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	[**]	[**]
Efficacy*	≥[**] reduction in RSV- related lower respiratory tract infection associated with hypoxemia over the first 3	[**]	[**]

Source: Global Access Commitments Agreement between the Bill & Melinda Gates Foundation and Novavax Inc (25 September 2015)

	months of life		
Duration of Protection	3 months	[**]	[**]
Onset of Immunity	Documented onset of immune response within [**]weeks of vaccination	[**]	[**]
Indirect (Herd) Protection	Not relevant	[**]	[**]
Safety	In Infant Subjects: • No safety signal in predefined categories of AEs and SAEs through the first year of life. • No evidence of vaccine-enhanced disease. 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	[**]	[**]
Presentation	Single dose vial, liquid formulation	[**]	[**]
Cold chain volume required	Consistent with	[**]	[**]

Source: Global Access Commitments Agreement between the Bill & Melinda Gates Foundation and Novavax Inc (25 September 2015)

	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)	0.5 ml	[**]	[**]
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 [Global Access and Price Commitments Agreement]	[**]	[**]
Manufacturing Capacities *(Candidate TPP Only)*	[**]	[**]	[**]

Source: Global Access Commitments Agreement between the Bill & Melinda Gates Foundation and Novavax Inc (25 September 2015)