Novavax Prepared to Deliver Protein-based Non-mRNA JN.1 COVID-19 Vaccine in Line with WHO Recommendation this Fall

April 26, 2024

Today the World Health Organization's (WHO) Technical Advisory Group on COVID-19 Vaccine Composition recommended the use of a monovalent JN.1 lineage COVID-19 vaccine as one approach to address the ongoing SARS-CoV-2 virus evolution, which is expected to lead to circulation of additional JN.1 descendant strains. Novavax plans to be ready to deliver our JN.1 protein-based non-mRNA COVID-19 vaccine globally this fall. We have been developing and manufacturing this vaccine candidate at risk and are well positioned for the upcoming vaccination season.

Our most recent nonclinical data have demonstrated that our JN.1 vaccine candidate induces neutralization responses to JN.1, JN.4, JN.1.11.1, JN.1.7, JN.1.13.1 and JN.1.16 strains. Our JN.1 vaccine candidate also produces polyfunctional cellular CD4+ T cell responses to a range of omicron strains including JN.1 and JN.1.11. These responses indicate once again that our vaccine technology can induce broadly neutralizing responses against multiple variant strains, including circulating forward drift variants.

Forward-Looking Statements

Statements herein relating to the future of Novavax, its operating plans and prospects, the scope, timing and outcome of future regulatory filings and actions, including the plan to be ready to deliver a JN.1 protein-based non-mRNA COVID-19 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; challenges or delays in obtaining regulatory authorization for its product candidates, including an JN.1 protein-based non-mRNA COVID-19 vaccine or for future COVID-19 variant strain changes; challenges or delays in clinical trials; manufacturing, distribution or export delays or challenges; Novavax's exclusive dependence on Serum Institute of India Pvt. Ltd. for co-formulation and filling and the impact of any delays or disruptions in their operations on the delivery of customer orders; 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, 2023 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.?