the Project Agreement; (2) competitive procedures were used to award the Project Agreement in question; and (3) the Project Agreement was successfully completed. This Agreement was the result of competitive procedures, and competitive procedures are used to award individual projects under this Agreement. The Agreements Officer shall be responsible for documenting whether or not a Project Agreement was successfully completed. Follow-on production efforts shall be strictly limited to the scope of the successfully completed prototype. This Agreement will not be used to award follow-on production efforts; Government customers will be responsible for working with their contracting personnel.

All Project Agreements shall include the following statement:

"In accordance with 10 U.S.C. § 2371b(f), and upon a determination that this competitively awarded prototype project has been successfully completed, this prototype project may result in the award of a follow-on production contract or transaction without the use of competitive procedures."

Article XXII. ASSIGNMENT OF AGENCY

Section 22.01 Assignment.

Neither this Agreement nor any rights or obligations of any party hereunder shall be assigned or otherwise transferred by either party without the prior written consent of the other party.

Article XXIII. ORDER OF PRECEDENCE

In the event of any inconsistency between the general terms of this Agreement, the inconsistency shall be resolved by giving precedence in the following order: (1) the Agreement; (2) Attachments to the Agreement; (3) the Project Agreement documentation (including but not limited to the PAH proposal selected for funding by the Government). In any event, specifically negotiated Project Agreement terms will govern over general terms of this Agreement.

Article XXIV. EXECUTION

This Agreement constitutes the entire Agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written consent of the PAH and the CMF Contracting Representative designated in this Agreement.

Attachment I – Assurance of Compliance with Title VI of the Civil Rights Act of 1964

Statement of Assurance of Compliance with
Title VI of the Civil Rights Act of 1964
For MCDC Member Organizations

The Regeneron Pharmaceuticals, Inc. hereby agrees that it will comply with the provisions of the Title VI Civil Rights Act of 1964 as amended (42 U.S.C 2000-d) and all requirements imposed pursuant thereto, to the end that, in accordance with Title VI of that Act and the Regulation, no person in the United States shall, on the ground of race, color, or national origin, be
excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination
under any MCDC Project for which the MCDC member organization receives Federal financial assistance from the Government.

The MCDC member organization agrees that compliance with this assurance constitutes a condition of continued receipt of Federal financial assistance, and that it is binding upon the MCDC member organization, its successors, transferees and assignees for the period during which such assistance is provided.

The MCDC member organization further recognizes and agrees that the United States shall have the right to seek judicial enforcement of this assurance.

The person or persons whose signature(s) appear(s) below is/are authorized to sign this assurance, and commit the MCDC member organization to the above provisions.

_____
Signature of Authorized Official

_____
Title of Authorized Official

_____
Name of MCDC Member Organization

_____
Date

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT, MARKED BY BRACKETS, WERE OMITTED BECAUSE THOSE PORTIONS ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL TO THE COMPANY IF PUBLICLY DISCLOSED.

Advanced Technology International

Applied Technologies Center
315 Sigma Drive
Summerville, SC 29486
www.ati.org

PROJECT AGREEMENT NO.: 1

MCDC BASE AGREEMENT NO.: 2020-504

PROJECT TITLE: MCDC2008-005; Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2

PARTIES: Advanced Technology International ("MCDC CMF") and Regeneron Pharmaceuticals, Inc. ("Project Agreement Holder")

This Project Agreement is awarded under the authority of MCDC Base Agreement No. 2020-504, and herein incorporates all the terms and conditions thereof, as such terms and conditions are modified by the terms of the Statement Of Work attached hereto as Exhibit A (the "Statement of Work" or "SOW"). The parties agree that, to the extent any terms or conditions of the Statement of Work conflict with the terms and conditions of MCDC Base Agreement No. 2020-504, the terms and conditions of the Statement of Work shall apply and take precedence.

1. PAYMENT METHOD

The Payment Method for this Project Agreement is Firm Fixed Price with a not to exceed ceiling.

2. TERM OF THE PROJECT AGREEMENT

The period of performance for this Project Agreement is from the effective date, which is the date of the last signature through June 30, 2021.

3. OBLIGATION

The MCDC CMF's liability to make payments to the Project Agreement Holder is limited to only those funds obligated under this Project Agreement or by modification to the Project Agreement. MCDC CMF may incrementally fund this Project Agreement.

4. TOTAL FIRM FIXED PRICE

The total firm fixed price for the services to be provided by the Project Agreement Holder is as follows:

Total Firm Fixed Price $450,262,000

5. TOTAL FUNDING

The total amount of funding currently available for payment and allotted to this Project Agreement is **$450,262,000**.

6. MILESTONE PAYMENT SCHEDULE

The Project Agreement Holder shall document the accomplishments of each Project Payable Milestone under each Project Agreement. Acceptance of Milestones shall be contingent upon approval from the Government Agreements Officer Representative (AOR) detailed in Clause No. 9, Technical and Administrative Representatives. Milestone payments will be paid in the amount indicated in the attached Milestone Payment Schedule (Attachment A).

7. APPROACH TO MEETING THE OTHER TRANSACTION AUTHORITY

In accordance with provision contained in 10 USC 2371b governing the use Other Transaction Agreements each MCDC Member Organization must meet at least one of the following conditions: have at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the performance of an awarded Project Agreement; all significant participants in the Project Agreement other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors; or provide a cost share of no less than one third of the value of the Project Agreement awarded to the Member Organization. The Project Agreement Holder's approach to meeting the Other Transaction Authority requirement is identified below. Throughout the period of performance of any Project Agreement, the CMF and the Government will actively monitor the award to ensure compliance with this provision in accordance with implementation guidance from Headquarters – Department of the Army (HQDA) and/or Office of the Secretary of Defense (OSD). The Project Agreement Holder will be given the opportunity to become compliant with the guidance should they be found non-compliant. Failure to comply may result in termination.

The warranties and representations submitted as part of the proposal are hereby incorporated into this Project Agreement. The Project Agreement Holder was proposed as a nontraditional defense contractor and determined to be providing a significant contribution.

8. STATEMENT OF WORK

The Statement of Work, Attachment A, provides a detailed description of the work to be accomplished and reports and deliverables required by this Project Agreement. All changes to Attachment A must be incorporated via written modification to this Project Agreement. Additional guidance on report requirements is in Attachment B, Report Requirements.

9. TECHNICAL AND ADMINISTRATIVE REPRESENTATIVES

The following technical and contractual representatives of the Parties are hereby designated for this Project Agreement. Either party may change their designated representatives by written notification to the other.

MCDC CMF Contractual Representative:
Contracts Administrator
Advanced Technology International
315 Sigma Drive
Summerville, SC 29486
Email:
Phone:

Government Technical Representatives:
Agreements Officer Representative (AOR):

Email:
Phone:

Project Agreement Holder's Representatives:

Technical Representative:	Contractual Representative:
777 Old Saw Mill River Rd	777 Old Saw Mill River Rd
Tarrytown, NY 10591	Tarrytown, NY 10591
Email:	Email:
Phone:	Phone:

10. MARKING OF DELIVERABLES
Any Data delivered under this Project Agreement, by the Project Agreement Holder, shall be marked with a suitable notice or legend.

11. SECURITY ADMINISTRATION
The security level for this project is UNCLASSIFIED.

12. ATTACHMENTS
Attachments listed herein are hereby incorporated by reference into this Project Agreement.
A. Statement of Work, "Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2"
B. Report Requirements
C. Technical Direction Letter (TDL) RPP-20-08 Regeneron

13. GOVERNMENT FURNISHED PROPERTY
At this time, Government Furnished Property is not provided for use under this Project Agreement.

14. PATENT RIGHTS AND DATA RIGHTS
Please reference Section 7 of Attachment A, Statement of Work.

15. FOLLOW-ON PRODUCTION PROVISION
Please reference Section 1 of Attachment A, Statement of Work.

16. SECURITY & OPSEC

The below language shall be used as Paragraph 6 of Article XVII in Regeneron's Base Agreement:

Access and General Protection/Security Policy and Procedures. This standard language text is applicable to ALL PAH employees working on critical program information or covered defense information related to Operation Warp Speed (OWS), and to those with an area of performance within an Army controlled installation, facility or area. PAH employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The PAH also shall provide all information required for background checks necessary to access critical program information or covered defense information related to OWS, and to meet installation access requirements to be accomplished by installation Provost Marshal Office, Director of Emergency Services or Security Office. The PAH workforce must comply with all personal identity verification requirements as directed by DOD, HQDA and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in PAH security matters or processes.

17. ENTIRE AGREEMENT

This Project Agreement and the MCDC Base Agreement under which it is issued constitute the entire understanding and agreement between the parties with respect to the subject matter hereof.

Except as provided herein (including in the SOW), all Terms and Conditions of the MCDC Base Agreement and its modifications remain unchanged and in full force and effect.

Advanced Technology International

Applied Technologies Center
315 Sigma Drive
Summerville, SC 29486
www.ati.org

The Project Agreement Holder is required to sign this document and return to Advanced Technology International to finalize this action.

Regeneron Pharmaceuticals, Inc.	**Advanced Technology International**
By: /s/ Robert Landry	By: /s/
Name: Robert Landry	Name:
Title: Executive Vice President- Finance and Chief Financial Officer	Title:
Date: Jul 6, 2020	Date: 6 July 2020

Attachment A
Statement of Work

This page intentionally left blank. See separate document for Attachment A.

Statement of Work
For
Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2

RPP #: RPP-20-08
Project Identifier: MCDC OTA 2008-005, W15QKN-16-9-1002
Consortium Member: Regeneron Pharmaceuticals, Inc.
Title of Proposal: Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

A. Preamble

Regeneron Pharmaceuticals, Inc. (referred to herein as "Regeneron", "Offeror", "Contractor" or "Recipient") has demonstrated experience with rapid scale-up of biopharmaceutical programs. Our excellent history of receiving development scale processes from Research and Development (R&D) laboratories, and then expanding to clinical or commercial Good Manufacturing Practice (GMP) scale production, is well documented. [* * *] We have consistently demonstrated our ability to expedite the delivery of high quality, safe and efficacious products (Ebola therapeutic) in partnership with the Government (anti-MERS, anti-Ebola).
Fully human monoclonal antibodies (mAbs) are molecules with high potency, predictable Pharmacokinetics (PK), and limited off-target toxicity, and thus provide attractive types of therapeutics for emerging diseases. Importantly, we have repeatedly demonstrated that candidate mAb-based drugs to prevent and/or treat emerging infections, can be rapidly obtained from Regeneron's proprietary VelocImmune® mice. Further, our ability to concurrently generate isogenic cell lines that are optimized for rapid antibody scale up and manufacturing using our proprietary Chemistry, Manufacturing, and Controls (CMC) platform technologies, have facilitated both testing of our mAbs in preclinical models and subsequent development of these mAbs into drugs suitable for human testing. In the process of completing many of these activities we have collaborated with other entities (including BARDA, Research Institutes, Government Laboratories and Universities). Our manufacturing has been designed to be paired with our proprietary VelocImmune® R&D technology, that is a proven process to rapidly take a research concept from the bench, into large scale production, with the ability to delivery medicines to patients.

The Government has advised Regeneron that it is appropriate for the project described in this Project Agreement to be performed through the Medical CBRN Defense Consortium (MCDC), under the authority of the MCDC Other Transaction Agreement No. W15QKN-16-9-1002. Regeneron is amenable to performing the project pursuant to such authority, based on the advice of the Government, and due to the unprecedented circumstances of the Coronavirus Disease 2019 (COVID-19) pandemic and, accordingly, the parties have entered into this Project Agreement.

[* * *]

B. Overall Objectives and Scope

This project is defined by discrete work segments for the continuous manufacture of drug substance, formulated drug substance and filled, packaged and labeled drug product, in accordance with a mutually agreed schedule.

Pursuant to this project, Regeneron will manufacture and sell drug product to the applicable United States (U.S.) Federal Government agency, for distribution in the U.S. All manufacturing described herein will be compliant with Food and Drug Administration (FDA) current Good Manufacturing Oractices (cGMP), as 21 CFR 210 and 211.

1.1 Introduction

The objective is to conduct the manufacturing production activities described in this proposal for prototypes consisting of novel, proprietary mAb therapeutics and prophylactics, to reduce pathology of COVID-19 disease and/or prevent development of disease when administered prophylactically.

1.2 Scope

These manufacturing production activities will include manufacturing at-scale, filling and finishing, and storage and shipping of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)-specific monoclonal antibodies (referred to herein as the “prototype”, the “prototype product”, the “product” or “drug product”) for treatment and/or prophylaxis against COVID-19.

1.3 Definition of the Prototype Project

Consistent with USG objectives, Regeneron will employ its proprietary manufacturing technology and processes, in a manner compliant with applicable laws and regulations, including 21 CFR 210 and 211 and the Drug Supply Chain Security Act, to manufacture the prototype product. This effort constitutes a prototype project because it will be used to evaluate the technical feasibility of manufacturing the prototype product during the ongoing COVID-19 pandemic. In addition, this is a prototype project because Regeneron will demonstrate, and prove-out the at-scale, multi-lot proprietary manufacturing activities of Regeneron in order to assess the feasibility of these activities to support the necessary quantity of the prototype product to treat the U.S. population. Successful completion of the prototype project will demonstrate Regeneron’s capability to (i) rapidly manufacture product, which can be further scaled-up to meet mutually agreed to surge requirements with little advance notification and (ii) facilitate the Government’s ability to stockpile and distribute large quantities of the drug product to respond when needed, including for use in clinical studies, under an Emergency Use Authorization (EUA), or pursuant to other clearance from the U.S. FDA. For clarity, any manufacturing and supply of drug product in excess of the

[* * *]

specific quantities set forth in Section 4.0 of this Statement of Work, shall be subject to a separate mutual agreement between Regeneron and the Government.

The scope of effort supported by this agreement is further clarified in Section 1.4. It is important to note that nonclinical and clinical studies for the prototype are being conducted by Regeneron outside of this agreement. The results of those studies may be used to develop use case scenarios and, in turn, inform the USG's deployment strategy as it relates to product manufactured under this agreement; however, such results (including the degree to which the data are "positive" or "negative") shall not be a factor in this prototype project.

1.4 Objective

- Conduct its proprietary manufacturing production activities described in this proposal for prototypes consisting of novel, proprietary mAb therapeutics and prophylactics, to reduce pathology of COVID-19 disease and/or prevent development of disease when administered prophylactically.
- The prototypes will include one or more of the following, as mutually agreed between Offeror and the Government:
  - the mAbs known as REGN10987 and REGN10933, as a cocktail;
  - Other mAbs (as monotherapies or a cocktail) as agreed to by bilateral modification between Offeror and the Government.
- The deliverables will be the products listed above (i.e., REGN10987 and REGN10933), in the form of bulk formulated drug substance and/or filled and finished product in vials, as mutually agreed between Offeror and the Government, packaged and labeled drug product, results, reports and records associated with generation of data demonstrating quality and control.
- The products will be delivered in the form and quantity to be agreed between Offeror and the Government. It is expected that the prototypes will be stored by Offeror until such time as (a) they can be used for pre-clinical or clinical development purposes under an Investigational New Drug application (IND), or (b) upon the FDA's grant of an EUA under Section 564 of the Food, Drug and Cosmetic Act (FD&C Act), or full marketing approval under a full Biologics License Application (BLA) under Section 351(a) of the Public Health Service Act (PHSA).

1.5 Follow-on Activity

In accordance with 10.U.S.C. 2371b(f), and upon successful demonstration of the prototype, or at the accomplishment of particularly favorable or unexpected results achieved outside of this Agreement that would justify transitioning to production (e.g., EUA or BLA), additional at-scale manufacturing of [* * *], supported by a mutually agreed upon follow-on production contract or Other Transaction Agreement, may be awarded to Regeneron, without further competition, to partially or completely meet the USG objective of supplying a safe and effective COVID-19 therapeutic or prophylactic treatment courses to ensure nationwide

[* * *]

access. For clarity, any manufacturing and supply of drug product in excess of the specific quantities set forth in Section 4.0 of this Statement of Work shall be subject to a mutually-agreed upon separate agreement between Regeneron and the Government. For further clarity, neither party shall be obligated to negotiate or enter into such a separate agreement for follow-on production.

During the performance of the prototype project, the Government and contractor may negotiate the scope and price of follow-on production.

2.0 APPLICABLE REFERENCES

Current Good Manufacturing Practices, 21 CFR 210, 211

[* * *]

4.0 DELIVERABLES

Offeror assumed [* * *]. Regeneron shall have the right to provide deliverables directly to the Government and not to the Consortium Management Firm (CMF).

Deliverable Table (June 2020 - June 2021)

Deliverable	Due Date	Total Program Funds	Data Rights
Project Kick-Off; Deliverable	[* * *]	[* * *]	[* * *]
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	[* * *]
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	[* * *]
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	[* * *]
Fill Product [* * *]	[* * *]	[* * *]	[* * *]
Fill Product [* * *]	[* * *]	[* * *]	[* * *]
Fill Product [* * *]	[* * *]	[* * *]	[* * *]
Package/Label Product	[* * *]	[* * *]	[* * *]
Storage of Drug Product [* * *]	[* * *]	[* * *]	[* * *]
Storage of Drug Product [* * *]	[* * *]	[* * *]	[* * *]
Storage of Drug Product [* * *]	[* * *]	[* * *]	[* * *]
Storage of Drug Product [* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
		$450,262,000 (FFP)	

*Upon payment, delivery and acceptance in accordance with the terms of this Project Agreement, the Government will have title to the product produced under this Statement of Work. The Government will have the rights described below in Section 7.3 to technical data disclosed under this Statement of Work.
** Packaging and labeling of product will be performed following the determination of the use of the applicable drug product (e.g., for clinical trials or for distribution under an EUA or BLA).

5.0 MILESTONE PAYMENT SCHEDULE; TERMINATION COSTS

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
5.1	[* * *]	[* * *]	[* * *]
5.2	[* * *]	[* * *]	[* * *]
5.3	[* * *]	[* * *]	[* * *]
5.4	[* * *]	[* * *]	[* * *]
5.5	[* * *]	[* * *]	[* * *]
5.6	[* * *]	[* * *]	[* * *]
5.7	[* * *]	[* * *]	[* * *]
5.8	[* * *]	[* * *]	[* * *]
5.9	[* * *]	[* * *]	[* * *]
5.10	[* * *]	[* * *]	[* * *]
5.11	[* * *]	[* * *]	[* * *]
Total (Include Payment Type; FFP):			**$450,262,000**
Period of Performance:			**June 2020 – June 2021**

The overall price is fixed price at $450,262,000. Milestone payments will be made quarterly as set forth in the table above, corresponding to the deliverables and any 3rd party commitments Regeneron needs to make. In the event the deliverables in a given quarter are less than or exceed the projected quantity, the milestone payment for such quarter will be equitably adjusted based on the shortfall or excess amount, as applicable, however the price will not exceed $450,262,000 Milestone payment terms will be net 30 days.

Total pricing is a firm fixed price per lot, [* * *]. Regeneron will deliver [* * *] of filled/finished drug product. Regeneron will be entitled to full payment for drug product upon delivery/acceptance (as described herein) of filled/finished drug product, prior to packaging and labeling. However, Regeneron shall be responsible for the packaging and labeling of product at no additional cost following the determination of the use of such drug product (e.g., for clinical trials or for distribution under an EUA or BLA). Drug product will comply with the Drug Supply Chain Security Act serialization and tracking requirements. Drug product will not be co-formulated, except as otherwise mutually agreed by the parties. Unless and until otherwise mutually agreed, the drug product produced under this Statement of Work will be filled for therapeutic use. [* * *] Regeneron will provide the Government with the timeline for fill/finish activities, including the dates by which the parties must determine

[* * *]

the allocation of fill/finish activities. Notwithstanding the foregoing, as part of this Project Agreement, Regeneron will have the right to utilize material and capacity supported by this agreement to fill up to [* * *], as well as any additional drug product mutually agreed upon by Regeneron and the Government (with respect to which use the Government will not unreasonably withhold consent.

In the event this Statement of Work is terminated prior to completion, termination costs recoverable by Regeneron under Section 2.04 of the MCDC Base Agreement, shall include the following: the full contract price for any drug product manufactured and not yet paid for; a pro-rated portion of the contract price for drug substance or drug product that is in process, based on the stage of production; [* * *] and raw materials that Regeneron purchased (or is obligated to purchase) that cannot be allocated to other products.

[* * *]

7.0 PATENT RIGHTS; DATA RIGHTS; PREP ACT AND TRANSPARENCY

Article X, (“PATENT RIGHTS”) and Article XI. (“DATA RIGHTS”) of Other Transaction Agreement number W15QKN-16-9-1002 shall not apply to this Project Agreement and are hereby replaced for the purpose of this Project Agreement, with this Section 7.0 (including Sections 7.1-7.4 and the Definitions Appendix).
Definitions:

Capitalized terms used in this Section 7.0 (including Sections 7.1-7.4) shall have the meanings ascribed to such terms in the Definitions Appendix to this Project Agreement.

For purposes of this Project Agreement, all rights of the Government in and to Data or Subject Inventions are granted solely to The United States of America, as represented by the Department of Health & Human Services, Office of the Assistant Secretary for Preparedness & Response (“ASPR”), Office of Biomedical Advanced Research and Development (“BARDA”) (represented by Office of Acquisition Management, Contracts and Grants (AMCG)) and to no other agency of the United States of America (including JPEO) or representative of any such other agency (including the CMF). The parties acknowledge that Regeneron is permitted to communicate solely with BARDA regarding the matters described in this Section 7.0 (including Sections 7.1-7.4) and is not obligated to communicate with any other Government agency or representative regarding such matters.

7.1 BACKGROUND INTELLECTUAL PROPERTY

Each party acknowledges that it has no rights to the other party’s inventions, discoveries, know-how, Data, technology or intellectual property generated, discovered, conceived or reduced to practice prior to or otherwise outside of this Statement of Work (also referred to herein as, this “Project Agreement” or this “Agreement”), and any improvements or modifications thereto, including, without limitation, the background intellectual property

[* * *]

(and improvements/modifications) for the Government and Regeneron described below, as follows:

Government Background Intellectual Property. None.

Contractor Background Intellectual Property:[* * *]

63/004,312, filed April 2, 2020 "Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments"

[* * *]

63/014,687, filed April 23, 2020 "Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments"

[* * *]

63/025,949, filed May 15, 2020 "Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments"

[* * *]

63/034,865, filed June 4, 2020 "Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments"

[* * *]

No party relinquishes rights in any of its background intellectual property to any other party under this contract.

Either Party may update its disclosure of background intellectual property under this Section 7.1 upon written notice to the other Party.

7.2 PATENT RIGHTS

a. Allocation of Principal Rights

The parties agree that the Bayh-Dole statute does not apply to this Project Agreement. Ownership of inventions Made in the performance of this Project Agreement shall follow inventorship, and inventorship shall be determined in accordance with United States patent laws. With respect to any Subject Invention Made (in whole or in part) by or on behalf of Regeneron, unless Regeneron shall have notified the Government (in accordance with Subparagraph b. below) that Regeneron does not intend to properly disclose and elect title to a Subject Invention, Regeneron shall retain the entire right, title, and interest throughout the world to such Subject Invention, and the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. This license does not include the right to use or allow others to use the Subject Invention for commercial purposes. If Regeneron does not properly disclose and elect title to any such Subject Invention (in

[* * *]

accordance with Subparagraph b. below), then the Government may exercise its rights to seek ownership of such Subject Invention, pursuant to clause 7.2.c. below.

b. Invention Disclosure, Election of Title, and Filing of Patent Application

i. Regeneron shall disclose in writing each Subject Invention to the OTTR within 12 months after the inventor discloses it in writing to Regeneron personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this Project Agreement under which the Subject Invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the Subject Invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the Subject Invention, or whether a manuscript describing the Subject Invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the Government funding agency (HHS/BARDA), Regeneron shall promptly notify the OTTR of the acceptance of any manuscript describing the Subject Invention for publication and any on sale or public use.

ii. Regeneron shall elect in writing whether or not to retain ownership of any Subject Invention by notifying the OTTR within 2 years of disclosure to the Government funding agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 calendar days prior to the end of the statutory period.

iii. Regeneron shall file either a provisional or a non-provisional patent application for an elected Subject Invention within 1 year after election of title. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, Regeneron shall file the application prior to the end of that statutory period. If Regeneron files an initial provisional application, it shall file a non-provisional application within 10 months of the filing of the initial provisional application. Regeneron shall include a Government Support Clause (GSC) within the specification of any United States patent applications and any patent issuing thereon covering a subject invention.

iv. Regeneron may request extensions of time for disclosure, election, or filing under subparagraphs (b)(i), (b)(ii) and (b)(iii) of this clause. An extension of time for each deadline, may be granted at the discretion of the Government funding agency.

v. If Regeneron determines that it does not intend to elect to retain title to any such Subject Invention, Regeneron shall notify the Government, in writing, within two (2) years of disclosure to the Government. However, in any case where publication, sale, or public use has initiated the one (1)-year statutory

[* * *]

period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by the Government to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

c. Conditions When the Government May Obtain Title

Upon the Government's written request, Regeneron shall convey title to any Subject Invention to the Government funding agency if Regeneron fails to disclose the Subject Invention or elects not to retain title to the Subject Invention within the times specified in Subparagraph b of Section 7.2. The Government may request title after learning of the failure of Regeneron to disclose or elect within the specified times for an unlimited time. The Government funding agency may request title upon Regeneron's omission to timely file patent applications in any country. The Government funding agency may request title in any country in which Regeneron decides to discontinue prosecution.

d. Rights to Regeneron and Protection of Regeneron's Right to File

Regeneron shall retain a fully paid up, sub-licensable, nonexclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title. Regeneron license extends to Regeneron's subsidiaries and other affiliates (outside this Agreement), if any, within the corporate structure of which Regeneron is a party and includes the right to grant licenses of the same scope to the extent that Regeneron was legally obligated or permitted to do so at the time the Project Agreement was executed. The license is otherwise transferable only with the approval of the Government, except when transferred to an Affiliate or successor of that part of Regeneron's business to which the Subject Invention pertains. The Government approval for license transfer shall be provided on a timely basis (and in no event later than 90 calendar days following Regeneron's request) and shall not be unreasonably withheld.

i. The Regeneron license may be revoked or modified by the Government to the extent necessary to achieve expeditious Practical Application of the Subject Invention pursuant to an application for an exclusive or nonexclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. Regeneron's license shall not be revoked in that field of use or the geographical areas in which Regeneron has achieved Practical Application of the Subject Invention and continues to make the benefits of the Subject Invention accessible to the public.

ii. Before revocation or modification of Regeneron's license, the Government shall furnish Regeneron with a written notice of its intention to revoke or modify the license, which notice shall include a detailed explanation of the reasons for such revocation or modification, and Regeneron shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

[* * *]

e. Action to Protect the Government's Interest

Regeneron agrees to execute or to have executed and promptly deliver to the Government all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which Regeneron elects to retain title, and (ii) convey title to the Government when requested under Subparagraph c of this Section 7.2 and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

i. Regeneron agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by Regeneron, each Subject Invention made under this Agreement so Regeneron can comply with the disclosure provisions of this Section 7.2. Regeneron shall use reasonable efforts to instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

ii. Regeneron shall notify the Government of any decisions not to continue the prosecution of a patent application for a Subject Invention, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent of a Subject Invention, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevant patent office.

Regeneron shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with Government support under Agreement **MCDC2020-504**, awarded by the U.S. Department of Health and Human Services. The Government has certain rights in the invention."

f. Lower Tier Agreements

Regeneron shall ensure that its Affiliate agreements and Sub-Recipient Agreements regardless of tier, for experimental, developmental, or research work entered into after the Effective Date and submitted for reimbursement under this Agreement, contain invention reporting and assignment requirements sufficient to permit Regeneron to comply with this Section 7.2.

g. Reporting on Utilization of Subject Inventions

i. Regeneron agrees to submit, during the term of this Project Agreement, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that is being made by Regeneron or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, and such other data and information as the agency may reasonably specify. Regeneron also agrees to

[* * *]

provide additional reports as may be requested by the Government in connection with any march-in proceedings undertaken by the Government in accordance with Subparagraph h of this Section 7.2. Consistent with 35 U.S.C. § 202(c)(5), the Government agrees it shall not disclose such information to persons outside the Government without permission of Regeneron.

ii. All required reports shall be submitted to the e-room, OTAS, OTAO, and OTTR.

h. Compulsory Licensing Rights

Regeneron agrees that, with respect to any Subject Invention in which it has retained title, the Government has the right to require Regeneron, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if Regeneron, assignee, or exclusive licensee refuses such a request, the Government has the right to grant such a license within the Field itself *only* if the Government determines that:

i. Action is necessary to alleviate the following health or safety needs that may affect the United States and Regeneron (itself or through its assignee, subcontractor or licensee) is unwilling or unable to manufacture or supply the Subject Invention to address such needs:

a. Declaration for Public Health Emergency by the Secretary of HHS;

b. Determination that there is a significant potential for a public Health emergency that has a significant potential to affect a national or health security of U.S. citizens as determined by the Secretary of HHS; or

c. Declaration by WHO Director General of a public health emergency of international concern.

7.3 DATA RIGHTS

a. Allocation of Principal Rights

i. For Data produced under this SOW including Computer Software, to the extent developed with Government funds provided under this SOW, except as expressly provided elsewhere in this Project Agreement (including Section 7.3.b.), Regeneron grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data (a) to exercise Government Purpose Rights for a period of ten (10) years following the production of such Data, (b) to exercise Unlimited Rights following the expiration of such ten (10)- year period. For Data produced under this Project Agreement, excluding Computer Software, to the extent developed with private funds and for other Data designated by

[* * *]

Regeneron as "Limited Rights Data", Regeneron grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data to exercise Limited Rights. The Government will not obtain any rights in Computer Software produced under this Project Agreement to the extent developed with private funds. For certificates of analysis and batch records pertaining to drug product purchased under this Project Agreement, the Government shall have Unlimited Rights.

ii. Regeneron agrees to retain and maintain in good condition all Data produced under this Project Agreement and necessary to achieve Practical Application of any Subject Invention in accordance with Regeneron's established record retention practices. In the event of an exercise of the Government's compulsory licensing rights as set forth under Section 7.2.h., Regeneron agrees, upon written request from the Government, to deliver at no additional cost to the Government, all existing Data produced under this Project Agreement necessary to achieve Practical Application of the relevant Subject Invention within sixty (60) calendar days from the date of the written request.

iii. Regeneron's right to use Data is not restricted and includes the right under Regeneron's established business policies to make public research Data (especially human research Data) by publication in the scientific literature, by making trial protocols, trial results summaries, and clinical studies reports publicly available, and by making trial patient-level data available for third-party analysis.

b. Proprietary Manufacturing Data

Notwithstanding anything to the contrary in this Project Agreement, Regeneron retains all rights in and to Data relating to or comprising Regeneron's proprietary manufacturing technology and processes, including any trade secrets, Chemistry, Manufacturing and Controls information (CMC Data), and Data concerning or arising from test method development, device or delivery system development, assay development, formulation, quality assurance/quality control development, technology transfer, process development and scale-up and cell-line development, and the Government shall have no rights to use such Data independently from this Agreement or to disclose such Data to any third party. Regeneron may designate certain Data concerning its manufacturing activities as Limited Rights Data, in which case the Government shall have Limited Rights in and to such Data. Regeneron will use reasonable efforts to mark any Limited Rights Data delivered under this Project Agreement with appropriate Limited Rights markings.

c. Identification and Disposition of Data

Regeneron shall keep copies of all Data relevant to this Project Agreement as required by the Food and Drug Administration (FDA) for the time specified by the FDA. The Government reserves the right to review any other data determined by the Government to be

[* * *]

relevant to this Agreement. The Government further acknowledges that Regeneron holds the commercialization rights for all products developed under this Agreement in the U.S. and will be responsible for their registration with the FDA. This provision is subject to any applicable limitations on the Government's rights under Article VIII.B.a-b of the BARDA OTA.

7.4 REGULATORY RIGHTS

The Contractor agrees to the following:

a. Regulatory Data. Regeneron shall provide to the OTTR and OTAS copies of formal FDA submissions pertaining to the scope of the project, no later than 10 business days before submission to the FDA. For clarity, CMC Data included in such submissions shall be subject to Section 7.3.b.

b. Rights of Reference. Upon mutual agreement, Regeneron will grant to the Government a right of reference to any Regulatory Application submitted in support of this Project Agreement, solely for the purpose of the Government conducting a clinical trial with the drug product supplied under this Project Agreement under a protocol approved by Regeneron for performance by the Government. In such a case, Regeneron agrees to provide a letter of cross-reference to the Government and file such letter with the appropriate FDA office. Nothing in this paragraph reduces the Government's data rights as articulated in other provisions of this award.

c. Clause 7.4.b. will survive the acquisition or merger of the Contractor by or with a third party. This clause will survive the expiration of this contract.

