Novavax Investor Relations

Novavax today announced the submission of a request to the World Health Organization (WHO) to update the Emergency Use Listing (EUL) of Nuvaxovid™ (NVX-CoV2373) COVID-19 vaccine for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as a homologous and heterologous booster in adults aged 18 and older.

The request is supported by data from Novavax' Phase 2 trial conducted in Australia, from a separate Phase 2 trial conducted in South Africa, and from the UK-sponsored COV-BOOST trial. As part of the Phase 2 trials, a single booster dose of Nuvaxovid was administered to healthy adult participants approximately six months after their primary two-dose vaccination series of Nuvaxovid. The third dose produced increased immune responses comparable to or exceeding levels associated with protection in Phase 3 clinical trials. In the COV-BOOST trial, Nuvaxovid induced a meaningful antibody response when used as a heterologous third booster dose.

In the Novavax-sponsored trials, following the booster, local and systemic reactions had a median duration of approximately two days. The incidence of Grade 3 or higher events remained relatively low. Safety reporting of reactogenicity events showed an increasing incidence across all three doses of Nuvaxovid, often seen with increased immunogenicity. Medically attended adverse events (AE), potentially immune-mediated medical conditions, and severe AEs occurred infrequently following the booster dose and were balanced between vaccine and placebo groups.

Nuvaxovid has also been approved in the European Union, Japan, Australia, New Zealand, and Switzerland as a booster in adults aged 18 and older and is actively under review in other markets.

The WHO previously granted EUL for Nuvaxovid for adults aged 18 and older in December 2021.

Trade Name in the U.S.

The trade name Nuvaxovid™ has not yet 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, its position in the global COVID-19 market, the timing of clinical trial results, the ongoing development of Novavax' COVID-19 vaccine, including for use in adolescents and as a booster, the ability of Novavax' COVID-19 vaccine to address current and future variant strains, the scope, timing and outcome of future regulatory filings and actions 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; unanticipated challenges or delays in conducting clinical trials; 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; 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' Annual Report on Form 10-K for the year ended December 31, 2021 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 statement. 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 statement 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.
