Novavax Requests Expanded Emergency Use Listing with World Health Organization for Nuvaxovid™ COVID-19 Vaccine for Adolescents Aged 12 Through 17

July 29, 2022

- If EUL is granted, Nuvaxovid™ would be the first protein-based COVID-19 vaccine made available to adolescents by the WHO

Novavax today announced the submission of a request to the World Health Organization (WHO) to expand the Emergency Use Listing (EUL) of Nuvaxovid™ (NVX-CoV2373) COVID-19 vaccine 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 is based on data from the ongoing pediatric expansionof 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 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 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 study.

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

The WHO previously granted EUL for Nuvaxovid in adults aged 18 and older in December 2021.

Trade Name in the U.S.

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