

# Novavax Statement on 2023-2024 COVID-19 Vaccination Season

October 16, 2023

Novavax remains confident in the ongoing rollout of its updated XBB protein-based non-mRNA COVID-19 vaccine (NVX-CoV2601) in the U.S. Following [arrival in pharmacies](#) and healthcare provider offices, and first doses administered last week, Novavax's vaccine is now widely available throughout the U.S. Novavax believes it is too soon to evaluate U.S. vaccination rates given that vaccinations will continue in the coming weeks. Novavax is encouraged by broad availability of its vaccine in the U.S. market and looks forward to gathering additional data as the season unfolds.

In the European Union, Novavax continues to work in close partnership with the European Medicines Agency (EMA) as they review the file for its updated COVID-19 vaccine for use in individuals aged 12 and older which is based on the global data package that has already supported [U.S. Emergency Use Authorization](#). As part of the ongoing review process, Novavax has responded to additional questions from the EMA's Committee for Medicinal Products for Human Use (CHMP); CHMP has acknowledged receipt of this additional information and Novavax is currently awaiting feedback.

Post-approval, Novavax expects to meet its full supply commitment for doses of its vaccine to European countries that have requested it through the Company's advanced purchase agreement (APA) and is on track to provide these doses in line with the APA requirements. Novavax values EMA's continued partnership and continues to work on the shared goal of bringing an updated protein-based non-mRNA COVID-19 vaccine to member states in the coming weeks.

The Company will provide an update on its upcoming Q3 earnings call in early November 2023.

## **Trade Name in the U.S.**

The trade name Nuvaxovid™ has not been approved by the U.S. Food and Drug Administration.

## **Forward-Looking Statements**

Statements herein relating to the future of Novavax, its operating plans and prospects, including information on vaccination rate data, interactions with CHMP and EMA, the timing of potential regulatory authorization by EMA and the expectation of supplying European countries with its 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; manufacturing, distribution or export delays or challenges; challenges in obtaining commercial adoption of our updated protein-based non-mRNA XBB COVID-19 vaccine, NVX-CoV2373 or any COVID-19 variant strain-containing formulation; 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, 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.