Execution Version

#### GLOBAL ACCESS COMMITMENTS AGREEMENT

**GRANT AGREEMENT OPP1127647** 

This Global Access Commitments Agreement (including all appendices, exhibits and attachments hereto, this "GACA"), is entered into as of date of last signature below ("Effective Date") by and between the Bill and Melinda Gates Foundation, a Washington Charitable Trust (the "Foundation") and Novavax, Inc., a Delaware corporation based in Maryland ("Novavax" or the "Company") in connection with the Foundation making a charitable grant of up to eighty nine million, eighty three thousand three hundred twelve U.S. dollars (\$89,083,312.00) to Company (the "Grant") and is subject to the terms and conditions of the Grant Agreement and related documents, including but not limited to this GACA. Each of the parties named above may be referred to herein as a "Party" and collectively as the "Parties". Capitalized terms not defined herein shall have the same meaning as in the Grant Agreement. In consideration of the Foundation making the grant on the terms and conditions in the Grant Agreement and herein, and for other good and valuable consideration, the undersigned hereby irrevocably agree as follows:

## 1. Charitable Purpose and Use of Funds

The Foundation's primary purpose in making the Grant to Company is to further significantly the accomplishment of the Foundation's charitable purposes, including its support of the research and development of drugs, vaccines and diagnostics to address diseases that have a disproportionate impact on people within developing countries. More specifically, the purpose of the Grant is to support development (including the Phase 3 Clinical Trial) of an affordably-priced RSV vaccine for use in maternal immunization to provide RSV protection to infants in Developing Countries and other low income countries including as reflected herein and in Company's proposal submitted to the Foundation together with other documentation provided to or made available to the Foundation prior to or after submission of the grant proposal and documents related to the Project (as defined in the Grant Agreement).

Company understands and acknowledges that a primary organizational objective of the Foundation is to support development of an affordably-priced RSV vaccine for use in maternal immunization to provide RSV protection to infants in Developing Countries and as otherwise agreed in this GACA further defines the specific Global Access commitments of Company.

# 2. <u>Definitions</u>

The following terms shall have the following meanings:

- (a) "Affiliate" means, as to any Person, any other Person that directly or indirectly controls, or is under common control with or is controlled by such Person.
  - (b) "Aggregate Minimum Supply" means [\*\*] Doses.
  - (c) "Annual Minimum Supply" has the meaning set forth in Section 3(d)(iii).

- [\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.
- (d) "Change in Control" means (i) the acquisition after the date of this GACA, directly or indirectly, by any Person or group (within the meaning of Section 13(d)(3) of the Exchange Act) of the beneficial ownership of securities of Company possessing more than 50% of the total combined voting power of all outstanding voting securities of Company; (ii) a merger, consolidation or other similar transaction involving Company, except for a transaction in which the holders of the outstanding voting securities of Company immediately prior to such merger, consolidation or other transaction hold, in the aggregate, securities possessing more than 50% of the total combined voting power of all outstanding voting securities of the surviving entity immediately after such merger, consolidation or other transaction; or (iii) the sale, transfer or other disposition (in one transaction or a series of related transactions) of all or substantially all of the assets of Company.
  - (e) "Charitability Default" has the meaning set forth in Section 6(a).
  - **(f)** "Charitable Purpose" has the meaning set forth in the Grant Agreement.
  - (g) "Cure Period" has the meaning set forth in Section 6.
  - (h) "cGMPs" means the then-current standards for good manufacturing practices as promulgated under applicable laws, including the standards of good manufacturing practices in the United States, as promulgated under 21 CFR Parts 210 and 211 as issued by the United States Food and Drug Administration ("FDA"), and all applicable regulations promulgated by a relevant foreign regulatory agency akin to the FDA.
    - (i) "Developed Countries" means the countries (each a "Developed Country") that are not listed in Appendix A.
- (j) "Developing Countries" means the countries (each a "Developing Country") listed on Appendix A as Developing Countries.
- (k) "Dose" (or "Doses" as applicable) means the amount of Released Product required for single administration of vaccine regardless of where such Released Product is filled, finished, packaged and/or labeled including at one or more different sites by the Company (or by any contract manufacturing organization (CMO) of Company).
  - (I) "Exchange Act" means the U.S. Securities Exchange Act of 1934, as amended.
  - (m) "Extended Term" has the meaning in Section 3(d)(v).
  - (n) "Global Access Commitments" has the meaning set forth in Section 3.
  - (0) "Global Access License" has the meaning set forth in Section 6.

- [\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request.

  An unredacted version of this exhibit has been filed separately with the Commission.
- **(p)** "**Grant Agreement**" means the Grant Agreement between Company and the Foundation of even date herewith, to which this GACA is an Appendix.
- (q) "IPDP" means Integrated Product Development Plan dated as of May 29, 2015 and referenced in the Grant Agreement or as otherwise updated and mutually agreed by the parties.
- **(r)** "**Maternal Immunization**" means a use for the Product for immunization of pregnant women to prevent severe RSV disease in newborns and infants pursuant to the Minimum TPP.
  - (s) "Minimum TPP" means the minimum target product profile described in Appendix B.
- **(t)** "**Person**" means any individual, partnership, corporation, limited liability company, association, trust, joint venture, unincorporated organization or other entity.
- (u) "Phase 3 Clinical Trial" means the Phase 3 clinical trial described in the IPDP conducted on a global basis to demonstrate efficacy of the Product for Maternal Immunization.
  - (v) "Price Commitment" has the meaning set forth in Section 3(c).
- (w) "Product" means the Respiratory Syncytial Virus (RSV) fusion (F) recombinant nanoparticle vaccine (including but not limited to candidate # BV683 or any subsequent modification or alternative version thereof) regardless of whether such vaccine is presented with or without Aluminum (or other adjuvant) and regardless of the dose of Aluminum (or adjuvant) used. Unless otherwise specified reference to the term "Product" shall include "Released Product" as defined below.
  - (x) "Public Sector Purchaser" means procurement agent of any of the following entities:

Gavi, the Vaccine Alliance ("Gavi");

The United Nations Children's Fund ("UNICEF");

The World Health Organization ("WHO");

Any other United Nations agency;

Governments in Developing Countries, including government ministries and agencies, together with government-funded institutions, such as hospitals, clinics and prison services;

NGOs including those recognized by the applicable local government ministry and UN-related organizations working for or in Developing Countries, including International Organization for Migration (IOM);

Not-for-profit organizations including but not limited to Médecins Sans Frontières, Save-the- Children, PATH, OXFAM and the International Committee of the Red Cross (ICRC);

Funding and/or procurement mechanisms including GDF, UNITAID, UNFPA, PEPFAR, USAID, DFID, Global Fund, etc. and agencies based outside of a Developing Country but who are supporting implementation and/or procurement to a Developing Country; and

Any global health finance mechanism existing or arising during the Term or Extended Term that are applicable to one or more Developing Countries.