7.5 PREP Act Coverage. It is the intent of the Parties that the drug product provided pursuant to this Agreement be covered by the March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C. § 247d-6d, 85 Fed Reg. 15,198 (March 17, 2020), or any amendments thereto that provides liability protection for such use. Based on an independent review by each of the Parties of the PREP Act Declaration issued by DHHS on March 10, 2020, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), and a related advisory opinion issued by the DHHS Office of General Counsel on April 14, 2020, the Parties believe that Regeneron is a covered person eligible for immunity under the PREP Act for activities related to medical countermeasures against COVID-19. To the extent DoD or BARDA is authorized to do so as an Authority Having Jurisdiction, the Government designates Regeneron as a covered person eligible for immunity under the PREP Act Declaration issued by DHHS on March 10, 2020, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), for activities related to medical countermeasures against COVID-19. The Government further warrants that the drug product provided pursuant to this Project Agreement will not be (a) sold to any entity nor will it be returned after acceptance under the terms of this contract or (b) distributed or used, or authorized for distribution or use, outside the United States or to the extent such activities are not protected from liability under an active PREP Act declaration.

[* * *]

7.6 Transparency. To the extent permitted under applicable laws, the Government will provide Regeneron in a timely manner copies of reports concerning this Project Agreement that are provided to other Government agencies or legislative or executive branches of the government.

8.0 SECURITY

The security classification level for this effort is UNCLASSIFIED.

9.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

10.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

None

11.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME:
EMAIL:
PHONE:
AGENCY NAME/DIVISION/SECTION: HHS/ASPR/BARDA

Alternate AOR

NAME:
MAILING ADDRESS:
EMAIL:
PHONE:
AGENCY NAME/DIVISION/SECTION:

Requiring Activity:

US Department of Health & Human Services (HHS), Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA)

[* * *]

Definitions Appendix

Computer Software:

To perform and further this Project Agreement:

Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and

Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

Does not include computer databases or computer software documentation.

Data: Means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and Computer Software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

Field: The development of anti-pathogen assets to treat, diagnose or prevent emerging infectious diseases.

Government: The United States of America, as represented by the Department of Health & Human Services ("Government"), Office of the Assistant Secretary for Preparedness & Response ("ASPR"), Office of Biomedical Advanced Research and Development ("BARDA") (represented by Office of Acquisition Management, Contracts and Grants (AMCG)).

Government Purpose: Any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose technical data for commercial purposes or authorize others to do so.

Government Purpose Rights: The rights by Government to—

1. Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and

2. Release or disclose technical data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data for United States Government Purpose.

Invention: Any invention or discovery that is or may be patentable or otherwise protectable under Title 35 of the United States Code.

[* * *]

Limited Rights: The rights to use, modify, reproduce, perform, display, or disclose Data, in whole or in part, within the Government solely for research purposes for the Field. Government will ensure that disclosed information is safeguarded in accordance with the restrictions of this Agreement. The Government may not, without the prior written permission of Recipient, release or disclose the Data outside the Government, use the Data for competitive procurement or manufacture, release or disclose the data for commercial purposes, or authorize the Data to be used by another party. The Parties shall maintain the confidentiality of all Data subject to or designated as falling within Limited Rights.

Limited Rights Data: Data, other than Computer Software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such Data pertain to items, components, or processes developed at private expense, including minor modifications.

Made: The conception or first actual reduction to practice of the invention as defined in this Agreement.

Option: An option, entered into by bilateral agreement pursuant to a Statement of Work and budget, by which, for a specified time, the Government may elect to purchase additional supplies or services called for by the Agreement.

Other Transaction Agreement Officer ("OTAO"): Is the responsible Government official authorized to bind the Government by signing this Agreement and bilateral modifications.

Other Transaction Agreement Specialist ("OTAS"): Is a supporting official that assists and represents the OTAO. The OTAO is the only official who can bind the Government.

Other Transaction Agreement Technical Representative ("OTTR"): Is the primary Government official for all technical matters on the Agreement.

Practical Application: With respect to a Subject Invention, to manufacture, in the case of a composition or product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public for a regulatory approved product.

Subject Invention: Any Invention Made in the performance of work under this Agreement within the Field for which Recipient pursues a patent.

Sub-Recipient: Akin to a subcontractor. Any supplier, distributor, vendor, or firm that furnishes supplies or services to or for the Recipient, an Affiliate, or a Sub-Recipient. A Sub-Recipient differs from an Affiliate in that Sub-Recipients are not listed as an Affiliate in Attachment 3 and may be used to execute tasks under the SOW by Recipient or Affiliate.

Sub-Recipient Agreement: Any contract entered into by a Sub-Recipient to furnish supplies or services for performance of this Agreement. This term describes an agreement with a 1st-Tier Sub-Recipient, except as expressly noted in this Agreement.

[* * *]

Attachment B
Report Requirements

This page intentionally left blank. See separate document for Attachment B.

REPORT REQUIREMENTS

If classified information is required to be submitted under this Agreement, it must be submitted to the addresses specified in the SOW or DD254. No classified information should be submitted directly to ATI.

Any applicable Contract Data Requirements Lists (CDRLs), Data Item Descriptions (DIDs) or other report guidance for this Project may be included at the end of this attachment.

ATI, in addition to the AOR, must receive a copy of the Quarterly Status Reports and the Final Status Report. Quarterly Status Reports, Annual Status Reports, and Final Status Reports should be submitted to . All other deliverables shall be submitted to the AOR only, but ATI must be notified that the deliverable has been submitted to the AOR. The AOR will provide ATI a completed Sign- off Memorandum as evidence the milestone deliverable was received and deemed acceptable.

If you would like a copy of the Report Requirements template in MS Word, please email

A. QUARTERLY STATUS REPORT

The Recipient shall submit or otherwise provide a Quarterly Status Report in the format as shown in this attachment on the last day of the month of the calendar quarter (i.e., **March 31, June 30, and December 31**). A sample template is provided.

I. The Recipient's Technical Status Report will, at a minimum, address the following: Comments on Technical/Cost/Schedule Performance, Project Quad Chart, Milestone Status, Non-Traditional Defense Contractor Participation and Plans for the Next Quarter.

B. PAYABLE MILESTONES/DELIVERABLES

The Recipient shall submit to the Agreements Officer Representative and MCDC CMF Representative documentation describing the extent of accomplishment of Payable Milestones and Deliverables.

I. **Submission of Payable Milestones/Deliverables**. The Recipient is required to submit all deliverables identified as Payable Milestones, as shown in the Payable Milestone Schedule, as well as any other deliverables/reports listed in the Statement of Work.

II. **Sign-off Memorandum.** The Sign-off Memorandum as shown in this attachment shall accompany all submissions indicated in section B.I. The Agreements Officer Representative shall provide written approval using the Sign-off Memorandum to the MCDC Consortium Management Firm. The Sign-off Memorandum will be used to verify that all submissions are technically acceptable. It will also be used to substantiate invoice payment for firm fixed price agreements.

C. ANNUAL STATUS REPORTING

I. The Project Agreement Holder shall submit an Annual Status Report on **September 30** each year (same format as Quarterly Status Report for one year period) for all projects whose periods of performances are greater than

one year in accordance with the terms and conditions of the MCDC Base Agreement. The Annual Status Report must also include the following:

i. A comparison of actual accomplishments with the goals and objectives of the project established for the period.
ii. Reasons why established goals and objectives were not met, if appropriate.
iii. A cumulative chronological list of written publications in technical journals. Include those in press as well as manuscripts in preparation and planned for later submission. Indicate likely journals, authors and titles.
iv. Papers presented at meetings, conferences, seminars, etc.
v. New discoveries, inventions or patent disclosures and specific applications stemming from the individual project provided that such disclosure shall not compromise the rights of the inventor.
vi. Reporting on Utilization of Subject Inventions should be included in the Annual Status Report per Section 10.08 of the Base Agreement.

Quarterly Status Report

for

<Project Agreement Holder Name>

Project No. MCDC-XX-XX-XXX

Reporting Period: DATE - DATE

Project Agreement Holder

<Project Lead>

<Other Project Team Member(s)>

Project Team Technical POC

Name Company Street Address
City, State Zip Code Phone Number Email address

Submitted: <date>

---

1. Comments on Technical/Cost/Schedule Performance

The purpose of this section is to bring project stakeholders up to speed on current project status. It is not intended to be a line-by-line account of the quarter's activities; details of that nature are reserved for the latter section of this report. Rather, this section should highlight technical, cost, and schedule performance for the quarter, and report overall progress towards successful technology transition and implementation – an executive summary-like synopsis. This section should also be used to cite project-related concerns.

Properly crafted, this section is typically about one-half page in length.

2. Project Quad Chart

Quad charts are used for many purposes, including high level briefings. Therefore, it is imperative that information be current and accurate, especially in regards to the lower quadrants. The text - where populated - in the quad chart below is for sample purposes only.

<table>
<tr><th colspan="2">< Project Agreement Title></th></tr>
<tr><td colspan="2"></td></tr>
<tr><th>Goals & Objectives</th><th>Project Information</th></tr>
<tr><td>Briefly describe the goals of the project; include the technical objectives and the implementation targets.</td><td>Project Lead:
Team Members:
Period of Performance:
Funding:
Cumulative Amt Invoiced:
Total Cost Share Reported:</td></tr>
<tr><th>Milestones & Technical Achievements</th><th>Implementation & Payoff</th></tr>
<tr><td rowspan="2">Apr 16: Kickoff Meeting
Jun 16: Design Analysis complete
Jul 16: Materials/Equipment Rec'd
Oct 16: Prototype construction complete
May 17: Initial testing complete
Oct 17: Production units implemented in shipyard processes</td><td>Schedule: Target date for implementation.
Status: Current status towards implementation event.</td></tr>
<tr><td>Briefly describe what benefits will accrue from this project's successful completion and implementation. Be quantitative to the greatest extent possible.</td></tr>
<tr><td colspan="2"><u>Current Status:</u> Technical = Green/Yellow/Red (delta) Schedule = Green/Yellow/Red (delta) Cost = Green/Yellow/Red (delta)</td></tr>
</table>

Current Status Legend: Green = Good/On Budget Yellow = Minor Weakness/Known Risk Red = Major Weakness/Critical Delta: ⇧ = upgrade from last assessment; ⇩ = downgrade from last assessment; ⇨ = no change

3. Supplemental Information

In order to improve the usefulness of the quad charts and provide sufficient project information, the Quarterly Status Report must be supplemented with data described below.

3.1 Milestone Status:

No.	Milestone	Due Date	Percent Complete This Period	Cumulative Percent Complete
1				
2				
3				

3.2 Non-Traditional Defense Contractor Participation

Name of Nontraditional*	Planned Start Date	Actual Start Date	Reason for Deviation from Plan

3.3 Plans for Next Quarter

- Major achievements planned for the next quarter

MEMORANDUM: Agreements Officer Representative Sign-Off

To: Agreements Officer Representative (AOR) From: ___
Date: ___
Reference: (a) MCDC Base Agreement between ATI and
_____ Agreement No. __
(b) Project Agreement No. ___
Subject: Milestone Approval

The following deliverable(s) associated with the Milestone(s) listed below have been completed:

MS#	Deliverable
XX	___

It is requested that verification of these accomplishments be provided to the MCDC Consortium Management Firm.

To: MCDC Consortium Management Firm

CERTIFICATION BY AGREEMENTS OFFICER REPRESENTATIVE:

The Project Agreement Holder has made satisfactory progress and provided the required deliverables associated with this milestone. I certify the work performed is in accordance with the approved Statement of Work (SOW) included in the agreement.

Other comments or concerns regarding this or future milestones:

[Note: For any non-satisfactory areas include a discussion of what was not acceptable, references to previous correspondence on the issue, and what corrective actions are needed to effect payment.]

_____ _____
Agreements Officer Representative Date:

Attachment C
Technical Direction Letter (TDL) RPP-20-08 Regeneron

This page intentionally left blank. See separate document for Attachment C.

DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PICATINNY ARSENAL, NEW JERSEY 07806-5000

REPLY TO
ATTENTION OF

06 July 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 9
Picatinny Arsenal, NJ 07806

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-08, Objective TRE-PRE-20-08 for "Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2" (Regeneron Pharmaceuticals, Inc.)

REF: Regeneron Request for Technical Direction Letter, RPP 20-08 under OTA W15QKN-16-9- 1002 for Objective TRE-PRE-20-08, dated 30 June 2020

Advanced Technology International
ATTN: Sr. Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Dear ,

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued MCDC RPP 20-08 on 17 May 2020. Members of the MCDC submitted proposals in accordance with this RPP. The Government received and evaluated all proposal(s) submitted and a Basis of Selection has been executed, selecting Regeneron as the awardee. The Government requests that a Firm-Fixed-Price Project Agreement be issued to Regeneron to award this proposal under Other Transaction Agreement W15QKN-16-9- 1002, to be performed in accordance with the attached Government Statement of Work (SOW).

Based upon the acceptable update of Regeneron's proposal for "Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2" and 1) The Project Agreement Recipient's concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and; 3) The cost proposal that has been analyzed and negotiated by the Government, you are hereby directed to issue a Project Agreement to Regeneron for the subject project. The total project value has been determined fair and reasonable and Regeneron's proposal has been selected IAW the above referenced Basis of Selection.

The total approved cost to the Government for this effort is not to exceed [* * *]. The break-out of the costs is as follows: $450,262,000.00 to perform project efforts included in the SOW and [* * *] for the Consortium Management Firm (CMF) Administrative Cost. [* * *] The effort currently has [* * *] of available funding, comprised of $450,262,000.00 for the Project Agreement and [* * *] for the CMF. PAH COVID-19 work shall be tracked separately using the funding obligated via modification P00074. [* * *]

The PAH is considered a small business, nontraditional defense contractor, or nonprofit research institution and determined to be providing a significant contribution. The affirmation of business status certifications submitted as part of the proposal are hereby incorporated into the agreement. The contractor shall notify the MCDC CMF of any deviation from the final proposed affirmation of business status certifications that would affect the contributions of the small business, nontraditional defense contractor, or nonprofit research institution as proposed.

In accordance with 10.U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

The Government and Advanced Technology International (“ATI”) hereby agree and confirm that (a) ATI, in its capacity as the Consortium Management Firm under the Medical CBRN Defense Consortium (MCDC) Other Transaction Agreement No. W15QKN-16-9-1002 (the MCDC Agreement), has the authorization to enter into the Medical CBRN Defense Consortium Base Agreement No. 2020-504 and the Statement of Work (collectively, the “Regeneron Agreement”) with Regeneron on behalf of the Government, (b) the Government is and shall be bound by its obligations set forth in the Regeneron Agreement, and the MCDC Agreement is hereby amended to incorporate these obligations in the MCDC Agreement, as that Agreement relates to Regeneron, and (c) Regeneron is an intended third-party beneficiary of such obligations that can enforce them directly against the Government, and (d) in the event of any conflict between the Regeneron Agreement, on the one hand, and the MCDC Agreement, on the other hand, the Regeneron Agreement shall control and take precedence.

Points of Contact:

Agreements Specialist:
E-mail:
Phone:

Agreements Officer:
E-mail:
Phone:

Regards,

Agreements Officer
Signed by:

Attachments:
Attachment 1: MCDC2008-005 - Regeneron - 7-3-2020
Attachment 2: OPSEC Language Addendum
[***]

_____
ATI Signatory

Exhibit 10.3

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT, MARKED BY BRACKETS, WERE OMITTED BECAUSE THOSE PORTIONS ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL TO THE COMPANY IF PUBLICLY DISCLOSED.

EXECUTION VERSION

License Agreement

This Agreement is entered into with effect as of August 18, 2020 (the "**Effective Date**")

by and between

F. Hoffmann-La Roche Ltd

with an office and place of business at Grenzacherstrasse 124, 4070 Basel, Switzerland ("**Roche Basel**")

and

Genentech, Inc.

with an office and place of business at 1 DNA Way, South San Francisco, California 94080, United States ("**Genentech**" together with Roche Basel "**Roche**")

on the one hand

and

Regeneron Pharmaceuticals, Inc.

with an office and place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591, United States ("**Regeneron**")

on the other hand.

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License Agreement

WHEREAS, Regeneron is developing an antibody cocktail directed to the SARS-CoV-2 spike protein consisting of two antibodies known as REGN10933 and REGN10987; and

WHEREAS, Roche has expertise in the development, manufacture and commercialization of pharmaceutical products in the field of infectious diseases, including the ability to rapidly scale up commercial supply for pandemic stockpiling and discussions with governments; and

WHEREAS, Roche Basel and Regeneron intend to develop, manufacture and commercialize the antibody cocktail directed to the SARS-CoV-2 spike protein consisting of REGN10933 and REGN10987 globally as a treatment for COVID19; and

WHEREAS, Roche Basel and Regeneron have entered into a Technology Transfer Agreement as of July 22, 2020 (the "**Technology Transfer Agreement**"); and

WHEREAS, Regeneron is willing to grant to Roche Basel rights to use certain of its intellectual property rights to make Compounds and Products in the Territory (as such terms are respectively defined below), develop Compounds and Products in the Territory, and use, offer for sale, sell and import Compounds and Products in the Roche Territory and export Compounds and Products to the Territory, in each case, for use in the Field (as such terms are respectively defined below), as contemplated herein; and

WHEREAS, Roche is willing to grant Regeneron rights to use certain of its intellectual property rights to make Compounds and Products in the Territory and to develop, use, offer for sale, sell and import and export Compounds and Products in the Territory for use in the Field, as contemplated herein; and

WHEREAS, Roche and Regeneron agree that Regeneron will continue to perform certain ongoing activities to develop the Compound; and

WHEREAS, Roche and Regeneron agree that Roche and Regeneron will perform certain activities to develop, manufacture and commercialize the Compound and Product.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, do hereby agree as follows:

1. Definitions

As used in this Agreement, the following terms, whether used in the singular or plural, shall have the following meanings:

1.1 Accounting Standards

The term "Accounting Standards" shall mean the maintenance of records and books of accounts in accordance with IFRS (International Financial Reporting Standards) or GAAP (Generally Accepted Accounting Principles), which standards or principals (as applicable) are currently used at the applicable time by, and as consistently applied by the applicable Party.

1.2 Affiliate

The term “Affiliate” shall mean any individual, corporation, association or other business entity that directly or indirectly controls, is controlled by, or is under common control with the Party in question. As used in this definition of “Affiliate,” the term “control” shall mean the direct or indirect ownership of more than fifty percent (>50%) of the stock having the right to vote for directors thereof or the ability to otherwise control the management of the corporation or other business entity whether through the ownership of voting securities, by contract, resolution, regulation or otherwise. Anything to the contrary in this paragraph notwithstanding, none of Chugai Pharmaceutical Co., Ltd, a Japanese corporation (“**Chugai**”) and its subsidiaries (if any) shall be deemed to be Affiliates of Roche unless mutually agreed by the Parties.

1.3 Agreement

The term “Agreement” shall mean this document including any and all appendices and amendments to it as may be agreed by the Parties from time to time in accordance with the provisions of this Agreement.

1.4 Agreement Term

The term “Agreement Term” shall mean the period of time commencing on the Effective Date and, unless this Agreement is terminated sooner as provided in Article 20, ending seven (7) years after the First Commercial Sale of the first Product in the EU and any extension thereto mutual agreed by the Parties in writing.

1.5 Alliance Director

The term “Alliance Director” shall mean one person of each Party appointed to be its point of contact with responsibility for facilitating communication and collaboration between the Parties who shall facilitate resolution of potential and pending issues and potential disputes to avert escalation of such issues or potential disputes.

1.6 Antibody

The term “Antibody” shall mean a protein or polypeptide sequence that includes a complementarity-determining region (CDR) of an antibody (e.g. mAb, Fab, scFv, other fragments of an antibody), whether polyclonal or monoclonal, fully human, humanized, chimeric, multiple or single chain, recombinant or naturally occurring. For clarity, Antibodies shall not include other modalities such as nucleic acid, viral or cellular therapy modalities, or antibodies conjugated to a toxin or other active agent where the primary intended function of the antibodies is not to neutralize a target, but to direct such toxin or other active agent to such target (each, an “**Antibody Conjugate**”).

1.7 Applicable Law

The term “Applicable Law” shall mean any law, statute, ordinance, code, rule or regulation that has been enacted by a government authority (including, any Regulatory Authority) and is in force as of the Effective Date or comes into force during the Agreement Term, in each case to the extent that the same is applicable to the Compounds, Products, or performance by the Parties of their respective obligations under this Agreement.

1.8 Back-Up Compound

The term “Back-Up Compound” shall mean [* * *].

1.9 BARDA

The term “BARDA” shall mean the US Biomedical Advanced Research and Development Authority.

1.10 Biosimilar Product

The term “Biosimilar Product” shall mean, with respect to a Product and a country,
any product that is claimed to be biosimilar to or interchangeable with such Product in such country (including a product that is the subject of a biologics license application submitted under Section 351(k) of the PHSA citing such Product as the reference product or any corresponding foreign application in the Territory, including, with respect to the European Union, an MAA for a similar biological medicinal product pursuant to Article 10(4) of Directive 2001/83/EC) or for which the biologics license application otherwise references or relies on such Product in such country.

1.11 Business Day

The term “Business Day” shall mean 9:00 am to 5:00 pm local time on a day other than a Saturday, Sunday or bank or other public or federal holiday in Switzerland (with regard to Roche) or New York, New York or elsewhere in the US (with regard to Regeneron).

1.12 Calendar Quarter

The term “Calendar Quarter” shall mean each period of three (3) consecutive calendar months, ending March 31, June 30, September 30, or December 31.

1.13 Calendar Year

The term “Calendar Year” shall mean the period of time beginning on January 1 and ending December 31, except for the first Calendar Year, which shall begin on the Effective Date and end on December 31.

1.14 Chugai Asset Criteria

The term “Chugai Asset Criteria” shall mean [* * *].

1.15 Chugai Asset Data Package Criteria

The term "Chugai Asset Data Package Criteria" shall mean data, reports, documentation and other information in the Chugai Asset Data Package that are reasonably sufficient to determine whether or not the Chugai Asset satisfies the Chugai Asset Criteria.

1.16 Clinical Study

The term "Clinical Study" shall mean any human clinical trial, including a Phase I Study, Phase II Study, or Phase III Study.

1.17 CMO

The term "CMO" shall mean a Third Party contract manufacturing organization.

1.18 Code

The term "Code" shall mean the US Internal Revenue Code of 1986, as amended.

1.19 Co-Funded Development Plan

The term "Co-Funded Development Plan" shall mean the development plan for the Co-Funded Studies agreed and approved by the JSC. The Co-Funded Development Plan shall initially include the Additional Regeneron Studies and shall be updated by the JSC to include any Clinical Studies described on Appendix 1.20(b) and may further be updated from time to time by the JSC to include additional Co-Funded Studies.

1.20 Co-Funded Studies

The term "Co-Funded Studies" shall mean (a) the Clinical Studies as set forth on Appendix 1.20(a) (the "**Additional Regeneron Studies**") and (b) any additional Clinical Studies for which the Parties, through the JSC, agree to share the out-of-pocket costs, including the Clinical Studies described Appendix 1.20(b).

1.21 Collaboration Timepoint

The term "Collaboration Timepoint" shall mean [* * *].

1.22 Combination Product

The term "Combination Product" shall mean any product containing both the Compound and one or more other pharmaceutically active agents, regardless of their finished forms or formulations or dosages.

1.23 Commercially Reasonable Efforts

The term "Commercially Reasonable Efforts" shall mean, with respect to a Party and any objective or decision pertaining to a Compound or Product under this Agreement, the level of efforts and resources [* * *], taking into account, without limitation, the public health need for therapeutics due to the SARS-CoV-2 pandemic, epidemiology of SARS-CoV-2, commercial

opportunity [* * *], the available production supply of Compound and Product, legal factors, regulatory factors (including requirements of Regulatory Authorities), target product profiles, product liability, market exclusivity, cost of goods, pricing and access considerations, relative safety and efficacy, competitive market conditions, and its proprietary position; provided that [* * *] shall not be considered as a factor to mitigate its obligation to use Commercially Reasonable Efforts under this Agreement.

1.24 Companion Diagnostic

The term “Companion Diagnostic” shall mean any product that is used for predicting or monitoring the response of a human being to treatment with a Product.

1.25 Competitive Infringement

The term “Competitive Infringement” shall mean any (i) known infringement or suspected infringement by a Third Party of any Joint Patent Rights by the exploitation of a Competing Product, or (ii) known or suspected unauthorized use or misappropriation by a Third Party of any Joint Know-How by the exploitation of a Competing Product.

1.26 Compound

The term “Compound” shall mean the Lead Compound and each Back-Up Compound.

1.27 [* * *]

[* * *].

1.28 [* * *]

[* * *].

1.29 Confidential Information

The term “Confidential Information” shall mean any and all information, data or know-how (including Know-How), whether technical or non-technical, oral or written, that is disclosed by or on behalf of one Party or its Affiliates (“**Disclosing Party**”) to the other Party or its Affiliates (“**Receiving Party**”) in connection with this Agreement (including pursuant to the Technology Transfer Agreement), whether prior to, on, or after the Effective Date, including information relating to the terms of this Agreement, the Compound, the Products, any development, manufacture or commercialization of the Products, any Know-How with respect thereto developed by or on behalf of the Disclosing Party or its Affiliates, or the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, (a) Joint Inventions, Joint Know-How and the terms of this Agreement shall be deemed to be the Confidential Information of both Parties and both Parties shall be deemed to be the Receiving Party and the Disclosing Party with respect thereto, and (b) Arising Regeneron Know-How shall be deemed the Confidential Information of Regeneron, and Regeneron shall be deemed to be the Disclosing Party, and Roche shall be deemed to be the Receiving Party, with respect thereto. For clarity, all Proprietary Manufacturing Information shall be Regeneron’s Confidential Information. Confidential Information shall not include any information, data or know-how of the Disclosing Party that the Receiving Party can demonstrate:

(i) was generally available to the public at the time of disclosure, or becomes available to the public after disclosure by the Disclosing Party other than through fault (whether by action or inaction) of the Receiving Party or its Affiliates,

(ii) to have been already known to the Receiving Party or its Affiliates prior to its receipt from the Disclosing Party; provided that this exception shall not apply with respect to Arising Regeneron Know-How or Arising Regeneron Inventions,

(iii) is obtained at any time lawfully from a Third Party under circumstances permitting its use or disclosure,

(iv) is developed independently by the Receiving Party or its Affiliates other than through knowledge of Confidential Information; provided that this exception shall not apply with respect to Arising Regeneron Know-How or Arising Regeneron Inventions, or

(v) is approved in writing by the Disclosing Party for release by the Receiving Party.

For clarity, the references to Arising Regeneron Know-How or Arising Regeneron Inventions in clauses (ii) and (iv) above, do not apply to any component or step of Arising Regeneron Know-How or Arising Regeneron Inventions that is not itself Arising Regeneron Know-How or Arising Regeneron Inventions.

Specific elements of Confidential Information shall not be deemed to be generally available to the public or in the possession of the Receiving Party merely because such elements are encompassed by more general information that falls within the foregoing exclusions. Furthermore, any combination of individual elements of Confidential Information shall constitute Confidential Information and shall not be deemed to fall within the foregoing exclusions merely because one or more individual elements of such combination fall within the foregoing exclusions.

1.30 Continuation Election Notice

The term “Continuation Election Notice” shall mean the notice Regeneron provides to Roche under Section 19.3.1 describing (i) Regeneron’s *bona fide* intentions to continue ongoing development and commercialization of Product(s) and (ii) Regeneron’s request for Roche’s continuation of activities or transfer of the data, material and information relating to the Product(s) in accordance with Section 19.3.1.

1.31 Control

The term “Control” with respect to a Party shall mean (as an adjective or as a verb including conjugations and variations such as “Controls” “Controlled” or “Controlling”) (a) with respect to patent rights, inventions or know-how, the possession by such Party of the ability to assign or grant a license or sublicense of such patent rights, inventions or know-how without violating the terms of any agreement or arrangement between such Party and any Third Party and (b) with respect to proprietary materials, the possession by such Party of the ability to supply such proprietary materials to the other Party as provided herein without violating the terms of any agreement or arrangement between such Party and any Third Party.

1.32 Cover

The term “Cover” shall mean (as an adjective or as a verb including conjugations and variations such as “Covered,” “Coverage” or “Covering”) that the developing, making, using, offering for sale, promoting, selling, exporting or importing of a given compound, formulation or product would infringe a Valid Claim in the absence of a license under or ownership in the Patent Rights to which such Valid Claim pertains. The determination of whether a compound, formulation, process or product is Covered by a particular Valid Claim shall be made on a country-by-country basis.

1.33 COVID19

The term “COVID19” shall mean the disease caused by the causative agent SARS-CoV-2.

1.34 CRO

The term “CRO” shall mean a Third Party contract research organization.

1.35 CTA

The term “CTA” shall mean clinical trial approval granted by national Regulatory Authorities in the EU.

1.36 Dollars

The term “Dollars” shall mean US dollars.

1.37 [* * *]

[* * *].

1.38 Drug Product

The term “Drug Product” shall mean a Product formulated and filled that meets the specifications determined pursuant to Section 4.1.3.

1.39 Drug Substance

The term “Drug Substance” shall mean drug substance of Product in formulated bulk form that meets the specifications determined pursuant to Section 4.1.3.

1.40 EMA

The term “EMA” shall mean the European Medicines Agency or any successor agency with responsibilities comparable to those of the European Medicines Agency.

1.41 Emergency Use Authorization or EUA

The term “Emergency Use Authorization” or “EUA” shall mean an emergency use authorization issued by the FDA pursuant to Section 564 of the FDCA. The duration of an EUA depends in part on the duration of the declaration of the U.S. Department of Health and Human Services

("**HHS**") that supports the EUA. The HHS declaration must be current for an EUA to remain in effect. The HHS declaration terminates upon the earlier of (a) HHS determining that the circumstances justifying the EUA's issuance no longer exist or (b) a change in the approval status of the product such that an EUA would no longer be needed.

1.42 EU

The term "EU" or "European Union" shall mean the European Union and all its member countries as of the Effective Date.

1.43 Expert

The term "Expert" shall mean a person with no less than ten (10) years of pharmaceutical or biotechnology industry experience and expertise having occupied at least one senior position within a large pharmaceutical company relating to product development or licensing but excluding (a) any current or former employee or consultant of either Party (or its Affiliates), and (b) any person who has known personal financial interest in or who would benefit from the outcome or resolution of the applicable dispute. Such person shall be fluent in the English language.

1.44 FDA

The term "FDA" shall mean the Food and Drug Administration of the United States of America or any successor agency thereto.

1.45 FDCA

The term "FDCA" shall mean the United States Federal Food, Drug and Cosmetic Act, as may be amended from time to time.

1.46 Field

The term "Field" shall mean all prophylactic, therapeutic and diagnostic uses in all indications.

1.47 Finished Product

The term "Finished Product" shall mean the final Product including packaging and its final container(s) ready for delivery to the market that meets the specifications therefor determined pursuant to Section 4.1.3.

1.48 First Commercial Sale

The term "First Commercial Sale" shall mean, on a country-by-country basis, the first invoiced sale or distribution [* * *] of a Product to a Third Party by either Party or any of its Affiliates or Sublicensees following the receipt of any Regulatory Approval required for the sale of such Product, or if no such Regulatory Approval is required, the date of the first invoiced sale or distribution [* * *] of a Product to a Third Party by either Party or any of its Affiliates in such country.

For clarity, compassionate use sales will not be considered in determining the First Commercial Sale.

1.49 [* * *]

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1.50 [* * *]

[* * *].

1.51 [* * *]

[* * *].

1.52 [* * *]

[* * *].

1.53 Fully Burdened Manufacturing Costs

The term "Fully Burdened Manufacturing Costs" shall mean with respect to a Product, each Party's consolidated fully-burdened cost incurred by such Party or any of its Affiliates in manufacturing such Product (including all commercial manufacturing activities related to CMC, formulation, quality control, packaging and labeling, failed batches, and including all activities related to the supply of plasmids, raw materials, and where applicable, Drug Substance, Drug Product and Finished Product) in accordance with this Agreement and each Party's Accounting Standards, in bulk, vialed or finished product form as the case may be, including: [* * *].

