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South Korea approves Nuvaxovid COVID-19 vaccine for use in adolescents

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Novavax and partner SK bioscience will provide the first protein-based COVID-19 vaccine approved for use in adolescents



US-based Novavax, Inc. has announced that partner, SK bioscience, has received a Post Approval Change Application approval from the Korean Ministry of Food and Drug Safety (KMFDS) for Nuvaxovid (NVX-CoV2373) COVID-19 vaccine for active immunization to prevent COVID-19 in adolescents aged 12 through 17.

The approval was based on data from the ongoing pediatric expansion of the Phase 3 PREVENT-19 trial of 2,247 adolescents aged 12 through 17 years across 73 sites in the US, to evaluate the safety, effectiveness (immunogenicity), and efficacy of Nuvaxovid. In the trial, Nuvaxovid achieved its primary effectiveness endpoint and demonstrated 80% clinical efficacy overall at a time when the Delta variant was the predominant circulating SARS-CoV-2 strain in the U.S.

In the 12 through 17 year-old population, Nuvaxovid has been granted authorization in India, the European Union, Australia, Thailand, and Japan, and is actively under review in other markets.

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