- [\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.
- **(y)** "Released Product" means Product that has met the Specifications set by Novavax and agreed upon by the relevant regulatory agency with appropriate jurisdiction, ensuring the Product has been manufactured, filled, finished, labeled & packed and is appropriate for distribution and/or sale and administration to a human.
- (z) "Specifications" means a list of tests, references to analytical procedures, and appropriate acceptance criteria which are numerical limits, ranges, or other criteria for the tests described that set criteria to which Product at other stages of its manufacture should conform to be considered acceptable for its intended use.
  - (aa) "Term" has the meaning in Section 4.
- **(bb)** "Total Product Manufacturing Capacity" means the total Doses the Company manufactures on an annual basis for any RSV product, either directly or through its CMO or Affiliates. The Company will forecast its manufacturing capacity on a rolling quarterly basis, which forecast will be subsequently trued-up quarterly based on the Total Product Manufacturing Capacity.
  - (cc) "Transfer" has the meaning in Section 5.
  - (dd) "Undemanded Capacity" has the meaning in Section 3(d)(v).
- (ee) "[\*\*] Costs" means the costs incurred that are necessary to complete production of Product [\*\*] and are deemed to include [\*\*]. For the avoidance of doubt, [\*\*]Costs will not include [\*\*].
  - **(ff)** "Volume Commitment" shall have the meaning described in Section 3(d).
  - (gg) "WHOPQ" means WHO prequalification of medicines.

#### 3. Global Access Commitments

In furtherance of the Charitable Purpose, Company agrees to the following "Global Access Commitments":

- (a) Prompt and Broad Dissemination of Knowledge and Information. Consistent with the Publication provisions of the Grant Agreement, Company will use reasonable and diligent steps to
- (i) publish (in a customary and reasonable manner as Company sees fit) information related to the Phase 3 Clinical Trial under the Project, which shall include:

- (A) prospective registration of clinical trials on a WHO compliant clinical trial registry (e.g., <a href="https://www.who.int/ictrp">www.who.int/ictrp</a>), with final clinical trial results publicized within 12 months from the completion date of the trial in accordance with WHO reporting guidelines/recommendations;
- (B) publication of status of each clinical trial conducted under the Project on clintrials.gov within the earlier of 12 months of completion of each such clinical trial or the date imposed or specified by applicable law; and
- (C) publication of final results of each clinical trial under the Project in one or more applicable peer reviewed open access journals within 12 months from the last subject last visit time point of any such clinical trial, consistent with the provisions in the Grant Agreement. In the event of an inability to obtain peer reviewed publication, Company agrees to publish in manner that the Foundation determines in its reasonable discretion satisfies the requirement that such research be published in a form that is "available to the interested public" as described in Treasury Regulation 1.501(c)(3)- 1(d)(5)(iii)(c)(2) (the "Publication Requirement").
- (ii) provide to the Foundation (or as applicable in section 3(a)ii)(C), to a technology transfer recipient) with access to information as follows:
- (A) in connection with any stage-gate review under the Grant or related to the Project, access to de-identified data and information regarding the Project including anticipated Product approval timelines;
- (B) upon the Foundation's reasonable request (no more frequently than quarterly), access to deidentified data and information regarding the Project including anticipated Product approval timelines; and
- (C) provide the information and documentation as contemplated in the Technology Transfer provisions set forth in Section 6(d).
- (b) Availability and Accessibility at Affordable Price to People in Developing Countries. Company will use reasonable and diligent steps to:
- (i) conduct all clinical trials specified in the IPDP to meet the Minimum TPP and keep the Foundation promptly informed of any information impacting the Product's ability to meet the Minimum TPP thereunder or that is otherwise deemed to impact the Project or timelines by three (3) months or more;
- (ii) obtain and maintain the regulatory and Project expertise to support Company's clinical, regulatory and development plans including with respect to Developing Country plans and WHOPQ;
- (iii) conduct activities set forth in the IPDP; meet specified timelines and criteria included in the IPDP; and keep the Foundation promptly informed of any information impacting Company's ability to meet such timelines or criteria by three (3) months or more;
- (iv) consider utilizing WHO's joint regulatory review mechanism for clinical trial approvals in Developing Countries provided always that all regulatory activity decisions will be Company's sole responsibility;
- (v) submit an applicable dossier to WHO for WHOPQ of the Product for Maternal Immunization in Developing Countries by [\*\*];
- (vi) develop Total Product Manufacturing Capacity to a minimum of [\*\*] Doses of the Released Product by [\*\*];

- [\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.
- (vii) keep the Foundation promptly informed of the activities related to progress on the Project (including providing the Foundation with information reasonably requested by the Foundation related to the Product, trials and deliberations of review committees) and Company's Global Access Commitments and consult with the Foundation in good faith in connection with Developing Country launch strategic decisions, including by holding meetings with the Foundation no less often than once every three (3) months;
- (viii) consider in good faith requests for donation of Released Product for Maternal Immunization by global health entities for demonstration studies/trials or additional research studies/trials supporting regulatory approval and/or demand stimulation in Developing Countries, provided however that Company's provision of Released Product for such purposes shall not be deemed a first sale hereunder;
- (ix) promptly, upon WHOPQ or any applicable regulatory approval for distribution of Released Products in a Developing Country for Maternal Immunization, provide reasonable publicity of the availability of the Product for sale for Maternal Immunization in each applicable Developing Country including to Public Sector Purchasers (regardless of the location of such Public Sector Purchaser, provided the Released Product procured is intended for use in or distribution to the applicable Developing Country) and responding to tender offers applicable to the Released Product for Maternal Immunization, subject to the Price Commitment outlined in Section 3(c) below;
- (x) promptly upon WHOPQ, seek local Developing Country registration, to the extent such Developing Country participates, for Released Product for Maternal Immunization through the WHO Collaborative Registration Procedure (CRP); and
- (xi) provide the Product to applicable Public Sector Purchasers for Maternal Immunization in accordance with this GACA and any applicable laws and regulations.
- (xii) pursue applicable regulatory approval of Released Product for Maternal Immunization in those countries listed on Appendix A as "Additional Countries" after WHOPQ, and, upon such approval, commit to make such Released Product available to Public Sector Purchasers in such countries at a price per dose to be negotiated in good faith by the parties.

#### (c) Price Commitment.

(i) Upon WHOPQ, and in compliance with applicable laws and regulations, Company will offer and provide to Public Sector Purchasers the Aggregate Minimum Supply at the Annual Minimum Supply (as set forth in section 3(d)) of the Released Product for Maternal Immunization in the Developing Countries at a maximum price as reflected in Table A:

## TABLE A

"Price Commitment" is equal to the [\*\*] Costs (as adjusted from time to time under this section 3(c)) plus[\*\*] mark-up but provided always that such price does not exceed:

[\*\*] per Dose (USD) herein after the "[\*\*]"

The Parties acknowledge and agree that (1) the [\*\*] described in Table A above is based on principle assumptions about Novavax future manufacturing efficiencies at the time of WHOPQ as set forth on Appendix C attached hereto and incorporated by reference herein, and (2) to the extent that actual results differ from such Appendix C principal assumptions, then the Parties shall take such factors causing differing results into account and will thereafter adjust such [\*\*] pursuant to Section 3(c)(ii).

