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South Korea approves Novavax Nuvaxovid COVID-19 vaccine as adult booster

19 January 2023 | News

Nuvaxovid (NVX-CoV2373) COVID-19 vaccine is authorised for use as an adult booster in more than 35 countries

US-based Novavax, Inc. has announced that partner SK bioscience, based in South Korea, has received expanded manufacturing and marketing approval from the Korean Ministry of Food and Drug Safety (KMFDS) for Nuvaxovid (NVX-CoV2373) for use as a booster for active immunisation to prevent COVID-19 in adults aged 18 and older.

Prior to the approval, in September 2022, the Korean Centers for Disease Control and Prevention set out recommendations that advised that Nuvaxovid could be used as a booster in adults aged 18 and older.

This approval is based on data from Novavax' Phase 2 trial conducted in the U.S. and Australia, from a separate Phase 2 trial conducted in South Africa, and from the United Kingdom-sponsored COV-BOOST trial. As part of the Novavax Phase 2 trials, a single booster dose of Nuvaxovid was administered to 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 significant antibody response when used as a booster dose following prior vaccination with other authorized COVID-19 vaccines.

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