

# Novavax Continues Progress Towards Delivery of its Protein-based Non-mRNA XBB COVID Vaccine to U.S.

September 11, 2023

*Doses of the updated protein-based non-mRNA Novavax COVID-19 Vaccine, Adjuvanted (Formula 2023-2024) arrived in the U.S. today and are ready to distribute for the fall vaccination campaign, pending FDA and CDC action*

*When authorized, Novavax's protein-based vaccine candidate will be the only non-mRNA COVID vaccine available in the U.S.*

Doses of the updated protein-based non-mRNA Novavax COVID-19 Vaccine, Adjuvanted (Formula 2023-2024) arrived in the U.S. today and will be ready for release pending Emergency Use Authorization (EUA) and recommendation from the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (CDC) (ACIP) and the CDC. Novavax will present the latest data on its vaccine at ACIP's September 12, 2023, meeting to discuss fall COVID vaccination.

Novavax's updated XBB version of its COVID vaccine is currently under review by the U.S. Food and Drug Administration (FDA) for EUA to prevent COVID-19 in individuals aged 12 and older. Novavax is currently responding to the FDA's requests to facilitate final review, and timing is ultimately at the discretion of the FDA.

"Novavax is ready for the commercial delivery of our updated protein-based non-mRNA COVID vaccine this fall, and we are working closely with the FDA on its review of our Emergency Use Authorization application," said John C. Jacobs, President and Chief Executive Officer, Novavax. "Pending FDA authorization and CDC recommendation, Novavax's vaccine will be widely available in major U.S. pharmacies, through Group Purchasing Organizations and through various government entities such as Vaccines for Children, as an option for individuals aged 12 and older to protect themselves against new variants this fall."

Novavax is working with other global regulatory authorities, including the European Medicines Agency and Health Canada, on authorizations for its vaccine.

## **Use of the updated Novavax COVID-19 Vaccine, Adjuvanted in the U.S.**

The updated version of the Novavax COVID-19 Vaccine, Adjuvanted targeting the XBB strain is currently under review by the U.S. FDA for EUA to prevent COVID-19 in individuals aged 12 and older.

## **Forward-Looking Statements**

Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the timing of clinical trial results, the scope, timing and outcome of future regulatory filings and actions, including the potential authorization of its updated XBB version of its COVID-19 Vaccine, Adjuvanted by the FDA, 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](http://www.sec.gov) and [www.novavax.com](http://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.