1.54 GAVI Eligible Countries

The term "GAVI Eligible Countries" shall mean the countries listed by the Global Alliance for Vaccines and Immunization (https://www.gavi.org/types-support/sustainability/eligibility) as of the Effective Date, and such other low income countries (as determined by the World Bank) as may otherwise be agreed by the Parties in writing.

1.55 Global Gross Profit

The term "Global Gross Profit" shall mean, with respect to each Presentation of Product in a given Calendar Quarter, the sum of the Parties' respective Gross Profit for such Presentation of Product for such Calendar Quarter.

1.56 Gross Profit

The term "Gross Profit" shall mean, with respect to each Party and each Presentation in a given Calendar Quarter, the result of the following, for each such Presentation, (a) the Net Sales of such Presentation by such Party or any of its Affiliates or Sublicensees in its Respective Territory during such Calendar Quarter minus (b) [* * *].

1.57 Handle

The term “Handle” (as an adjective or as a verb including conjugations and variations such as “Handling”) shall mean one or more of preparing, filing, prosecuting (including interferences, reissue, re-examination, post-grant reviews, inter-partes reviews, nullity actions, derivation proceedings and opposition proceedings) and maintaining any Patent Rights.

1.58 Hospitalized Patients

The term “Hospitalized Patients” shall mean COVID19 patients that are treated in hospital institutions providing acute, in-patient medical and surgical treatment and nursing care.

1.59 Indemnitees

The term “Indemnitees” shall mean the Regeneron Indemnitees or the Roche Indemnitees, as applicable.

1.60 Insolvency Event

The term “Insolvency Event” shall mean circumstances under which a Party or any entity that controls such Party (i) has a receiver or similar officer appointed over all or a material part of its assets or undertaking; (ii) passes a resolution for winding-up (other than a winding-up for the purpose of, or in connection with, any solvent amalgamation or reconstruction) or a court makes an order to that effect or a court makes an order for administration (or any equivalent order in any jurisdiction); (iii) enters into any composition or arrangement with its creditors (other than relating to a solvent restructuring) or assignment for the benefit of creditors; (iv) ceases to carry on business; (v) is unable to pay its debts as they become due in the ordinary course of business; (vi) files in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the person or of its assets; or (vii) is the subject of an involuntary petition in any bankruptcy or insolvency proceeding, and such petition is not dismissed within sixty (60) days after the filing thereof.

1.61 Invention

The term “Invention” shall mean an invention that is conceived or first reduced to practice in connection with any activity carried out pursuant to this Agreement. Under this definition, an Invention may be made by or on behalf of Regeneron or any of its Affiliates or Sublicensees solely or jointly with a Third Party (a “**Regeneron Invention**”), by or on behalf of the Roche Group solely or jointly with a Third Party (a “**Roche Invention**”), or jointly by or on behalf of Regeneron or any of its Affiliates, on the one hand, and by or on behalf of the Roche Group, on the other hand, with or without a Third Party (a “**Joint Invention**”); provided any Invention that is specifically related to any Compound or Product (including the composition of, formulations containing, any methods of using, or the manufacture of, a Compound or Product) (an “**Arising Regeneron Invention**”) shall be a Regeneron Invention. For clarity, Roche Invention shall not include Roche Independent IP, and Arising Regeneron Invention shall not include Roche Independent IP, or any Invention that is generally but not specifically related to a Product. For example, an Invention relating to the purification of antibodies generally but not specific to purification of a Compound or Product shall not be considered an Arising Regeneron Invention.

1.62 Joint Know-How

The term “Joint Know-How” shall mean Know-How that is made jointly by or on behalf of Regeneron or any of its Affiliates or Sublicensees, on the one hand, and by or on behalf of the Roche Group, on the other hand, with or without a Third Party in connection with any activity carried out pursuant to this Agreement, excluding any Arising Regeneron Know-How.

1.63 Joint Patent Rights

The term “Joint Patent Rights” shall mean all Patent Rights Covering a Joint Invention.

1.64 Know-How

The term “Know-How” shall mean data, knowledge and information, including materials, samples, chemical manufacturing data, toxicological data, pharmacological data, preclinical and clinical data, assays, platforms, formulations, specifications, quality control testing data, that are confidential and necessary or useful for the discovery, manufacture, development or commercialization of Products.

1.65 Knowledge

The term “Knowledge” shall mean [* * *].

1.66 Lead Compound

The term “Lead Compound” shall mean Regeneron’s proprietary Antibody cocktail consisting of the Antibodies REGN10933 and REGN10987 which as of the Effective Date is under development by Regeneron. The sequences of REGN10933 and REGN10987 are specified in Appendix 1.66.

1.67 Lead Product

The term “Lead Product” shall mean any product containing the Lead Compound as its sole pharmaceutically active agent, regardless of the finished form or formulation or dosage.

1.68 Manufacturing Collaboration Timepoint

The term “Manufacturing Collaboration Timepoint” shall mean [* * *].

1.69 Major Country

The term “Major Country” shall mean any of the following countries: any country in the EU, Australia, Canada, the United Kingdom, Japan and China.

1.70 Net Sales

The term “Net Sales” shall mean, with respect to each Party and Presentation of Product in a particular period, (a) the sum of (i) Sales of such Party and its Affiliates and Sublicensees and (ii) Sublicensee Compensation for such Party, less (b) the Additional Deductions.

"**Sales**" shall mean, with respect to each Party, its Affiliates and, unless otherwise agreed by Regeneron pursuant to Section 2.2.2 or by Roche pursuant to Section 2.5, as applicable, Sublicensees, the amount of net sales of such Presentation of Product for such period (excluding sales among such Party, any of its Affiliates and Sublicensees) as calculated in accordance with such Party's Accounting Standards.

"**Sublicensee Compensation**" for a Party shall mean the compensation received by such Party and its respective Affiliates from [* * *] any other Sublicensees to the extent agreed by Regeneron pursuant to Section 2.2.2 or by Roche pursuant to Section 2.5, as applicable, in each case in accordance with the sublicensee contractual terms and their then-currently used Accounting Standards.

"**Additional Deductions**" shall mean:

(a) A lump sum deduction of [* * *]; and

(b) [* * *]; and

(c) government mandated fees and taxes and other government charges accrued during such period not already taken as a gross-to-net deduction in accordance with the then currently used Accounting Standards in the calculation of Net Sales of such Presentation of Product for such period, including, for example, any fees, taxes or other charges that become due in connection with any healthcare reform, change in government pricing or discounting schemes, or other action of a government or regulatory body.

For clarity, any compensation received from [* * *] will not be considered party of Net Sales and will be addressed as provided in Section 7.4.

Net Sales in currency other than Dollars shall be converted into Dollars according to the provisions of Section 11.4. For purposes of determining Net Sales, (i) the Product shall be deemed to be sold in accordance with the applicable Party's (or its applicable Affiliate's or Sublicensee's) Accounting Standards consistently applied; (ii) and a "sale" shall not include transfers or dispositions of the Product among a Party, its Affiliates, and unless otherwise agreed by the Parties in writing, its or their Sublicensees. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but that are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of the Product for consideration other than cash, such as barter or countertrade, or Sublicensee Compensation received in consideration other than cash, Net Sales shall be calculated on the fair market value of such consideration received as agreed by the Parties.

1.71 NGO

The term "NGO" shall mean a not-for-profit, non-governmental organization providing or facilitating the provision of health care in low income countries (e.g., GAVI Eligible Countries), such as the World Health Organization, UNICEF and Red Cross International. For the avoidance of doubt, the term NGO is limited to organizations that operate independently of government and does not include governmental or quasi-governmental organizations such as the EU or its institutions, bodies or agencies.

1.72 Non-US Affiliate

The term “Non-US Affiliate” shall mean any Affiliate that is not a US Affiliate.

1.73 Ongoing Regeneron Studies

The term “Ongoing Regeneron Studies” shall mean the Clinical Studies that are being conducted by Regeneron as of the Effective Date to support the initial Regulatory Approval for treatment of Hospitalized Patients or Out-Patients that are listed on Appendix 1.73.

1.74 Out-Patients

The term “Out-Patients” shall mean COVID19 patients that are not treated in hospital institutions providing acute, in-patient medical and surgical treatment and nursing care.

1.75 Party

The term “Party” shall mean Regeneron or Roche, as the case may be, and “Parties” shall mean Regeneron and Roche collectively.

1.76 Patent Rights

The term “Patent Rights” shall mean all rights under any patent or patent application, in any country of the Territory, including any patents issuing on such patent application or claiming priority to any such patent or patent application, and further including any substitution, extension or supplementary protection certificate, reissue, reexamination, renewal, divisional, continuation or continuation-in-part of any of the foregoing.

1.77 Pharmaceutical Company

The term “Pharmaceutical Company” shall mean any company whose primary business is the research, development, marketing and distribution of pharmaceutical or biopharmaceutical products, limited to the top 20 in global sales.

1.78 Phase I Study

The term “Phase I Study” shall mean a human clinical trial in any country that would meet the description in 21 C.F.R. § 312.21(a), as amended from time to time, and the foreign equivalent thereof.

1.79 Phase II Study

The term “Phase II Study” shall mean a human clinical trial, for which the primary endpoints include a determination of dose ranges or a preliminary determination of efficacy in patients being studied as described in 21 C.F.R. § 312.21(b), as amended from time to time, and the foreign equivalent thereof.

1.80 Phase III Study

The term “Phase III Study” shall mean a human clinical trial that is prospectively designed to demonstrate with statistical significance whether a product is safe and effective for use in humans in a manner sufficient to obtain Regulatory Approval to market such product in patients having the disease or condition being studied as described in 21 C.F.R. § 312.21(c) (FDCA), as amended from time to time, and the foreign equivalent thereof.

1.81 PHSA

The term “PHSA” shall mean the Public Health Service Act as set forth at 42 U.S.C. Chapter 6A, as may be amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.82 PPQ

The term “PPQ” shall mean process performance qualification that is a component of process validation. The PPQ combines the actual facility, utilities, equipment (each now qualified), and the trained personnel with the commercial manufacturing process, control procedures, and components to produce commercial batches (i.e. commercial scale Drug Substance batches executed for the purpose of process validation which are commercially eligible upon license approval). PPQ batches do not include preceding engineering/technical batches.

1.83 Presentation

The term “Presentation” shall mean, (a) with respect to a Drug Product, such Drug Product filled in one or more distinct quantities of Drug Substance, and (b) with respect to a Finished Product, such Finished Product filled, packaged and labeled in one or more distinct quantities of Drug Substance.

1.84 Product

The term “Product” shall mean any product containing a Compound as its sole pharmaceutically active agent, regardless of its finished form or formulation or dosage. One Product may be distinguished from another Product by the Compound being a distinctive active pharmaceutical ingredient.

1.85 Product Know-How

The term “Product Know-How” shall mean any Regeneron Know-How that is specifically related to any Product that, without a license from Regeneron or its applicable Affiliate, would be infringed or misappropriated by the exploitation (other than manufacturing) of any Product by a Third Party.

1.86 Product Patent Right

The term “Product Patent Right” shall mean any Regeneron Patent Rights that includes at least one claim specifically related to a Product that, without a license from Regeneron or its applicable Affiliate, would be infringed (or, in the case of a patent application would be infringed

if it were to issue in a patent) by the exploitation (other than manufacturing) of any Product by a Third Party.

1.87 Proprietary Manufacturing Information

The term “Proprietary Manufacturing Information” shall mean all Regeneron Know-How that is used, or intended to be used, to manufacture the Products (or any component or intermediate thereof).

1.88 Regulatory Approval

The term “Regulatory Approval” shall mean any approvals (excluding pricing and reimbursement approvals), licenses, registrations or authorizations by a Regulatory Authority, necessary for the manufacture and sale of a Product in the Field in a regulatory jurisdiction in the Territory, including an Emergency Use Authorization, Biologics License Application submitted to FDA under Section 351 of the PHSA (“**BLA**”), and, with respect to the EU, an application for marketing authorization approval (“**MAA**”) filed with the EMA pursuant to the centralized approval procedure, or with the applicable national Regulatory Authority of a country in the European Union with respect to the mutual recognition procedure, decentralized procedure or any other national approval.

1.89 Regulatory Authority

The term “Regulatory Authority” shall mean any national, supranational (e.g., the European Commission, the Council of the European Union, the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity including the FDA, in each country involved in the granting of regulatory approval for the development, manufacture or sale of a Product.

1.90 Regeneron Base Patent Rights

The term “Regeneron Base Patent Rights” shall mean Product Patent Rights in the Territory that are Controlled by Regeneron or any of its Affiliates at the Effective Date, said Patent Rights being exhaustively listed in Appendix 1.90 of this Agreement.

1.91 Regeneron Cell Media

The term “Regeneron Cell Media” shall mean any cell culture media that is proprietary to Regeneron and used by Regeneron or any of its Affiliates to manufacture any Drug Substance.

1.92 Regeneron Controlled Infringement

The term “Regeneron Controlled Infringement” shall mean (a) any Infringement of a Product Patent Right or Product Know-How, in either case, in the Regeneron Territory or (b) any Competitive Infringement of a Joint Patent Right or Joint Know-How, in either case, in the Regeneron Territory (including any Competitive Infringement of a Joint Patent Right or Joint Know-How, in each case, in both the Regeneron Territory and the Roche Territory).

1.93 Regeneron-DOD/BARDA Agreement

The term “Regeneron-DOD/BARDA Agreement” shall mean that certain agreement between Regeneron and Advanced Technology International for the sale of Products entitled “Project Agreement NO. 1, MCDC BASE AGREEMENT NO. 2020-504, Project Title: MCDC2008-005; Large Scale Manufacturing of Antibodies Directed to SARS-CoV-2”, including any amendment thereto.

1.94 Regeneron Existing BARDA Commitment

The term “Regeneron Existing BARDA Commitment” shall mean Regeneron’s commitment as of the Effective Date to manufacture a total of twenty eight (28) lots of the Antibodies included in the Lead Product for supply under the Regeneron-DOD/BARDA Agreement.

1.95 Regeneron Know-How

The term “Regeneron Know-How” shall mean the Know-How that Regeneron or any of its Affiliates Controls at the Effective Date or during the Agreement Term, including any Arising Regeneron Know-How, For clarity, Regeneron Know-How shall not include any Roche Independent IP or Roche Know-How.

1.96 Regeneron Patent Rights

The term “Regeneron Patent Rights” shall mean the Patent Rights that Regeneron or any of its Affiliates Controls, relating to or arising from the discovery, manufacture, development or commercialization of or Covering a Compound, Product or Regeneron Invention. The term Regeneron Patent Rights shall include Regeneron Base Patent Rights, but excludes any Joint Patent Rights. For clarity, Regeneron Patent Rights shall not include any Roche Independent IP or Roche Patent Rights.

1.97 Regeneron Patent Territory

The term “Regeneron Patent Territory” shall mean the Regeneron Territory.

1.98 Regeneron Territory

The term “Regeneron Territory” shall mean the US.

1.99 Respective Territory

The term “Respective Territory” shall mean, with respect to Regeneron, the Regeneron Territory and with respect to Roche, the Roche Territory.

1.100 Roche Major Countries

The term “Roche Major Countries” shall mean each of the following countries: [* * *].

1.101 Roche Group

The term “Roche Group” shall mean collectively Roche, its Affiliates and its Sublicensees.

1.102 Roche Independent IP

The term “Roche Independent IP” shall mean inventions, patents, trade secrets, know-how or other intellectual property that Roche or any of its Affiliates Controls at the Effective Date, or made or lawfully obtained by Roche or any of its Affiliates independent of the activities carried out pursuant to this Agreement, and without referring to or using any Confidential Information of Regeneron.

1.103 Roche Know-How

The term “Roche Know-How” shall mean the Know-How arising from activities carried out pursuant to this Agreement and that Roche or any of its Affiliates Controls during the Agreement Term. For clarity, the Roche Know-How does not include the Arising Regeneron Know-How or Roche Independent IP.

1.104 Roche Manufacturing Facilities

The term “Roche Manufacturing Facilities” shall mean the facilities listed in Appendix 1.104.

1.105 Roche Patent Rights

The term “Roche Patent Rights” shall mean the Patent Rights that Roche or any of its Affiliates Controls, relating to or arising from the discovery, manufacture, development or commercialization of or Covering a Compound, Product or Roche Invention, but excluding any Roche Independent IP, Regeneron Patent Rights or Joint Patent Rights.

1.106 Roche Production Contribution

The term “Roche Production Contribution” shall mean a fraction, (a) the numerator of which is equal to the sum of [* * *], for which the Drug Substance was manufactured by the Roche Group, and (b) the denominator of which is the equal to the sum of [* * *]; provided that beginning with the Calendar Quarter, if any, in which Regeneron first supplies Drug Substance to Roche for commercial use by Roche in the Roche Territory, Roche may elect to determine in accordance with Appendix 1.106 [* * *] for such Calendar Quarter for which the Drug Substance was manufactured by the Roche Group.

1.107 Roche Shared Infringement

The term “Roche Shared Infringement” shall mean (a) any Infringement of a Product Patent Right or Product Know-How, in either case, in the Roche Territory or (b) any Competitive Infringement of a Joint Patent Right or Joint Know-How, in either case, in the Roche Territory that is unrelated to any Competitive Infringement of a Joint Patent Right or Joint Know-How in the Regeneron Territory.

1.108 Roche Territory

The term “Roche Territory” shall mean all countries other than the US, excluding any Terminated Country from and after the effective date of termination for such Terminated Country.

1.109 ROW

The term “ROW” shall mean all countries in the Roche Territory other than the Roche Major Countries.

1.110 Sales Volume

The term “Sales Volume” shall mean, with respect to each Presentation of Product and a Party for the period measured, the number of units of such Presentation of Product that are sold in such Party’s Respective Territory (i.e., that constitute Net Sales for such Party) during such period (for the avoidance of doubt, excluding any such units distributed as [* * *] by or on behalf of such Party or any of its Affiliates or Sublicensees during such period).

1.111 SARS-CoV-2

The term “SARS-CoV-2” shall mean the virus known as the severe acute respiratory syndrome coronavirus 2.

1.112 Sensitive Information

The term “Sensitive Information” shall mean any Proprietary Manufacturing Information or information relating to Regeneron’s cell lines for any Product.

1.113 Standard Cost

The term “Standard Cost” shall mean, with respect to a Party for a given Calendar Year, (a) with respect to Product in its respective form (Drug Substance, Drug Product, Finished Product), such Party’s reasonable best estimate of its Fully Burdened Manufacturing Costs for such Product for such Calendar Year (without markup) based on such Party’s Fully Burdened Manufacturing Costs for the prior Calendar Year for such Product and any anticipated changes in Fully Burdened Manufacturing Costs for such Calendar Year (e.g., manufacturing efficiencies, changes in cost of raw materials) calculated on a per unit basis (i.e. kilogram for Drug Substance, and unit for Drug Product and Finished Product) and, for Finished Product, on a per Presentation basis, for such Party and with respect to Drug Product and Finished Product, each Party may have a different Standard Cost for each Permutation of each applicable Presentation of such Product, in each case determined pursuant to Section 4.2 and (b) with respect any manufacturing-related services (e.g., filling, finishing, packaging and labelling) that one Party performs for the other Party, the cost for such services determined by the Parties based on the Fully Burdened Manufacturing Costs of performing such services (without mark-up), in each case ((a) and (b)), in accordance with such Party’s Accounting Standards. For clarity, if Finished Product distributed by a Party contains Drug Substance supplied by the other Party or the other Party performed any manufacturing services (e.g., filling, finishing, packaging and labelling) with respect to such Finished Product, then such Party would pay the other Party such other Party’s Standard Costs for such Drug Substance or such services and such Standard Costs shall be included in the Standard Cost for such Finished Product for such first Party. A Party may have a different Standard Costs for Drug Product or Finished Product that is manufactured entirely by or on behalf of such Party as well as Drug Product or Finished Product that is filled, finished, packaged or labelled, or incorporates Drug Substance or Drug Product supplied by or on behalf of the other Party (each such permutation of Drug Product or Finished Product that is manufactured using a different combination of materials and services provided by or on behalf

of the Parties, a "**Permutation**"). Notwithstanding the foregoing, a Party may calculate and use a blended Standard Cost for use with all Permutations of a Presentation of Drug Product or Finished Product as provided in Section 4.2, in its own discretion.

1.114 Sublicensee

The term "Sublicensee" shall mean a Third Party to which either Party has (sub)licensed rights (through one or multiple tiers) licensed to it under this Agreement, other than any Affiliate [* * *].

1.115 Territory

The term "Territory" shall mean all countries of the world.

1.116 Third Party

The term "Third Party" shall mean a person or entity other than (i) Regeneron or any of its Affiliates or (ii) Roche or any of its Affiliates.

1.117 Third Party IP License

The term "Third Party IP License" shall mean any license or other agreement with a Third Party entered into by a Party pursuant to Section 14.18.

1.118 Third Party IP Payments

The term "Third Party IP Payments" shall mean any amounts paid by a Party or any of its Affiliates under any Third Party IP License that are reasonably allocable to the Products.

1.119 US

The term "US" shall mean the United States of America and its territories and possessions.

1.120 US Affiliate

The term "US Affiliate" shall mean any Affiliate that is a US Person.

1.121 US Person

The term "US Person" shall mean a "United States person", as such term is defined in Section 7701(a)(30) of the Code.

1.122 Valid Claim

The term "Valid Claim" shall mean a claim in any unexpired and issued Patent Right that has not been disclaimed, revoked or held invalid by a final non-appealable decision of a court of competent jurisdiction or government agency.

1.123 Additional Definitions

Each of the following definitions is set forth in the Section of this Agreement indicated below:

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[* * *]	10.2
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[* * *]	2.8
[* * *]	2.8
[* * *]	2.8
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2. Grant of License

2.1 Licenses granted by Regeneron

Regeneron hereby grants to Roche Basel under the Regeneron Patent Rights and Regeneron Know-How and Regeneron's interest in the Joint Patent Rights and Joint Know-How (and in the case of clause (v) below, under Regeneron's rights in the Global Trademarks):

(i) a non-exclusive right and license to make, have made, import, have imported, export and have exported Compounds and Products in the Territory as contemplated by this Agreement, including the right to sublicense pursuant to Section 2.2;

(ii) a non-exclusive right and license to research, have researched, develop, have developed, Compounds and Products in the Territory as contemplated by this Agreement, including the right to sublicense pursuant to Section 2.2;

(iii) a co-exclusive right and license (together with Regeneron) to seek and maintain Regulatory Approval for, and have Regulatory Approval sought and maintained for, Compounds and Products in the Roche Territory as contemplated by this Agreement including the right to sublicense pursuant to Section 2.2;

(iv) an exclusive (even as to Regeneron) right and license to market, have marketed, commercially distribute, have commercially distributed, sell and have sold Products in the Field in the Roche Territory and to use, have used, import and have imported Products in the Field in the Roche Territory in connection with such marketing, commercial distribution and sale, including the right to sublicense pursuant to Section 2.2; and

(v) subject to Section 14.3, a non-exclusive, royalty-free, fully paid-up, license to use the Global Trademarks owned by Regeneron in the Regeneron Territory to (a) conduct activities with respect to the Products in the Field in the Regeneron Territory solely to support the marketing, commercial distribution and sale of the Products in the Field in the Roche Territory, if applicable and (b) supply Products to Regeneron pursuant to this Agreement or the Supply Agreement.

2.2 Roche's Right to Sublicense

2.2.1 Right to Sublicense to its Affiliates and [* * *]

Roche Basel shall have the right to grant (a) written sublicenses to its Affiliates (through multiple tiers) and (b) [* * *].

For the avoidance of doubt, if Chugai is not added as an Affiliate hereunder, Chugai shall be considered a Third Party hereunder, provided that Roche Basel may still sublicense rights granted under Section 2.1 to Chugai in Japan without the prior written approval of Regeneron pursuant to this Section.

[* * *]

[* * *]

Roche Basel shall inform Regeneron promptly after having granted a sublicense pursuant to this Section 2.2.1 other than to an Affiliate.

Each permitted sublicense shall be in writing and consistent in all material respects with the terms and conditions of this Agreement and Roche Basel shall ensure that all of the applicable terms and conditions of this Agreement shall apply to the applicable Affiliate or [* * *] to the same extent as they apply to Roche Basel for all purposes; provided that a separate written sublicense shall not be required for Affiliates or distributors who have existing agreements with Roche or its Affiliates that are consistent with the terms and conditions of this Agreement. Roche Basel assumes full responsibility for the performance of all obligations and observance of all terms so imposed on such Affiliate or [* * *], as applicable, and shall itself account to Regeneron for all payments due under this Agreement by reason of such sublicense.

2.2.2 Right to Sublicense to Other Third Parties

Roche Basel and its Affiliates shall have the right to grant written sublicenses to Third Parties (other than [* * *], which are addressed in Section 2.2.1), through multiple tiers, under its rights granted under Section 2.1(i) only upon prior written approval of Regeneron.

Roche Basel and its Affiliates shall have the right to grant written sublicenses to Third Parties (other than [* * *], which are addressed in Section 2.2.1), through multiple tiers, under its rights granted under Section 2.1(ii) - 2.1(v) (a) upon the prior written approval of Regeneron (i) in Regeneron's sole discretion if the Third Party is a Pharmaceutical Company, (ii) not to be unreasonably withheld, conditioned or delayed, if such sublicense is granted with respect to a Roche Major Country, and (iii) in Regeneron's sole discretion, if such proposed Sublicensee would have access to any Proprietary Manufacturing Information, including in connection with regulatory filings with applicable Regulatory Authorities in such country, and (b) otherwise without the prior approval of Regeneron.

[* * *]

Each permitted sublicense shall be in writing and consistent in all material respects with the terms and conditions of this Agreement and Roche Basel shall ensure that all of the applicable terms and conditions of this Agreement shall apply to the applicable Sublicensee to the same extent as they apply to Roche Basel for all purposes; provided that a separate written sublicense shall not be required for distributors who have existing agreements with Roche or its Affiliates that are consistent with the terms and conditions of this Agreement. Roche Basel assumes full responsibility for the performance of all obligations and observance of all terms so imposed on such Sublicensee and shall itself account to Regeneron for all payments due under this Agreement by reason of such sublicense.

2.3 Roche Basel Right to Subcontract

Roche Basel, at its own cost and discretion, shall have the right to subcontract the work performed under Section 2.1(i) through Section 2.1(iv) to Affiliates without the prior approval of Regeneron.

Roche Basel, at its own cost and discretion, shall have the right to subcontract the work performed under Section 2.1(i) to CMOs or other Third Parties in the Territory only with the prior approval of Regeneron; provide that Roche Basel may subcontract the work performed under Section 2.1(i) to CMOs with respect to Finished Product or the conversion of Drug Substance to Drug Product or Finished Product or Drug Product to Finished Product (but not with respect to the manufacture of Drug Substance) without the prior approval of Regeneron; provided further that Roche shall notify Regeneron in writing of such subcontracting in sufficient time for Regeneron to update its applicable regulatory filings for the applicable Product and shall use diligent efforts to ensure that there is no interruption for supply of such Product in the Regeneron Territory as a result of such subcontracting.

Roche Basel, at its own cost and discretion, shall have the right to subcontract the work performed under Section 2.1(ii) through Section 2.1(iv) to Third Parties in the Territory without the prior approval of Regeneron.

Each permitted subcontract shall be consistent in all material respects with the terms and conditions of this Agreement and Roche Basel shall ensure that all of the applicable terms and conditions of this Agreement shall apply to the applicable subcontractor to the same extent as they apply to Roche Basel for all purposes. Roche Basel assumes full responsibility for the performance of all obligations and observance of all terms so imposed on such subcontractor and shall itself account to Regeneron for all payments due under this Agreement by reason of such subcontract.

2.4 Licenses granted by Roche

Roche hereby grants to Regeneron under the Roche Patent Rights and Roche Know-How and Roche Independent IP and Roche's interest in the Joint Patent Rights and Joint Know-How (and in the case of clause (v) below, under Roche's rights in the Global Trademarks):

(i) a non-exclusive right and license to make, have made, import, have imported, export and have exported Compounds and Products in the Territory as contemplated by this Agreement, including the right to sublicense pursuant to Section 2.5;

(ii) a non-exclusive right and license to research, have researched, develop, have developed, seek and maintain Regulatory Approval for, and have Regulatory Approval sought and maintained for, Compounds and Products in the Territory as contemplated by this Agreement, including the right to sublicense pursuant to Section 2.5;

(iii) an exclusive (even as to Roche) right and license to seek and maintain Regulatory Approval for, and have Regulatory Approval sought and maintained for, Compounds and Products in the Regeneron Territory as contemplated by this Agreement, including the right to sublicense pursuant to Section 2.5;

(iv) an exclusive (even as to Roche) right and license to market, have marketed, commercially distribute, have commercially distributed, sell and have sold Products in the Field in the Regeneron Territory and to use, have used, import and have imported Products in the Regeneron Territory in connection with such marketing, commercial distribution and sale, including the right to sublicense pursuant to Section 2.5;

(v) subject to Section 14.3, a non-exclusive, royalty-free, fully paid-up, license to use the Global Trademarks owned by Roche in the Roche Territory to (i) conduct activities with respect to the Products in the Field in the Roche Territory solely to support the marketing, commercial distribution and sale of the Products in the Field in the Regeneron Territory, if applicable and (ii) supply Products to Roche pursuant to this Agreement or the Supply Agreement.

2.5 Regeneron's Right to Sublicense

Regeneron shall have the right to grant written sublicenses to its Affiliates (through multiple tiers) and Third Parties under its rights granted under Section 2.4 without prior approval of Roche; provided that, (a) with respect to any rights granted under Sections 2.4(i), Regeneron and its Affiliates shall not grant a sublicense (other than to a [* * *]) to a CMO or another Third Party to manufacture Drug Substance without Roche's prior written consent (other than sublicensing manufacture of Drug Substance to CMOs in the Territory up to the Minimum Committed Regeneron Capacity, which may be without the prior approval of Roche); and (b) Regeneron and its Affiliates shall not grant a sublicense (other than to a [* * *]) under Section 2.4(ii) with respect to Roche Independent IP to a Third Party without Roche's prior written consent, not to be unreasonably withheld, conditioned, or delayed. Regeneron must provide Roche reasonable notice before granting any [* * *], and upon Roche's request the Parties shall discuss in good faith options to avoid the grant of any [* * *] and Regeneron shall use diligent efforts to avoid having to grant any [* * *].

If Regeneron licenses a Third Party in the Regeneron Territory under the rights granted to Roche under Section 2.1(iv) in the Roche Territory (whether or not Regeneron sublicenses the rights granted to Regeneron by Roche under Section 2.4(iv) to such Third Party), then, unless otherwise agreed by Roche in writing in its sole discretion, such Third Party will be considered a Sublicensee of Regeneron.

[* * *]

Each permitted sublicense shall be consistent in all material respects with the terms and conditions of this Agreement and Regeneron shall ensure that all of the applicable terms and conditions of this Agreement shall apply to the applicable Affiliate or Sublicensee to the same extent as they apply to Regeneron for all purposes; provided that a separate written sublicense shall not be required for Affiliates or distributors who have existing agreements with Regeneron or its Affiliates that are consistent with the terms and conditions of this Agreement. Regeneron assumes full responsibility for the performance of all obligations and observance of all terms so imposed on such Affiliate or Sublicensee, as applicable, and shall itself account to Roche for all payments due under this Agreement by reason of such sublicense. Regeneron shall inform Roche promptly after having granted a sublicense pursuant to this Section 2.5.

2.6 Regeneron Right to Subcontract

Regeneron, at its own cost and discretion, shall have the right to subcontract any work performed under this Agreement to Third Parties in the Territory without the prior approval of Roche, except that Regeneron shall not have the right to subcontract manufacture of Drug Substance to CMOs or other Third Parties in the Territory without the prior approval of Roche; provided that Regeneron may subcontract manufacture of Drug Substance to CMOs in the Territory up to the Minimum Committed Regeneron Capacity without the prior approval of Roche. Unless otherwise agreed by the Parties, any grant of rights by Regeneron to a CMO or Third Party under the rights granted to Roche Basel pursuant to Section 2.1(i) shall be considered a "subcontract" for purposes of restrictions under this Section 2.6, regardless of the structure of such arrangement with the CMO or Third Party.

Each permitted subcontract shall be consistent in all material respects with the terms and conditions of this Agreement and Regeneron shall ensure that all of the applicable terms and conditions of this Agreement shall apply to the applicable subcontractor to the same extent as they apply to Regeneron for all purposes. Regeneron assumes full responsibility for the performance of all obligations and observance of all terms so imposed on such subcontractor and shall itself account to Roche for all payments due under this Agreement by reason of such subcontract.

