Novavax Statement on Omicron Variant Response

December 2, 2021

Novavax is rapidly responding to the emergence of the latest potential threat of the SARS-CoV-2 Omicron (B.1.1.529) variant of concern (VoC). The company is executing a two-pronged variant strategy.

First, Novavax is evaluating its vaccine against the Omicron variant, as the company has done for previous variants including Alpha, Beta and Delta. Second, Novavax has initiated development of an Omicron-specific vaccine construct.

Novavax is conducting ongoing studies to evaluate multiple variants, and we are encouraged by our current and ongoing data, which shows efficacy and safety against variants of interest (VoIs) and VoCs (see clinical data below). Based on this, we will evaluate whether immune responses induced by NVX-CoV2373, the company's recombinant nanoparticle protein-based COVID-19 vaccine, will offer similar cross-protection against Omicron as seen with other variants.

Novavax will begin testing whether antibodies from previously vaccinated individuals can neutralize the Omicron variant, with lab-based data expected in the coming weeks. Clinical samples from participants in Novavax' clinical trials will be evaluated as samples and viral reagents become available, and we will work diligently to expedite this analysis. Additionally, we plan on testing whether vaccinees' antibodies can block Omicron-hACE2 receptor binding (a step that is required in the viral invasion process).

In parallel, Novavax has initiated development of an Omicron-specific construct of its SARS-CoV-2 Spike protein (rS) antigen, currently in use in NVX-CoV2373. The initial steps required to manufacture an Omicron-specific spike are underway and GMP manufacturing in a commercial facility is anticipated in January 2022. Lab-based assessment of a new strain-matched nanoparticle vaccine will begin within a few weeks.

Clinical Trial Data Supporting Novavax' Nanoparticle Vaccine Technology with Matrix-M™ Adjuvant:

Following the emergence of other VoCs (Alpha, Beta, Delta), antibody responses were analyzed in Novavax' ongoing Phase 1/2 study in the US and Australia. Patients who received a third (6-month booster) dose of NVX-CoV2373 were evaluated for the production of antibodies against known VoCs in August 2021. The responses were encouraging for the protection against new variants:

- NVX-CoV2373 produced robust anti-Spike IgG responses following a booster dose at Day 189. Neutralization titers increased 4.3-fold overall compared to the peak response seen after the primary vaccination series (up 3.7-fold in adults aged 18-59 and 4.7-fold in adults aged 60-84).
- The boosted anti-Spike IgG responses were greater than what was observed in our Phase 3 clinical trials. UK Phase 3 efficacy was 96% against the prototype strain and 86% against Alpha. US/Mexico efficacy was 100% against non-VoI/VoCs, 93% against VoI/VoC and 94% against Alpha.
- The boosted antibody responses were functional. Microneutralization was greater than what was observed in Phase 3 studies, with a 4.6-5.5-fold increase.
- After boosting, all trial participants developed consistently high levels of functional hACE2 responses against all tested VoCs. There was a 10.8-fold increase against Alpha, a 6.6-fold increase against Beta and an 8.1-fold increase Delta. The responses against Delta and Beta suggest the maturation of the immune response and comparable efficacy to what was observed in our Phase 3 trials.
- A third dose booster of NVX-CoV2373 resulted in low rates of severe and serious adverse events and was well tolerated.

In PREVENT-19, Novavax' Phase 3 trial of NVX-CoV2373 in the U.S. and Mexico, we observed 93% efficacy against predominantly circulating VoI/VoCs, which represents 79% of cases for which sequence is available. Further, a post-hoc analysis showed 94% efficacy against the Alpha variant. We also observed 100% efficacy against variants not considered VoI/VoC.

Novavax' Phase 3 trial of NanoFlu™, our quadrivalent nanoparticle vaccine candidate against seasonal influenza, demonstrated the strong role our proprietary Matrix-M™ adjuvant can play in addressing rapid viral genetic drift. Matrix-M adjuvant was shown to increase and broaden immune response, with a demonstrated ability to stimulate high levels of neutralizing antibodies and T-cell responses.

Cumulatively, these clinical experiences are encouraging for insights into the performance of and our confidence in NVX-CoV2373 during an evolving COVID-19 pandemic.