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New Zealand gives provisional nod to first protein-based COVID-19 vaccine

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Medsafe grants provisional approval for Novavax' COVID-19 vaccine



US-based Novavax, Inc. has announced that New Zealand's Medsafe has granted provisional approval of NVX-CoV2373, Novavax' COVID-19 vaccine (adjuvanted), for active immunization in individuals 18 years of age and older. The vaccine will be supplied to New Zealand under the brand name Nuvaxovid™.

The provisional approval by Medsafe is based on evaluation of the quality, safety, and efficacy data submitted for review. This includes two pivotal Phase 3 clinical trials: PREVENT-19 enrolled approximately 30,000 participants in the U.S. and Mexico, the results of which were published in The New England Journal of Medicine (NEJM); and a trial with almost 15,000 participants in the U.K., the results of which were also published in NEJM.

Novavax and the New Zealand Government previously announced an advance purchase agreement (APA) for 10.7 million doses of Novavax' COVID-19 vaccine. This provisional approval leverages Novavax' manufacturing partnership with Serum Institute of India (SII), the world's largest vaccine manufacturer by volume, which will supply initial doses toNew Zealand. The provisional approval will later be supplemented with data from additional manufacturing sites in Novavax' global supply chain.