

Novavax Investor Relations

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.

<https://ir.novavax.com/Novavax-Files-in-the-European-Union-for-Expanded-Conditional-Marketing-Authorization-of-COVID-19-Vaccine-as-a-Booster-in-Individuals-Aged-18-and-Over>