2.7 Combination Products and Companion Diagnostics

Each Party shall not, and shall cause its Affiliates not to develop, have developed, seek and maintain Regulatory Approval for, and have Regulatory Approval sought and maintained for, use, have used, make, have made, import, have imported, export, have exported, market, have marketed, commercially distribute, have commercially distributed, sell or have sold any Combination Product or Companion Diagnostic, unless and until the Parties have agreed in writing on the terms and conditions with respect thereto.

2.8 Back-Up Compounds

[* * *].

2.9 Antibody Conjugates

During the Agreement Term, Regeneron will not, and will cause its Affiliates not to, clinically develop or commercialize an Antibody Conjugate that contains the Lead Compound or any Antibody in the Lead Compound, or grant a license to a Third Party to do so.

3. Research and Development

3.1 Responsibilities

Regeneron shall, at its own cost and expense, use Commercially Reasonable Efforts to conduct the Ongoing Regeneron Studies and shall have the right to pursue Third Party funding for the Ongoing Regeneron Studies. Regeneron shall provide Roche Basel periodic updates at interim analysis points regarding the progress and status of the Ongoing Regeneron Studies, including a high-level summary of any available data from the Ongoing Regeneron Studies.

The JOC will discuss and align on a strategy for investigator-sponsored studies with respect to the Compounds and the Products in the Territory (for example key clinical questions of interest, areas that the Parties do not wish to address, and any potential supply constraint) (the "**ISS Strategy**"). Regeneron shall have the right, but not the obligation, to provide support for any investigator-sponsored studies with respect to the Compounds and the Products in the Regeneron Territory, consistent with the ISS Strategy, and will consult with Roche Basel regarding such studies and consider Roche Basel's comments in good faith. Roche shall have the right, but not the obligation, to provide support for any investigator-sponsored studies with respect to the Compounds and the Products in the Roche Territory, consistent with the ISS Strategy, and will consult with Regeneron regarding such studies and consider Regeneron's comments in good faith. Unless otherwise agreed by the Parties, each Party will provide support for any investigator-sponsored studies for the Compounds and the Products [* * *].

Prior to initiating a new Clinical Study that is not an Ongoing Regeneron Study and is not included in the then-current Co-Funded Development Plan and is not an ongoing Unilateral Study, the Party that desires to conduct such Clinical Study (the "**Proposing Party**") shall propose such Clinical Study to the JOC, which proposal shall include a synopsis of the protocol for such Clinical Study and an estimated budget for such Clinical Study. The JOC shall review and submit such Clinical Study to the JSC for approval. If the JSC agrees that the Parties shall share the [* * *] with respect to such Clinical Study, then the Parties shall amend the Co-Funded Development Plan to include such Clinical Study and such Clinical Study shall be a Co-Funded Study. With respect to each Co-Funded Study, the Party conducting such Co-Funded Study shall provide the other Party periodic updates at least once a Calendar Quarter regarding the progress and status of such Co-Funded Study, including a high-level summary of any available data from such Co-Funded Study.

If the JSC does not agree [* * *] with respect to such Clinical Study, then the Proposing Party shall have the right, but not the obligation, to conduct such Clinical Study [* * *] (each such Clinical Study, a "**Unilateral Study**"). [* * *].

Each Party shall use Commercially Reasonable Efforts to perform the development activities with respect to the Co-Funded Studies that are assigned to such Party in the Co-Funded Development Plan and shall do so in accordance with the Co-Funded Development Plan. The Parties acknowledge and agree that Regeneron is responsible for conducting the Additional Regeneron Studies, and Regeneron shall provide Roche Basel periodic updates at interim analysis points regarding the progress and status of the Additional Regeneron Studies, including a high-level summary of any available data from the Additional Regeneron Studies. Each Party will be responsible for its own internal costs associated with development activities for the Co-Funded Studies. [* * *] by or on behalf of either Party or any of its Affiliates in connection with the Co-Funded Studies (including, for clarity, such [* * *] incurred by or on behalf of Regeneron or any of its Affiliates with respect to the Additional Regeneron Studies prior to the Effective Date) that are not reimbursed by a Third Party shall be [* * *]. [* * *].

Each Party shall [* * *] be responsible for all development activities with respect to each Unilateral Study conducted by such Party. For clarity, neither Party shall have the obligation to conduct or, except as may be required by Applicable Law or ethical requirements, complete any Unilateral Study.

Prior to initiating any development activities with respect to any delivery device for the Products (e.g., pre-filled syringe) (the "**Device Development Activities**"), the Party that desires to conduct such Device Development Activities shall provide a proposed development plan for such delivery device to the JOC (the "**Device Development Plan**"), which Device Development Plan will include an estimated budget for such Device Development Activities. The JOC shall review and submit such Device Development Plan to the JSC for approval. If the JSC agrees [* * *] with respect to such Device Development Activities, then the Parties will agree to a final Device Development Plan and such Device Development Activities shall be "**Co-Funded Device Development Activities**". With respect to Co-Funded Device Development Activities, the Party conducting such Co-Funded Device Development Activities shall provide the other Party periodic updates regarding the progress and status of such Co-Funded Device-Development Activities.

If the other Party does not agree [* * *] with respect to proposed Device Development Activities, then the Party proposing such Device Development Activities shall have the right, but not the obligation, to conduct such Device Development Activities [* * *] (such Device Development Activities, "**Unilateral Device Development Activities**"). [* * *].

Each Party shall use Commercially Reasonable Efforts to perform the Device Development Activities with respect to Co-Funded Device Development Activities that are assigned to such Party in the final agreed Device Development Plan for such Co-Funded Device Development Activities and shall do so in accordance with such final agreed Device Development Plan. Each Party will be responsible for its own internal costs associated with the Co-Funded Device Development Activities and the [* * *] incurred by or on behalf of either Party or any of its Affiliates in connection with the Device Development Activities under the Device Development Plan shall be [* * *]. [* * *].

Each Party shall, [* * *], be responsible for all Unilateral Device Development Activities conducted by such Party. For clarity, neither Party shall have the obligation to conduct or, except as may be required by Applicable Law or ethical requirements, complete any Unilateral Device Development Activities.

[* * *]

Notwithstanding anything to the contrary in the foregoing, unless otherwise agreed by the Parties, Regeneron shall have the sole right, but not the obligation, to conduct any clinical assay that is designed to measure [* * *]. Regeneron shall use Commercially Reasonable Efforts to perform or have performed any [* * *] on biological samples collected in connection with any Clinical Study with respect to the Product conducted by or on behalf of Roche or its Affiliates or Sublicensees.

Each Party shall conduct its development activities with respect to the Compounds and Products in accordance with Applicable Law and the terms of this Agreement.

3.2 Co-Funded Development Plan

The Parties shall conduct the Co-Funded Studies in accordance with the Co-Funded Development Plan.

Any proposed modifications to the Co-Funded Development Plan to include any additional Co-Funded Studies or to modify any existing Co-Funded Studies shall be made pursuant to Article 8.

3.3 Exchange of Information

Each Party shall disclose and make available to the other Party all data and information necessary for such other Party to conduct the development activities under this Agreement. Each Party shall answer any questions reasonably posed by the other Party with respect to the development activities under this Agreement and provide any information reasonably requested by the other Party with respect thereto that is in the possession of such first Party.

Without limiting reporting obligations under Section 3.1, each Party shall provide to the other Party (a) headline data on each Clinical Study with respect to a Product conducted by such Party as soon as possible after such data or results become available and before the final report(s) are written and (b) final reports of each Clinical Study with respect to a Product conducted by such Party promptly after such reports become available. The data exchanged between the Parties under this Section 3.3 shall be delivered in an electronic format that is appropriate for purposes of submission to Regulatory Authorities in support of Regulatory Approval.

3.4 Development Records

Each Party shall maintain records of its development activities under this Agreement (or cause such records to be maintained) in sufficient detail and in good scientific manner as will properly reflect all work done and results achieved by or on behalf of such Party in the performance of the development.

3.5 PII/Samples

In connection with Clinical Studies or other activities associated with the development and commercialization of Products, the Parties may collect (i) personally identifiable information about individual human subjects or (ii) human biological samples (collectively, "**PII/Samples**"). Each Party shall collect the PII/Samples in compliance with Applicable Law and Roche shall use Commercially Reasonable Efforts to obtain all consents necessary for such PII/Samples to be transferred to Regeneron upon expiration or termination of this Agreement.

4. Manufacturing

4.1 Manufacturing Responsibility

4.1.1 Shared Responsibility during the Agreement Term

Each Party shall use diligent efforts to promptly complete those activities assigned to it pursuant to the Transfer Plan (as defined in the Technology Transfer Agreement) pursuant to the Technology Transfer Agreement. Notwithstanding Section 7 of the Technology Transfer Agreement, the Parties agree (a) they shall not terminate the Technology Transfer Agreement separate from this Agreement and (b) if either Party breaches the Technology Transfer Agreement, such breach shall be deemed to be a breach by such Party under this Agreement. Upon the Manufacturing Collaboration Timepoint, Roche shall, at its own cost, (i) dedicate and

utilize the equivalent of at least 100,000 liters of annualized bioreactor capacity on a full-time campaign basis [* * *] for the manufacture of Drug Substance at the Roche Manufacturing Facilities or at CMOs (subject to Section 2.3) ("**Minimum Committed Roche Capacity**"), unless the JMC decides a Minimum Committed Capacity Reduction pursuant to Section 8.2.3(g) and (ii) reserve sufficient capacity to fill, finish, pack and label, at its discretion, at Roche facilities or CMOs (subject to Section 2.3) the Drug Substance it manufactures.

Unless otherwise agreed by the Parties in writing, any Product supplied by Roche to Regeneron under this Agreement or the Supply Agreement shall be Finished Product. Prior to beginning to manufacture Drug Substance at a Roche Manufacturing Facility other than the Roche Manufacturing Facility in Vacaville, California, Roche will notify the JMC for review and discussion of the Roche Manufacturing Facility pursuant to Section 8.2.3(i); provided that the JMC shall not have an approval right over use of such Roche Manufacturing Facility and Roche may determine to use such Roche Manufacturing Facility in its discretion.

Upon the Manufacturing Collaboration Timepoint, Regeneron shall at its own cost, dedicate and utilize the equivalent of at least 40,000 liters of annualized bioreactor capacity on a full-time campaign basis [* * *] for the manufacture of Drug Substance at Regeneron's facilities or at CMOs (subject to Section 2.6) ("**Minimum Committed Regeneron Capacity**"), unless the JMC decides a Minimum Committed Capacity Reduction pursuant to Section 8.2.3(g). Unless otherwise agreed by the Parties in writing, any Products supplied by Regeneron to Roche Basel under this Agreement or the Supply Agreement shall be Drug Substance.

If the JMC decides to reduce the Minimum Committed Roche Capacity and Minimum Committed Regeneron Capacity because the demand in the Territory drops below 140,000 liters of bioreactor capacity on an annualized basis for commercial manufacture of the Drug Substance for the Lead Product, then, unless the JSC decides by mutual consent on a different proportion, the Minimum Committed Roche Capacity shall be reduced at the same proportion as the Minimum Committed Regeneron Capacity.

4.1.2 Excess Capacity

In addition to its responsibilities set forth in Section 4.1.1 each Party shall have the right to make available bioreactor capacity for Drug Substance at its own facilities consistent with the terms of this Agreement, in excess of, respectively, the Minimum Committed Roche Capacity and the Minimum Committed Regeneron Capacity.

Roche Basel shall consider in good faith any request by Regeneron to convert Drug Substance which Regeneron manufactures to Drug Product or Finished Product. For the avoidance of doubt, if Roche Basel determines that it does not or will not have sufficient excess capacity to accommodate Regeneron's request, that shall be a sufficient good faith reason for denying such request. [* * *].

4.1.3 Specifications

Regeneron shall be solely responsible for establishing the specifications for each Drug Substance and Drug Product. Prior to Regeneron finalizing any specifications, Regeneron will provide Roche with the proposed specifications and provide Roche with a reasonable opportunity to provide comments thereto, which Regeneron will consider in good faith. Each

Party shall be solely responsible for establishing the specifications for packaging and labeling of the Finished Product in its respective territory.

4.2 Standard Costs

(a) The Parties, through the JMC (in consultation with the FWG), shall determine each Party's Standard Cost for each Drug Substance, Drug Product (which shall be on a Presentation-by-Presentation and Permutation-by-Permutation basis) and Finished Product (which shall be on a Presentation-by-Presentation and Permutation-by-Permutation basis), and any manufacturing services (i.e., filing, finishing, packaging and labelling) to be performed by or on behalf of such Party for the other Party, in each case prior to the [* * *] and prior to each October 31 thereafter; provided that, with respect to each Presentation of Drug Product or Finished Product, the manufacturing Party may use a blended Standard Cost based on the weighted average of the Fully Burdened Manufacturing Costs for all applicable Permutations of such Presentation. Prior to each such date, each Party shall provide to the JMC, with such supporting cost breakout information as determined by the JMC, (i) the Fully Burdened Manufacturing Costs for each Drug Substance, Drug Product or Finished Product, for each applicable Presentation, manufactured by or on behalf of such Party or its Affiliates in the prior Calendar Year and any manufacturing services (i.e., filling, finishing, packaging and labelling) performed by or on behalf of such Party or any of its Affiliates for the other Party in the prior Calendar Year, (ii) its reasonable best estimate of its Fully Burdened Manufacturing Costs for each Drug Substance, Drug Product or Finished Product, including for each applicable Presentation, to be manufactured by or on behalf of such Party or its Affiliates in such Calendar Year and any manufacturing services (i.e., filling, finishing, packaging and labelling) to be performed by or on behalf of such Party or any of its Affiliates for the other Party in such Calendar Year, in each case, taking into account any anticipated changes in Fully Burdened Manufacturing Costs for such Calendar Year (e.g., manufacturing efficiencies, changes in cost of raw materials), and (iii) for any Presentation of Drug Product or Finished Product for which the manufacturing Party elects to use one blended Standard Cost, the information used by such Party to determine the weighted average of the Fully Burdened Manufacturing Costs for the various Permutations of such Presentation.

(b) The Parties shall discuss and agree on, through the JMC (in consultation with the FWG), the Standard Costs for each Party with respect to each Drug Substance, Drug Product or Finished Product, including for each applicable Presentation to be manufactured by or on behalf of such Party or its Affiliates for the coming Calendar Year and for any manufacturing services (i.e., filling, finishing, packaging and labelling) to be performed by or on behalf of a Party or any of its Affiliates for the other Party, in each case, based on the information provided by each Party in accordance with Section 4.2(a).

(c) [* * *].

(d) Within [* * *] after the end of each of Calendar Year, with respect to each Presentation for which the manufacturing Party used one blended Standard Cost for all Permutations of such Presentation, such manufacturing Party shall report to the JMC such manufacturing Party's actual Fully Burdened Manufacturing Costs for each Permutation and the quantity of each such Permutation that was manufactured during such Calendar Year. [* * *].

4.3 Regeneron Cell Banks and Cell Media.

4.3.1 Regeneron Cell Banks

In connection with the technology transfer under the Technology Transfer Agreement and for the sole purposes of enabling Roche or its Affiliates to manufacture the Product(s) pursuant to this Agreement, Regeneron will, upon Roche's request, supply to Roche [* * *] of vials of the working cell bank for the manufacture of Drug Substance (the "**Working Cell Bank**"), subject to the terms and conditions herein and in the Technology Transfer Agreement.

Roche shall pay [* * *] in connection with the supply of any quantity of Working Cell Bank requested by Roche after completion of the technology transfer pursuant to the Technology Transfer Agreement.

Roche shall not, and shall cause its Affiliates not to, (i) use or duplicate any Working Cell Bank (or any component thereof) for any purpose other than to manufacture the Drug Substance for purposes of manufacturing the Product(s), or (ii) transfer any Working Cell Bank (or any component thereof) to any Third Party, other than a CMO approved by Regeneron.

4.3.2 Regeneron Cell Media

The Roche Group shall only purchase Regeneron Cell Media from Regeneron or its Affiliates, or from any Third Party that Regeneron has authorized to manufacture Regeneron Cell Media, in each case, solely to enable Roche to manufacture the Product(s) pursuant to this Agreement, and upon Roche's reasonable request, Regeneron shall provide a letter of authorization to any such Third Party in order to permit such Third Party to supply Regeneron Cell Media to Roche.

Regeneron shall not be required to disclose to Roche the composition, formula, properties or method of making any Regeneron Cell Media. Roche shall not, and shall cause its Affiliates not to, (a) use Regeneron Cell Media for any purpose other than to manufacture the Product(s) pursuant to this Agreement or (b) transfer Regeneron Cell Media to any Third Party other than a CMO approved by Regeneron.

Nothing in this Section 4.3.2 shall be deemed or construed to limit Roche or any of its Affiliates with respect to any cell culture media that Roche can demonstrate was in the possession of Roche or any of its Affiliates as of the Effective Date other than under this Agreement or the Technology Transfer Agreement.

4.3.3 Ownership and Restrictions

(a) Regeneron shall own exclusively the Working Cell Bank. Regeneron hereby grants to Roche Basel a non-exclusive, royalty-free, fully paid-up, non-sublicensable (other than to any of its Affiliates or CMO approved by Regeneron), non-transferable (except as permitted in Section 21.5) license to use the Working Cell Bank and Regeneron Cell Media solely for the purposes of manufacturing the Product(s) pursuant to this Agreement.

(b) Roche Basel shall not, and shall ensure that its Affiliates, and its and their permitted Sublicensees do not, reverse engineer any cell lines, media or feeds or any other proprietary materials in the Working Cell Bank or Regeneron Cell Media.

(c) Roche Basel shall destroy any quantities of Working Cell Bank and Regeneron Cell Media remaining upon expiration or termination of this Agreement within [* * *] following such expiration or termination. Roche shall provide written certification of such destruction to Regeneron.

5. Supply

5.1 Allocation

Until the [* * *], Regeneron, may sell Product manufactured by Regeneron in the Regeneron Territory or transfer such Product to Roche Basel for sale in the Roche Territory by Roche Basel, its Non-US Affiliates or Sublicensees in accordance with this Section 5.1 and Section 10.2 (a) – (c).

Until the [* * *], Roche may sell Product manufactured by Roche in the Roche Territory or transfer such Product to Regeneron for sale in the Regeneron Territory by Regeneron, its Affiliates or Sublicensees in accordance with this Section 5.1 and Section 10.2 (a) - (c).

Starting [* * *], the Parties shall manufacture Drug Substance for the Lead Product at the Minimum Committed Roche Capacity and the Minimum Committed Regeneron Capacity, respectively. For clarity, each Party may, at its discretion, prior to [* * *] manufacture Drug Substance for the Lead Product that counts towards the Minimum Committed Roche Capacity or the Minimum Committed Regeneron Capacity, as the case may be, for the year 2021.

[* * *]

[* * *]

For clarity, the actual amount of Product provided from one Party to the other Party pursuant to this Section 5.1 will be determined in accordance with the forecasting and ordering process set forth in the Supply Agreement.

Notwithstanding anything to the contrary in this Agreement, Regeneron shall not be required to sell any Product to any US Affiliate of Roche.

5.2 Supply Price

If one Party supplies to the other Party Drug Substance, Drug Product or Finished Product, as the case may be, such supply shall be [* * *].

5.3 Supply Agreement

Unless otherwise agreed by the Parties, no later than [* * *] following the Effective Date, the Parties will negotiate in good faith and enter into a supply agreement on reasonable and customary terms for the process of ordering and supply of Products among the Parties, with a related quality agreement (collectively, the "**Supply Agreement**"). The principles set forth in Sections 5.1 and 5.2 shall be further detailed in the Supply Agreement. The Supply Agreement shall also encompass precise descriptions of Drug Product manufacturing and labeling and packaging.

6. Regulatory

6.1 Responsibility

6.1.1 Regeneron's Responsibilities.

Regeneron shall be solely responsible [* * *] for all regulatory affairs specifically with respect to any Product in the Regeneron Territory, including pursuing, compiling and submitting all regulatory filing documentation, and for interacting with Regulatory Authorities including the preparation and filing of applications for any or all Regulatory Approvals, as well as any or all governmental approvals required to develop, have developed, make, have made, use, have used, manufacture, have manufactured, import, have imported, sell and have sold Products in the Regeneron Territory. Regeneron or its Affiliates shall own, maintain and file in their discretion all regulatory filings and Regulatory Approvals for all Products throughout the Regeneron Territory. Roche shall, upon Regeneron's reasonable request and [* * *], provide assistance with respect to any such regulatory activities conducted by Regeneron, including that Roche shall prepare the portions of any regulatory filing documentation in the Regeneron Territory to the extent relating to Roche's manufacture of Drug Substance, Drug Product or Finished Product, as applicable. Notwithstanding the foregoing, Roche shall be responsible for the Roche Regulatory Activities (including any such activities in the Regeneron Territory), and to the extent permitted by Applicable Law, Roche and its Affiliates shall own, maintain and file all regulatory filings and Regulatory Approvals with respect to the Roche Regulatory Activities in the Regeneron Territory. To the extent permitted by Applicable Law, Regeneron shall (a) provide Roche reasonable advance notice of any meeting with any Regulatory Authority in the Regeneron Territory related to the preparation or filing of such applications, and Roche may appoint up to [* * *] Roche employees to attend any such meeting with Regulatory Authorities in the Regeneron Territory; and (b) upon Roche's request, Regeneron shall provide Roche with copies of all material filings and submissions prepared and exchanged with Regulatory Authorities in support of obtaining or maintaining Regulatory Approval for the Products in the Regeneron Territory.

Regeneron shall also be solely responsible [* * *] for all regulatory affairs related to (a) (i) the conduct of the Ongoing Regeneron Studies and (ii) any Co-Funded Study or Unilateral Study, in either case, conducted by or on behalf of Regeneron and (b) Regeneron's manufacture of the Products, in each case ((a) or (b)), anywhere in the Territory (collectively, the "**Regeneron Regulatory Responsibilities**"), including pursuing, compiling and submitting all regulatory filing documentation, and for interacting with Regulatory Authorities including the preparation and filing of applications for any or all Regulatory Approvals, as well as any or all governmental approvals with respect to the Regeneron Regulatory Responsibilities ("**Regeneron Regulatory Activities**"); provided, that the Parties shall [* * *] Regeneron's [* * *] for all regulatory affairs related to any Co-Funded Study. Regeneron and its Affiliates shall own, maintain and file all regulatory filings and Regulatory Approvals with respect to the Regeneron Regulatory Activities in the Territory (but not, for clarity, any Regulatory Approval for commercialization of any Product in the Roche Territory except as provided in the next paragraph). Regeneron shall (A) provide reasonable advance notice of any meeting with any Regulatory Authority in the Roche Territory related to any Regeneron Regulatory Responsibilities, and, to the extent permitted by Applicable Law, Roche may appoint up to [* * *] Roche employees to attend any such meeting with Regulatory Authorities in the Roche Territory; and (B) consider in good faith any input from Roche in preparing such regulatory materials and interactions. Roche shall, upon Regeneron's

reasonable request, provide assistance with respect to any such regulatory activities conducted by Regeneron, subject to the following paragraph with respect to the First Approval Activities.

Regeneron shall, in coordination with Roche, be responsible, [* * *], for pursuing, compiling and submitting all regulatory filing documentation, and for interacting with Regulatory Authorities (including the preparation and filing of applications) for the first MAA for the Lead Product in the EU (the "**First EU Approval**") and the first Regulatory Approval for the Lead Product in the United Kingdom (the "**First UK Approval**"), in each case, as determined by the JOC, either (A) in the name of Regeneron, or (B) in the name of Roche (in which case, Regeneron shall act as an agent of Roche) (collectively, the "**First Approval Activities**"). If Regeneron acts as an agent of Roche and file the application for the First EU Approval or for the First UK Approval, as applicable, in the name of Roche, then upon Regeneron's reasonable request, Roche shall execute any documentation necessary to enable Regeneron to act as Roche's agent with respect to the applicable First Approval Activities. Roche shall, upon Regeneron's reasonable request and [* * *], provide assistance with respect to the First Approval Activities, including that Roche shall prepare the portions of the application for the First EU Approval or the First UK Approval, as applicable, to the extent relating to Roche's manufacture of Drug Substance, Drug Product or Finished Product, as applicable. To the extent permitted by Applicable Law, (i) Regeneron shall provide Roche reasonable advance notice of any meeting with any Regulatory Authority in the EU or the United Kingdom, as applicable, related to the preparation or filing of such application, and Roche may appoint [* * *] Roche employees to attend any such meeting with Regulatory Authorities in the EU or the United Kingdom, as applicable; and (ii) Regeneron shall seek input from Roche in preparing such regulatory materials and interactions, and Roche at its own discretion shall have the right to review and approve all documentation prepared and exchanged with Regulatory Authorities in support of filing for such First EU Approval or First UK Approval, as applicable, related to manufacturing sites and manufacturing specifications, label wording and claims (summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL), primary/secondary packaging text) and negotiation of pediatric investigational plans or post-approval commitments. If Regeneron files the application for the First EU Approval or for the First UK Approval, as applicable, in the name of Regeneron, then, as soon as practicable after obtaining the First EU Approval or the First UK Approval, as applicable, Regeneron shall undertake all actions necessary to transfer to Roche such First EU Approval or First UK Approval, as applicable, and any regulatory filings in Regeneron's possession with respect thereto (but excluding, for clarity, any CTA for the Lead Product) and, Regeneron shall, at Roche's reasonable request, cooperate as necessary for such First EU Approval or First UK Approval, as applicable, to be transferred to Roche.

Promptly after the Effective Date, Regeneron shall coordinate and cooperate with Roche to share with Roche, upon Roche's reasonable request, (i) relevant historical clinical safety data, copies of all material correspondence with the Regulatory Authorities of the Roche Territory, (ii) electronic Clinical Study data (including Clinical Study reports, datasets, summaries, overviews and other relevant documentation) in an appropriate format and (iii) regulatory dossiers containing information necessary or useful to Roche in connection with its regulatory filings for any Products in the Roche Territory, including clinical trial dossiers, material regulatory correspondence, and study reports from completed non-clinical studies, in each case, ((i) - (iii)) to the extent in the possession of Regeneron or any of its Affiliates. Regeneron shall, upon Roche's request and at Roche's cost, assist Roche in conducting any required GCP audit related to the above-mentioned documentation.

Regeneron shall maintain the company core data sheet for each Product (the "**CCDS**") for purposes of enabling commercialization of such Product throughout the Territory. Either Party may propose modifications to the CCDS and the Parties shall then discuss whether to modify the CCDS, with each Party considering the other Party's comments with respect thereto in good faith; provided, however, that Regeneron shall have the final decision-making authority with respect to any update to the CCDS.

6.1.2 Roche's Responsibilities.

From and after the Effective Date, subject to the remainder of this paragraph and Regeneron's obligations in Section 6.1.1, Roche shall be solely responsible [* * *] for all regulatory affairs specifically with respect to any Product in the Roche Territory, including the preparation and filing of applications for Regulatory Approval, as well as any or all governmental approvals required to develop, have developed, make, have made, use, have used, manufacture, have manufactured, import, have imported, sell and have sold Products in the Roche Territory. Roche shall be responsible for pursuing, compiling and submitting all regulatory filing documentation, and for interacting with regulatory agencies, for all Products throughout the Roche Territory. To the extent permitted by Applicable Law, (i) Roche shall provide Regeneron reasonable advance notice of any meeting with any Regulatory Authority in a Major Country related to the preparation or filing of such applications, and Regeneron may appoint [* * *] Regeneron employees to attend any such meeting with Regulatory Authorities in such Major Country; and (ii) Roche shall seek input from Regeneron in preparing such regulatory materials and interactions, and Regeneron shall have the right to review and comment on all material filings and submissions prepared and exchanged with Regulatory Authorities in support of obtaining or maintaining Regulatory Approval for the Products in each Major Country, and Roche shall consider such comments in good faith. Without limiting the foregoing, in preparing regulatory filings with Regulatory Authorities with respect to the Products in the Roche Territory, Roche shall not disclose any Sensitive Information to any Regulatory Authority without Regeneron's prior written approval, [* * *]. Roche shall not submit to a Regulatory Authority, or otherwise agree to any Product labeling (or any modification thereto) that is not consistent with the CCDS, without the prior written consent of Regeneron. During the Agreement Term, Roche or its Affiliates shall own, maintain and file in their discretion all regulatory filings and Regulatory Approvals for all Products throughout the Roche Territory. Notwithstanding the foregoing, Regeneron shall be responsible for the First Approval Activities and the Regeneron Regulatory Responsibilities, in each case, as described in Section 6.1.1 and Regeneron and its Affiliates shall own, maintain and file all regulatory filings and Regulatory Approvals with respect to the Regeneron Regulatory Activities in the Roche Territory.

Roche shall also be solely responsible [* * *] for all regulatory affairs related to (a) the conduct of any Co-Funded Study or Unilateral Study conducted by or on behalf of Roche and (b) Roche's manufacture of the Products anywhere in the Territory (the "**Roche Regulatory Responsibilities**"), including pursuing, compiling and submitting all regulatory filing documentation, and for interacting with Regulatory Authorities including the preparation and filing of applications for any or all Regulatory Approvals, as well as any or all governmental approvals with respect to the Roche Regulatory Responsibilities ("**Roche Regulatory Activities**"); provided, that the Parties shall [* * *] Roche's [* * *] for all regulatory affairs related to any Co-Funded Study. Roche and its Affiliates shall own, maintain and file all regulatory filings and Regulatory Approvals with respect to the Roche Regulatory Activities in the Territory (but not, for clarity, any BLA for a Product in the Regeneron Territory).

In the event Roche cannot conduct regulatory activities independent of Regeneron which would be needed to pursue Roche Regulatory Responsibilities, including for Regulatory Approval of a Product in the Roche Territory, Regeneron shall use Commercially Reasonable Efforts to assist Roche [* * *], subject to Section 16.1(c). In addition, Regeneron shall prepare the portions of any regulatory filing documentation in the Roche Territory to the extent relating to Regeneron's manufacture of Drug Substance, Drug Product or Finished Product, as applicable.

6.2 Regulatory Diligence Obligation

Regeneron shall use Commercially Reasonable Efforts to obtain (subject to Roche's responsibilities pursuant to Section 6.1) and maintain Regulatory Approval for the Product in the Regeneron Territory; and to obtain the First EU Approval and First UK Approval, as applicable; provided, however, that Regeneron shall not be obligated to conduct any Clinical Studies other than the Ongoing Regeneron Studies and Additional Regeneron Studies to obtain such Regulatory Approval in the EU and the United Kingdom, as applicable.

[* * *].

In the case of multiple Products, then the Parties' diligence obligations under this Section 6.2 shall be with respect to all such Products, taken as a whole.

6.3 Pharmacovigilance and Global Safety Database

The Parties mutually agree to execute a separate safety data exchange agreement as deemed applicable but no later than the initiation of the first Clinical Study for a Product by Roche or the first Regulatory Approval in the Roche Territory (whichever comes first) (the "**Safety Data Exchange Agreement**"). Such Safety Data Exchange Agreement shall set forth the responsibilities and obligations of the Parties with respect to the procedures and timeframes for compliance with the Applicable Law pertaining to safety reporting of the Product(s) and their related activities.

Regeneron shall be responsible for the establishment, holding and maintenance of the global safety database with respect to any Product at its expense.

7. Commercialization

7.1 Responsibility

Regeneron, [* * *], shall have sole responsibility and decision-making authority for all activities associated with marketing, promotion, sale, medical affairs and distribution of Products in the Regeneron Territory.

Roche Basel, [* * *], shall have sole responsibility and decision-making authority for all activities associated with marketing, promotion, sale, medical affairs and distribution of Products in the Roche Territory.

Notwithstanding the foregoing, in no event shall either Party or any of its Affiliates (a) if such Party or its Affiliates sell a Product in the Field in their Respective Territory to a customer who also purchases other products or services from any such entity, such Party shall not, and shall cause its Affiliates not to, bundle or include any Product as part of any multiple product offering

or discount or price the Products in a manner that is reasonably likely to disadvantage a Product in order to benefit sales or prices of other products offered for sale by such Party or its Affiliates to such customer or (b) accept funding from a Third Party for any other products of services for such Party or any of its Affiliates that is reasonably likely to disadvantage the pricing of a Product.