- Notwithstanding Table A, within three (3) months prior to the estimated date for WHOPQ, and unless (ii) otherwise agreed by the Parties, at every third anniversary thereafter, coinciding with UNICEF tenders, the Parties shall, in good faith, discuss applicable adjustments to the Price Commitment (whether upwards or downwards) to proportionately, fairly, and reasonably reflect the factors set forth in Appendix C, including the impact on such factors caused by external or internal circumstances, including inflation, currency fluctuations, efficiencies of scale, product demand and yield improvements. In preparation for considering any such price adjustment, in the event that there are changes in [\*\*] Costs that, in the aggregate exceed [\*\*] since the last calculation, then Company shall provide to the Foundation an update to its [\*\*] Costs consistent with Appendix C and the Foundation's COGS Principles and Assessment Methodology Handbook, at least sixty (60) days in advance of such third anniversary and the Parties shall meet in good faith to discuss such changes within sixty (60) days after Company provides the Foundation with such update. In the event of any conflict between Appendix C of this GACA and the Foundation's COGS Principles and Assessment Methodology Handbook, Appendix C of this GACA shall control. Upon agreement of the Parties to any price adjustment (which shall be reflected in a signed writing by the parties), the applicable price adjustments shall become effective within three (3) months after such written agreement or in time for the coinciding UNICEF tender, whichever is earlier. In the event that the Parties are unable to agree on a revised Price Commitment, an independent third-party, with specific expertise in assessing costs, [\*\*], and with experience with vaccines, reasonably acceptable to both Parties, shall be appointed to provide analysis of such potential adjustment upon the request of either Party and the cost of such analysis shall be shared equally by the Parties. That analysis will be shared with Company and the Foundation who will work together to resolve any adjustments to the Price Commitment. If there is no resolution within forty-five (45) days, the matter will be referred to Company's President/CEO and the Foundation's President of Global Health (or the equivalent in the event of any reorganization following which such position no longer exists). If these individuals are unable to resolve the matter of the revised Price Commitment based on this analysis within a further forty-five (45) days, then the price will be adjusted upwards in event that the third party analysis points to an upward adjustment or downwards if the third party analysis points to a downward adjustment, in each case, capped as follows: if the parties are unable to agree with respect to the first adjustment of the [\*\*], then the adjustment shall be [\*\*], as the case may be (based on the direction of the third party analysis) and if the parties are unable to agree as to any subsequent adjustments to the [\*\*], then the adjustment shall be [\*\*] as the case may be (based on the direction of the third party analysis).
- (iii) Upon the written request of the Foundation and not more than once in each calendar year, Company will permit an independent third party accounting firm, with specific expertise in assessing costs [\*\*] and with experience with vaccines selected by the Foundation and reasonably acceptable to Company, at Foundation's expense, to have access during normal business hours to such of the records of Company as may be reasonably necessary for any year ending not more than three (3) years prior to the date of such request for the sole purpose of verifying the basis and accuracy of [\*\*] Cost consistent with Appendix C and the Foundation's COGS Principles and Assessment Methodology Handbook, for determining [\*\*] Cost. Such third party accounting firm shall provide any such report to both the Foundation and Company and if such third party accounting firm identifies a discrepancy in [\*\*] Cost made during such period, appropriate adjustments will be determined within ninety (90) days of the date such accounting firm's written report is delivered to both Parties.

- (iv) Multi Dose Vial Options: Notwithstanding the foregoing, if the Parties agree that to the extent the Company switches to a multi-dose presentation of the Product that meets WHOPQ requirements and satisfies the Company's Global Access Commitments, the Price Commitment shall be appropriately reviewed and may be adjusted by mutual written agreement of the Parties, consistent with the process described in Section 3(c)(ii) above.
- (v) Notwithstanding section 3(c)(i) above, in the event that Company sells Released Product for Maternal Immunization to a Public Sector Purchaser in any country (whether a Developing Country or a Developed County) at a lower than the Price Commitment in subsection 3(c)(i) above, Company will promptly offer such Released Product for sale at such lower price to any Developing Countries in which the sale, use or marketing of Released Product is authorized by WHOPQ or applicable country registrations. Company will promptly notify the Foundation of any price decrease of the Released Product for Maternal Immunization.

#### (d) Volume Commitment.

- (i) In order to provide the greatest health benefit of the Product, Company desires to address worldwide need for the Product including demand for its use in Maternal Immunization from Developed and Developing Countries. The Parties recognize that introduction and demand for the Product occurs over a period of time and that Company may not be fully able to address such demand in the period proximate to introduction and approval. Notwithstanding the foregoing, the Parties acknowledge that Company's current and planned Total Product Manufacturing Capacity may not be sufficient to meet worldwide demand. Accordingly, the Parties desire to define the allocation of Product that Company intends to reserve to fulfill orders for use in Maternal Immunization in Developing Countries.
- (ii) Upon applicable regulatory approval(s), the Company shall make the Released Product, available and accessible to Public Sector Purchasers for Maternal Immunization on the terms set forth in this GACA.
- (iii) Company shall ensure Aggregate Minimum Supply is met subject to the Annual Minimum Supply as defined in Table B below in the context of Timing of First Sales set forth in Table B ("Annual Minimum Supply"). Company shall ensure that this Annual Minimum Supply is available each year starting at the date of the first sale of Released Product to a Public Sector Purchaser for a Developing Country and ending upon termination of this GACA, including any Extended Term as described in Section 3(d)(v). Company shall use reasonable and diligent efforts to manufacture, fill finish, package, label, store and ship the Released Product in accordance with (a) all tender, purchase and sale agreements with any Public Sector Purchaser(s) up to the Aggregate Minimum Supply, (b) all applicable safety, legal, ethical, and regulatory requirements, and (c) the terms of this GACA. Shipping terms will be FCA Incoterms 2010, unless agreed in writing otherwise.

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#### **TABLE B**

### **Timing of First Sales**

# **Annual Minimum Supply**

If the first sale to a Public Sector Purchaser for Maternal Immunization for a Developing Country (following WHOPQ) is within 0-3\* years of first sale in a Developed Country

Annual Minimum Supply shall be the greater of (a) [\*\*] of Company's Total Product Manufacturing Capacity per year, or (b)[\*\*] Doses of Released Product per year for Maternal Immunization; which Annual Minimum Supply shall apply for the first 3\* years after first sale in a Developed Country.

