Novavax and SK bioscience File a Post Approval Change Application in South Korea for Nuvaxovid™ COVID-19 Vaccine as a Booster in Adults Aged 18 and Older

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Novavax today announced that partner, SK bioscience, has submitted a Post Approval Change Application to the Korean Ministry of Food and Drug Safety (KMFDS) for Nuvaxovid™ (NVX-CoV2373) COVID-19 vaccine for use as a heterologous and homologous booster for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adults aged 18 and older. In September 2022, the Korean Centers for Disease Control and Prevention advised that Nuvaxovid can be used off-label as a booster in adults aged 18 and older.

This request is based on 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 been authorized in the European Union, Japan, Australia, New Zealand, and Switzerland as a booster and is actively under review in other markets.

KMFDS approved Nuvaxovid for use in adults aged 18 and older in January 2022 and for use in adolescents aged 12 through 17 in July 2022. In Korea, SK bioscience signed a licensing agreement with Novavax and is manufacturing drug substance and drug product of Nuvaxovid for domestic use.

Trade Name in the U.S.

The trade name Nuvaxovid™ has not yet been approved by the U.S. Food and Drug Administration.