Novavax Requests Expanded Authorization of Nuvaxovid™ COVID-19 Vaccine to Adolescents Aged 12 through 17 Years in Great Britain*

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If granted, Nuvaxovid™ would be the first protein-based COVID-19 vaccine option authorized for adolescents in Great Britain

Novavax today announced the submission of a request to the Medicines and Healthcare products Regulatory Agency (MHRA) in Great Britain to expand the authorization of 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.

The MHRA previously granted conditional marketing authorization (CMA) for Nuvaxovid 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.

This request for CMA expansion is based on the totality of pre-clinical, clinical, and manufacturing-related (CMC) data provided to the agency. 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.

?This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you are concerned about an adverse event, it should be reported on a Yellow Card. Reporting forms and information can be found at https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. When reporting please include the vaccine brand and batch/Lot number if available.

**Great Britain conditional marketing authorization includes England, Scotland and Wales*