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Novavax and SII gets EUA for COVID-19 vaccines for adolescents in India

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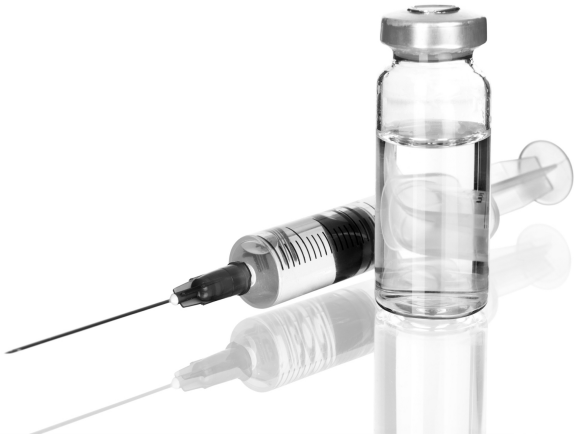
Novavax and Serum Institute of India Announce First Emergency Use Authorization of Novavax' COVID-19 Vaccine in Adolescents ?12 to <18 in India



Novavax, a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, and Serum Institute of India Pvt. Ltd. (SII), the world's largest vaccine manufacturer by volume, announced that the Drugs Controller General of India (DCGI) has granted emergency use authorization (EUA) for Novavax' protein-based COVID-19 vaccine for adolescents aged ?12 to <18 years in India. The vaccine, also known as NVX-CoV2373, is manufactured and marketed in India by SII under the brand name Covovax™ and is the first protein-based vaccine authorized for use in this age group in India.

A Phase 2/3, observer-blinded, randomized, controlled study in a total of 460 Indian adolescents aged ?12 to <18 years was conducted to evaluate the safety and immunogenicity of Covovax. The study demonstrated that Covovax was well-tolerated with a reassuring safety profile. Furthermore, the data indicated that Covovax is immunogenic in adolescents aged ?12 to <18 years. The authorization in India also references the ongoing PREVENT-19 pivotal Phase 3 pediatric expansion trial of NVX-CoV2373 in adolescents in the U.S. aged ?12 to <18, results of which were shared in February.