After such 3\* years, Annual Minimum Supply will increase to the greater of (a) [\*\*] of Company's Total Product Manufacturing Capacity per year, or (b) [\*\*] Doses of Released Product per year for Maternal Immunization

If the first sale to a Public Sector Purchaser for Maternal Immunization for a Developing Country (following WHOPQ) is more than 3\* years after the first sale in a Developed Country

Annual Minimum Supply is the greater of (a) [\*\*] of Company's Total Product Manufacturing Capacity per year, or (b) [\*\*] Doses of Released Product per year for Maternal Immunization

- (iv) **Obligation to Bid on Public Sector Purchaser Tenders.** Subject at all times to the Aggregate Minimum Supply and Annual Minimum Supply, the Volume Commitment requires the Company to use reasonable and diligent efforts to bid on applicable Public Sector Purchaser tenders in accordance with the Price Commitment for any Public Sector Purchaser purchase order with an effective date that falls within the Term or Extended Term.
- (v) **Volume Commitment Rollover**. During the Term of this GACA, in the event that during a calendar year the full amount of the Annual Minimum Supply is not committed for purchase by applicable Public Sector Purchasers ("**Undemanded Capacity**"), Company shall have the right to allocate such Undemanded Capacity as it sees fit and the same amount of Undemanded Capacity shall be rolled over into one or more extended years, depending on the amount of such Undemanded Capacity, which shall thereby extend the Term of this GACA ("**Extended Term**"). During the Extended Term, the terms and conditions of this GACA shall apply, until the Aggregate Minimum Supply is met. For the avoidance of doubt and notwithstanding any other provision of this GACA, this volume commitment rollover provides for an Extended Term that ensures that Company provides the Aggregate Minimum Supply over the Term or Extended Term. Notwithstanding the foregoing, Company may, but will not be obligated to, provide more than the Annual Minimum Supply to Public Sector Purchasers within any given calendar year during the Term or Extended Term. The Parties agree that in any event, the Extended Term shall not exceed five (5) additional years at which time the Volume Commitment will be deemed fulfilled.

<sup>\*</sup>Novavax shall have the right to request in writing that such period be extended to 4 years and the Foundation shall reasonably consider in good faith such request in a timely manner, in light of the current or anticipated demand from Developing Country(ies) and/or Public Sector Purchaser(s) and in light of factors provided to Foundation by Company.

- [\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.
- (vi) **Expanded Capacity.** In the event the Foundation desires additional expanded capacity beyond the Aggregate Minimum Supply, the Foundation may at its full discretion request a proposal from Company detailing whether and how Company would meet such increased capacity and Company will respond promptly and in good faith with such a proposal; provided, however, that nothing in this paragraph is or will be deemed a promise of future funding and any such proposal is subject to all internal reviews, processes and approvals by the Foundation and any applicable laws and regulations, and any such proposal or future funding must be reflected in a definitive written agreement between the Parties. Nothing in this GACA is a promise or obligation for either Party to enter into any future agreement.
- **(e)** Representations, Warranties, Covenants of Company: Company hereby represents, warrants and covenants to the Foundation:
- (i) **Project Diligence and Necessary Skill**. Company will use reasonable and diligent efforts to meet the Project obligations, develop the Product, and meet its obligations under the Grant Agreement and this GACA, and Company has, and will maintain, the necessary expertise, personnel, facilities and equipment to meet the Project obligations, develop the Product, and meet its obligations under the Grant Agreement and this GACA;
- Compliance with Applicable Laws & Regulations. Company will comply with all applicable laws, regulations, and rules and will not infringe, misappropriate, or violate the intellectual property rights of any third party and is in compliance in all material respects with all applicable laws, regulations, and rules (including all laws and regulations related to clinical trials, human health and safety, the protection of the environment, research, development and manufacture of vaccines intended for human use) regarding the use, design, research, development, production, manufacture, licensure, offer-for-sale, sale, distribution, import and export of the Product as contemplated by the Project, and no action has been filed or commenced against Company alleging any such failure. Company is in material compliance with all applicable cGMPs, Good Clinical Practices, Good Laboratory Practices and has (or will obtain prior to any applicable activity) all applicable licenses, approvals and permits related to the foregoing. Company is not aware of facts that (with or without notice or lapse of time, or both) could reasonably be expected to result in Company being in violation in any material respect of any law materially applicable to the use, design, research, development, production, manufacture, licensure, offer-for-sale, sale, distribution, import and export of any Product as contemplated by the Project. Company has in place and shall continue to maintain during the Term or Extended Term, a compliance program reasonably designed to identify, prevent, and address any material compliance issues.
- (iii) **Licenses and Permits**. Company currently holds (or will hold prior to any applicable activities related to the Product): all necessary foreign, federal, state, local and other governmental licenses, approvals and permits necessary to use, design, develop, produce, manufacture, offer-for-sale, sell, distribute, import and export the Product for use as contemplated hereunder by the Project and this GACA.
- (iv) **Records Compliance**. Company will maintain, in accordance with and for the period required under cGMPs and applicable laws, complete and adequate records pertaining to the methods, and the facilities, manufacture, procedures, testing and the like, related to the Products.
- (v) **No Conflict**. Company will not enter into any agreement or arrangement with any third party which will prevent it from performing or impair its ability to perform its obligations hereunder.

- [\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.
- (vi) **IP Due Diligence**. Company currently has (or will have prior to any commercialization of the Product), conducted reasonable due diligence with respect to the Product, including intellectual property and freedom to operate analyses related to such Product.
- (vii) **IP Rights**. Company currently has (or will have prior to commercialization of the Product) rights to any and all intellectual property (including rights in any patents, data, confidential information, know-how or other proprietary right) required to commercialize (make, have made, sell, offer- for-sale, distribute, import, export and use as contemplated by the Project) the Product.
- (viii) **Product Modification**. In the event of any injunction or prohibition against Company's manufacture, licensure, import, export, sale, offer-for-sale, distribution, or use of the Product by reason of infringement of a patent, proprietary, or intellectual property right, or if in Company's opinion the Product is likely to become the subject of a claim of infringement of a patent, proprietary, or intellectual property right Company will, at its option and at its expense, either: (a) procure (such as by licensing or otherwise) the right to continue to make, have made, import, export, sell, offer-for-sale, distribute, and use such Product, or (b) replace or modify such Product so it becomes non-infringing, but is reasonably equivalent or superior in terms of efficacy, quality and safety. Notwithstanding the previous, Company's inability to further develop, manufacture, sell or license the Product because it cannot reasonably procure rights or modify the Product as prescribed hereunder, which limitation has been reasonably verified by the Foundation, shall not be deemed a Charitability Default provided the Foundation reasonably agrees that such procurement or modification is not reasonable.
- (ix) **No Disputes**. The Product, including its commercialization, manufacture, sale, offer-for-sale, distribution, import, export and use as contemplated by the Project, is not the subject of any current third party intellectual property claims and is not currently subject to any disputes with a third party. Company agrees to notify the Foundation of any such claims or disputes which arise during the Term or Extended Term.
- (x) **Disqualification and Debarment**. Company, its employees or contractors or agents are not and will not be, at the time of performance of any activity contemplated hereunder, (a) disqualified or debarred by any applicable governmental authority for any purpose pursuant to applicable law or regulation or threatened with any such disqualification or debarment or (b) charged or convicted for conduct relating to the development or approval of, or otherwise relating to the regulation of, any product under any applicable law or regulation, which activity with respect to (a) or (b) could adversely impact the Project or Product or obligations under this GACA.
- (xi) **Warranty**. The Product is or will be manufactured by Company (and/or its CMOs or Affiliates) in conformity with its regulatory label and package insert and all applicable laws and regulations.
- (xii) **Company is Sponsor**. Company is and shall be responsible for all aspects and stages of the Project and Product, including Product research, development, clinical trials, and commercialization (including any applicable legal, regulatory, and governmental requirements and/or registrations), including acting as the sponsor of any clinical trials or research studies related thereto. In no event shall the Company make any representation or statement that the Foundation is a sponsor of any trial, study, Product registration, or marketing authorization or the like. Except as may be required by law, Company shall not include the Foundation on any document relating to the foregoing or in any communication with any governmental or regulatory body without the express prior written consent of the Foundation. Any input, consultation, or communication to Company by the Foundation shall not diminish the foregoing.

