Novavax Files in Switzerland for Expanded Conditional Marketing Authorization of Nuvaxovid™ COVID-19 Vaccine for Adolescents Aged 12 Through 17 and as a Booster in Individuals Aged 18 and Over

July 7, 2022

Novavax today announced the submission of a request to Swissmedic to expand the conditional marketing authorization (CMA) of Nuvaxovid™ (NVX-CoV2373) COVID-19 vaccine in Switzerland for active immunization to prevent COVID-19 caused by SARS-CoV-2 in adolescents aged 12 through 17 years and as a booster dose for individuals aged 18 and over.

The request for expanded CMA for adolescents aged 12 through 17 is based on data from the ongoing pediatric expansion of PREVENT-19, a pivotal Phase 3 trial of 2,247 adolescents aged 12 through 17 years across 73 sites in the U.S., 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.

Preliminary safety data from the trial showed that serious and severe adverse events were low in number and balanced between vaccine and placebo groups, and not considered related to the vaccine. Local and systemic reactogenicity was generally lower than or similar to adults, after the first and second dose. The most common adverse reactions observed were injection site tenderness/pain, headache, myalgia, fatigue, and malaise. There was no increase in reactogenicity in younger (12 to <15 years old) adolescents compared to older (15 to <18 years old) adolescents. No new safety signal was observed through the placebo-controlled portion of the study.

The request for expanded CMA for the booster dose 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 significant 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, 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.

Swissmedic granted CMA in April 2022 for use of Nuvaxovid in individuals aged 18 and over.

In the 12 through 17 year-old population, Nuvaxovid has been granted emergency use authorization in India and expanded CMA by the European Commission. In addition, the vaccine has been approved in Japan and provisionally registered in Australia as a booster.

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.