U.S. CDC & ACIP Recommend Use of Authorized and Approved 2024-2025 COVID-19 Vaccines

June 27, 2024

Today the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted unanimously in favor of a universal recommendation for the use of 2024-2025 COVID-19 vaccines authorized under Emergency Use Authorization (EUA) or approved by Biologics License Application in individuals aged six months and older. This vote was later endorsed by the CDC.

Novavax intends to provide doses of our 2024-2025 COVID-19 vaccine at the start of the vaccination season and upon EUA by the U.S. Food and Drug Administration (FDA). When authorized, our vaccine will be the only protein-based option available in the U.S. for individuals aged 12 and older. Non-clinical data has demonstrated broad cross-neutralizing antibodies against multiple variant strains, including JN.1, KP.2 and KP.3, indicating the potential to protect against future-drift JN.1 lineage strains.[1,2] Recent public statements made by the FDA indicate that there will be no preference between JN.1 or KP.2 compositions, and both will be referred to as the 2024-2025 Formula.[3]

Having vaccine options is one way to potentially increase COVID-19 vaccination rates among individuals who have ceased to seek vaccination for a variety of reasons.[4,5] We are working with global regulatory authorities to ensure access to our vaccine and have filed for authorization with both the U.S. FDA and the European Medicines Agency.

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 JN.1 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, the immunogenic response of its vaccine technology against variant strains, 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, and its vaccine being the only protein-based vaccine on the U.S. market 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, antigenic drift or shift in the SARS-CoV2 spike protein, 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; entry of other protein-based COVID-19 vaccines on the U.S. market 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.

References

1. U.S. Centers for Disease Control and Prevention. Variant Proportions [Data set]. In COVID Data Tracker. 2024. Available at: https://covid.cdc.gov/covid-data-tracker/#variant-proportions.
2. World Health Organization. Statement on the antigen composition of COVID-19 vaccines. April 26, 2024. Available at: https://www.who.int/news/item/26-04-2024-statement-on-the-antigen-composition-of-covid-19-vaccines.

3. COVID-19 Vaccine Education and Equity Project (CVEEP). Webinar on Strain Selection. June 21, 2024.
4. Markovic-Denic L, Nikolic V, Pavlovic N, et al. Changes in Attitudes toward COVID-19 Vaccination and Vaccine Uptake during Pandemic. *Vaccines (Basel)*. 2023;11(1):147.
5. Kutasi K, Koltai J, Szabó-Morvai Á, et al. Understanding hesitancy with revealed preferences across COVID-19 vaccine types. *Sci Rep*. 2022;12(1):13293.