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Thailand gives Emergency Use Authorisation for Novavax' COVID-19 vaccine

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NVX-CoV2373 is a protein-based vaccine engineered from the genetic sequence of the first strain of SARS-CoV-2

US-based Novavax, Inc. and Serum Institute of India have announced that the Thailand Food and Drug Administration (Thai FDA) has granted emergency use authorization (EUA) for Novavax' protein-based vaccine for active immunization to prevent COVID-19 in individuals 18 years of age and older. The vaccine, also known as NVX-CoV2373, is manufactured and marketed by SII under the brand name Covovax.

The Thai FDA decision was based on the totality of preclinical, manufacturing and clinical trial data submitted for review. This includes two pivotal Phase 3 clinical trials: PREVENT-19, which enrolled approximately 30,000 participants aged 18 years and older in the US and Mexico and was published in the New England Journal of Medicine (NEJM); and a trial with almost 15,000 adult participants in the U.K. which was also published in NEJM. In both trials, the vaccine demonstrated efficacy and a reassuring safety and tolerability profile. Serious and severe adverse events were low in number and balanced between vaccine and placebo groups.

Covovax has received Emergency Use Listing (EUL) from the World Health Organization, as well as EUA in India, Indonesia, the Philippines, and Bangladesh. It is also authorized for use in adolescents aged ?12 to <18 years in India.