#### 4. Term; Survival

Except as to any provision subject to survival and subject to any Extended Term under section 3(d)(v), this GACA and the obligations hereunder will expire at the later of (a) 15 years after the Effective Date, or (b) 10 years after the first sale of Released Product to a Public Sector Purchaser for Maternal Immunization for a Developing Country following WHOPQ ("Term"); provided, however the Term may be lengthened to account for the Extended Term. The following sections will survive the expiration or termination of this GACA: Sections 1 (Charitable Purposes and Use of Funds), 2 (Definitions), 3(e) (Representations, Warranties, Covenants of Company), 5 (Obligations in the Event of Acquisition of Product or Company by Another), 6 (Global Access License), 7 (Required Reporting), 10 (Waiver), 11 (Further Assurances), 12 (Indemnification of Foundation) 13 (Interpretation), 14 (Counterparts), 17 (Miscellaneous) and this sentence.

### 5. Obligations in the Event of Acquisition of Product or Company by Another

In the event Company, Company assets necessary to perform Company's obligations hereunder are licensed to, transferred to, sold to or otherwise acquired by a third party, including as a result of a Change in Control (any such license, transfer, sale or acquisition, including a Change in Control, is referred to herein as a "**Transfer**"), Company will ensure all such obligations are assumed by the licensee, purchaser, transferee, acquirer or successor in a written agreement reasonably acceptable to the Foundation. Company will not grant to a third party any rights or enter into any arrangements that would prohibit, prevent or otherwise restrict Company or any purchaser, transferee, acquirer, or successor of Company assets or Company from fulfilling its obligations hereunder. For clarity, notwithstanding anything to the contrary herein, the Foundation's rights hereunder which exist on the date of the Transfer shall not be terminated by such Transfer. A breach of this provision will constitute a Charitability Default.

## 6. Global Access License

- (a) "Charitability Default" means that Company:
- (i) fails to comply with the restrictions on the use of funds or the other related U.S. tax obligations set forth in the Grant Agreement or the requirements set forth in this GACA;
  - (ii) commits a material breach of term of the Grant Agreement or this GACA;
  - (iii) commits gross negligence, fraud or willful misconduct; or
- (iv) makes a strategic decision to discontinue the Product development and/or commercialization of the Product which meets the Minimum TPP; or
  - (v) experiences a Change of Control or Transfer in violation of section 5 of this GACA; or

- [\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.
- (vi) experiences any Force Majeure Event, failure to cure or nonperformance exceeding 150 days, unless otherwise agreed to by the Parties in writing.
- Notice of Charitability Default. Except as to Charitability Default under Section 6(a)(vi), each Party agrees **(b)** that if it becomes aware of a Charitability Default it will promptly notify the other Party, and Company shall thereafter provide to the Foundation a proposed strategy to cure the Charitability Default within forty-five (45) days of notification. Notwithstanding anything in this GACA to the contrary, the Foundation will not lose any rights or remedies solely as a result of a failure to notify Company after it becomes aware of a Charitability Default, provided that such failure to notify shall not otherwise impede, prevent, or materially and detrimentally impact the ability and/or expense associated with Company's cure of such Charitability Default. In addition, Company agrees to promptly notify the Foundation of any facts and circumstances which could reasonably cause a Charitability Default hereunder (including with respect to any Charitability Default under Section 6(a)(i) through (vi)). Subject to Section 15(b), if Company fails to either cure the Charitability Default within ninety (90) days of notice of a Charitability Default (the "Cure Period") or if such Charitability Default requires additional time to be cured as agreed by the parties ("Extended Cure Period") and the Company fails to use reasonable and diligent efforts to cure such Charitability Default, then the Foundation will immediately be granted the Global Access License rights set forth in this Section 6. For the avoidance of doubt, if the period of the Force Majeure event or any attempt to cure or any nonperformance (including due to Force Majeure) exceeds one hundred and fifty (150) days from the notice, unless otherwise agreed to by the Parties in writing, the Foundation shall immediately be granted the Global Access License as set forth in Section 6.

#### (c) License Triggers

- (i) If a Charitability Default is not cured by the end of the Cure Period or Extended Cure Period, effective immediately, Company hereby grants a non-exclusive, irrevocable, perpetual, sublicenseable, royalty-free and fully-paid up, worldwide (subject to Section 6(c)(ii) below) license to the Foundation to all intellectual property, technology, know-how, and information owned, controlled or used (subject to reasonably sublicensability by third party licensor(s)) by the Company at the time of such Charitability Default that are necessary or useful to research, develop, make, have made, offer-for-sale, sell, import, export, distribute or use the Product, such license solely to research, develop, make, have made, offer-for-sale, sell, import, export, distribute or use Product for Maternal Immunization intended for the benefit of people in Developing Countries ("Global Access License"). Upon a Global Access License, Company may reasonably seek to assign any and all such intellectual property rights, including third-party licenses, to the Foundation or the Foundation's licensee as appropriate, and the Foundation will reasonably work with the Company to accept such assignment.
- (ii) The Parties agree and acknowledge that in order to achieve Global Access and make the Product available and accessible in Developing Countries, certain activities may be required to occur in one or more Developed Countries, such as manufacture, distribution, or sale (such as to an entity procuring Product for use in Developing Countries). For example, the manufacture of Product (intended for use in Developing Countries) may occur in a Developed Country. Similarly, certain aspects of the distribution or supply chain may occur in (or pass through) one or more Developed Countries, e.g. the Product may be transported through a Developed Country en route to the final destination of the Product in a Developing Country. Similarly, the procurement entities which may purchase Product (for or on behalf of a Developing Country) may be located in a Developed Country or the sales transactions related thereto may occur in a Developed Country, even though the final destination of the Product is a Developing Country. Accordingly, the Global Access License hereunder is intended to permit such Developed Country activities which are incidental or necessary to making the Product available and accessible in Developing Countries.

- [\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.
- (iii) The provisions of this Section will survive the Term, Extended Term or any earlier termination of this GACA.

