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Japan approves Novavax's COVID-19 vaccine for adolescents

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Nuvaxovid is the first protein-based COVID-19 vaccine approved for use in adolescents in Japan



US-based Novavax has announced that Nuvaxovid (NVX-CoV2373) COVID-19 vaccine received expanded manufacturing and marketing approval from the Japan Ministry of Health, Labour and Welfare (MHLW) for primary immunization to prevent COVID-19 in adolescents aged 12 through 17. Novavax has partnered with Takeda to develop, manufacture, and distribute Nuvaxovid in Japan.

The expanded approval was 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.

Novavax licensed and transferred its manufacturing technologies and is supplying the Matrix-M™ adjuvant to enable Takeda to manufacture the vaccine at its Hikari facility.

In the 12 through 17 year-old population, Nuvaxovid has been granted conditional authorization in the European Union, emergency use authorization in India, and provisional registration in Australia, and is actively under review in other markets.Ã¢â?¬Â¯