# Novavax to Participate in Vaccines and Related Biological Products Advisory Committee Review of COVID-19 Vaccines Strain Composition

June 28, 2022

Novavax is pleased to be one of three companies invited to participate in the U.S. Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting scheduled for June 28, 2022 to discuss whether and how the SARS-CoV-2 strain composition of COVID-19 vaccines should be modified. The FDA briefing book for the meeting is available here.

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

In May, Novavax initiated a Phase 3 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 also seeks to assess 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. Results and product availability are expected in the fall of this year.

Novavax submitted a request to the FDA for Emergency Use Authorization (EUA) in January 2022. The VRBPAC Committee voted 21 to 0 with one abstention on June 7, 2022, to recommend that the FDA grant EUA for NVX-CoV2373 for individuals aged 18 years and over.

**Authorization in the U.S.**

The Novavax COVID-19 vaccine (NVX-CoV2373) has not yet been authorized for use in the U.S.