Novavax Files in Taiwan for Expanded Emergency Use Authorization of Nuvaxovid™ COVID-19 Vaccine in Adolescents Aged 12 Through 17

August 15, 2022

Novavax today announced the submission of a request for expanded emergency use authorization (EUA) to Taiwan's Food and Drug Administration (TFDA) for Nuvaxovid™ (NVX-CoV2373) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adolescents aged 12 through 17.

This request 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 U.S., to evaluate the safety, effectiveness (immunogenicity), and efficacy of Nuvaxovid. In the pediatric expansion, 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 pediatric expansion showed the vaccine to be generally well-tolerated. 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 pediatric expansion.

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.

TFDA authorized Nuvaxovid for individuals 18 and older in June 2022 and began administering doses of the vaccine in this population in July under the COVAX Facility.

Trade Name in the U.S.

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