7.2 Pricing

All decisions for each Product related to any pricing matter, including list price, targeted net pricing, sales-weighted average discounts and rebates, pricing strategy (including the approach to pricing with different types of accounts and plans, including types of discounts and rebates), and modifications to any of the foregoing, will be solely made by (a) Regeneron for the Regeneron Territory and (b) Roche Basel for the Roche Territory; [* * *].

7.3 Commercialization Diligence Obligation

Following receipt of Regulatory Approval in the US, Regeneron shall use Commercially Reasonable Efforts to commercialize the Product in the US.

With respect to each Roche Major Country, following receipt of Regulatory Approval in such Roche Major Country, Roche Basel shall use Commercially Reasonable Efforts to commercialize the Product in such Roche Major Country.

Roche Basel shall use Commercially Reasonable Efforts to commercialize the Product in the ROW. Roche (and its Affiliates) shall [* * *].

[* * *].

In the case of multiple Products, then the Parties' diligence obligations under this Section 7.3 shall be with respect to all such Products, taken as a whole.

7.4 [* * *]

[* * *].

7.5 Distribution of Products

Each Party shall manage its Finished Product inventory in the ordinary course of business consistent with its regular practices without regard to the calculation of the Global Gross Profit sharing. [* * *].

7.6 Distribution Audit

If, for a given period (but in no event shorter than [* * *]), one Party has a reasonable inquiry about the other Party's distribution of any Product (including both sales of the Product and distribution of the Product as [* * *]) in such other Party's Respective Territory [* * *], then, upon request by the first Party, the Parties shall discuss such inquiry in good faith through the JMC. Without limiting a Party's right to conduct financial audit pursuant to Section 13.1, each Party shall have the right to audit the applicable books and records of the other Party (or, where applicable, its Affiliates and Sublicensees) relating to distribution of the Product by such other

Party, its Affiliates and Sublicensees, or its or their Third Party logistics service providers, including, to the extent permitted under the applicable agreements between such other Party (or, where applicable, its Affiliates and Sublicensees) and its or their Third Party logistics service providers, the distribution records furnished by such Third Party logistics service providers, for the sole purposes of confirming such other Party's compliance with Section 7.5 (each such audit, a "**Product Distribution Audit**"). The terms and conditions set forth in Section 13.1 with respect to the confidentiality obligations, and the auditing process, limitations, and expenses shall apply, *mutatis mutandis*, to a Product Distribution Audit.

Notwithstanding the foregoing, Regeneron shall not have the right under this Section 7.6 to conduct a Product Distribution Audit with respect to any period for which Roche elects to determine in accordance with Appendix 1.106 the total number of units of all applicable Presentations of the Product that constituted Net Sales [* * *] for each applicable Calendar Quarter [* * *].

8. Governance

8.1 Joint Steering Committee

8.1.1 Formation

Promptly after the Effective Date, the Parties shall establish a joint steering committee ("**JSC**") to oversee the development, manufacturing and commercialization activities under this Agreement.

8.1.2 Members

The JSC shall be composed of six (6) persons ("**Members**"). Roche and Regeneron each shall be entitled to appoint three (3) Members with appropriate seniority and functional expertise. Each Party may replace any of its Members and appoint a person to fill the vacancy arising from each such replacement upon written notice to the other Party; provided, that a Party that replaces a Member shall notify the other Party at least [* * *] prior to the next scheduled meeting of the JSC. Each Party may invite a reasonable number of additional experts or advisors to attend part or the whole JSC meeting with prior notification to the JSC; provided that any such expert or advisor who is not an employee of the applicable Party must be approved in advance by the other Party and bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 18. The JSC shall be co-chaired by a Member from Regeneron and a Member from Roche.

8.1.3 Responsibilities of the JSC

The JSC shall have the responsibility and authority to:

(a) review and discuss the development, commercialization and manufacturing activities of both Parties;

(b) approve the Co-Funded Development Plan (including any Clinical Study for which the Parties will share [* * *] as a Co-Funded Study) and any material amendment to the Co-Funded Development Plan submitted by the JOC, including provisions regarding the

responsibility for the performance of the respective development activities with respect to any additional Co-Funded Studies, provided that, (i) with respect to an Additional Regeneron Study any portion of the initial Co-Funded Development Plan with respect to such Additional Regeneron Study that is consistent with the protocol existing as of the Effective Date for such Additional Regeneron Study shall be deemed to have been approved by the JSC; and (ii) with respect to any amendment to the Co-Funded Development Plan for an Additional Regeneron Study, only such amendment that involves [* * *] (each, a "**Material Additional Study Change**") shall be subject to the JSC's approval;

(c) discuss the progress and status of each Unilateral Study;

(d) approve the initial Device Development Plan submitted by the JMC and any material amendment thereto;

(e) [* * *];

(f) review all commercialization activities for the Products in the Territory;

(g) facilitate the exchange of information between the Parties with respect to the development, seeking and obtain Regulatory Approval and commercialization of the Compounds and Products in the Territory;

(h) establish and delegate specifically defined duties to the JMC and JOC;

(i) establish additional subcommittees or operational teams as deemed appropriate and delegate specifically defined duties to them;

(j) attempt to resolve any matters escalated to the JSC by the JMC or JOC; and

(k) perform such other tasks as set forth in this Agreement or as otherwise agreed by the Parties in writing.

The JSC shall have no responsibility and authority other than that expressly set forth in this Section 8.1.3.

8.1.4 Meetings

The Alliance Directors will be responsible for sending invitations and agendas for all JSC meetings to all Members at least [* * *] before the next scheduled meeting of the JSC, provided that the Alliance Director from either Party may request a JSC meeting under exigent circumstances by providing [* * *] prior notice. The JSC shall hold meetings no less than twice each Calendar Year during the Agreement Term, either in person or by tele-/video-conference, and in any case as frequently as the Members of the JSC agree is necessary. The Alliance Director of each Party may attend the JSC meetings as a permanent participant.

8.1.5 Minutes

The Alliance Directors shall be responsible for recording, preparing and, within a reasonable time, issuing minutes of the JSC meetings, and shall circulate draft minutes of JSC meetings to all members of the JSC for comment and review within [* * *] after the relevant meeting. The Members of the JSC shall have [* * *] to provide comments. The Alliance Directors shall incorporate timely received comments and distribute finalized minutes to all Members of the JSC within [* * *] of the relevant meeting. Both co-chairpersons of the JSC must approve the final version of the minutes before its distribution.

8.1.6 Decisions

8.1.6.1 Decision Making Authority

The JSC shall decide matters within its responsibilities set forth in Section 8.1.3.

8.1.6.2 Consensus; Good Faith

The Members of the JSC shall act in good faith to cooperate with one another and seek agreement with respect to issues to be decided by the JSC. The Parties shall endeavor to make decisions by consensus with the Members of the JSC from each Party collectively having one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a Member from each Party is present and participating in the vote.

8.1.6.3 Failure to Reach Consensus, Escalation

If the JSC is unable to decide a matter by consensus, then:

(a) Roche shall have final decision authority on any matter relating to (i) the commercialization of Product in the Roche Territory, subject to Regeneron's performance of the First Approval Activities pursuant to Section 6.1.1,; and (ii) selection of Alternative Product Trademarks;

(b) Regeneron shall have final decision authority on any matter relating to (i) the commercialization of Product in the Regeneron Territory; (ii) [* * *]; (iii) any Material Additional Study Change; and (iv) the Global Trademarks;

(c) If the JSC is unable to resolve any other matters not addressed in the foregoing clauses (a) - (b), including any matter escalated to the JSC by the JMC or the JOC, then such matter shall be referred to the CEO of Regeneron and the CEO of Roche Pharmaceuticals for resolution, who shall use reasonable and good faith efforts to reach a decision by consensus within [* * *] after the date such matter is referred to them. If the CEOs of both Parties are unable to reach a decision within such [* * *] period, then unless otherwise agreed by the Parties, [* * *].

8.2 Joint Manufacturing Committee

8.2.1 Formation

Promptly after the Effective Date, the Parties shall establish a joint manufacturing committee ("***JMC***"), which will be a subcommittee of the JSC, to oversee the manufacturing activities under this Agreement.

8.2.2 Members

The JMC shall be composed of four (4) Members. Roche and Regeneron each shall be entitled to appoint two (2) Members with appropriate seniority and functional expertise. Each Party may replace any of its Members and appoint a person to fill the vacancy arising from each such replacement upon written notice to the other Party; provided, that a Party that replaces a Member shall notify the other Party at least [* * *] prior to the next scheduled meeting of the JMC. Each Party may invite a reasonable number of additional experts or advisors to attend part or the whole JMC meeting with prior notification to the JMC; provided that any such expert or advisor who is not an employee of the applicable Party must be approved in advance by the other Party and bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 18. The JMC shall be co-chaired by a Member from Regeneron and a Member from Roche.

8.2.3 Responsibilities of the JMC

The JMC shall have the responsibility and authority to:

(a) Discuss, review and approve a rolling, 12-month production forecast for Drug Substance of each Product for each Party (the "**Production Forecast**") and an Alternative Supply Allocation plan (as the case may be pursuant to Section 8.2.3(b)) to be used under the Supply Agreement. [* * *];

(b) decide on changing the allocation of the total Drug Substance of Product produced between the Regeneron Territory and the Roche Territory as foreseen in Section 5.1, including in accordance with demand for the Product in each Respective Territory ("**Alternative Supply Allocation**");

(c) determine each Party's Standard Cost for Drug Substance, Drug Product or Finished Product, including for each applicable Presentation or Permutation, in accordance with Section 4.2;

(d) oversee all aspects of the manufacture of Products under the Supply Agreement, including product specifications and quality;

(e) discuss and approve any transfer of Drug Substance, Drug Product or Finished Product between Parties not included in the Supply Agreement;

(f) discuss and approve any request for one Party to convert the other Party's Drug Substance or Drug Product to Drug Product or Finished Product respectively;

(g) decide on appropriate reductions to the Minimum Committed Roche Capacity or Minimum Committed Regeneron Capacity, including, in light of a decrease in demand such that there is no longer a demand for the equivalent of at least 140,000 liters of bioreactor capacity on an annualized basis for the manufacture of Drug Substance in the Territory;

(h) discuss any disproportional distribution by either Party of Product containing Drug Substance manufactured and supplied by the other Party;

(i) discuss and review use by Roche of an additional Roche Manufacturing Facility, as provided in Section 4.1.1;

(j) report on a regular basis to the JSC; and

(k) escalate to the JSC as required.

The JMC shall have no responsibility and authority other than that expressly set forth in this Section 8.2.3, except if the JSC decides to delegate specifically defined duties to the JMC pursuant to Section 8.1.3(h).

8.2.4 Meetings

The co-chairpersons of the JMC will be responsible for sending invitations and agendas for all JMC meetings to all Members at least [* * *] before the next scheduled meeting of the JMC. The JMC shall hold meetings either in person or by tele-/video-conference, and in any case as frequently as the Members of the JMC agree is necessary. The Alliance Director of each Party may attend the JMC meetings as a permanent participant.

8.2.5 Minutes

The co-chairpersons of the JMC will be responsible for designating a Member to record in reasonable detail and circulate draft minutes of JMC meetings to all members of the JMC for comment and review within [* * *] after the relevant meeting. The Members of the JMC shall have [* * *] to provide comments. The Party preparing the minutes shall incorporate timely received comments and distribute finalized minutes to all Members of the JMC within [* * *] of the relevant meeting. Both co-chairpersons of the JMC must approve the final version of the minutes before its distribution.

8.2.6 Decisions

8.2.6.1 Decision Making Authority

The JMC shall decide matters within its responsibilities set forth in Section 8.2.3.

8.2.6.2 Consensus; Good Faith

The Members of the JMC shall act in good faith to cooperate with one another and seek agreement with respect to issues to be decided by the JMC. The Parties shall endeavor to make decisions by consensus with the Members of the JMC from each Party collectively having one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a Member from each Party is present and participating in the vote.

8.2.6.3 Failure to Reach Consensus

If the JMC is unable to decide a matter by consensus, then such matter shall be referred to the JSC for resolution.

8.3 Joint Operations Committee

8.3.1 Formation

Promptly after the Effective Date, the Parties shall establish a joint operations committee ("**JOC**"), which will be a subcommittee of the JSC, to oversee the development and commercialization activities under this Agreement.

8.3.2 Members

The JOC shall be composed of six (6) Members. Roche and Regeneron each shall be entitled to appoint three (3) Members with appropriate seniority and functional expertise. Each Party may replace any of its Members and appoint a person to fill the vacancy arising from each such replacement upon written notice to the other Party; provided, that a Party that replaces a Member shall notify the other Party at least [* * *] prior to the next scheduled meeting of the JOC. Each Party may invite a reasonable number of additional experts or advisors to attend part or the whole JOC meeting with prior notification to the JOC; provided that any such expert or advisor who is not an employee of the applicable Party must be approved in advance by the other Party and bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 18. The JOC shall be co-chaired by a Member from Regeneron and a Member from Roche.

8.3.3 Responsibilities of the JOC

The JOC shall have the responsibility and authority to:

(a) submit to the JSC the Co-Funded Development Plan and any material amendment to the Co-Funded Development Plan, including any proposal to add any Clinical Study for which the Parties will share [* * *] as a Co-Funded Study, and any proposal regarding the responsibility for the performance of the respective development activities with respect to any additional Co-Funded Studies; provided that, (i) with respect to any amendment to the Co-Funded Development Plan for an Additional Regeneron Study, only a Material Additional Study Change requires the JSC's approval, and (ii) Regeneron may submit any Material Additional Study Change directly to the JSC without first submitting to the JOC;

(b) determine the ISS Strategy;

(c) submit to the JSC the initial Device Development Plan and any material amendment thereto;

(d) review and monitor the development activities for the Products, including regulatory activities undertaken pursuant to this Agreement;

(e) submit to the JSC for approval proposals to pursue Third Party funding for either Party for Co-Funded Studies [* * *];

(f) discuss and review all commercialization activities for the Products in the Territory;

(g) discuss and approve [* * *] in the Roche Territory and the Regeneron Territory;

(h) align on global guidelines and strategy for pricing for the Products;

(i) align on global contracting and communications strategy; including strategies for interactions with governments, media, international institutions and stakeholders;

(j) [* * *];

(k) select the Global Trademarks and, if applicable, Alternative Product Trademarks, and establish any applicable rules regarding the use of Global Trademarks or Alternative Product Trademarks;

(l) [* * *];

(m) discuss and determine whether the regulatory filing for the First EU Approval or the First UK Approval will be made in Regeneron's name or in Roche's name with Regeneron acting as agent (provided that notwithstanding anything to the contrary in this Agreement, Regeneron will have the final decision making authority with respect to either filing being made in Regeneron's name);

(n) discuss each Party's plan for publication;

(o) discuss and approve the Other Chugai Asset Activities;

(p) report on a regular basis to the JSC;

(q) oversee the operation and activities of the FWG and approve any matter submitted by the FWG;

(r) discuss updates provided by Regeneron pursuant to Section 2.8 and discuss any progress made on Additional Compounds, if any;

(s) escalate to the JSC as required.

The JOC shall have no responsibility and authority other than that expressly set forth in this Section 8.3.3, except if the JSC decides to delegate specifically defined duties to the JOC pursuant to Section 8.1.3(h).

8.3.4 Meetings

The co-chairpersons of the JOC will be responsible for sending invitations and agendas for all JOC meetings to all Members at least [* * *] before the next scheduled meeting of the JOC. The JOC shall hold meetings either in person or by tele-/video-conference and in any case as frequently as the Members of the JOC agree is necessary. The Alliance Director of each Party may attend the JOC meetings as a permanent participant.

8.3.5 Minutes

The co-chairpersons of the JOC will be responsible for designating a Member to record in reasonable detail and circulate draft minutes of JOC meetings to all members of the JOC for comment and review within [* * *] after the relevant meeting. The Members of the JOC shall have [* * *] to provide comments. The Party preparing the minutes shall incorporate timely received comments and distribute finalized minutes to all Members of the JOC within [* * *] of the relevant meeting. Both co-chairpersons of the JOC must approve the final version of the minutes before its distribution.

8.3.6 Decisions

8.3.6.1 Decision Making Authority

The JOC shall decide matters within its responsibilities set forth in Section 8.3.3.

8.3.6.2 Consensus; Good Faith

The Members of the JOC shall act in good faith to cooperate with one another and seek agreement with respect to issues to be decided by the JOC. The Parties shall endeavor to make decisions by consensus with the Members of the JOC from each Party collectively having one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a Member from each Party is present and participating in the vote.

8.3.6.3 Failure to Reach Consensus

If the JOC is unable to decide a matter by consensus, such matter shall be referred to the JSC.

8.4 Financial Working Group

8.4.1 Formation.

Promptly after the Effective Date, the Parties will establish a financial working group (the "**FWG**") to oversee the accounting, financial (including planning, reporting and controls) and funds flow matters related to this Agreement.

8.4.2 Operation of the FWG.

Promptly following the Effective Date, each Party shall designate its respective initial representatives to the FWG to allow such FWG to begin operating under the direction of the JOC. The FWG shall have no decision-making authority and shall report to the JOC.

9. Exclusivity

9.1 Non-Compete Obligation

Roche and its Affiliates shall not, directly or indirectly, whether alone or with or through any Third Party, (a) prior to the first approval of the first MAA for a Product in the EU, clinically develop or (b) at any time during the Agreement Term, manufacture (other than for purposes of research and development activities of Roche and its Affiliates permitted hereunder), have manufactured (other than for purposes of research and development activities of Roche and its Affiliates permitted hereunder), sell, distribute or otherwise commercialize, in each case ((a) and (b)), any

product containing Antibody(ies) [* * *] other than the Products (each, a "**Competing Product**"), or directly or indirectly assist any Third Party to do so. [* * *].

For clarity, prior to the first approval of the first MAA for a Product in the EU, Roche and its Affiliates may conduct pre-clinical or non-clinical research and development activities (including technology transfer activities and preclinical evaluation of Third Party assets) on any Competing Product.

9.2 Regeneron Right of First Negotiation to Chugai Asset

As of the Effective Date, Chugai has [* * *] (the "**Chugai Asset**"). Roche may enter into an agreement with Chugai for an option for an exclusive right and license under any Patent Rights and know-how owned or controlled by Chugai to develop, register, use, sell, market and import the Chugai Asset in [* * *] (such countries of the world, the "**Chugai Asset Territory**"; and such option, the "**Roche Chugai Option**"). Prior to Roche's exercise of the Roche Chugai Option, Roche shall have the right to [* * *] (the "**Permitted Chugai Activities**"). Regeneron acknowledges and agrees that is it not a breach of Section 9.1 by Roche for Chugai to [* * *] conduct the Permitted Chugai Activities. Roche shall have the right to [* * *] Roche shall not [* * *] without the agreement of the Parties through the JOC ("**Other Chugai Asset Activities**") (disputes with respect to which, for clarity, shall be subject to Section 8.1.6.3(c)).

Roche hereby grants Regeneron an exclusive option to obtain the right and sublicense under any Patent Rights and know-how owned or controlled by Chugai that Roche obtains through the exercise of the Roche Chugai Option to [* * *] and a financial interest in the commercialization of the Chugai Asset in the entire Territory, in each case, in accordance with this Section 9.2 (the "**Chugai Asset Option**").

Roche shall provide Regeneron periodic updates regarding the development and characteristics of the Chugai Asset at each JOC meeting.

Without Regeneron's consent in its discretion, Roche will not enter into any agreement with a Third Party (including, for clarity, Chugai) that would conflict with the rights that Regeneron would have with respect to the Chugai Asset if Regeneron exercises the Chugai Asset Option.

9.2.1 Chugai Asset Data Package

If Roche desires to exercise the Roche Chugai Option, then after [* * *] Roche shall provide, or cause Chugai to provide, Regeneron a complete data package with respect to the Chugai Asset, including all data, reports, documentation and other information relating to the Chugai Asset, necessary or reasonably useful for the Parties to determine whether the Chugai Asset has satisfied the Chugai Asset Criteria, including the results of such Clinical Study and any other clinical or non-clinical data, all information regarding the manufacturing process (including yields), route or frequency of administration, and the proprietary position of the Chugai Asset (the "**Chugai Asset Data Package**").

Within [* * *] after Regeneron receives the Chugai Asset Data Package, the Parties shall discuss in good faith and endeavor to mutually agree (a) whether or not the Chugai Asset Data Package satisfies the Chugai Asset Data Package Criteria and (b) if the Chugai Asset Data Package satisfies the Chugai Asset Data Package Criteria, then whether or not the Chugai Asset satisfies the Chugai Asset Criteria. If the Parties cannot agree within [* * *] following Regeneron's receipt

of the Chugai Asset Data Package (x) whether or not the Chugai Asset Data Package satisfies the Chugai Asset Data Package Criteria, or (y) whether or not the Chugai Asset satisfies the Chugai Asset Criteria, then, in either case ((x) or (y)), such dispute shall be determined in accordance with Section 21.2, and if still not resolved, then decided by an Expert Committee pursuant to Section 21.4.

If both Parties agree, or the Executive Officers or Expert Committee, as applicable, determines that the Chugai Asset Data Package does not satisfy the Chugai Asset Data Package Criteria or that the Chugai Asset has not satisfied the Chugai Asset Criteria, then, in either case, Roche shall not exercise the Roche Chugai Option and the Chugai Asset shall remain a Competing Product for purposes of this Agreement, and the obligations set forth in Section 9.1 shall continue to apply to Roche with respect to the Chugai Asset.

Thereafter, if Roche receives any additional data or information with respect to the Chugai Asset and desires to exercise the Roche Chugai Option, Roche shall deliver to Regeneron an updated Chugai Asset Data Package, and the process set forth in this Section 9.2.1 shall apply to determine whether the updated Chugai Asset Data Package satisfies the Chugai Asset Data Package Criteria, and whether the Chugai Asset satisfies the Chugai Asset Criteria.

9.2.2 Chugai Asset Agreement

If both Parties agree, or the Executive Officers or Expert Committee determines that the Chugai Asset satisfies the Chugai Asset Criteria (such agreement or determination, "**Chugai Asset Positive Determination**"), then Regeneron shall have the right, within [* * *] following the date on which the Chugai Asset Positive Determination is made (the "**Exercise Period**"), to exercise the Chugai Asset Option by providing written notice to Roche ("**Exercise Notice**").

Roche shall not exercise the Roche Chugai Option until the Chugai Asset Positive Determination has been made, and either (a) Regeneron exercises the Chugai Asset Option by providing the Exercise Notice, or (b) Regeneron notifies Roche in writing that Regeneron will not exercise the Chugai Asset Option or fails to provide the Exercise Notice during the Exercise Period.

If Regeneron exercises the Chugai Asset Option by providing the Exercise Notice within the Exercise Period, then Regeneron and Roche shall, and Roche shall cause Chugai to, promptly negotiate and execute a separate license agreement (the "**Chugai Asset Agreement**") or an amendment to this Agreement (the "**Chugai Asset Amendment**") that is consistent with the terms and conditions set forth on Appendix 9.2 and on other terms mutually acceptable to Regeneron, Roche and Chugai, which the Parties anticipate will be substantially similar to the terms of this Agreement except as set forth on Appendix 9.2.

If (A) Regeneron notifies Roche in writing that Regeneron will not exercise the Chugai Asset Option or (B) Regeneron fails to provide the Exercise Notice during the Exercise Period, then the Chugai Asset Option shall expire. If thereafter Roche exercises the Roche Chugai Option or otherwise obtains any right to develop or commercialize the Chugai Asset, then (X) Roche shall promptly notify Regeneron of such exercise or receipt of such other right, and (Y) Regeneron shall have the right to terminate this Agreement upon [* * *] prior written notice to Roche, which right must be exercised within [* * *] after notice from Roche of the first commercial sale of the

Chugai Asset, and such termination by Regeneron shall be deemed to be a termination by Roche pursuant to Section 19.2.5 for purposes of post-termination effect and obligations.

Additionally, if the Chugai Asset receives Regulatory Approval in Japan, and the Parties have not entered into the Chugai Asset Agreement or Chugai Asset Amendment, as applicable, then upon Regeneron's request, Roche shall immediately terminate Chugai's sublicense with respect to the Products in Japan.

During the Agreement Term, neither Party shall have the right to develop or commercialize the Chugai Asset until the Chugai Asset Agreement or Chugai Asset Amendment is executed by the Parties and Chugai, except that (i) Roche shall have the right to conduct the Permitted Chugai Activities and Other Chugai Asset Activities approved by the JOC; (ii) if (A) Regeneron notifies Roche in writing that Regeneron will not exercise the Chugai Asset Option or (B) Regeneron fails to provide the Exercise Notice during the Exercise Period, then Roche shall thereafter have the right to develop and commercialize the Chugai Asset, and (iii) if Regeneron exercises the Chugai Asset Option by providing the Exercise Notice within the Exercise Period, then, for clarity, the last sentence of the first paragraph of Section 9.2 shall remain in effect while the Parties and Chugai are negotiating the Chugai Asset Agreement or Chugai Asset Amendment, [* * *].

10. Payment

10.1 Reimbursement [* * *] for Development Activities

With respect to each Co-Funded Study, the Party not performing such Co-Funded Study shall reimburse the Party performing such Co-Funded Study for [* * *] incurred by or on behalf of such performing Party or any of its Affiliates in connection with performing such Co-Funded Study (including, for clarity, such [* * *] incurred by or on behalf of Regeneron or any of its Affiliates with respect to the Additional Regeneron Studies prior to the Effective Date) to the extent such [* * *] are not funded by a Third Party. For clarity, each Party shall bear its internal costs with respect to performing any Co-Funded Study.

With respect to Co-Funded Device Development Activities, the Party not performing such Co-Funded Device Development Activities shall reimburse the Party performing such Co-Funded Device Development Activities for [* * *] incurred by or on behalf of such performing Party or any of its Affiliates in connection with performing such Device Development Activities to the extent such [* * *] are not funded by a Third Party. [* * *]

With respect to each Unilateral Study, if the Party not performing such Unilateral Study uses any data or results from such Unilateral Study to obtain, maintain or expand any Regulatory Approval or any pricing or reimbursement for, otherwise includes such data or results in the label for, or uses such data and results to commercialize, a Product in its Respective Territory, then such non-performing Party shall reimburse the Party that performed such Unilateral Study for [* * *] incurred by or on behalf of such performing Party or any of its Affiliates in connection with such Unilateral Study to the extent such [* * *] are not funded by a Third Party. For clarity, the submission of data and results from a Unilateral Study to a Regulatory Authority only for safety reporting purposes in connection with periodic safety reporting or as a courtesy copy shall not result in a reimbursement obligation under this paragraph. The Party not performing the applicable Unilateral Study shall promptly notify the performing Party of any use of the data or

results of such Unilateral Study that would result in a reimbursement obligation under this paragraph.

With respect to Unilateral Device Development Activities, if the Party not performing such Unilateral Device Development Activities wishes to use the delivery device or other results of such Unilateral Device Development Activities for a Product in its Respective Territory, then such non-performing Party shall reimburse the Party that performed such Unilateral Device Development Activities for [* * *] incurred by or on behalf of such performing Party or any of its Affiliates in connection with such Unilateral Device Development Activities to the extent such [* * *] are not funded by a Third Party, and the performing Party shall provide the results of the Unilateral Device Development Activities to the non-performing Party and such other information and assistance as is required for the non-performing Party to manufacture and use the delivery device resulting from such Unilateral Device Development Activities.

10.2 Global Gross Profit Sharing

Beginning with the Calendar Quarter in which the Collaboration Timepoint occurs, with respect to each Presentation of Product, Roche Basel shall be entitled to the product of (i) [* * *] of the Global Gross Profit for such Presentation in such Calendar Quarter, multiplied by the Roche Production Contribution for such Presentation in such Calendar Quarter ("**Roche Global Gross Profit**") and (ii) Regeneron will be entitled to the remainder of the Global Gross Profit; provided, that for the Calendar Quarter in which the Collaboration Timepoint occurs, for purposes of this Section 10.2 the amount of the Global Gross Profit for such Calendar Quarter shall be prorated based on the ratio of the number of days in such Calendar Quarter from and after the Collaboration Timepoint and the total number of days in such Calendar Quarter.

Example:

[* * *]

Notwithstanding the foregoing:

(a) if prior to the [* * *], Roche Basel has received all Regulatory Approvals necessary to manufacture Finished Product for commercial use in the EU but not the Regeneron Territory, Roche Basel may sell Product in the Roche Territory and, in the case of such sales, may retain [* * *] of the Global Gross Profit for the Roche Territory prior to the [* * *] (and shall provide [* * *] of such Global Gross Profits to Regeneron), [* * *]. For clarity, Roche Basel shall not be entitled to share any of the Global Gross Profit in the Regeneron Territory until Roche Basel has received all Regulatory Approvals necessary to manufacture Finished Product for commercial use in the Regeneron Territory; or

(b) if prior to the [* * *], Roche Basel has received all Regulatory Approvals necessary to manufacture Finished Product for commercial use in the Regeneron Territory, but not the EU, [* * *], then (i) Roche shall transfer such Product to Regeneron for sale in the Regeneron Territory by Regeneron in accordance with the allocation provided in Section 5.1 following the [* * *], and Roche may, upon mutual agreement of the Parties, transfer additional Product to Regeneron for sale in the Regeneron Territory by Regeneron; and (ii) the Parties shall share the Global Gross Profits for the Regeneron Territory as provided in the first paragraph of this Section 10.2; or

(c) if prior to the [* * *], Roche Basel has received all Regulatory Approvals necessary to manufacture Finished Product for commercial use (X) in the EU and the Regeneron Territory, or (Y) in the Regeneron Territory but not the EU, and in either case ((X) or (Y)), [* * *], then Roche shall transfer such Product to Regeneron for sale in the Regeneron Territory by Regeneron in accordance with the allocation provided in Section 5.1 following the [* * *], and in the case of clause (Y), Roche may, upon mutual agreement of the Parties, transfer additional Product to Regeneron for sale in the Regeneron Territory by Regeneron; provided that, in either case ((X) or (Y)), [* * *], (A) Regeneron may retain [* * *] of the Global Gross Profit for the sales of Products supplied by Roche in the Regeneron Territory [* * *] and (B) [* * *].

[* * *]

[* * *]

[* * *]

10.3 Disclosure of Payments

Each Party acknowledges that the other Party may be obligated to disclose this financial arrangement, including all fees, payments and transfers of value, as required under Applicable Law; provided, however, that any such disclosure shall be subject to the provisions of Section 18.2.

11. Accounting and Reporting

11.1 Mechanics and Timing of Payments

For Global Gross Profit payments, on a Presentation-by-Presentation basis, commencing with the first Calendar Quarter after the Collaboration Timepoint or any Interim Collaboration Timepoint in which a Party incurs Net Sales (a) within [* * *] after the end of each Calendar Quarter, such Party shall share with the other Party a good faith estimate of (i) such Party's Net Sales of such Presentation, (ii) the units of such Presentation sold by or on behalf of such Party, its Affiliates and Sublicensees in such Calendar Quarter, (iii) the units of such Presentation sold by or on behalf of such Party, its Affiliates and Sublicensees in such Calendar Quarter for which the Drug Substance was manufactured by the Roche Group (which may be determined in accordance with Appendix 1.106, if applicable), (iv) [* * *], and (v) the units of such Presentation distributed as [* * *], in each case, by or on behalf of such Party, its Affiliates and Sublicensees in such Calendar Quarter; and (b) as soon as practicable after the end of each such Calendar Quarter, but in any event no later than [* * *] after the end of each such Calendar Quarter, such Party shall share with the other Party the actual Net Sales in accordance with the foregoing subclause (i) and units dispersed in accordance with the foregoing subclauses (ii) - (v) of such Presentation, together with a calculation of such Party's Gross Profit for such Presentation for such Calendar Quarter (each report described in this clause (b), a "**Gross Profit Interim Report**"). Each Party shall have [* * *] after the delivery of the other Party's Gross Profit Interim Report to review and ask questions. Within [* * *] following the end of such Calendar Quarter, each Party shall update its Gross Profit Interim Report to reflect the final amounts and the Parties shall coordinate to aggregate the final reports to calculate the total Global Gross Profit and Roche Global Gross Profit (**"Global Gross Profit Final Report"**). The Party that owes

payment to the other Party pursuant to the Global Gross Profit Final Report shall pay such amount within [* * *] after receipt of an invoice from the Party that is due payment.

