Novavax Files in the European Union for Expanded Conditional Marketing Authorization of COVID-19 Vaccine as a Booster in Individuals Aged 18 and Over

May 20, 2022

Novavax today announced the submission of a request to the European Medicines Agency to expand the conditional marketing authorization (CMA) of Nuvaxovid™ (NVX-CoV2373) COVID-19 vaccine in the European Union (EU) as a homologous and heterologous booster dose for individuals aged 18 and over.

This request for expanded CMA 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 NVX-CoV2373. 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, NVX-CoV2373 induced a robust antibody response when used as a heterologous third booster dose.

Following the booster, local and systemic reactions were generally short-lived with 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 NVX-CoV2373, reflecting the increased immunogenicity seen with a third dose. Medically attended adverse events, potentially immune-mediated medical conditions, and severe adverse events occurred infrequently following the booster dose and were balanced between vaccine and placebo groups.

The European Commission granted CMA in December 2021 for use of Nuvaxovid in individuals aged 18 and over, and Novavax filed for expanded CMA for use in adolescents aged 12 through 17 in March 2022.

Authorization in the U.S.

NVX-CoV2373 has not yet been authorized for use in the U.S. and the trade name Nuvaxovid™ has not yet been approved by the U.S. Food and Drug Administration (FDA). The U.S. FDA's Vaccines and Related Biological Products Advisory Committee will review NVX-CoV2373 COVID-19 Vaccine for active immunization against SARS-CoV-2 during a meeting scheduled for June 7, 2022.