## (d) Technology Transfer

- (i) In connection with any Global Access License hereunder, such Global Access License shall be subject to the execution of the following reasonably acceptable written agreements between the Company and the recipient of the technology transfer (which recipient may be a Foundation sub-licensee or entities selected by the Foundation): quality agreement, safety data exchange agreement, and other customary agreements related to technology transfer of the Product; provided always that such entity shall not be required to pay any royalties, milestones or fees associated with such agreements. Company will cooperate with the Foundation in good faith to make available to the Foundation (or the entities of the Foundation's choosing) (including providing electronic copies), all necessary intellectual property, technology, know-how and other information relating to the Product (including but not limited to master batch records, SOPs, QA/QC information, detailed bill of materials for the Product and other manufacturing documentation) for the purpose of permitting the Foundation (or its selected entities) to utilize its Global Access License and to continue to research and develop and manufacture the Product, and to enable the manufacture, licensure, sale, offer-for-sale, import, export, distribution, and use of such Product intended for use in the Developing Countries. For the purpose of facilitating Technology Transfer the Company shall provide electronic copies of all such applicable records and manufacturing documentation related to the Product for Maternal Immunization and the Foundation (or the entities of the Foundation's choosing) and will be permitted to inspect the same for the purpose of assuring complete and accurate technology transfer by Company.
- (ii) Company will continue to meet its Global Access Commitments towards and until completion of all intellectual property, know-how and information technology transfer associated with a Global Access License herein. Company and the Foundation will cooperate in good faith to effect an orderly and complete transition of any activities, including the research, development, manufacture, licensure, sale, offer-for-sale, distribution, import, export and use of the Product to the Foundation or its selected entities.
- (iii) Company shall permit the Foundation (or its sublicenses) the right to access and cross-reference any applicable IND, BLA, WHOPQ or other regulatory file relating to the Product and shall, upon request, provide an electronic copy of each such file.
- (iv) To the extent applicable, the Parties further agree to take all reasonable and diligent steps to eliminate or reduce any third party costs or royalties (set forth in Appendix D or otherwise attributable to the Product) associated with such Global Access License, including negotiation of any third party royalties and to negotiate access to such third party licenses by the Foundation (or its selected entities).

- [\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.
- (v) The provisions of this Section will survive the Term, Extended Term, or any earlier termination of this GACA.

#### (e) Indemnification of Company by Technology Transfer Recipient in Connection with Technology Transfer.

- Unless otherwise agreed by the Parties, upon the triggering of a Global Access License and as a condition of technology transfer associated with the Product, the recipient of the technology transfer (which recipient may be a Foundation sub-licensee or entities selected by the Foundation) (hereinafter "Technology Transfer Recipient") will be required to indemnify, hold harmless and defend Company and its Affiliates and its and their officers, directors, employees and agents (the "Company Indemnified Parties") against any and all expenses, costs of defense (including reasonable attorneys' fees, witness fees, damages, judgments, fines, and amounts paid in settlement) and any amounts any such indemnitee becomes legally obligated to pay ("Losses") because of any Third Party claim or claims against it ("Third Party Claims") to the extent that such Third Party Claims arise from or are due or attributable to: (a) any defect in the Product manufactured or produced by the Technology Transfer Recipient or (b) any act or omission involving the gross negligence, intentional misconduct, or fraud of the Technology Transfer Recipient related to the Product; except, in each case ((a) or (b)), to the extent such Losses result from: (i) Company's manufacture or production of Product (whether directly or by any agent or CMO of Company), (ii) any fraud, gross negligence or willful misconduct (whether by act or omission) of any Company Indemnified Parties, (iii) the breach by Company of any warranty, representation or covenant made by Company in this GACA or the Grant Agreement, (iv) any defect in the manufacturing process design or Product design attributable to Company, (v) Company's failure to provide complete and accurate technology transfer consistent with industry standards and consistent with any applicable agreements between the Company and Technology Transfer Recipient; or (vi) Company's violation of any applicable laws or regulations related to the Product or technology transfer thereof.
- (ii) Notice & Control of Defense. In the event any Company Indemnified Parties seeks indemnification under this section, the applicable Company Indemnified Party shall provide the Technology Transfer Recipient with prompt written notice of any such claim, provided that, any failure to give prompt notice will not waive any rights of any Company Indemnified Party except to the extent the rights of the Technology Transfer Recipient are actually prejudiced by such failure. The Technology Transfer Recipient will have the right to conduct the defense of such Third Party Claim at its sole cost and expense provided Company may retain separate counsel at Company sole cost and expense. Company and Company Indemnified Parties agree to provide reasonable cooperation to Technology Transfer Recipient in defense of such Third Party Claim.

# 7. Required Reporting

In addition to any and all reports required to be delivered to the Foundation under the Grant Agreement, Company shall furnish, or cause to be furnished, to the Foundation the following reports, information and certifications:

- [\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.
- (a) Provide the Foundation with written reports in form and detail reasonably satisfactory to the Foundation and confer with the Foundation (by teleconference or in scheduled site visits as appropriate) regarding progress with respect to the milestones (under the Grant Agreement) and the Global Access Commitments herein;
- (b) Coordinate with the Foundation to determine reasonable times for the Foundation's representatives to make site visits to Company's facilities with respect to the Project or Product;
- (c) Make available to the Foundation (or at the Foundation's election auditors selected by the Foundation and reasonably acceptable to Company), the Company books and records related to the Project and Product for four years after funds are fully spent and make such records and reports available to enable the Foundation to monitor and evaluate how funds have been used;
- (d) Make available to the Foundation (or at the Foundation's election auditors selected by the Foundation and reasonably acceptable to Company) those Company books and records related to the Project, including records evidencing sales to Public Sector Purchasers and obligations under this GACA;
  - (e) Provide the Foundation with the date upon which Company achieves WHOPQ; and
- (f) Provide the Foundation with the date and location of the first sale to a Public Sector Purchaser for Maternal Immunization for a Developing Country following WHOPQ.

## 8. Entire Agreement; Modification

This GACA and the Grant Agreement, including all exhibits hereto and thereto, set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the parties with respect to the subject matter, and supersede and terminate all prior agreements, negotiation and understandings between the parties, whether oral or written, with respect to such subject matter. No subsequent alteration, modification, amendment, change or addition to this GACA shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties. In the event of a conflict between the terms of this GACA and the terms of the Grant Agreement, the terms of this GACA shall control.

## 9. <u>Authority</u>

Each of Company and the Foundation covenants, represents and warrants with respect to itself that it has all authority necessary to execute this GACA and that, on execution, this GACA will be fully binding and enforceable in accordance with its terms, and that no other consents or approvals of any other Person or third parties are required or necessary for this GACA to be so binding.

# 10. Waiver

Failure or delay by either Party in exercising or enforcing any provision, right, or remedy under this GACA, or waiver of any remedy hereunder, in whole or in part, shall not be deemed a waiver thereof, or prevent the subsequent exercise of that or any other rights or remedy. Other than that arising out of this GACA or Grant Agreement, in no event will either party have any liability for any indirect, incidental, consequential or special damages, even if advised of the possibility of such damages.

#### 11. Further Assurances

From time to time after the Effective Date, each Party shall execute, acknowledge and deliver to each other any further documents, assurances, and other matters, and will take any other action consistent with the terms and conditions of this GACA, that may reasonably be requested by a Party and necessary or desirable to carry out the purpose of this GACA.

