U.S. CDC and Advisory Committee Recommend Use of Authorized and Approved 2023-2024 Monovalent XBB COVID-19 Vaccines

September 12, 2023

Today the U.S. Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) voted in favor (13 in favor and 1 against) of a universal recommendation for the use of 2023-2024 (monovalent, XBB containing) COVID-19 vaccines authorized under Emergency Use Authorization (EUA) or approved by Biologics License Application. This vote was later endorsed by the CDC.

“Novavax is pleased that discussions at today’s ACIP meeting showed broad support for COVID vaccination this season via a universal recommendation, and also highlighted the urgent need for a protein-based option. Based on today’s discussion and upon authorization from the FDA, we anticipate that Novavax’s XBB COVID vaccine will be included in the ACIP’s recommendations in accordance with our label,” said John C. Jacobs, President and Chief Executive Officer, Novavax. “Doses of Novavax’s vaccine are already in the U.S. and once authorized, will be the only protein-based non-mRNA vaccine option available for individuals aged 12 and older.

Novavax presented non-clinical data at the ACIP meeting showing that Novavax’s COVID-19 Vaccine, Adjuvanted (Formula 2023-2024) induced neutralizing antibody responses to a broad range of circulating variants including new data on the FL.1.5.1 (“Fornax”) subvariant as well as robust CD4 polyfunctional cellular (T-cell) responses against EG.5.1 and XBB.1.16.6, which are becoming more prevalent in the U.S. These data indicate the vaccine can stimulate both arms of the immune system and is capable of inducing a broad response against circulating variants.

Following FDA authorization, Novavax’s vaccine will be widely available across the U.S., including but not limited to, retail pharmacies, physician offices and public health clinics, and through various government entities such as Vaccines for Children, Federal Qualified Health Centers, Indian Health Services and the U.S. Department of Defense.

Novavax is working with other global regulatory authorities, including the European Medicines Agency, Health Canada and the World Health Organization, 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, 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; challenges or delays obtaining regulatory authorization for our product candidates, including its updated XBB version of its COVID-19 vaccine in time for the fall 2023 vaccination season or for future COVID 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 in obtaining commercial adoption of our updated protein-based non mRNA XBB COVID vaccine, NVX-CoV2373 or any COVID 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
couraged 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 CDC. Understanding How COVID-19 Vaccines Work. Available at: https://www.cdc.gov/coronavirus/2019-
ncov/vaccines/different-vaccines/how-they-work.html.

doi:10.1126/science.add2897.