For Co-Funded Study reimbursement and Co-Funded Device Development Activities reimbursement, respectively, the Parties shall share a good faith estimate of the applicable costs incurred, within [* * *] after the end of each Calendar Quarter in which such costs are incurred. As soon as practicable after the end of each such Calendar Quarter, but in any event no later than [* * *] after the end of each such Calendar Quarter, each Party shall share with the other Party [* * *] incurred by such Party (each, a **"Reconciliation Interim Report"**), together with reasonable supporting documentation for such [* * *]. Each Party shall have [* * *] after the delivery of the other Party's Reconciliation Interim Report to review and ask questions. Within [* * *] following the end of such Calendar Quarter, each Party shall update its Reconciliation Interim Report to reflect the final amounts and the Parties shall coordinate to aggregate the reports to calculate the total amount to be reimbursed under this Agreement (**"Reconciliation Final Report"**). The Party that owes payment to the other Party pursuant to the Reconciliation Final Report shall pay such amount within [* * *] after receipt of an invoice from the Party that is due payment.

With respect to each Unilateral Study for which reimbursement becomes due, within [* * *] after the Party that performed such Unilateral Study becomes aware that such reimbursement is due, such performing Party shall share with the other Party the [* * *] incurred by such conducting Party for such Unilateral Study (a "**Unilateral Study Costs Report**"), together with reasonable supporting documentation for such [* * *]. The non-performing Party shall have [* * *] after the delivery of the Unilateral Study Costs Report to review and ask questions. If the non-performing Party raises any questions to be addressed, the performing Party shall update its Unilateral Study Costs Report to reflect the final amounts within [* * *] after the delivery of the initial Unilateral Study Costs Report. The non-performing Party shall pay the performing Party the applicable amount within [* * *] after receipt of an invoice from the performing Party.

Any payments of Standard Costs for Product supplied by one Party to the other Party or for manufacturing services performed by one Party to the other Party under this Agreement shall be paid in accordance with Section 11.5.

Any payment required to be made to Regeneron by Roche pursuant to this Section 11.1 or Section 11.5 shall be made by Roche Basel.

11.2 Late Payment

Any payment under this Agreement that is not paid on or before the date such payment is due shall bear interest, to the extent permitted by Applicable Law, at a rate equal to [* * *] points above the average one-month Euro Interbank Offered Rate (EURIBOR), as reported by Reuters from time to time, calculated on the number of days such payment is overdue, unless such payment amount is reasonably disputed in good faith, in which case the amount payable after such dispute is resolved shall start to earn interest hereunder on the date such dispute is resolved.

11.3 Method of Payment

All amounts payable by one Party hereunder shall be paid by the other Party in Dollars (the "**Payment Currency**") by bank wire transfer in immediately available funds to account(s) designated by the other Party.

11.4 Currency Conversion

In those cases where the amount due in Dollars is calculated based upon one or more currencies other than Dollars, the Party converting such amounts to Dollars shall use their respective then-current internal foreign currency translation method actually used on a consistent basis in preparing its audited financial statements. As of the Effective Date, the internal foreign currency translation method (a) for Roche, is to convert currencies other than Dollars or Swiss Francs to Swiss Francs and then to Dollars at the year-to-date average rate as reported by Reuters (or any successor thereto), and (b) for Regeneron, is to convert currencies other than Dollars to Dollars using the average of the daily spot rates (the Mid Price Close) found on Bloomberg (or any successor thereto). Each Party shall promptly notify the other Party if there is any change to its then-current internal foreign currency translation method.

11.5 Reimbursement

For all amounts for which a Party (the "**Owing Party**") is obligated to reimburse or pay the other Party (the "**Owed Party**") pursuant to this Agreement or the Technology Transfer Agreement, for which no specific provision is provided hereunder or thereunder regarding how such payment shall be made, or any payments under Section 4.2(c), the Owed Party shall send to the Owing Party an invoice for such amount within [* * *] after the Owed Party's determination that such amount is payable by the Owing Party, which invoice shall include a reference to the section of this Agreement under which the Owed Party is requesting reimbursement or payment and be accompanied by reasonable documentation of the incurrence or accrual of the costs to be reimbursed. Payment with respect to each such invoice shall be due within [* * *] after receipt by the Owing Party thereof and shall be made in accordance with Section 11.3 and Section 11.4.

11.6 Payment Disputes

With respect to any payment obligations under this Agreement, if the Owing Party in good faith disputes any portion of any such payment, it shall pay the undisputed portion and shall provide the Owed Party with written notice of the disputed portion and its reasons therefor, and the Owing Party shall not be obligated to pay such disputed portion unless and until such dispute is resolved in favor of the Owed Party. The Parties shall use good faith efforts to resolve any such disputes promptly.

12. Taxes

12.1 Certain Taxes

Regeneron shall pay all sales, turnover, income, revenue, value added, and other taxes levied on account of any payments accruing or made to Regeneron under this Agreement.

Roche shall pay all sales, turnover, income, revenue, value added, and other taxes levied on account of any payments accruing or made to Roche under this Agreement.

12.2 Withholding Taxes

If provision is made in law or regulation of any country for withholding or deduction of taxes of any type, levies or other charges with respect to any amounts payable under this Agreement to Regeneron or Roche, then Roche or Regeneron (as applicable) shall be entitled to withhold or deduct the amount of such taxes, levies, or other charges from such amount payable and shall promptly pay such tax, levy or charge for and on behalf of Regeneron or Roche (as applicable) to the proper governmental authority, and shall promptly furnish Regeneron or Roche (as applicable) with receipt of payment. Roche or Regeneron (as applicable) shall be entitled to deduct any such tax, levy or charge actually paid from payment due Regeneron or Roche (as applicable) or be promptly reimbursed by Regeneron or Roche (as applicable) if no further payments are due to Regeneron or Roche (as applicable). Each Party agrees to reasonably assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted. Any amounts deducted and withheld from any payment to a Party pursuant to this Section 12.2 shall be treated as having been paid to such Party.

12.3 FDII Documentation

To the extent applicable and reasonably requested by Regeneron, Roche shall use commercially reasonable efforts to provide Regeneron with any documentation or other certifications required pursuant to Section 250(b) of the Code, and any regulations or other guidance promulgated thereunder necessary for any payments made to Regeneron pursuant to this Agreement to qualify as “foreign-derived deduction eligible income” within the meaning of Section 250(b)(4) of the Code. Regeneron shall reimburse Roche for all reasonable out-of-pocket costs incurred by Roche in connection with providing such documentation or other certification to Regeneron. The Parties intend that Regeneron shall be entitled to any deduction under Section 250(b) of the Code for which Regeneron is eligible with respect to the remainder of the Global Gross Profit under Section 10.2, and this Agreement shall be interpreted accordingly.

13. Auditing

13.1 Right to Audit

Each Party shall keep, and shall require its Affiliates and its and their Sublicensees, if any, to keep, full, true and accurate books of account containing all particulars that may be necessary for the purpose of calculating all payments payable under this Agreement (e.g. the Parties’ calculation of Standard Costs). Such books of accounts shall be kept at such Party’s, Affiliate’s or Sublicensee’s, as applicable, principal place of business. At the expense of the auditing Party, the auditing Party shall have the right, in accordance with the remainder of this Section 13.1, Section 13.2 and Section 13.3, to engage an internationally recognized independent public accountant reasonably acceptable to the audited Party to perform, on behalf of the auditing Party, an audit of such books and records of the audited Party and its Affiliates and its and their Sublicensees that are deemed necessary by the independent public accountant to report on the correctness of any financial report or payments made under this Agreement for the period or

periods requested by the auditing Party. The Parties shall cause such accountant to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such accountant to retain all such financial information in confidence pursuant to terms no less stringent than those set forth in Article 18.

Upon timely request and at least [* * *] prior written notice from the auditing Party, such audit shall be conducted for those countries the auditing Party has specifically requested, during regular business hours in such a manner as to not unnecessarily interfere with the audited Party's normal business activities. Such audit shall be limited to books and records with respect to the [* * *] Calendar Years prior to audit notification, and if the auditing Party requests an audit for a country for a given Calendar Year, no additional audits may be conducted for such country for such Calendar Year unless a material discrepancy is found in such audit. If auditing Party does not request an audit for a given Calendar Year on or before the [* * *] anniversary of the end of such Calendar Year, then the auditing Party shall no longer have the right to conduct an audit for such Calendar Year under this Section 13.1.

Such audit for a country shall not be performed more frequently than once per Calendar Year nor more frequently than once with respect to records covering any specific country for any specific period of time unless a material discrepancy is found in such audit.

All books of accounts herein referred and any information contained therein shall be (a) used by the auditing Party only for the purpose of verifying payments and reports hereunder and (b) treated as the audited Party's Confidential Information subject to the obligations of this Agreement.

13.2 Audit Reports

The auditors shall only state factual findings in the audit reports and shall not interpret this Agreement. The auditors shall share all draft audit findings with the audited Party before sharing such findings with the auditing Party and before the final audit report is issued and shall remove any information reasonably identified by the audited Party as being confidential or competitively sensitive or proprietary information. The final audit report shall be shared with the audited Party at the same time it is shared with the auditing Party. The auditors shall not reveal to the auditing Party the details of its review, except for the findings of such review and such information as is required to be disclosed under this Agreement. The results of any such audit shall be final and binding upon the Parties, unless disputed by a Party within [* * *] of delivery. Notwithstanding any other provision of this Agreement to the contrary, the obligation to pay any amount based on a disputed audit shall not be deemed to have been triggered until such dispute is resolved hereunder; provided that all amounts that are not in dispute shall be paid in accordance with the provisions of this Agreement.

13.3 Over-or Underpayment

If the audit reveals an overpayment, the overpaid Party shall reimburse the other Party for the amount of the overpayment within [* * *] (and, if such overpayment was made due to an error in an invoice or report provided by such overpaid Party, with interest thereon as provided in Section 11.2). If the audit reveals an underpayment, the underpaying Party shall reimburse the other Party for the amount of the underpayment within [* * *] (and, if such additional amounts are owed due to an error in an invoice or report provided by such underpaying Party, with interest

thereon as provided in Section 11.2). The audited Party shall reimburse the auditing Party for the audit costs if the cumulative discrepancy of amounts reported or paid during the applicable audited period exceeds [* * *].

14. Intellectual Property

14.1 Ownership of Intellectual Property

Nothing in this Agreement shall affect the ownership of any Patent Rights, know-how or other intellectual property, in each case, developed prior to the Effective Date or independent of this Agreement, including, for clarity, Roche Independent IP. Regeneron shall own all Regeneron Inventions and all Patent Rights and other intellectual property rights that Cover the Regeneron Inventions. Roche shall own all Roche Inventions and all Patent Rights and other intellectual property rights that Cover the Roche Inventions. Regeneron and Roche shall jointly own all Joint Inventions and Joint Patent Rights. Regeneron and Roche each shall require, and shall cause its respective Affiliates to require (a) all of its (or its Affiliates') employees and consultants to assign all inventions related to Compounds or Products made by them to Roche or Regeneron (or such Affiliate), as the case may be and (b) all other persons or entities who perform any activities for or on behalf of such Party to assign (or, if such Party is unable to cause such person or entity to agree to such assignment obligation despite such Party's using Commercially Reasonable Efforts to negotiate such assignment obligation, provide an exclusive license under) their rights in any such Inventions or Patent Rights to such Party.

Each Party shall promptly disclose to the other Party in writing, the discovery, development or creation of any Invention made solely or jointly by or on behalf of such Party, any of its Affiliates, or, if applicable, Sublicensees in connection with the performance of obligations under this Agreement. Each Party shall promptly disclose to the other and shall cause its Affiliates and Sublicensees to disclose any Know-How made solely or jointly by or on behalf of such Party or any of its Affiliates or Sublicensees in connection with the performance of obligations under this Agreement that constitutes an improvement to the process of manufacturing the Compounds or Products.

The determination of inventorship for Inventions shall be in accordance with US inventorship laws as if such Inventions were made in the US.

Subject to the licenses granted under this Agreement and Roche's obligation under Article 9, Regeneron and Roche will each have an equal undivided share in the Joint Patent Rights, without obligation to account to the other for exploitation thereof, or to seek consent of the other Party for the grant of any license thereunder.

Except as specifically set forth herein, this Agreement shall not be construed as (i) giving either of the Parties any license, right, title, interest in or ownership to the Confidential Information of the other Party; (ii) granting any license or right under any intellectual property rights; or (iii) representing any commitment by either Party to enter into any additional agreement, by implication or otherwise.

With respect to Know-How (other than Inventions) generated pursuant to this Agreement, (a) Regeneron shall own such Know-How (i) generated by or on behalf of Regeneron or any of its Affiliates or Sublicensees solely or jointly with a Third Party or (ii) generated by or on behalf of

the Roche Group solely or jointly with Regeneron or any of its Affiliates or a Third Party that is specifically related to any Product (including the composition of, formulations containing, any methods of using, or the manufacture of, a Product) ((i) and (ii) together, "**Arising Regeneron Know-How**"), (b) Roche shall own such Know-How generated by or on behalf of the Roche Group solely or jointly with a Third Party, excluding any Arising Regeneron Know-How, and (c) the Parties shall jointly own any Joint Know-How. For clarity, Arising Regeneron Know-How shall not include any Roche Independent IP or any Know-How of general applicability to antibody products and not specific to the Product. For example, Know-How that can be applied to purification of antibodies generally but not specific to manufacturing of a Compound or Product shall not be considered Arising Regeneron Know-How.

Each Party shall, and does hereby, assign, and shall cause its Affiliates and its and their Sublicensees, as applicable, to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Inventions, Know-How, Patent Rights or other intellectual property rights as is necessary to fully effect, as applicable, the sole or joint ownership provided for in this Section 14.1. Pursuant to Section 21.18, each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such applications, approvals, assignments, agreements, documents, and instruments, and shall provide any additional consents, as may be necessary or as the other Party may reasonably request for a Party to perfect or exercise its rights provided for in this Section 14.1.

Roche here grants Regeneron a non-exclusive, worldwide, royalty-free, perpetual, irrevocable, transferable, sublicensable (through multiple tiers) license under any Arising Roche Manufacturing IP for any and all purposes. "**Arising Roche Manufacturing IP**" shall mean any Inventions, Know-How, Patent Rights and other intellectual property rights arising under this Agreement generated by or on behalf of the Roche Group solely or jointly with Regeneron or any of its Affiliates or a Third Party that is related to Regeneron's manufacturing process for a Product and that does not constitute Arising Regeneron Invention, Arising Regeneron Know-How or a Patent Right that Covers any Arising Regeneron Invention or Arising Regeneron Know-How (which Patent Rights, for clarity, shall be owned by Regeneron). For clarity, Roche shall own any Arising Roche Manufacturing IP.

14.2 Inventions Made by Employees, Subcontractors and Services Providers

In accordance with any Applicable Law regarding employee's inventions, each Party agrees to claim the ownership or exclusive and unlimited use of any Invention conceived, reduced to practice, developed, made or created in the performance of, or as a result of, any activities under or in connection with this Agreement by employees of such Party or its applicable Affiliates. For the avoidance of doubt, each Party, or its Affiliates (as applicable) is responsible for fulfilling the obligations towards its or their respective employees under any Applicable Law providing for compensation to employees for inventions.

Each Party shall, and shall cause its Affiliates and Sublicensees to, obtain an assignment from subcontractors or service providers to such Party or its applicable Affiliates or Sublicensees of all Inventions related to a Product made by such individuals during the course of and as a result of their performance under this Agreement.

14.3 Trademarks and Labeling

Regeneron shall have the right and responsibility to create, select and obtain the International Non-proprietary Name (INN) from the World Health Organization and the US Adopted Name (USAN) from the US Adopted Names Council (USANC) as the generic name(s) for the Products.

The JOC shall select one or more global trademark(s) for use on the Product in the Territory, including any accompanying logos, slogans, trade names, domain names, trade dress or other indicia of origin, excluding the corporate names and logos of either Party (the "**Global Trademarks**"). If, under Applicable Law, none of the Global Trademarks for a Product can be used for the commercialization of such Product in a country in the Roche Territory, the JOC shall discuss and select one (1) or more alternative trademarks, including any accompanying logos, slogans, trade names, domain names, trade dress or other indicia of origin, for the commercialization of such Product in such country (each, an "**Alternative Product Trademark**"); provided, that if the Parties are unable to agree on such Alternative Product Trademarks, the JOC shall have the right to select such Alternative Product Trademarks.

Regeneron shall own all Global Trademarks in the Regeneron Territory, and shall, at its sole cost, be responsible for procurement, maintenance, enforcement and defense of all Global Trademarks in the Regeneron Territory.

Roche shall own all Global Trademarks and, if applicable, Alternative Product Trademarks, in the Roche Territory, and shall, at its sole cost, be responsible for procurement, maintenance, enforcement and defense of Global Trademarks and if applicable, Alternative Product Trademarks, in the Roche Territory.

Each Party shall keep the other Party reasonably informed regarding any material, substantive issue or any opposition, cancellation, invalidity or other proceeding that may be raised or asserted against any application or registration for a Global Trademark, or, with respect to Roche if applicable, Alternative Product Trademark in its Respective Territory.

Each Party and its Affiliates and its and their Sublicensees shall not license (or, as applicable, sublicense) rights to use, or otherwise transfer ownership of the Global Trademark(s) or, if applicable with respect to Roche, Alternative Product Trademarks, without the prior written consent of the other Party except with respect to any manufacturing or development activities permitted hereunder. Each Party and its Affiliates and its and their Sublicensees shall only utilize the Global Trademark(s) or, if applicable with respect to Roche, Alternative Product Trademarks, on materials related to the Products in its Respective Territory (including package inserts, packaging, trade packaging, internet pages, social media, advertising and promotional materials used or distributed in connection with the Products).

Each Party agrees that at no time during the Agreement Term will it or any of its Affiliates attempt to use or register in its Respective Territory any trademarks, trade dress, service marks, trade names or domain names confusingly similar to any Global Trademark or, if applicable with respect to Roche, any Alternative Product Trademark, in relation to a product that is not a Product, or take any other action that damages or dilutes the rights to, or goodwill associated with, any Global Trademark or, if applicable with respect to Roche, any Alternative Product Trademark.

All use of the Global Trademarks and Alternative Product Trademarks, as applicable, by a Party or its Affiliates or Sublicensees, or, where applicable, its or their distributors, shall be in accordance with (a) rules established by the JOC, if any, and (b) quality standards established by the respective trademark owner, in each case ((a) or (b)), that are reasonably necessary in order to preserve the validity and enforceability of the Global Trademarks and Alternative Product Trademarks, as applicable.

14.4 Use of Corporate Names.

Roche shall not, and shall cause its Affiliates and Sublicensees not to, include Regeneron's name on materials related to the Products in the Roche Territory (including package inserts, packaging, trade packaging, internet pages, social media, advertising and promotional materials used or distributed in connection with the Products), unless (a) with respect to packaging for the Products (including package inserts, packaging and trade packaging for the Products) requested by Regeneron in writing (unless it is commercially unreasonable to do so, or prohibited by Applicable Law) or required under Applicable Law, or (b) with respect to other materials related to the Products (including internet pages, social media, advertising and promotional materials used or distributed in connection with the Products) upon mutual agreement by the Parties or required under Applicable Law, in which case ((a) or (b)), Regeneron's name shall have equal prominence with Roche's name on such materials. Regeneron hereby grants to Roche Basel the right (which right may be sublicensed to Roche Basel's Affiliates and Sublicensees), free of charge, to use Regeneron's name and logo on package inserts, packaging, trade packaging, internet pages, social media and all promotional materials used or distributed in connection with the Products in the Roche Territory during the Agreement Term, in each case, only to the extent pursuant to subclause (a) or (b) in this paragraph. During the Agreement Term, Roche shall submit samples of each such package inserts, packaging, trade packaging, internet pages, social media and all promotional materials using Regeneron's name or logo to Regeneron for approval in accordance with the review and approval process established below.

Regeneron shall not, and shall cause its Affiliates and Sublicensees not to, include Roche's name on materials related to the Products in the Regeneron Territory (including package inserts, packaging, trade packaging, internet pages, social media, advertising and promotional materials used or distributed in connection with the Products), unless (i) with respect to packaging for the Products (including package inserts, packaging and trade packaging for the Products) requested by Roche in writing (unless it is commercially unreasonable to do so, or prohibited by Applicable Law) or required under Applicable Law, or (ii) with respect to other materials related to the Products (including internet pages, social media, advertising and promotional materials used or distributed in connection with the Products) upon mutual agreement by the Parties or required under Applicable Law, in which case ((i) or (ii)), Roche's name shall have equal prominence with Regeneron's name on such materials. Roche hereby grants to Regeneron the right (which right may be sublicensed to Regeneron's Affiliates and Sublicensees), free of charge, to use Roche's name and logo on package inserts, packaging, trade packaging, internet pages, social media and all promotional materials used or distributed in connection with the Products in the Regeneron Territory during the Agreement Term, in each case, only to the extent pursuant to subclause (i) or (ii) in this paragraph. During the Agreement Term, Regeneron shall submit samples of each such package inserts, packaging and trade packaging, internet pages, social media and all promotional materials using Roche's name or logo to Roche for approval in accordance with the review and approval process established below.

Promptly following the Effective Date, the Parties shall discuss in good faith and establish guidelines and an expedited review and approval process regarding the use of each Party's name on material related to the Products. During the Agreement Term, if a Party's name is included on materials related to the Product in the other Party's Respective Territory in accordance with the terms hereunder, the other Party shall comply with the applicable use guideline with respect thereto.

Except as expressly provided herein, no right, express or implied, is granted by this Agreement to use in any manner the name of the other Party or its Affiliates or any other trade name, symbol, logo or trademark of the other Party or its Affiliates.

14.5 Prosecution of Product Patent Rights in the Regeneron Patent Territory

Regeneron shall have the sole right, but not the obligation, to Handle all Product Patent Rights in the Regeneron Patent Territory. The Parties shall share [* * *] all of Regeneron's [* * *] incurred with respect to Handling the Product Patent Rights in the Regeneron Patent Territory. Regeneron shall use good faith efforts to notify Roche Basel of filing of any provisional or utility application for any Product Patent Right in the Regeneron Patent Territory, if practicable, and shall notify Roche Basel of filing of any application under the Patent Cooperation Treaty for any Product Patent Right. At Regeneron's reasonable request, Roche Basel shall cooperate, in all reasonable ways with the Handling of all Product Patent Rights in the Regeneron Patent Territory.

14.6 Prosecution of Product Patent Rights in the Roche Territory and Joint Patent Rights in the Territory

Regeneron shall have the first right, but not the obligation, to Handle all Product Patent Rights in the Roche Territory and all Joint Patent Rights in the Territory. Regeneron shall promptly inform Roche Basel of all material steps with regard to the Handling of such Patent Rights, including by providing Roche Basel with a copy of material communications to and from the applicable patent authorities regarding such Patent Rights. Regeneron shall provide Roche Basel drafts of any material filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for Roche Basel to review and comment thereon, and Regeneron shall consider in good faith the requests and suggestions of Roche Basel with respect to such drafts and with respect to strategies for filing and prosecuting such Patent Rights. At Regeneron's reasonable request, Roche Basel shall cooperate, in all reasonable ways with the Handling of all Product Patent Rights in the Regeneron Patent Territory.

If Regeneron determines to abandon any Product Patent Right in the Roche Territory or Joint Patent Right in the Territory then, prior to such abandonment, Regeneron shall offer such Patent Right to Roche Basel to Handle, subject to the following: Roche Basel's Handling of such Patent Right must be consistent with Regeneron's global patent strategy for the Products. Roche Basel shall promptly inform Regeneron of all material steps with regard to the Handling of such Patent Rights, including by providing Regeneron with a copy of material communications to and from the applicable patent authorities regarding such Patent Right. Roche Basel shall provide Regeneron drafts of any material filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for Regeneron to review and comment thereon, and Roche Basel shall consider in

good faith the requests and suggestions of Regeneron with respect to such drafts and with respect to strategies for filing and prosecuting any such Patent Right; provided that if Regeneron determines that any proposed actions by Roche Basel with respect to any such Patent Right would reasonably be expected to have a negative impact on the global patent portfolio for the Products, then Roche Basel must implement Regeneron's comments with respect to any such actions.

The Parties shall share [* * *] all of the Handling Party's [* * *] incurred with respect to Handling the Product Patent Rights in the Roche Territory and the Joint Patent Rights in the Territory; provided that, with respect to each Joint Patent Right, the non-Handling Party for such Joint Patent Right may elect, upon written notice to the Handling Party for such Joint Patent Right to no longer share the Handling Party's [* * *] and expenses incurred for such Joint Patent Right, in which case the non-Handling Party shall assign all of its right, title and interest in and to such Joint Patent Right to the Handling Party.

14.7 Handling of Other Patent Rights.

Roche Basel shall, at its own expense and discretion, have the sole right, but not the obligation, to Handle (including abandon) all Roche Patent Rights and Regeneron, shall, at its own expense and discretion, have the sole right, but not the obligation, to Handle (including abandon) all Regeneron Patent Rights that are not Product Patent Rights, in each case, without any coordination with, or notice to, the other Party. At the Handling Party's reasonable request, the other Party shall cooperate, in all reasonable ways, with the Handling of the Patent Rights described in this Section 14.7.

14.8 Coordination; No Invention Overlap

If the Parties need to consult with each other on the Handling of Patent Rights, the Parties may establish a patent coordination team by mutual agreement and shall adopt procedures for interacting on patent matters.

The Party Handling the Regeneron Patent Rights shall ensure that, unless otherwise agreed by the Parties in writing, no Patent Right that Covers a Regeneron Invention also Covers a Roche Invention or a Joint Invention. The Party Handling the Roche Patent Patents shall ensure that, unless otherwise agreed by the Parties in writing, no Patent Right that Covers a Roche Invention also Covers a Regeneron Invention or a Joint Invention. The Party Handling the Joint Patent Rights shall ensure that, unless otherwise agreed by the Parties in writing, no Patent Right that Covers a Joint Invention also Covers a Regeneron Invention or a Roche Invention.

14.9 Unified Patent Court (Europe)

At any time prior to the end of the "transitional period" as such term is used in Article 83 of the Agreement on a Unified Patent Court between the participating Member States of the European Union, Regeneron shall have the sole right to make decisions regarding whether, for a given relevant Product Patent Right or Joint Patent Right in the European Union, to (i) opt out from the exclusive competence of the Unified Patent Court or (ii) if applicable, withdraw a previously-registered opt-out, and Regeneron shall so notify the Registry of the Unified Patent Court in the manner specified by Rule 5 of the Rules of Procedure of the Unified Patent Court, pay any such registry fee and take such other action as may be necessary to effect the opt-out or opt-out

withdrawal ("**Register**"). The costs to Register shall be shared in the same manner as the Handling costs are shared for the applicable Patent Right.

14.10 CREATE Act

In the event that either Party to this Agreement intends to overcome a rejection of a claimed Invention pursuant to the provisions of 35 USC §§ 102(a)-(d), such Party shall first obtain the prior written consent of the other Party.

14.11 Infringement of Product Patent Rights and Joint Patent Rights

Each Party shall promptly provide written notice to the other Party during the Agreement Term of any (i) known infringement or suspected infringement by a Third Party of any Product Patent Right or Joint Patent Rights, or (ii) known or suspected unauthorized use or misappropriation by a Third Party of any Product Know-How or Joint Know-How ((i) and (ii) collectively, "**Infringement**"), and shall provide the other Party with all information in its possession supporting such Infringement.

Regeneron shall have the sole right, but not the obligation, to initiate a suit or action regarding any Regeneron Controlled Infringement, including to settle any such suit or action. Regeneron shall use good faith efforts to notify Roche Basel of any material progress in connection with any such suit or action. At Regeneron's written request, Roche Basel shall offer reasonable assistance to Regeneron in connection any such suit or action at no charge to Regeneron except for reimbursement [* * *] incurred by Roche in rendering such assistance ([* * *]). The Parties will [* * *] of Regeneron's [* * *] in connection with any suit or action with respect to any Regeneron Controlled Infringement as follows: [* * *].

Regeneron shall have the first right, but not the obligation, to initiate a suit or action regarding any Roche Shared Infringement. Within[* * *] after Regeneron provides or receives written notice of any Roche Shared Infringement (such [* * *] period, the "**Enforcement Decision Period**"), Regeneron, in its sole discretion, shall decide whether or not to initiate a suit or action regarding such Roche Shared Infringement and shall notify Roche of its decision in writing ("**Enforcement Suit Notice**"). If Regeneron decides to bring a suit or take action with respect to any Roche Shared Infringement, once Regeneron provides the applicable Enforcement Suit Notice, Regeneron may immediately commence such suit or take such action. In the event that Regeneron (i) does not in writing advise Roche Basel within the Enforcement Decision Period that Regeneron will commence suit or take action with respect to a Roche Shared Infringement, or (ii) fails to commence suit or take action within a reasonable time after providing the applicable Enforcement Suit Notice, Roche shall thereafter have the right (subject to Regeneron's written consent, not to be unreasonably conditioned, withheld or delayed) to commence suit or take action with respect to such Roche Shared Infringement and shall provide written notice to Regeneron of any such suit commenced or action taken by Roche.

The Party bringing suit or taking action with respect to any Roche Shared Infringement (the "**Initiating Party**") shall keep the other Party reasonably informed of the progress of such suit or action and shall provide the other Party with advance copies, to the extent the Initiating Party is lawfully permitted to do so, of all material documents or communications to be filed or positions to be taken in such suit or action and will consider the other Party's comments with respect

thereto in good faith. The Initiating Party shall have the sole and exclusive right to select counsel for any such suit or action.

If Regeneron is the Initiating Party with respect to any suit or action with respect to any Roche Shared Infringement, the Parties will [* * *] of Regeneron's [* * *] in connection with such suit or action [* * *]. If Roche Basel is the Initiating Party with respect to any suit or action with respect to any Roche Shared Infringement, the Parties will [* * *] of Roche Basel's [* * *] in connection with such suit or action as follows: [* * *].

Unless otherwise agreed by the Parties, all monies recovered upon the final judgment or settlement of any action with respect to any Regeneron Controlled Infringement or Roche Shared Infringement shall be used as follows:

(a) First, (i) with respect any Regeneron Controlled Infringement, to reimburse each Party for its share of Regeneron's [* * *] associated with such action and (ii) with respect to any Roche Shared Infringement, to reimburse each Party for its share of the Initiating Party's [* * *] associated with such action; and

(b) Second, any remaining amount shall be retained by or paid to (i) with respect any Regeneron Controlled Infringement, Regeneron and (ii) with respect to any Roche Shared Infringement, the Initiating Party; provided, however, any such amount shall constitute Global Gross Profit.

If the Initiating Party believes it is reasonably necessary or desirable to obtain an effective remedy for the other Party to be joined as a party to the applicable suit or action, upon written request the other Party agrees to be joined as a party to such suit or action but shall be under no obligation to participate except to the extent that such participation is required as the result of its being a named party to the suit or action. At the Initiating Party's written request, the other Party shall offer reasonable assistance to the Initiating Party in connection therewith at no charge to the Initiating Party except for reimbursement of reasonable out-of-pocket expenses incurred by the other Party in rendering such assistance (which shall then be subject to same reimbursement provisions as the out-of-pocket costs of the Initiating Party). The other Party shall have the right to participate and be represented in any such suit or action by its own counsel at its own expense.

The Initiating Party may settle, consent to a judgment or otherwise voluntarily dispose of any Roche Shared Infringement suit or action ("**Settlement**") without the written consent of the other Party; provided, that, Roche, as the Initiating Party, shall not admit non-infringement or grant a license or other right, including any covenant not to sue, with respect to any Product Patent Right, Product Know-How, Joint Patent Rights or Joint Know-How or otherwise settle in a manner that would reasonably be expected to have a negative impact on a Product or the global patent portfolio for the Products, or on the employees of Regeneron or on Regeneron's reputation, in each case, without Regeneron's consent.

Roche shall, at its own cost and expense, have the sole right, but not the obligation, to decide whether or not to initiate (or settle) any suit or action in the Territory with respect to any (i) known infringement or suspected infringement by a Third Party of any Roche Patent Right, or (ii) known or suspected unauthorized use or misappropriation by a Third Party of any Roche Know-How in each case, without any coordination with, or notice to, Regeneron. Regeneron, shall, at its own

costs and expense, have the sole right, to decide whether or not to initiate (or settle) any suit or action in the Territory with respect to any (iii) known infringement or suspected infringement by a Third Party of any Regeneron Patent Rights that are not Product Patent Rights, or (iv) known or suspected unauthorized use or misappropriation by a Third Party of any Regeneron Know-How that is not Product Know-How, in each case, without any coordination with, or notice to, Roche. Each Party, shall, at its own costs and expense, have the sole right, to decide whether or not to initiate (or settle) any suit or action in the Territory with respect to any (v) known infringement or suspected infringement by a Third Party of any Joint Patent Rights, or (vi) known or suspected unauthorized use or misappropriation by a Third Party of any Joint Know-How, in each case ((v) and (vi)), that is not Competitive Infringement, without any coordination with, or notice to, the other Party. The Party initiating any suit or action pursuant to this paragraph shall retain all monies recovered upon the final judgment or settlement of any action. With respect to any suit or action initiated pursuant to this paragraph, at the acting Party's written request, the other Party shall offer reasonable assistance to the acting Party in connection therewith at no charge to the acting Party except for reimbursement of reasonable out-of-pocket expenses incurred by the other Party in rendering such assistance.