## 12. Indemnification of Foundation

Company will indemnify, defend, and hold harmless the Foundation and its trustees, employees, and agents ("Indemnified Parties") from and against any and all demands, claims, actions, suits, losses, damages (including property damage, bodily injury, and wrongful death), arbitration and legal proceedings, judgments, settlements, or costs or expenses (including reasonable attorneys' fees and expenses) (collectively, "Claims") arising out of or relating to the acts or omissions, actual or alleged, of Company or its employees, subcontractors, contingent workers, agents, and affiliates with respect to the Project, the Product, this GACA or the Grant Agreement. Company agree that any activities by the Foundation in connection with the Project or Product, such as its review or proposal, input, or suggested modifications to the Project or Product, will not modify or waive the Foundation's rights under this paragraph. An Indemnified Party may, at its own expense, employ separate counsel to monitor and participate in the defense of any Claim.

### 13. <u>Interpretation</u>

The headings contained in this GACA are for reference purposes only and shall not affect in any way the meaning or interpretation of this GACA. Whenever the words "include," "includes" or "including" are used in this GACA, they shall be deemed to be followed by the words "without limitation."

# 14. Counterparts

This GACA may be executed in one or more counterparts, including by signatures delivered by facsimile or pdfs, each of which shall be deemed an original, but all of which shall be deemed to be and constitute one and the same instrument.

## 15. Force Majeure

(a) If Company is unable to perform its obligations or enjoy the benefits of this GACA because of the occurrence of any contingency beyond all reasonable and diligent efforts, including, but not limited to, war (whether a declaration thereof is made or not), terrorism, sabotage, insurrection, rebellion, riot or other act of civil disobedience, act of a public enemy, act of any government or any agency or subdivision thereof, judicial action, general strikes, fire, accident, explosion, epidemic, quarantine, restrictions, storm, flood, earthquake, adverse weather conditions, other natural disasters, Acts of God, unless such occurrence is caused by Company's negligent act or omission, (a "Force Majeure Event"), Company shall give prompt written notice to the Foundation and shall use all reasonable and diligent efforts to resume performance as soon as practicable. Subject to Section 6, upon receipt of such notice, all obligations affected by such Force Majeure Event under this GACA shall be suspended for the duration of such Force Majeure Event. Upon the termination of any Force Majeure Event, Company shall be obligated to cure or remedy any failure to perform by reason of such Force Majeure Event.

(b) Notwithstanding anything in this GACA, if the period of the Force Majeure event or any attempt to cure or any nonperformance (including due to Force Majeure) exceeds one hundred and fifty (150) days from the notice, unless otherwise agreed by the Parties in writing, the Foundation shall immediately be granted the Global Access License as set forth in Section 6.

# 16. **Dispute Resolution**

Any disputes or conflicts relating to the Project will first be attempted to be resolved by the Parties designated representatives in a timely manner. In the event an issue cannot be resolved by the Parties representatives, the President/CEO of the Company and the President of Global Health of the Foundation will meet within thirty (30) days for the purposes of resolution. Notwithstanding the forgoing, neither party waives any legal or other remedy it may have in law or equity under the Grant Agreement or this GACA.

#### 17. **Miscellaneous**

(a) **Notice.** Any notice, request, demand, consent or other communication required or permitted hereunder shall be in writing and effectively given if delivered personally or by FedEx, DHL, or other nationally recognized overnight courier service (with evidence of receipt thereof), or sent by first class mail, using certified or registered mail, postage prepaid, addressed to the Party for which it is intended at its address as set out below or as may be designated by notice pursuant hereto.

To Company: Novavax, Inc.

20 Firstfield Road Gaithersburg, MD 20878 Fax: 240-268-2100 Attention: General Counsel

To Foundation: Bill & Melinda Gates Foundation

PO Box 23350 Seattle, WA 98102 Fax: (206) 494-7039 Attn: Director, Pneumonia

with a copy to:

Bill & Melinda Gates Foundation PO Box 23350 Seattle, WA 98102 Fax: (206) 494-7123

Fax: (206) 494-7123 Attn: General Counsel

- [\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request.

  An unredacted version of this exhibit has been filed separately with the Commission.
- (b) **Severability.** If any provision herein is found to be unenforceable, it is the intent of the Parties that such provision be replaced, reformed or narrowed so that its original business purpose may be accomplished to the extent permitted by law. The invalidity or unenforceability of any provision of this GACA shall not affect the validity or enforceability of any other provisions of this GACA, which shall remain in full force and effect.
- (c) **Amendments.** No supplement, amendment, modification or rescission of this GACA shall be valid or enforceable unless set forth in writing and signed by both Parties.
- (d) **Assignment.** The Grant Agreement and this GACA, and all rights and obligations of the Parties hereunder, shall not be assigned or delegated by either Party without the prior written consent of the other Party; provided, however, that Company may assign this Agreement to any Affiliate or successor in interest with the consent of the Foundation, not to be unreasonably withheld, provided that such successor
- in interest assume all obligations hereunder. Subject to the foregoing, the Grant Agreement and this GACA shall be binding upon and shall inure to the benefit of the Parties and their respective successors and assigns.
- (e) Governing Law. This GACA shall be governed by and construed under the laws of the State of New York in all respects as such laws are applied to agreements among New York residents entered into and performed entirely within New York, without giving effect to conflict of laws principles thereof. The Parties agree that any action brought by either Party under or in relation to this Agreement, including to interpret or enforce any provision of this Agreement, shall be brought and filed in, and each Party agrees to and does hereby submit to the exclusive jurisdiction and venue of, any state or federal court located in the State of New York.
- (f) **Entire Agreement.** The Grant Agreement and this GACA and all attachments, including any amendments, constitute the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior agreements, understandings, discussions, and negotiations, whether oral or written, express or implied, of the Parties with respect hereto.
- Confidentiality. The Parties acknowledge and agree that the provisions of the Nondisclosure Agreement between them dated as of March 26, 2013 and amended as of April 29, 2015, (and further amended from time to time as agreed in a signed writing by the parties), shall be deemed to govern all disclosures of "Confidential Information" (as defined therein) that may occur hereunder. For clarity, the Grant Agreement, this GACA, and all attachments thereto shall not be deemed Confidential Information, other than those aspects of such documents that are covered by a CDA between the parties and are granted confidential treatment by the U.S. Securities and Exchange Commission, as requested by Novavax, provided always that any such Confidential Information relevant to UNICEF, WHO, Gavi and Public Sector Purchasers will be made available to such entities in preparation for review by the WHO Strategic Advisory Group of Experts on immunization (SAGE). In addition, Company agrees to collaborate in good faith with the applicable material immunization experts in order to prepare documentation needed for SAGE review. Following SAGE review, Company agrees to disclose applicable price and volume information consistent with public sector procurement procedure (which may require public disclosure of such information).

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Global Access Commitments Agreement to be executed by their duly authorized representatives as of the Effective Date.

