Novavax Statement on Initial Com-COV2 Phase 2 Clinical Trial Results Presented at World Vaccine Congress Europe

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Today, topline immunogenicity and reactogenicity data from Comparing COVID-19 Vaccine Schedule Combinations – Stage 2 (Com-COV2), a Phase 2 clinical study conducted by the University of Oxford, were presented at the World Vaccine Congress taking place in Barcelona. Novavax' recombinant nanoparticle protein-based COVID-19 vaccine candidate, NVX-CoV2373, was one of four COVID-19 vaccines studied to provide data regarding heterologous primary immunization.

The study showed that NVX-CoV2373 remains well-tolerated and generates a robust immune response when given as the second dose in a mixed, or heterologous, regimen after either the Oxford/Astra Zeneca or Pfizer/BioNTech vaccines as the first dose. Across all six study arms, local and systemic reactogenicity was favorable after the 2nd dose of NVX-CoV2373, with a low frequency and severity of reactogenicity events after both the Oxford/AstraZeneca and Pfizer/BioNTech vaccines.

"Novavax was pleased to see an encouraging side effect profile in which a second dose of NVX-CoV2373 was comparable to a homologous regimen of either the Pfizer/BioNTech or Oxford/AstraZeneca vaccines and was the least reactogenic of the heterologous boost regimens," said Filip Dubovsky, MD, Executive Vice President, Chief Medical Officer, Novavax. "Two doses of Novavax' vaccine demonstrated high efficacy in large Phase 3 trials. As a second heterologous dose in this study, it generated a broad-based Th1 biased CD4+ cellular response and demonstrated that heterologous dosing with NVX-CoV2373 may offer advantages over other widely used COVID vaccines in inducing neutralizing antibodies against the Delta and Beta variants."

Novavax believes that in the absence of correlates of protection and standardized assays, more work is needed to interpret the clinical significance of the Immunoglobulin G (IgG) data. The company is conducting ongoing homologous booster studies with additional heterologous studies in the planning stages.

While Com-COV2 did not include a homologous regimen of NVX-CoV2373 as a comparison, the vaccine demonstrated efficacy of 96.4% against the original virus strain, 86.3% against the Alpha (B.1.1.7) variant and 89.7% efficacy overall in a UK-based pivotal Phase 3 trial. In the PREVENT-19 trial in the U.S. and Mexico, it demonstrated 100% protection against moderate and severe disease and 90.4% efficacy overall.
The University of Oxford expects to submit full findings from the study to a peer-review publication in the near future.

About Com-COV2
Com-COV2 included approximately 1070 adults 50 years of age or older who received their first vaccination during the prior 8-12 weeks. Volunteer study participants then received one of four different vaccines as a second dose, 359 of whom were administered NVX-CoV2373. Under the protocol, which was a designed as a non-inferiority study, participants were followed for reactogenicity (safety) and immune responses, comparing those who received a heterologous regimen to those who received a homologous regimen. Additional information is about the study is available here.