Novavax Initiates Phase 3 Trial of its COVID-19 Omicron Strain Vaccine as a Booster

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- *Trial will assess safety and antibody responses of NVX-CoV2515 to the Omicron variant of COVID-19*
- *Two-dose primary regimen of NVX-CoV2373 already demonstrated cross-reactive immune responses against Omicron and other variants*

Novavax today announced the initiation of its Phase 3 strain change trial to determine if its Omicron variant specific vaccine, NVX-CoV2515 (Omicron BA.1 strain), induces superior antibody responses against the Omicron variant compared to its Wuhan prototype vaccine, NVX-CoV2373, in participants who have received either a primary (two doses) or booster (three doses) series of an mRNA vaccine. The trial will also seek to determine the antibody responses to a bivalent vaccine, containing both NVX-CoV2373 and NVX-CoV2515, administered in participants who have received a booster series of an mRNA vaccine.

The observer blinded, randomized trial, will analyze reactogenicity and immune responses to NVX-CoV2515 and a bivalent vaccine in approximately 1,340 participants in Australia. Two doses of either NVX-CoV2515 or NVX-CoV2373 will be administered following three doses of either the Pfizer-BioNTech and/or Moderna vaccines received at least three months before joining the trial. Similarly, two doses of NVX-CoV2515 or NVX-CoV2373 will be administered following two doses of either mRNA vaccine received at least six months before joining the trial. Two doses of the bivalent vaccine will be administered in participants previously vaccinated with three doses of either mRNA vaccine at least three months before joining the trial. The duration of the trial is 10 months and initial results are expected in the second half of 2022.

Non-clinical animal data has shown NVX-CoV2515 demonstrated robust immune responses against Omicron BA.1 and Omicron BA. 2 spike proteins as measured by IgG, hACE2 receptor inhibition, and neutralizing antibodies. No notable safety findings were observed.

Novavax' original COVID-19 vaccine, NVX-CoV2373, has demonstrated broad cross-reactivity against Omicron and other circulating variants from a primary two-dose regimen, with responses that increased following a third dose at six months.

Authorization in the U.S.

The Novavax COVID-19 vaccine (NVX-CoV2373) has not yet been authorized for use in the U.S. and the trade name Nuvaxovid™ has not yet been approved by the U.S. Food and Drug Administration (FDA). The U.S. FDA's Vaccines and Related Biological Products Advisory Committee will review the Novavax COVID-19 vaccine for active immunization against SARS-CoV-2 during a meeting scheduled for June 7, 2022.