NOVAVAX, INC. BILL & MELINDA GATES FOUNDATION By: /s/ Stanley C. Erck By: /s/ Keith Klugman Name: Stanley Erck Name: Keith Klugman President and Chief Executive Officer Title: Title: Director, Pneumonia Date: September 25, 2015 Date: September 18, 2015

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## APPENDIX A

# **Developing Countries**

Afghanistan Ghana Nicaragua Angola Guinea Niger Armenia Nigeria Guinea Bissau Pakistan Azerbaijan Guvana Bangladesh Haiti Papua New Guinea Benin Honduras Rwanda Sao Tome e Principe Bhutan India Bolivia Indonesia Senegal Sierra Leone Burkina Faso Kenya Kiribati Solomon Islands Burundi Cambodia Korea DPR Somalia Cameroon Kyrgyz Republic Sri Lanka Central African Republic Lao PDR Republic of Sudan South Sudan Chad Lesotho Comoros Liberia **Taiikistan** Congo Republic Tanzania Madagascar Cote d'Ivoire Malawi Timor Leste Mali Cuba Togo Democratic Republic of Congo Mauritania Uganda Djibouti Moldova Ukraine Eritrea Mongolia Uzbekistan Ethiopia Mozambique Viet Nam Gambia Myanmar Yemen Georgia Nepal Zambia

Certain countries in this Appendix A may be subject to U.S. comprehensive embargo restrictions at present or in the future. The Parties acknowledge that such restrictions could preclude one or both Parties' ability to include such countries in any efforts under this GACA.

Zimbabwe

## Additional Countries

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# APPENDIX B

# Respiratory Syncytial Virus Vaccine - Target Product Profile Executive Summary

Variable	Minimum	Optimistic	Annotations
	The minimal target should be considered as a potential go/no go decision point.	The optimistic target should reflect what is needed to achieve broader, deeper, quicker global health impact.	For all parameters, include here the rationale for why this feature is important and/or for the target value.
Indication*	Prevention of RSV- related lower respiratory tract infection associated with hypoxemia in subjects from birth to 3 months of age	[**]	[**]
Product (Maternal Immunization)	Nanoparticle vaccine containing 120µg of RSV-F and 0.4mg of aluminum	[**]	[**]
Target Population*	Pregnant women ≥18 years of age between [**] weeks of gestation	[**]	[**]
Target Countries	United States and Gavi (eligible and graduating) countries	[**]	[**]
		22	

Variable	Minimum	Optimistic	Annotations
	The minimal target should be considered as a potential go/no go decision point.	The optimistic target should reflect what is needed to achieve broader, deeper, quicker global health impact.	For all parameters, include here the rationale for why this feature is important and/or for the target value.
			[**]
Efficacy*	≥[**] reduction in RSV- related lower respiratory tract infection associated with hypoxemia over the first 3 months of life	[**] [**]	
			[**]
Duration of Protection	3 months	[**]	
Onset of Immunity	Documented onset of immune response within [**] weeks of vaccination	[**]	[**]
		23	

Variable	Minimum	Optimistic	Annotations
	The minimal target should be considered as a potential go/no go decision point.	The optimistic target should reflect what is needed to achieve broader, deeper, quicker global health impact.	For all parameters, include here the rationale for why this feature is important and/or for the target value.
			[**]
Indirect (Herd) Protection	Not relevant	[**]	
	L. L. Cout C. Lineter		[**]
Safety*	<ul> <li>In Infant Subjects:</li> <li>No safety signal in predefined categories of AEs and SAEs through the first year of life.</li> <li>No evidence of vaccine-enhanced disease.</li> </ul>	[**]	
Salety	In Maternal Subjects: No safety signal in predefined categories of AEs and SAEs, antenatally, intrapartum and for 6 months postpartum.		
Co- administration	Safe administration without interference with other maternal vaccines (e.g., influenza, Tdap, and tetanus toxoid) in accordance with local recommendations	[**]	

Variable	Minimum	Optimistic	Annotations
	The minimal target should be considered as a potential go/no go decision point.	The optimistic target should reflect what is needed to achieve broader, deeper, quicker global health impact.	For all parameters, include here the rationale for why this feature is important and/or for the target value.  [**]
Presentation	Single dose vial, liquid formulation	[**]	l J
Cold chain volume required	Consistent with VPPAG Guidance, i.e. Maximum 4.0, 6.5, 13.0, and 15.0 cm3 per dose for 10-, 5-, 2-, 1-dose vials, respectively	[**]	[**] [**]
Dosing Schedule and Route of Administration*	Single intramuscular injection at [**] weeks of gestation	[**]	
Vaccine Volume (cm3 /dose)	0.5ml	[**]	
		25	

Variable	Minimum	Optimistic	Annotations
	The minimal target should be considered as a potential go/no go decision point.	The optimistic target should reflect what is needed to achieve broader, deeper, quicker global health impact.	For all parameters, include here the rationale for why this feature is important and/or for the target value.
Stability / Shelf Life	Shelf life of [**] at 2-8°C Use of vaccine vial monitors and freeze monitors	[**]	
Product Registration Path	U.S. BLA approval and WHOPQ	[**]	[**]
Target US BLA Submission Date	[**]	[**]	
Target WHO PSF Submission Date	Within [**] of US BLA approval	[**]	
Primary Target Delivery Channel	Through Antenatal Care (ANC) programs	[**]	[**]
Price	Consistent with this GACA	[**]	[**]
Manufacturing Capacities (Candidate TPP Only)	[**]	[**]	[**]
		26	

#### APPENDIX C

## **Principal Assumptions for Price Cap Calculation**

The initial Maximum Price Cap described in Table A is based on the assumptions of Novavax' US-based facility having the capacity to produce, [\*\*] by the date of WHOPQ, 120 microgram (120 µg) Doses of Product annually using up to [\*\*] reactors (or equivalent) assuming [\*\*] weeks of production per year, an overall batch success rate of [\*\*] percent [\*\*], and an average of [\*\*] yield, and [\*\*] percent [\*\*] overage/loss (averaged over all batches per year). These assumptions are expected to be a base case for production at the time of WHOPQ. Since a primary objective of this GACA is to assure affordable and accessible Product to people in Developing Countries, the Company agrees that a decline in the overall batch success rate below [\*\*] from the base case will not have an upward impact on the Product cost per Dose nor an upward impact on the [\*\*].

TABLE C: Components of [\*\*] Cost

Component	Cost	Notes
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
Total	[**]	The [**] Total Cost is the sum total of [**] described in this table are for convenience; for the avoidance of doubt, Total Cost is calculated in the aggregate and will not be held to the characterization of any single component or multiple components.
Impact of Grant	[**]	The proposed grant would represent a reduction to [**]costs calculated as the \$89 million grant, amortized over 10 years, and divided by [**] doses.
Subtotal	[**]	The total cost per dose including the grant is the previous total [**] minus the impact of the grant[**].
Markup	[**]	Represents a [**] markup over the cost to produce the Product.
[**]	[**]	[**] represents the Subtotal plus the Markup
	[Remaind	ler of page left intentionally blank]