Novavax Intends to Deliver Protein-based XBB COVID Vaccine as Specified in U.S. HHS Letter to COVID Manufacturers

July 13, 2023

Today the U.S. Department of Health and Human Services (HHS) issued a letter to COVID vaccine manufacturers, including Novavax, requesting that updated vaccines are ready for Food and Drug Administration (FDA) regulatory action and the Centers for Disease Control and Prevention (CDC) recommendations on vaccination by the latter part of September 2023. Novavax has developed an updated protein-based monovalent XBB.1.5 COVID vaccine candidate and is manufacturing at commercial scale with the intent to meet HHS' September timeline, pending FDA regulatory action and CDC recommendations on vaccination.

"Upon authorization, Novavax's XBB.1.5 protein-based vaccine would be the only non-mRNA vaccine available in the U.S.," said John C. Jacobs, President and Chief Executive Officer, Novavax. "Novavax is committed to continuing to partner with HHS and its agencies to meet the shared goal of protecting those at risk of COVID infection and re-infection and maximizing access to COVID vaccine options this fall season."

In addition, Novavax is in discussions with HHS and leading pharmacy retailers regarding the "Bridge Access Program For COVID-19 Vaccines and Treatments" to provide access to Novavax's protein-based vaccine option for adults in the U.S. without other sources of coverage. Novavax is committed to protecting consumers' vaccine options and will continue to work with HHS on program participation.

Forward-Looking Statements

Statements herein relating to the future of Novavax, its operating plans and prospects, the ongoing development and manufacturing of a monovalent XBB.1.5 COVID vaccine, the scope, timing and outcome of future regulatory filings and actions, possible authorizations of a monovalent XBB.1.5 COVID vaccine by government agencies for use in adults and adolescents, and as a booster, the evolving COVID-19 pandemic, the potential impact and reach of Novavax and a monovalent XBB.1.5 COVID vaccine in addressing vaccine access, protecting populations, the efficacy, safety intended utilization, and the expected administration of a monovalent XBB.1.5 COVID vaccine are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, without limitation, challenges satisfying, alone or together with partners, various safety, efficacy, and product characterization requirements, including those related to process qualification and assay validation, necessary to satisfy applicable regulatory authorities; difficulty obtaining scarce raw materials and supplies; resource constraints, including human capital and manufacturing capacity, on the ability of Novavax to pursue planned regulatory pathways; unanticipated challenges or delays in conducting clinical trials; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities; and those other risk factors identified in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Novavax's Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent Quarterly Reports on Form 10-Q, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at **www.sec.gov** and **www.novavax.com**, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of the statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.