14.12 Invalidity or Unenforceability Defenses or Actions

Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Product Patent Rights or Joint Patents Rights by a Third Party of which such Party becomes aware.

Regeneron shall have the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the Product Patent Rights in the Regeneron Patent Territory. The Parties shall share [* * *] all of Regeneron's [* * *] incurred with respect to defending the Product Patent Rights in the Regeneron Patent Territory. Regeneron shall use good faith efforts to notify Roche of any material steps taken in connection with defending the Product Patent Rights in the Regeneron Patent Territory. At Regeneron's written request, Roche shall offer reasonable assistance to Regeneron in connection with defending the Product Patent Rights in the Regeneron Patent Territory at no charge to Regeneron except for reimbursement of reasonable out-of-pocket expenses incurred by Roche in rendering such assistance (which shall then be subject to same reimbursement provisions as the out-of-pocket costs of Regeneron).

Regeneron shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of the Product Patent Rights in the Roche Territory and the Joint Patent Rights in the Territory (such Patent Rights, the "**Roche-Shared Defense Patents**"). Within [* * *] after Regeneron provides or receives written notice of any alleged or threatened assertion of invalidity or unenforceability of any of the Roche-Shared Defense Patents (such [* * *] period, the "**Defense Decision Period**"), Regeneron, in its sole discretion, shall decide whether or not to defend and control the defense of the validity and enforceability of such Roche-Shared Defense Patents and shall notify Roche of its decision in writing ("**Defense Suit Notice**"). If Regeneron decides to defend and control the defense of the validity and enforceability of such Roche- Shared Defense Patents, once Regeneron provides the applicable Defense Suit Notice, Regeneron may immediately commence such defense. In the event that Regeneron (i) does not in writing advise Roche within the Defense Decision Period that Regeneron will defend and control the defense of an Roche-Shared Defense Patent, or (ii) fails to commence the defense of such Roche-Shared Defense Patent within a reasonable time after providing the applicable Defense Suit Notice, Roche shall thereafter have the right (subject to

Regeneron's written consent, not to be unreasonably conditioned, withheld or delayed) to defend and control the defense of such Roche-Shared Defense Patent and shall provide written notice to Regeneron of any such defense taken by Roche.

The Party defending and controlling the defense with respect to any Roche-Shared Defense Patent (the "**Defending Party**") shall keep the other Party reasonably informed of the progress of such suit or action and shall provide the other Party with advance copies, to the extent the Defending Party is lawfully permitted to do so, of all material documents or communications to be filed or positions to be taken in such suit or action and will consider the other Party's comments with respect thereto in good faith; provided, that, with respect to Roche as the Defending Party, if Regeneron determines that any proposed actions by Roche with respect to such defense would reasonably be expected to have a negative impact on the global patent portfolio for the Products, then Roche must implement Regeneron's comments with respect to any such actions. The Defending Party shall have the sole and exclusive right to select counsel for any such suit or action. At the Defending Party's written request, the other Party shall offer reasonable assistance to the Defending Party in connection with defending the Roche-Shared Defense Patents at no charge to the Defending Party except for reimbursement of reasonable out-of-pocket expenses incurred by the other Party in rendering such assistance (which shall then be subject to same reimbursement provisions as the out-of-pocket costs of the Defending Party).

If Regeneron is the Defending Party with respect to any Roche-Shared Defense Patent, the Parties will share all of Regeneron's [* * *] in connection with such defense [* * *]. If Roche is the Defending Party with respect to any Roche-Shared Defense Patent, the Parties will share all of Roche's [* * *] in connection with such suit or action as follows: [* * *].

14.13 Defense

If an action for infringement is commenced against either Party, its Affiliates or its licensees or its sublicensees (including Sublicensees) related to the discovery, development (including the conduct of the Co-Funded Development Plan), manufacture, use or sale of a Product (a "**Third Party Infringement Action**"), then, subject to Article 16, the following shall apply:

(a) The Party (or its Affiliate, licensee or sublicensee, as applicable) who is named as the defendant shall have the right (but not the obligation) to defend such Third Party Infringement Action at its own expense; provided, however, that if a Third Party Infringement Action is commenced against both Regeneron (or any of its Affiliates, licensees or sublicensees), on the one hand, and Roche (or any of its Affiliates, licensees or Sublicensees), on the other hand (a "**Joint Infringement Action**"), then Regeneron shall have the first right, but not the obligation, to conduct and control the defense of such Third Party Infringement Action, using counsel of its own choice. Roche shall assist and cooperate with Regeneron, at Regeneron's expense, to the extent necessary in the defense of such suit. If Regeneron elects not to defend or control the defense of, or otherwise fails to initiate and maintain the defense of, any such Joint Infringement Action, Regeneron shall notify Roche of such election within such time periods so Roche is not prejudiced by any delays, and Roche shall have the right (but not the obligation), to conduct and control the defense of such Joint Infringement Action using counsel of its own choice. The Parties will share the [* * *] of the controlling Party in defense of a Joint Infringement Action as follows: [* * *].

(b) The Party entitled to defend any Third Party Infringement Action shall have the right to settle the suit or consent to an adverse judgment thereto, in its sole discretion; provided, that Roche shall not enter into any settlement of any Third Party Infringement Action that [* * *] in each case ((i) - (iii)), without Regeneron's prior written consent in its sole discretion, and provided, that Regeneron shall not enter into any settlement of any Third Party Infringement Action that [* * *] in each case ((iv) and (v)), without Roche's prior written consent in its sole discretion. Unless otherwise agreed by the Parties, with respect any settlement of a Third Party Infringement Action, the Parties shall share responsibility for the payment of any award for damages, or any amount due pursuant to such settlement as follows: to the extent that such settlement is with respect to the Regeneron Territory, [* * *].

(c) Each Party will provide the other Party with prompt written notice of the commencement of any proceedings under this Section 14.13 and such Party will keep the other Party reasonably informed of all material developments in connection with any such Third Party Infringement Action, including by promptly furnish the other Party with a copy of all documents or communications filed in such action.

14.14 Common Interest Disclosures

The Parties have a common legal interest in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of the Co-Funded Development Plan or Compounds or Products, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the conduct of the Co-Funded Development Plan or Compounds or Products. Accordingly, any information or opinions disclosed pursuant to this Agreement by one Party to each other regarding intellectual property or technology owned by Third Parties will be used solely for purposes of the Parties' common legal interests with respect to the conduct of this Agreement. All information and materials will be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Party's prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against any other Party. Notwithstanding the foregoing, neither Party's attorney represents the other Party.

14.15 Biosimilars

Notwithstanding anything herein to the contrary, if either Party receives notice or a copy of an application submitted to a Regulatory Authority in the Territory for a Biosimilar Product or similar notice or communication pursuant to which a product is claimed to be interchangeable with a Product, whether or not such notice or copy is provided under any Applicable Law, or otherwise becomes aware that such an application, notice or communication has been submitted to a Regulatory Authority in the Territory for approval, such Party shall notify and provide the other Party copies of such application, notice, communication and any other relevant information to the extent permitted by Applicable Law. The Parties shall cooperate in good faith with one another with respect to the foregoing, including with respect to proceedings related thereto, in a manner consistent with the rights and obligations of the Parties set forth in Section 14.11, Section 14.12 or Section 14.13, as applicable.

14.16 Patent Term Extensions

"**Patent Term Extensions**" shall mean all available patent term extensions, adjustments or restorations, or supplementary protection certificates.

Regeneron shall have the sole right, but not the obligation, to file for Patent Term Extensions with respect to the Products in the Regeneron Patent Territory. The Parties will share all of Regeneron's [* * *] for such Patent Term Extensions [* * *]. Roche shall have the sole right, but not the obligation, to file for Patent Term Extensions, including Supplementary Protection Certifications, with respect to the Products in the Roche Territory; provided, that if filing for any such Patent Term Extension would reasonably be expected to have a negative impact on the Product in the US then Regeneron's prior approval, in its sole discretion, shall be required for such Patent Term Extension. The Parties will share all of Roche's [* * *] for such Patent Term Extensions [* * *].

With respect to Patent Term Extensions with respect to the Products in the Roche Territory, subject to Roche obtaining Regeneron's approval if necessary, Regeneron shall (a) grant Roche the right to file for such Patent Term Extension and (b) execute such authorizations and other documents and take such other actions as may be reasonably requested by Roche to obtain such Patent Term Extensions. Each Party shall execute such authorizations and other documents and take such other actions as may be reasonably requested by the other Party to obtain such Patent Term Extensions. The Parties shall cooperate with each other in gaining Patent Term Extensions with respect to the Products.

With respect to any filings made to Regulatory Authorities with respect to any Compounds or Products, including, as required or allowed in the US, the FDA's Purple Book, if applicable, or outside the US, other international equivalents, Regeneron will have the sole right to make any such decision whether to list Regeneron Patent Rights, but in all events will comply with Applicable Law, provided that Regeneron will consider in good faith any timely comments received from on behalf of Roche with respect to such filings in the Roche Territory prior to submission. Upon Regeneron's request, Roche will reasonably cooperate in the implementation of Regeneron's decision made under this Section 14.16.

14.17 Interference, Opposition and Reissue of Third Party Patents

If either Party or one of its Affiliates or its or their Sublicensees desires to initiate any interference, opposition, post-grant review, reissue or reexamination proceeding relating to a Patent Right of a Third Party in furtherance of a Product in the Territory, then such Party shall notify the other Party in writing of such desire. As soon as reasonably practicable after the receipt of such notice, the Parties shall meet and discuss the appropriate course of action with respect to such proposed interference, opposition, post-grant review, reissue or reexamination proceeding; provided, that after such discussion either Party may initiate any interference, opposition, post-grant review, reissue or reexamination proceeding relating to a Patent Right of a Third Party in furtherance of a Product in the Territory, except that Roche may not initiation any such interference, opposition, post-grant review, reissue or reexamination proceeding in the US without Regeneron's prior written consent in its sole discretion.

14.18 Third Party IP Licenses

With respect to any Patent Right or other intellectual property right of a Third Party that is necessary or reasonably useful for the development, manufacture or commercialization of the Products, (a) Regeneron shall have the exclusive right to negotiate and enter into any such license or other agreement with a Third Party to obtain rights to any such Patent Right or other intellectual property right solely in the Regeneron Patent Territory, (b) Roche Basel shall have the exclusive right to negotiate and enter into any such license or other agreement with a Third Party to obtain rights to any such Patent Right or other intellectual property right solely in the Roche Territory and (c) the Parties must mutually agree on the terms and conditions of any license or other agreement with a Third Party to obtain rights to any such Patent Right or other intellectual property right in both (i) some or all of the Regeneron Patent Territory and (ii) some or all of the Roche Territory.

15. Representations and Warranties

15.1 Regeneron Representations and Warranties

Regeneron represents and warrants to Roche, as of the Effective Date:

(a) Product Data

The data, results, reports, and other documentation disclosed by Regeneron to Roche, either via the electronic data room or direct communication in writing between the business representatives of the Parties, in each case, to the extent related to any Compound or Product, are true and accurate.

(b) Ownership of Patent Rights

Regeneron owns all of the Regeneron Base Patent Rights. Appendix 1.90 contains a complete and accurate list of all patents and patent applications included in the Regeneron Base Patent Rights.

(c) Inventors

The inventors of the inventions disclosed or claimed in the Regeneron Base Patent Rights have transferred full ownership of such inventions to Regeneron, or are under an obligation to transfer the full ownership of such inventions to Regeneron.

(d) Grants

To Regeneron’s Knowledge, Regeneron has the lawful right to grant Roche the rights and licenses described in this Agreement.

(e) Validity of Patent Rights; Inventorship Disputes

To Regeneron’s Knowledge, the claims in the Regeneron Base Patent Rights are valid and enforceable. Regeneron has no Knowledge of any inventorship disputes concerning any Regeneron Base Patent Rights.

(f) Ownership and Validity of Know-How

To Regeneron's Knowledge, Regeneron's Know-How has not been misappropriated from any Third Party. Regeneron has taken reasonable measures to protect the confidentiality of its Know-How.

(g) No Limitations on Manufacturing

Without limiting Regeneron's representation and warranty in Section 15.3(a), neither [* * *] nor any other indenture, mortgage, deed of trust, lease, agreement, or other instrument to which Regeneron is a party or by which Regeneron or any of its property is bound, contains a term that would restrict Roche from using any of the Roche Manufacturing Facilities to supply Regeneron with Products for the Regeneron Territory or to otherwise fulfill any of Roche's manufacturing and supply obligations under this Agreement.

(h) Regeneron and its Affiliates have not clinically developed or commercialized or granted a license to a Third Party to clinically develop or commercialize an Antibody Conjugate that contains any Antibody in the Lead Compound.

15.2 Roche Representations and Warranties

Roche represents and warrants to Regeneron that, as of the Effective Date:

All written information disclosed by Roche to Regeneron regarding Roche's and its Affiliates' manufacturing or organization manufacturing capabilities and compliance history is true and accurate.

15.3 Mutual Representations and Warranties

Each Party represents and warrants to the other Party as of the Effective Date, and covenants, as follows:

(a) Authorization

The execution, delivery and performance of this Agreement by such Party and all instruments and documents to be delivered by such Party hereunder: (i) are within the corporate power of such Party; (ii) have been duly authorized by all necessary or proper corporate action; (iii) are not in contravention of any provision of the organization documents of such Party; (iv) to the Knowledge of such Party, will not violate any law or regulation or any order or decree of any court of governmental instrumentality; (v) will not violate the terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument to which such Party is a party or by which such Party or any of its property is bound, which violation would have an adverse effect on the financial condition of such Party or on the ability of such Party to perform its obligations hereunder; and (vi) do not require any filing or registration with, or the consent or approval of, any governmental body, agency, authority or any other person, which has not been made or obtained previously (other than Regulatory Approvals required for the sale of Products and filings with Regulatory Authorities required in connection with Products).

Without limiting the foregoing, (A) such Party is duly organized and validly existing under the Applicable Laws of its jurisdiction of incorporation; (B) such Party has full corporate power and

authority and the legal right to own and operate property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement; (C) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to Applicable Laws of bankruptcy and moratorium); and (D) the individuals executing this Agreement for such Party have been duly authorized to execute and deliver this Agreement on behalf of such Party.

(b) No Claims

There are no claims or investigations pending or, to such Party's Knowledge, threatened against such Party or any of its Affiliates, at law or in equity, or before or by any governmental authority relating to the matters contemplated under this Agreement or that would materially impair, prevent or delay such Party's ability to perform its obligations hereunder. During the Agreement Term, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

(c) Insurance

During the Agreement Term and for a minimum period of [* * *] thereafter and for an otherwise longer period as may be required by Applicable Law, each of Regeneron and Roche will procure and maintain insurance consistent with industry practice or required by Applicable Law, which may be through self-insurance. Such insurance shall insure against liability arising from this Agreement on the part of Regeneron or Roche, respectively, or any of their respective Affiliates, due to injury, disability or death of any person or persons, or property damage arising from activities performed by such Party or its Affiliates in connection with this Agreement. Any insurance proceeds received by a Party in connection with any indemnified claim shall be retained by such Party and shall not reduce any obligation of the other Party under Article 16 with respect to such claim.

(d) Debarment

Each Party covenants that it and its Affiliates and, to the best of such Party's knowledge, its and their respective employees who are involved in the development or commercialization of the Compounds or the Products will not be debarred under 21 U.S.C. §335a, disqualified under 21 C.F.R. §312.70 or §812.119, sanctioned by a Federal Health Care Program (as defined in 42 U.S.C §1320 a-7b(f)), including the federal Medicare or a state Medicaid program, or debarred, suspended, excluded or otherwise declared ineligible from any other similar federal or state agency or program in the United States or any other country ("**Debarred**"). In the event a Party receives notice of, or becomes aware that any of its Affiliates or any employee of such Party or any of its Affiliates receives notice of, in either case, debarment, suspension, sanction, exclusion, ineligibility or disqualification under the above-referenced statutes or any other similar federal or state agency or program in the United States or any other country, such Party shall promptly notify the other Party in writing.

Each Party has adopted and implemented compliance policies that conform to industry standards. Each Party will use commercially reasonable efforts to ensure that no employees of such Party or its Affiliates who are involved in the development or commercialization of the Compounds or the Products are Debarred.

(e) No Force Majeure Event

Each Party represents and warrants that as of the Effective Date it is not currently under the effects of a force majeure event as contemplated by Section 21.9 such as would prevent or materially hinder or delay its performance hereunder.

15.4 No Other Representations and Warranties

EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, THE FOREGOING REPRESENTATIONS AND WARRANTIES ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF PRODUCTS. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE.

16. Indemnification

16.1 Indemnification by Roche

Roche shall indemnify, hold harmless and defend Regeneron, Regeneron's Affiliates and its and their respective directors, officers, employees and agents ("**Regeneron Indemnitees**") from and against any and all losses, expenses, cost of defense (including reasonable attorneys' fees, witness fees, damages, taxes, judgments, fines and amounts paid in settlement) (collectively, "**Losses**") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "**Claims**") arising from or occurring as a result of (a) the breach of this Agreement or the Supply Agreement by Roche or any of its Affiliates, if applicable, (b) the negligence or willful misconduct of any Roche Indemnitee or a Sublicensee of Roche in performing its or their obligations under this Agreement, (c) any regulatory activities conducted by Regeneron or its Affiliates to assist Roche to obtain Regulatory Approval for a Product (other than the First Approval Activities) in the Roche Territory pursuant to Section 6.1.2, or (d) any employee of Roche or its Affiliates who is involved in the development or commercialization of the Compounds or the Products being Debarred, except, in the case of (a) and (b), to the extent Regeneron has an obligation to indemnify Roche for Losses pursuant to Section 16.2, as to which Losses each Party shall indemnify the other Party to the extent of their respective liability for such Losses.

16.2 Indemnification by Regeneron

Regeneron shall indemnify, hold harmless and defend Roche, Roche's Affiliates and its and their respective directors, officers, employees and agents ("**Roche Indemnitees**") from and against any and all Losses in connection with any and all Claims arising from or occurring as a result of (a) the breach of this Agreement or the Supply Agreement by Regeneron or any of its Affiliates, if applicable, (b) the negligence or willful misconduct of any Regeneron Indemnitee or a Sublicensee of Regeneron in performing its or their obligations under this Agreement, or (c) any employee of Regeneron or its Affiliates who is involved in the development or commercialization of the Compounds or the Products being Debarred, except, in each case ((a) and (b)), to the extent Roche has an obligation to indemnify Regeneron for Losses pursuant to Section 16.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability for such Losses.

16.3 No Fault Claims

With respect to any Claim arising out of or related to the research, development, seeking and obtaining Regulatory Approval for, making, using, importing or exporting of the Compounds or Products under this Agreement that is not subject to indemnification under Section 16.1 or Section 16.2 and is not subject to Section 14.13 (each, a "**No Fault Claim**"), (a) the provisions of Section 16.4 shall not apply with respect to the defense of such No Fault Claim and the Parties shall cooperate in good faith to establish a mutually agreeable strategy with respect to defending such No Fault Claim, including whether to settle any such No Fault Claim and (b) [* * *]. For clarity, neither Party shall settle any No Fault Claim without the other Party's consent, not to be unreasonably withheld, conditioned or delayed.

16.4 Indemnification Procedure

All indemnification claims in respect of a Regeneron Indemnitee or a Roche Indemnitee shall be made solely by Regeneron or Roche, as applicable (each of Regeneron or Roche in such capacity, the "**Indemnified Party**"). The Indemnified Party shall promptly notify the other Party ("**Indemnifying Party**") in writing of the Claim, and any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under Section 16.1 or Section 16.2 (an "**Indemnification Claim Notice**").

With respect to each Claim, the obligations of the Indemnifying Party shall be governed by and contingent upon the following:

(a) At its option, the Indemnifying Party may assume the defense of any Claim by notifying the Indemnified Party in writing within [* * *] after the Indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Claim by the Indemnifying Party shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify the Indemnified Party or its Indemnitees, in respect of such Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against the Indemnified Party's or its Indemnitees' claim for indemnification. Upon assuming the defense of a Claim, the Indemnifying Party may appoint the lead counsel in the defense of such Claim. If the Indemnifying Party assumes the defense of a Claim, the Indemnified Party shall promptly deliver to the Indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party or any of its Indemnitees in connection with the Claim. If the Indemnifying Party assumes the defense of a Claim, except as provided in subsection (b) below, the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by the Indemnified Party or any of its Indemnitees in connection with the analysis, defense or settlement of such Claim unless specifically requested in writing by the Indemnifying Party. If it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party or its Indemnitees from and against the Claim, the Indemnified Party shall reimburse the Indemnifying Party for any Losses incurred by the Indemnifying Party in its defense of the Claim.

(b) The Indemnified Party shall be entitled to participate in, but not control, the defense of a Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the Indemnified Party's sole cost and expense unless (i) the employment thereof, and the assumption by the Indemnifying Party of such cost and expense, have been specifically requested in writing by the Indemnifying Party, (ii) the Indemnifying Party

has failed to assume the defense and employ counsel in accordance with Section 16.4(a) (in which case the Indemnified Party shall control the defense) or (iii) the interests of the applicable Indemnitees and the Indemnifying Party with respect to such Claim are sufficiently adverse to prohibit the representation by the same counsel of both entities under Applicable Law, ethical rules or equitable principles (in which case the Indemnified Party shall control its defense).

(c) With respect to any Losses relating solely to the payment of money damages in connection with a Claim and that shall not result in the applicable Indemnitee becoming subject to injunctive or other relief or otherwise adversely affecting the business of the applicable Indemnitee in any manner and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnitee hereunder, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with any Claim, if the Indemnifying Party has assumed the defense of the Claim in accordance with Section 16.3, the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; provided it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the Indemnifying Party controls the defense of a Claim as provided above, the Indemnified Party shall not settle such Claim without the prior written consent of the Indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).

(d) Regardless of whether the Indemnifying Party chooses to defend or prosecute any Claim, the Indemnified Party shall, and shall cause each Indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party and Indemnitees of, records and information that are reasonably relevant to such Claim and making Indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder and the Indemnifying Party shall reimburse the Indemnified Party for all its out-of-pocket expenses in connection therewith.

(e) Except as provided above, the Losses incurred by the Indemnified Party in connection with any Claim shall be reimbursed on a Calendar Quarter basis by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party or its Indemnitees.

17. Liability

EXCEPT FOR INDEMNIFICATION OBLIGATIONS OF A PARTY UNDER ARTICLE 16, BREACHES OF CONFIDENTIALITY IN ARTICLE 18, BREACHES OF ARTICLE 9, GRANT BY EITHER PARTY OF A LICENSE IN BREACH OF THE Exclusive license granted BY IT under Section 2.1(IV) or Section 2.4(IV), GROSS NEGLIGENCE, WILLFUL MISCONDUCT, AND ANY OTHER LIABILITY TO THE EXTENT SUCH LIABILITY CANNOT BE LIMITED UNDER APPLICABLE LAW, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE

OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, DAMAGES FOR LOSS OF PROFIT, LOSS OF REVENUE, OR LOST OPPORTUNITY IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES.

18. Obligation Not to Disclose Confidential Information

18.1 Non-Use and Non-Disclosure

During the Agreement Term and for [* * *] thereafter, a Receiving Party shall (a) treat Confidential Information of the Disclosing Party as strictly confidential and with similar care as it would treat its own information of a similar nature, and (b) not use such Confidential Information other than for fulfilling its obligations or exercising its rights under this Agreement; provided that with respect to any Confidential Information that is specifically identified as a trade secret, or that the other Party has reason to know is a trade secret under Applicable Law, such obligations shall survive until such Confidential Information is no longer a trade secret under Applicable Law.

The Receiving Party covenants that neither it nor any of its respective Affiliates shall disclose any Confidential Information of the other Party (or its Affiliates) to any Third Party except (i) to its employees, agents, consultants or any other person under its authorization; provided that such employees, agents, consultants or persons are subject in writing to substantially the same confidentiality obligations as the Parties, (ii) as approved by both Parties hereunder, (iii) Third Parties to the extent reasonably necessary to market the Product in the Territory; provided that such Third Parties are subject in writing to substantially the same confidentiality obligations as the Parties under this Agreement, (iv) to permitted potential and actual Sublicensees or subcontractors; provided that such permitted potential and actual Sublicensees or subcontractors are subject in writing to substantially the same confidentiality obligations as the Parties under this Agreement, or (v) as set forth elsewhere in this Agreement; provided that the exceptions in clauses (iii), (iv) and (v) shall not apply with respect to Proprietary Manufacturing Information.

18.2 Permitted Disclosure

Notwithstanding the obligation of confidentiality, non-use and non-disclosure set forth in Section 18.1 but subject to Section 18.3, the Parties recognize the need for certain exceptions to this obligation, and each Receiving Party may disclose Confidential Information of the Disclosing Party to the extent that such disclosure is:

(a) made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the Receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law, including by reason of filing with securities regulators; provided, however, that the Receiving Party shall first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment; provided, further, that the Confidential Information disclosed in response to such order or as required by Applicable Law shall be limited to that information that is legally required to be disclosed in response to such order or by such Applicable Law;

(b) made by or on behalf of the Receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval pursuant to the terms of this Agreement; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law;

(c) made to a US government agency or contractor in connection with performance of a US government agreement or sub-agreement (provided that appropriate markings to protect Confidential Information pursuant to US government regulations are applied to Confidential Information to the extent applicable); provided, however, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law; or

(d) with respect to Joint Know-How, made by either Party or its Affiliates as may be necessary or useful in connection with the exploitation of any product that is not a Competing Product in the Territory.

18.3 Proprietary Manufacturing Information

Without limitation of any of the foregoing, Roche shall adopt and implement reasonable firewall procedures to prevent the disclosure of and use of Proprietary Manufacturing Information beyond the persons who are required to receive such information in order to manufacture the Products or to prepare, submit, obtain or maintain Regulatory Approvals for the Products in the Field in the Roche Territory in accordance with this Agreement (and who are bound by confidentiality obligations no less stringent than those provided in this Agreement), including by establishing reasonable physical and electronic safeguards, segregating all Proprietary Manufacturing Information from its own information or materials or that of others (including Affiliates) in order to prevent commingling; not copying or otherwise duplicating any embodiments of the Proprietary Manufacturing Information, except as necessary to manufacture the Products or to prepare, submit, obtain or maintain Regulatory Approvals for the Products in the Field in the Roche Territory in accordance with this Agreement (provided that any such copies or duplications of such Proprietary Manufacturing Information shall be marked “confidential,” “proprietary”, or the like); and notifying Regeneron immediately, and cooperating with Regeneron as Regeneron may reasonably request, upon any discovery of any loss or compromise of Proprietary Manufacturing Information.

[* * *]

Notwithstanding anything else in this Agreement to the contrary, if Roche or any of its Affiliates receives a request for any Proprietary Manufacturing Information from any governmental authority under any freedom of information law, including the United States Freedom of Information Act or the State Council Regulations on Open Government Information, then Roche shall (i) notify Regeneron of such request within [* * *], (ii) permit Regeneron or any of its Affiliates to oppose such request or to seek other limitations on such request, in each case, to the extent consistent with the Applicable Law and (iii) provide Regeneron with reasonable assistance in opposing such request or seeking such limitations. Roche shall not, and shall cause its Affiliates not to, disclose any Proprietary Manufacturing Information to any governmental authority in response to a request under any freedom of information law without Regeneron’s prior written consent, not to be unreasonably withheld, conditioned or delayed;

provided that Regeneron acknowledges and agrees that it would be unreasonable for it to not consent to any disclosure if such lack of disclosure would cause Roche or any of its Affiliates to violate Applicable Law.

Any Regeneron Confidential Information (as the term is defined in the Technology Transfer Agreement) that constitutes Proprietary Manufacturing Information shall be governed by the applicable terms under this Agreement.

18.4 Press Releases; Use of Name

The Parties shall mutually agree on the content of any press releases, and shall coordinate on the initial press release promptly after the Effective Date. Except as otherwise expressly provided herein or for any such disclosure that is, in the opinion of the issuing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the issuing Party (or any parent entity thereof) are listed, neither Party shall issue any other public announcement or press release or make any other public disclosure regarding this Agreement, its terms or its subject matter without the other Party's prior written consent, such consent not to be unreasonably withheld, delayed or conditioned. Notwithstanding the foregoing, Regeneron shall be responsible for, and shall have the final decision-making authority on any press releases for any Ongoing Regeneron Studies.

The restrictions imposed by this Section 18.4 shall not prohibit either Party from making any disclosure if, in the opinion of the counsel of the Party making such disclosure, such disclosure is required by Applicable Law or the rules of a stock exchange on which the securities of the first Party, provided, that such Party shall submit the proposed disclosure to the other Party in advance (and in no event less than [* * *] prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon, and shall consider the other Party's comments in good faith.

Except as expressly provided herein or required by Applicable Law, neither Party shall use the name, logo or trademark of the other Party or any of its Affiliates or any of its or their Sublicensees (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material or other form of publicity without the prior written approval of such other Party.

18.5 Publications

During the Agreement Term, the following restrictions shall apply with respect to disclosure by any Party of Confidential Information relating to the Compounds or Products in any publication or presentation:

(a) With respect to publications or presentations relating to Co-Funded Studies where Roche is involved in operationalizing the Co-Funded Study and for other joint publications or presentations, the Parties will work together in good faith to co-author such publication or presentation, and will mutually agree in good faith on all aspects of such publication or presentation, including without limitation the content of the publication or presentation and the timing and manner of its publication or presentation. If the Parties cannot reach agreement, then the Party that sponsors, or is primarily responsible for operationalizing, the Co-Funded Study will make the final determination on all aspects of such publication or presentation except with respect to disclosure of an invention, solely or jointly conceived or

reduced to practice by the other Party, or the Confidential Information of the other Party (other than the results of the Co-Funded Study).

(b) With respect to publications or presentations relating to Co-Funded Studies where Roche is not involved in operationalizing the Co-Funded Study (including, for clarity, the Additional Regeneron Studies), Regeneron shall provide Roche with a copy of such proposed publication or presentation at least [* * *] (or at least [* * *] in the case of oral presentations) prior to submission for publication so as to provide Roche with an opportunity to recommend any changes it reasonably believes are necessary to continue to maintain the Confidential Information disclosed by Roche to Regeneron in accordance with the requirements of this Agreement. The incorporation of such recommended changes shall not be unreasonably refused; and if Roche notifies ("**Roche Publishing Notice**") Regeneron in writing, within [* * *] after receipt of the copy of the proposed publication or presentation (or at least [* * *] in the case of oral presentations), that such publication or presentation in its reasonable judgment (i) contains an invention, solely or jointly conceived or reduced to practice by Roche, for which Roche reasonably desires to obtain patent protection, in which case Regeneron shall delay such publication for a mutually agreeable period of time not to exceed [* * *] from the date of the Roche Publishing Notice; or (ii) contains Confidential Information of Roche (other than the results of any Co-Funded Study), in which case, Regeneron shall, upon Roche's request, remove from the publication such information.

(c) With respect to publications or presentations related to Unilateral Studies or other unilateral publications or presentations by a Party relating to the Compounds or Products, subject to Section 18.5(d), the Party proposing such publication or presentation ("**Publishing Party**") shall provide the other Party with a copy of such proposed publication or presentation at least [* * *] (or at least [* * *] in the case of oral presentations) prior to submission for publication so as to provide such other Party with an opportunity to recommend any changes it reasonably believes are necessary to continue to maintain the Confidential Information disclosed by the other Party to the Publishing Party in accordance with the requirements of this Agreement. The incorporation of such recommended changes shall not be unreasonably refused; and if such other Party notifies ("**Publishing Notice**") the Publishing Party in writing, within [* * *] after receipt of the copy of the proposed publication or presentation (or at least [* * *] in the case of oral presentations), that such publication or presentation in its reasonable judgment; (i) contains an invention, solely or jointly conceived or reduced to practice by the other Party, for which the other Party reasonably desires to obtain patent protection, in which case the Publishing Party shall delay such publication for a mutually agreeable period of time not to exceed [* * *] from the date of the Publishing Notice; or (ii) contains Confidential Information of such other Party (other than the results of any Clinical Study conducted under this Agreement, if applicable), in which case, the Publishing Party shall, upon the other Party's request, remove from the publication such information. In the case of publications or presentations by Roche relating to a Roche Unilateral Study, Roche agrees to include authors from Regeneron in such publication or presentation.

