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Novavax begins Ph 1/2 trial of COVID-19 vaccine

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US based Novavax, Inc., a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, has announced enrollment of the first participants in a Phase 1/2 clinical trial of its coronavirus vaccine candidate, NVXÃ¢â?¬â??CoV2373, a stable, prefusion protein made using its proprietary nanoparticle technology.

NVXÃ¢â?¬â??CoV2373 includes Novavax' proprietary MatrixÃ¢â?¬â??M™ adjuvant to enhance immune responses and stimulate high levels of neutralizing antibodies. Preliminary immunogenicity and safety results from the Phase 1 portion of the trial are expected in July 2020.

The Phase 1/2 clinical trial is being conducted in two parts. The Phase 1 portion is a randomized, observer-blinded, placebo-controlled trial designed to evaluate the immunogenicity and safety of NVXÃ¢â?¬â??CoV2373, both adjuvanted with MatrixÃ¢â?¬â??M and unadjuvanted. The trial is enrolling approximately 130 healthy participants 18 to 59 years of age at two sites in Australia. The protocol's two-dose trial regimen assesses two dose sizes (5 and 25 micrograms) with MatrixÃ¢â?¬â??M and without.

The Phase 2 portion is expected to be conducted in multiple countries, including the United States, and would assess immunity, safety and COVIDÃ¢â?¬â??19 disease reduction in a broader age range. This Phase 1/2 approach allows for rapid advancement of NVXÃ¢â?¬â??CoV2373 during the pandemic. The trial is being supported by the recently announced funding arrangement with the Coalition for Epidemic Preparedness Innovations (CEPI).

Novavax identified NVXÃ¢â?¬â??CoV2373 as its lead SARS-CoV-2 candidate following pre-clinical testing that demonstrated high immunogenicity and high levels of neutralizing antibodies. These results provide strong evidence that the vaccine candidate will be highly immunogenic in humans, potentially leading to protection from COVIDÃ¢â?¬â??19 and thus helping to control the spread of this disease.