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Australia grants provisional registration for Novavax COVID-19 vaccine

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NuvaxovidÃ¢â??Â¢ is the first protein-based COVID-19 vaccine to receive approval for provisional registration in Australia



Novavax, Inc. has announced that Australia's Therapeutic Goods Administration (TGA) has granted approval for provisional registration of NVX-CoV2373, Novavax' COVID-19 vaccine (adjuvanted), for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals 18 years of age and older. The vaccine will be supplied to Australia under the brand name Nuvaxovid™.

Australia has played a pivotal role in Novavax' Phase 1 and Phase 2 clinical trials supporting the development of Nuvaxovid. Additionally, a booster trial for Nuvaxovid and a Phase 1/2 trial for a combination seasonal influenza and COVID-19 vaccine are currently underway in Australia. Overall, nearly 1,500 Australians have participated in Novavax COVID-19 and combination vaccine clinical trials.

Novavax and the Commonwealth of Australia announced an advance purchase agreement (APA) for 51 million doses of Novavax' COVID-19 vaccine in January 2021, with the option for an additional 10 million doses (up to 61 million doses total). The approval for provisional registration leverages Novavax' manufacturing partnership with Serum Institute of India (SII), the world's largest vaccine manufacturer by volume, which will supply initial doses to Australia. It will later be supplemented with data from additional manufacturing sites in Novavax' global supply chain.