(d) The obligations under Section 18.5(c) shall not apply to any publications or presentations by Regeneron or any of its Affiliates related to activities conducted with respect to the Compounds or Products prior to the Effective Date, and Regeneron shall provide Roche an advance copy of any such publications or presentations.

19. Term and Termination

19.1 Commencement and Term

This Agreement shall commence upon the Effective Date and continue for the Agreement Term (which, for clarity, includes any extension agreed by the Parties).

19.2 Termination

19.2.1 Termination for Breach

A Party ("**Non-Breaching Party**") shall have the right to terminate this Agreement in its entirety in the event the other Party ("**Breaching Party**") is in breach of any of its material obligations under this Agreement. The Non-Breaching Party shall provide written notice to the Breaching Party, which notice shall identify in reasonable detail the facts underlying or constituting the alleged breach. The Breaching Party shall have a period of [* * *] after such written notice is provided ("**Peremptory Notice Period**") to cure such breach. If the Breaching Party has a bona fide dispute as to whether such breach occurred or has been cured, it will so notify the Non-Breaching Party, and the expiration of the Peremptory Notice Period shall be tolled until such bona fide dispute is resolved pursuant to Section 21.2. Upon a determination of breach or failure to cure, the Breaching Party may have the remainder of the Peremptory Notice Period to cure such breach. If such breach is not cured within the Peremptory Notice Period, then absent withdrawal of the Non-Breaching Party's request for termination, this Agreement shall terminate in its entirety effective as of the expiration of the Peremptory Notice Period. A Party's failure to meet the Minimum Committed Regeneron Capacity or the Minimum Committed Roche Capacity, as the case may be, shall be considered a breach of a material obligation by such Party. Notwithstanding the foregoing, Regeneron's rights with respect to Roche's breach of its diligence obligations set forth in Section 6.2 or Section 7.3 shall be subject to Section 19.2.2(a) and Section 19.2.2(b).

19.2.2 Termination for Roche Diligence Breach or Failure to Commercialize

Notwithstanding any provision to the contrary set forth in this Agreement,

(a) Roche's breach of its regulatory diligence obligation set forth in Section 6.2 or its commercialization diligence obligations set forth in Section 7.3 with respect to a Roche Major Country will not give Regeneron the right to terminate this Agreement in its entirety and will give Regeneron the right to terminate this Agreement solely with respect to such Roche Major Country.

(b) Roche's breach of its regulatory diligence obligation set forth in Section 6.2 or its commercialization diligence obligations set forth in Section 7.3 with respect to the ROW, taken as a whole, will not give Regeneron the right to terminate this Agreement in its entirety and will give Regeneron the right to terminate this Agreement solely with respect to the ROW.

(c) If, after [* * *] following the First Commercial Sale of the Lead Product in any country in the EU or the United Kingdom, Roche is not commercializing any Product in a country in the Roche Territory, and upon Regeneron's written inquiry to the Roche Chair of the JOC, confirms in writing that it has no plans to commercialize any Product in such country, or

does not provide Regeneron within [* * *] after receiving such inquiry from Regeneron with a reasonable written plan to commercialize a Product in such country during the Agreement Term, and Regeneron in good faith plans to commercialize the Product in such country, then Regeneron shall have the right to terminate this Agreement solely with respect to such country immediately upon written notice to Roche.

The notice requirement and opportunity to dispute and cure a breach as set forth in the second through fifth sentences of Section 19.2.1 above shall apply to any termination pursuant to clauses (a) or (b) of this Section 19.2.2, provided that Regeneron's right to terminate will be limited as set forth in this Section.

19.2.3 Insolvency

A Party shall have the right to terminate this Agreement, if the other Party incurs an Insolvency Event; provided, however, in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if the Party that incurs the Insolvency Event consents to the involuntary bankruptcy or such proceeding is not dismissed within [* * *] after the filing thereof.

19.2.4 Termination by Roche for Technical Failure

If (i) both of the first two Ongoing Regeneron Studies listed in Appendix 1.73 are placed on clinical hold by the FDA or EMA that continues for thirty (30) days, unless Regeneron is undertaking reasonable actions to have either such clinical hold removed, in which case if such hold continues for ninety (90) days, (ii) the Lead Product has not received an Emergency Use Authorization prior to May 31, 2021, (iii) Regeneron has not filed for full Regulatory Approval of the Lead Product in the US prior to May 31, 2021, or (iv) Regeneron terminates further development of the Lead Product, then Roche shall have the right to terminate this Agreement in its entirety upon thirty (30) days' prior written notice, provided in each case, such notice of termination is delivered by Roche within thirty (30) days after the occurrence of the condition giving rise to the right of termination.

19.2.5 Termination by Roche due to [* * *] Third Party Product

If a Third Party Antibody product targeting SARS-CoV-2 in form of a single Antibody or a cocktail of at least two Antibodies is [* * *] the safety and efficacy profile of such Third Party Antibody product confers a substantial public health benefit over the Lead Product [* * *] (an "**Alternative Third Party Product**"), then Roche shall have the right to terminate this Agreement in its entirety upon (a) sixty (60) days prior written notice at any time if such notice is given prior the First Commercial Sale of the Lead Product in the Territory; or (b) six (6) months prior written notice at any time if such notice is given after First Commercial Sale of the Lead Product in the Territory; provided, that, with respect to the Chugai Asset as the Alternative Product, Roche shall not have the right to terminate this Agreement pursuant to this Section 19.2.5 unless Regeneron has notified Roche in writing that Regeneron will not exercise the Chugai Asset Option or Regeneron does not provide the Exercise Notice during the Exercise Period.

If the Parties cannot agree on whether the safety and efficacy profile of an Alternative Third Party Product confers a substantial public health benefit over the Lead Product in either treatment or prophylactic use, such matter shall be determined in accordance with Section 21.2, and if still not resolved, then decided by an Expert Committee pursuant to Section 21.4, and

Roche shall not have the right to terminate this Agreement pursuant to this Section 19.2.5 unless and until such Expert Committee determines that the safety and efficacy profile of such Alternative Third Party Product confers a substantial public health benefit over the Lead Product in either treatment or prophylactic use.

19.3 Consequences of Expiration or Termination

19.3.1 Transfer of Products

Upon the expiration or earlier termination for any reason of this Agreement, the rights and licenses granted by each Party to the other under this Agreement shall terminate in their entirety, on the effective date of expiration or termination, as applicable, subject to Regeneron's rights in Section 19.3.1(c).

Upon any termination or expiration of this Agreement, if Regeneron desires to continue development or commercialization of Product(s), Regeneron shall give a Continuation Election Notice to Roche within [* * *] of Regeneron's notice of termination (in the event of termination by Regeneron) or receipt of Roche's notice of termination (in the event of termination by Roche). If Roche receives such a timely Continuation Election Notice, and to the extent requested by Regeneron and consistent with ensuring a smooth and orderly transition to Regeneron or its designee, Roche shall perform the following activities (the "**Roche Transfer Activities**"):

(a) Roche shall assign and transfer to Regeneron or its designee all regulatory filings and approvals, regulatory communications, all final pre-clinical and Clinical Study reports and Clinical Study protocols, Product Trademarks and all data, including clinical data, in Roche's possession or control related to all Product(s). All data shall be transferred in the form and format in which it is maintained by Roche or otherwise reasonably requested by Regeneron. Original paper copies shall also be transferred. Roche shall not be required to prepare or finalize any new data, reports or information solely for purposes of transfer to Regeneron.

(b) Roche shall assign to Regeneron or its designee agreements between Roche or any of its Affiliates on the one hand, and any Third Party on the other hand (including such agreements with CROs, CMOs or distributors) to the extent relating to the Product(s), provided that, with respect to any such Third Party agreement entered into by Roche or any of its Affiliates prior to the Effective Date, to the extent that the assignment by Roche requires any notice to or consent of the relevant Third Party counterparty to such agreement, or requires the separation of such agreement into an agreement that is retained by Roche or any of its Affiliates and an agreement that is assignable to (or entered into by) Regeneron, as applicable, (i) Roche shall use reasonable efforts to give such notice, or (ii) the Parties will reasonably cooperate to (A) obtain such consent or (B) at the request and with the reasonable assistance of Roche, negotiate such separation, in each case ((i) and (ii)), as soon as practicable, provided that neither Roche nor any of its Affiliates shall agree to any material undertakings in connection therewith, and until such assignment is executed, the Parties will reasonably cooperate to provide Regeneron the benefits under such agreement to the extent applicable to the rights to be assigned to Regeneron, provided further that Regeneron will be responsible for all payments under such agreement to the extent applicable to the benefits provided to Regeneron with respect to the Product(s), and any payments required by such Third Party as pursuant to any such agreement to secure such consent.

(c) Roche shall grant and hereby grants (effective as of expiration or termination of this Agreement) to Regeneron a non-exclusive, worldwide, sublicenseable (through multiple tiers) license under the Roche Independent IP, Roche Patent Rights, Roche Know-How, and Roche's interest in the Joint Patent Rights and Joint Know-How, to the extent necessary or reasonably useful to allow Regeneron, its Affiliates or licensees to develop, manufacture, have manufactured, use, offer to sell, sell, promote, export and import the applicable Product(s) in the Territory, provided that, if Roche identifies in writing to Regeneron that any Roche Independent IP, Roche Patent Rights or Roche Know-How granted to Regeneron under this Section 19.3.1(c) is under a Third Party agreement between Roche or any of its Affiliates on the one hand, and any Third Party on the other hand, and if such Third Party agreement is not assigned to Regeneron pursuant to Section 19.3.1(b), then Regeneron shall be responsible for the payment obligations under such Third Party agreement to the extent related to any Product(s) sold on or after the expiration or termination of this Agreement; provided, that the Parties shall negotiate in good faith the financials terms for any such license under the Roche Independent IP, taking into account the value of such Roche Independent IP. If the Parties are unable to agree on such financial terms, such dispute shall be submitted for resolution by a Third Party expert jointly selected by the Parties.

(d) Roche shall, and shall cause its Affiliates and subcontractors to conduct such other actions as are reasonably necessary to ensure a smooth and orderly transition without interruption.

19.3.2 Other Obligations

19.3.2.1 Obligations Related to Ongoing Activities

If Regeneron does not provide a timely Continuation Election Notice to Roche then Roche (a) shall have the right to cancel such ongoing obligations, and (b) shall complete all non-cancellable obligations at its own expense.

Subject to the foregoing, from the date of notice of termination until the effective date of termination, Roche shall continue activities, including preparatory activities, ongoing as of the date of notice of termination, but shall not be obliged to initiate any new activities not ongoing at the date of notice of termination. With respect to any Clinical Study or other development activities with respect to the Product that Regeneron does not elect to assume, unless the continued conduct of such Clinical Study or other development activity is required by the applicable Regulatory Authority or Applicable Law or the termination of such Clinical Study or other development activity would be inconsistent with standards of ethical conduct of human clinical trials, Roche shall wind-down such activities in a smooth, orderly and efficient manner in compliance with Applicable Law and with due regard for patient safety and the rights of any subjects that are participants in any such Clinical Studies, and take any actions that is reasonably necessary or appropriate to avoid any human health or safety problems or that is otherwise required by Applicable Law.

After the end of the effective date of termination, Roche shall have no obligation to perform or complete any activities or to make any payments for performing or completing any activities under this Agreement, except for the Roche Transfer Activities or as otherwise expressly stated herein.

19.3.2.2 Obligations Related to Manufacturing

If a Product is marketed in any country in the Territory on the date either Party provides a notice of termination of this Agreement (other than a termination pursuant to Section 19.2.4), then upon the request of Regeneron, Roche shall manufacture and supply such Product to Regeneron at the then-current Minimum Committed Roche Capacity prior to expiration or termination for a period that shall not exceed [* * *] from the end of the Agreement Term at [* * *], then [* * *]; (b) if this Agreement is terminated by Roche pursuant to Section 19.2.1, then Roche shall not be obligated to supply Product to Regeneron under this Section 19.3.2.2. Without limiting Roche's obligation under Section 19.3.1, Regeneron shall use Commercially Reasonable Efforts to take over the manufacturing as soon as practicable after termination of this Agreement; and (c) if this Agreement is terminated by Roche for an Alternative Third Party Product pursuant to Section 19.2.5, and, during the [* * *] post-termination supply period, Roche enters into an agreement with the applicable Third Party with respect to such Alternative Third Party Product and, as a result, will have insufficient capacity to manufacture such Alternative Third Party Product and the Product at the Roche Manufacturing Facilities, then Roche may reduce its supply of the Product to Regeneron as needed to manufacture such Alternative Third Party Product upon [* * *] prior written notice (which notice may be delivered at any time concurrently with or after Roche executing the agreement with the applicable Third Party with respect to such Alternative Third Party Product). During the post-termination supply period, Roche shall cooperate with Regeneron to facilitate a smooth and orderly transition of manufacturing of the Product to Regeneron or its designee. Upon expiration of the post-termination supply period, Roche shall, upon Regeneron's request, sell to Regeneron all or any requested portion of its inventory, if any, of Drug Substance, Drug Product and Finished Product remaining after fulfillment of Regeneron's orders during the post-termination supply period at Roche's Fully Burdened Manufacturing Cost.

19.3.2.3 Ancillary Agreements

Except as otherwise provided in this Agreement (including pursuant to Section 19.3.2.2), the termination of this Agreement shall cause the automatic termination of all ancillary agreements related hereto, if any.

19.3.2.4 Limitations on Grant-Backs; Transfer Expenses

For purposes of clarity, irrespective of anything to the contrary in this Agreement:

(a) Roche shall transfer to Regeneron all PII/Samples promptly following expiration or termination of this Agreement subject to compliance with applicable contractual restrictions, patient consents and Applicable Law. Roche shall not be obligated to transfer an PII/Samples that Roche in good faith believes would be prohibited or would subject Roche to potential liability by reason of Applicable Law, contractual restrictions or insufficient patient consent. Upon completion of such transfers, Regeneron shall use the transferred PII/Samples for the sole purpose of developing, manufacturing and commercializing the Product(s), and Regeneron shall be responsible for the correct use of the PII/Samples in line with the informed consent forms (including but not limited to potential re-consenting of the patients at Regeneron's costs).

(b) The costs and expenses incurred in connection with the Roche Transfer Activities shall be shared by the Parties as follows:

(i) if this Agreement is terminated by Regeneron pursuant to Section 19.2.1, Section 19.2.3 (or, with respect to a Terminated Country, pursuant to Section 19.2.2(a) or Section 19.2.2(b)), Roche shall be responsible for its own costs and expenses incurred for the Roche Transfer Activities, and shall reimburse Regeneron for all reasonable out-of-pocket costs and expenses incurred by or on behalf of Regeneron for the Roche Transfer Activities;

(ii) if this Agreement is terminated by Roche pursuant to Section 19.2.1 or Section 19.2.3, Regeneron shall be responsible for its own costs and expenses incurred for the Roche Transfer Activities, and shall reimburse Roche for all reasonable out-of-pocket and internal costs and expenses incurred by or on behalf of Roche for the Roche Transfer Activities;

(iii) if this Agreement is terminated pursuant to Section 19.2.4 or Section 19.2.5 (or, with respect to a Terminated Country, pursuant to Section 19.2.2(c)), Regeneron shall be responsible for its own costs and expenses incurred for the Roche Transfer Activities and shall reimburse Roche for all reasonable out-of-pocket costs and expenses incurred by or on behalf of Roche for the Roche Transfer Activities;

provided further that transfer activities corresponding to the return of material remains, data, reports, records, documents, regulatory filings and Regulatory Approvals originally provided by Regeneron to Roche no less than three (3) years from the effective date of termination or expiration shall be returned to Regeneron free of charge.

(c) Unless otherwise agreed to by the Parties, transfer of physical materials that are required under Roche Transfer Activities shall be delivered, at Roche's option, FCA international courier near location where materials stored at time of transfer (Incoterms 2010) or CPT Regeneron or Regeneron's designee (Incoterms 2010).

19.3.2.5 Payment Obligations

Termination of this Agreement by a Party, for any reason, shall not release either Party from any obligation to make any payments that are payable prior to the effective date of termination.

19.3.2.6 Return or Destruction of Confidential Information

Except as expressly permitted under this Agreement, including, with respect to Regeneron, for purposes of continuing development, manufacture and commercialization of the Product(s), following expiration or earlier termination of this Agreement and upon the written request from either Party, each Party shall promptly return to the other Party (or destroy) all Confidential Information of the other Party, including any copies thereof (except one (1) copy of such Confidential Information, which may be retained for archival purposes, solely to ensure compliance with the terms of this Agreement).

19.3.3 Termination with respect to a country.

If this Agreement is terminated by Regeneron with respect to a particular country, but not in its entirety, pursuant to Section 19.2.2 (each, a "**Terminated Country**"), then (a) the Terminated Country shall be excluded from the Roche Territory for purposes of this Agreement from and after the effective date of such termination, and Regeneron shall have the sole right, but not the obligation, to import, export, sell, offer to sell or otherwise commercialize or explore any Compound or Product in the Terminated Country, at its sole cost and expense, and any and all profits for any Compound or Product sold in the Terminated Country shall be retained by Regeneron and shall not be subject to the Global Gross Profits sharing under this Agreement; (b) the licenses granted by Regeneron to Roche under Section 2.1(iii) and Section 2.1(iv) shall terminate with respect to the Terminated Country; and (c) Section 19.3.1 and Section 19.3.2 (other than Section 19.3.2.2) shall apply *mutatis mutandis* with respect to such Terminated Country; provided that, (i) unless otherwise agreed by the Parties, removal of a Terminated Country from the Roche Territory shall not reduce the Minimum Committed Roche Capacity or increase the Minimum Committed Regeneron Capacity, (ii) Regeneron, any of its Affiliates or Sublicensees, shall have the right to sell in a Terminated Country any Product supplied by Roche, and, (iii) notwithstanding Section 19.3.1(c), with respect to any Product sold by Regeneron, any of its Affiliates or Sublicensees in a Terminated Country for which the Drug Substance is manufactured by Roche, Regeneron shall pay to Roche plus a five percent (5%) royalty on the Net Sales of such Product.

19.4 Survival

Article 1 (Definitions, to the extent necessary to interpret this Agreement), Section 4.3.1 3rd paragraph (Regeneron Cell Bank), Section 4.3.2 (Regeneron Cell Media) (second and third paragraphs), Section 4.3.3 other than the second sentence of subsection (a) thereof (Ownership and Restrictions), Section 15.4 (No Other Representations and Warranties), Section 19.3 (Consequences of Termination), Section 19.4 (Survival), Articles 10, 11 and 13 (Payment, Accounting and Reporting, and Auditing, each to the extent payment obligations exist at the time of termination), Article 12 (Taxes, to the extent such were incurred at the time of termination), Section 14.1 (Ownership of Intellectual Property); Article 16 (Indemnification), Article 17 (Liability), Article 18 other than Section 18.5 (Obligation Not to Disclose Confidential Information); Article 20 (Bankruptcy) and Article 21 other than Section 21.4 (Miscellaneous) shall survive any expiration or termination of this Agreement for any reason.

20. Bankruptcy

The Parties intend to take advantage of the protections of Section 365(n) (or any successor provision) of the U.S. Bankruptcy Code (the "**Bankruptcy Code**") to the maximum extent permitted by Applicable Law. All rights and licenses granted under or pursuant to this Agreement, but only to the extent they constitute licenses of a right to "intellectual property" as defined in Section 101 of the Bankruptcy Code shall be deemed to be "intellectual property" for the purposes of Section 365(n). The Parties shall retain and may fully exercise all of their rights and elections under the Bankruptcy Code, including the right to obtain the intellectual property from another entity.

21. Miscellaneous

21.1 Governing Law; Jurisdiction

This Agreement shall be governed by and construed in accordance with the laws of the State of New York, United States, without reference to its conflict of law principles that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

Each Party (a) irrevocably submits to the exclusive jurisdiction of (i) the state courts of the State of New York in Manhattan, New York, and (ii) the United States District Court for the Southern District of New York, for the purposes of any suit, action, or other proceeding arising out of or relating to this Agreement or out of any transaction contemplated hereby, (b) waives any objections to such jurisdiction and venue and (c) agrees not to commence any suit, action or other proceeding arising out of or relating to this Agreement except in such courts.

Notwithstanding anything to the contrary in this Agreement, issues regarding the scope, construction, validity or enforceability of any Patent Rights shall be determined in a court of competent jurisdiction under the local patent laws of the jurisdictions that issued the Patent Rights in question.

21.2 Disputes

Unless otherwise set forth in this Agreement, in the event of any dispute in connection with this Agreement, such dispute shall be referred to the respective executive officers of the Parties designated below (the "**Executive Officers**") or their designees, for good faith negotiations attempting to resolve the dispute for a period of [* * *]. Such Executive Officers are as follows:

For Regeneron: [* * *]

For Roche: [* * *]

21.3 Equitable Relief

The Parties hereby acknowledge and agree that the restrictions on the Parties under Article 9 and Article 18 are special, unique and of extraordinary character, that the Parties would not have entered into this Agreement absent the restrictions set forth in Article 9 and Article 18, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of Article 9 or Article 18, such refusal or failure may result in irreparable injury to the other Party, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if either Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of Article 9 or Article 18, then, in addition to any other remedy that may be available to the other Party at law or in equity, such other Party will be entitled to seek specific performance and injunctive relief. Nothing in this Section 21.3 or elsewhere in this Agreement is intended or should be construed to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

21.4 Expert Committee

If, after escalation to the Executive Officers in accordance with Section 21.2, the Parties are unable to agree on whether (a) the safety and efficacy profile of an Alternative Third Party Product confers a substantial public health benefit over the Lead Product in either treatment or prophylactic use settings, (b) whether or not the Chugai Asset Data Package satisfies the Chugai Asset Data Package Criteria, (c) if the Chugai Asset Data Package satisfies the Chugai Asset Data Package Criteria, then whether or not the Chugai Asset satisfies the Chugai Asset Criteria, (d) whether or not an Additional Compound Data Package satisfies the Additional Compound Data Package Criteria, or (e) whether or not an Additional Compound or a Back-Up Compound, as applicable, satisfies the Additional Compound Criteria (each of (a) - (e), an "**Expert Matter**"), then any such Expert Matter shall be decided by the following procedure. Roche will select one (1) individual who would qualify as an Expert, Regeneron will select (1) individual who would qualify as an Expert, and those two (2) individuals shall select one (1) individual who would qualify as an Expert and who shall be chairperson of a committee of the three Experts (the "**Expert Committee**"), each Expert with a single deciding vote. The Parties shall use good faith efforts to form the Expert Committee within [* * *] after expiration of the Executive Officers' negotiation period. The Expert Committee will promptly (but no more than [* * *] after the appointment of the third (3rd) Expert) hold a meeting to review the issue under review and will provide the Parties with at least [* * *] notice of such meeting. At such meeting, the Expert Committee will consider memoranda submitted by each Party at least [* * *] before the meeting, as well as reasonable presentations that each Party may present at the meeting. The Expert Committee may order the Parties to produce any additional documents or information that are relevant to the Expert Committee decision. The agreement of two (2) of the three (3) Experts on the Expert Committee shall be sufficient to render a decision. The Parties shall use diligent efforts to cause the completion of any such dispute resolution within [* * *] following expiration of the Executive Officers' negotiation period. The determination of the Expert Committee as to the issue under review will be binding on both Parties. The Parties will share equally in the costs of the Expert Committee. Unless otherwise agreed to by the Parties, the Expert Committee may not decide any issues other than the applicable Expert Matter.

21.5 Assignment

Except as otherwise expressly provided herein, neither Party shall have the right to assign this Agreement or any part hereof or any of the rights or obligations hereunder without the prior written approval of the other Party except (a) in whole or in part to an Affiliate of the assigning Party, or (b) in whole to any Third Party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise; *provided* that the assigning Party shall remain primarily liable hereunder with respect to any assignment under this clause (b) with respect to obligations and liabilities relating to the period prior to such assignment, and in each case ((a) and (b)), so long as such Affiliate or Third Party agrees in writing to be bound by the terms of this Agreement. Notwithstanding the foregoing, Roche Basel shall not assign its rights under this Agreement or any part thereof to any US Person without the prior written consent of Regeneron. Any attempted assignment in violation hereof shall be void. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

21.6 Affiliates

Each Party may perform its obligations under this Agreement through one or more of its Affiliates. Each Party absolutely, unconditionally and irrevocably guarantees to the other Party the prompt and timely performance of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Without limiting the foregoing, no Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly.

21.7 Independent Contractor

No employee or representative of either Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever or to create or impose any contractual or other liability on the other Party without said Party's prior written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, the Parties' legal relationship under this Agreement shall be that of independent contractors, and nothing contained in this Agreement shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between the Parties or any of their respective Affiliates. Nothing contained in this Agreement shall be deemed or construed by the Parties, any of their Affiliates, or any third party to treat the relationship between the Parties contemplated by this Agreement as a partnership, joint venture or other business entity under US federal, state, local, or non-US tax law, and the Parties shall not take any position, on a tax return or otherwise, inconsistent therewith. Each Party shall bear its own costs and expenses incurred in the performance of its obligations hereunder without charge or expense to the other Party except as expressly provided for in this Agreement.

21.8 Unenforceable Provisions and Severability

If any of the provisions of this Agreement are held to be invalid, illegal or unenforceable at law or in equity, then such invalid, illegal or unenforceable provisions shall be enforced to the maximum extent permitted under Applicable Law, and the Parties shall consult and use all reasonable efforts to agree upon, and hereby agree and consent to, replacement legal, valid and enforceable provisions that will achieve as far as possible the intentions of the Parties (including the economic benefits and rights contemplated herein) while avoiding any unjust enrichment of either Party. However, the remainder of this Agreement will remain in full force and effect, provided that the material interests of the Parties are not affected, i.e. the Parties would presumably have concluded this Agreement without the unenforceable provisions.

21.9 Force Majeure

Except for payment obligations, each Party shall be excused from any failure or delay in performance required hereunder (and any liability or responsibility for such failure or delay) to the extent such failure or delay is caused by or results from any catastrophes or other major events beyond its reasonable control, including, embargoes, acts of terrorism, civil commotions, acts of God, disease, pandemics, lockouts or other labor disturbances, war, riot, and insurrection; laws, proclamations, edicts, ordinances, or regulations; strikes, lockouts, or other serious labor disputes; and floods, fires, explosions, or other natural disasters. When such events have abated, such Party's obligations hereunder will resume. The affected Party will notify the other Party of such force majeure circumstances as soon as reasonably practical and

will use commercially reasonable efforts to mitigate the effects of such force majeure circumstances.

21.10 Waiver

The failure by either Party to require strict performance or observance of any obligation, term, provision or condition under this Agreement will neither constitute a waiver thereof nor affect in any way the right of the respective Party to require such performance or observance. The waiver by either Party of a breach of any obligation, term, provision or condition hereunder shall not constitute a waiver of any subsequent breach thereof or of any other obligation, term, provision or condition. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

21.11 Interpretation

Except where the context expressly requires otherwise:

(a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa),

(b) the words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”,

(c) the word “will” shall be construed to have the same meaning and effect as the word “shall”,

(d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein),

(e) any reference herein to any Party or Third Party or person shall be construed to include the Party’s or Third Party’s or person’s permitted successors and assigns,

(f) any reference herein to a number of “days” shall be construed to refer to calendar days,

(g) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof,

(h) all references herein to Articles, Sections or Appendices shall be construed to refer to Articles, Sections or Appendices of this Agreement, and references to this Agreement include all Appendices hereto,

(i) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof,

(j) the term “or” shall be interpreted in the inclusive sense commonly associated with the term “and/or”, and

(k) references to a decision that must be agreed by the Parties, such agreement must be evidenced in writing between the Parties, irrespective of whether the applicable provisions provides for such agreement to be in writing throughout this Agreement.

21.12 Entire Understanding

This Agreement (including all Appendices attached hereto), together with the Supply Agreement, and the Safety Data Exchange Agreement, constitute the entire understanding between the Parties with respect to the subject matter hereof and supersedes any and all prior agreements, understandings and arrangements, whether written or oral, other than the Technology Transfer Agreement.

21.13 Amendments

No amendments of the terms and conditions of this Agreement shall be binding upon either Party unless in writing and signed by both Parties.

21.14 Invoices

All invoices that are required or permitted hereunder shall be in writing and sent by the invoicing Party to the other Party at the following address or such other address as such other Party may later provide; provided that, with respect to Regeneron, all invoices to be submitted hereunder shall only be submitted in PDF format via email to the invoice email addresses indicated below and Roche may similarly request that invoices be submitted in PDF format via email and provide an email address for such submissions:

Roche:
[* * *]

Regeneron:

[* * *]

21.15 Notice

All notices that are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as set forth below. Any such notice shall be deemed to have been delivered (a) upon receipt if delivered by hand, (b) upon confirmation of transmission if transmitted by facsimile, (c) one (1) Business Day after it is sent via a nationally recognized overnight courier service or (d) upon receipt of proof of delivery if sent by registered or certified mail, postage prepaid, return receipt requested. Either Party

may change its address by giving notice to the other Party in the manner provided above. This Section 21.15 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

if to Regeneron, to: [* * *]

if to Roche, to: [* * *]

21.16 Counterparts

This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. This Agreement may be executed by exchange between the Parties of electronically transmitted signatures (via facsimile, PDF format via e-mail or other electronic means) and such signatures shall be deemed to bind each Party as if they were original signatures.

21.17 Third Party Beneficiaries

Except as provided below in this Section 21.17, none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of either Party. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party. Notwithstanding the foregoing, Article 16 is intended to benefit, in addition to the Parties, the other Regeneron Indemnitees and Roche Indemnitees as if they were parties hereto, but this Agreement is only enforceable by the Parties.

21.18 Further Assurances

Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure such other Party its rights and remedies under this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Effective Date.

Regeneron Pharmaceuticals, Inc.

_/s/ Nouhad Husseini_____

Name: Nouhad Husseini

Title: SVP, Business Development

F. Hoffmann-La Roche Ltd

__/s/ James Sabry_____

Name: James Sabry

Title: SVP, Head of Partnering

__/s/ F. Bächler_____

Name: Dr. Franziska Bächler

Title: Attorney-at-Law

Genentech, Inc.

__/s/ Edward Harrington_____

Name: Edward Harrington

Title: CFO Genentech

SIGNATURE PAGE TO THE LICENSE AGREEMENT

Appendix 1.20(a)

Additional Regeneron Studies

[* * *]

Appendix 1.20(b)

Other Agreed Co-Funded Studies

[* * *]

Appendix 1.66

Lead Compound

[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]		
	[* * *]	[* * *]	[* * *]
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	[* * *]	[* * *]	[* * *]

Appendix 1.73

Ongoing Regeneron Studies

[* * *]

Appendix 1.106

Product Contribution Alternative Principles

“Roche Quarterly Distribution” shall mean, with respect to a Presentation and a [* * *].

With respect to each Presentation, the number of units of the Roche Quarterly Distribution for which the Drug Substance was manufactured by the Roche Group for inclusion in the numerator of the Roche Production Contribution shall be determined based on the following principles:

(a) With respect to the portion of the Roche Quarterly Distribution for a Presentation for a Calendar Quarter that is less than or equal to Roche’s [* * *].

(b) [* * *].

(c) [* * *].

An example of the application of such principles is attached as Exhibit A.

Exhibit A

[* * *]

Appendix 1.90
Regeneron Base Patent Rights

[* * *]

Appendix 1.104

Roche Manufacturing Facilities

[* * *]

Appendix 9.2

[* * *]

Exhibit 31.1

**Certification of Principal Executive Officer Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2020

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Robert E. Landry, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2020

/s/ Robert E. Landry
Robert E. Landry
Executive Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Principal Executive Officer of the Company, and Robert E. Landry, as Principal Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)
November 5, 2020

/s/ Robert E. Landry
Robert E. Landry
Executive Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)
November 5, 2020

Attachment: XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT

Attachment: XBRL TAXONOMY EXTENSION CALCULATION LINKBASE DOCUMENT

Attachment: XBRL TAXONOMY EXTENSION DEFINITION LINKBASE DOCUMENT

Attachment: XBRL TAXONOMY EXTENSION LABEL LINKBASE DOCUMENT

Attachment: XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE DOCUMENT