Novavax Submits Variations to Expand Australian and New Zealand Provisional Approval of Nuvaxovid™ COVID-19 Vaccine to Adolescents aged 12 Through 17 Years

May 6, 2022

Novavax today announced the submission of variations to the Australian Therapeutic Goods Agency (TGA) and Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, to expand the provisional approval of its Nuvaxovid™ (NVX-CoV2373) COVID-19 Vaccine (recombinant, adjuvanted) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in adolescents aged 12 through 17 years.

TGA previously granted provisional registration in individuals 18 years of age and older in January 2022. Medsafe previously granted provisional approval in individuals 18 years of age and older in February 2022. The vaccine is given as a primary vaccination in two doses administered 21 days apart.

The request for provisional authorization is based on the totality of pre-clinical, clinical and manufacturing-related (CMC) data provided to the agencies. This submission includes clinical 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. The vaccine achieved its primary effectiveness endpoint in the trial and demonstrated 80 percent efficacy overall at a time when the Delta variant was the predominant circulating SARS-CoV-2 strain in the U.S.

Additionally, preliminary safety data from the pediatric expansion of PREVENT-19 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.

In the 12 through 17 year-old population, Novavax continues to submit regulatory filings worldwide, with emergency use authorization in this age range granted in India.

Novavax' sponsor in Australia is Biocelect Pty. Ltd. and in New Zealand is Biocelect New Zealand Ltd.

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.