Novavax Files Supplement to a New Drug Submission in Canada for Nuvaxovid™ COVID-19 Vaccine for Adolescents Aged 12 Through 17

June 23, 2022

Novavax today announced the filing of a Supplement to a New Drug Submission with Health Canada to expand the label of Nuvaxovid™ (NVX-CoV2373) COVID-19 vaccine for active immunization to prevent COVID-19 caused by SARS-CoV-2 to adolescents aged 12 through 17 years.

This request 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 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, emergency use authorization has been granted in India.

Health Canada approved Nuvaxovid in individuals 18 years of age and older in February 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.