Novavax Files in the United Kingdom for Expanded Conditional Marketing Authorization of COVID-19 Vaccination as a Booster in Adults Aged 18 and Over

June 2, 2022

Novavax today announced the submission of a request to the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK) to expand the conditional marketing authorization (CMA) of Nuvaxovid™ (NVX-CoV2373) COVID-19 vaccine? 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 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 robust antibody response when used as a heterologous third booster dose.

In the Novavax-sponsored trials, 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 Nuvaxovid, 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 MHRA granted CMA in February 2022 for Nuvaxovid's use in individuals aged 18 and over and Novavax filed for expanded CMA for use in adolescents aged 12 through 17 in April 2022.

Authorization in the U.S.

The Novavax COVID-19 vaccine (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 the Novavax COVID-19 vaccine for active immunization against SARS-CoV-2 during a meeting scheduled for June 7, 2022.

?This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you are concerned about an adverse event, it should be reported on a Yellow Card. Reporting forms and information can be found at https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. When reporting please include the vaccine brand and batch/Lot number if available.