

Novavax Announces Plan to Deliver Updated Protein-based Vaccine Consistent with FDA Recommendations for 2023/2024 Vaccination Season at VRBPAC Meeting

January 27, 2023

- *FDA Advisory Committee votes to harmonize vaccine strain composition of primary series and booster doses*
- *Novavax' protein-based option remains an important part of the current U.S. vaccine portfolio*

Novavax participated in yesterday's U.S. Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee's (VRBPAC) meeting, which resulted in a unanimous vote recommending harmonizing vaccine strain composition of primary series and booster doses. During the meeting, Novavax shared data demonstrating that the Novavax COVID-19 Vaccine, Adjuvanted (NVX-CoV2373), when used as a booster induces a broad functional immune response, including against forward drift variants.

“Offering vaccine choices – and ensuring continuous access to those choices – must be at the center of any strategy to protect public health against COVID-19,” said Silvia Taylor, Executive Vice President and Chief Communications Officer, Novavax. “As expressed by several VRBPAC members, the Novavax protein-based COVID-19 vaccine plays an important role in protecting public health as part of a diverse portfolio. Novavax is prepared to deliver an updated vaccine following FDA guidance on strain change.”

Use of the Novavax COVID-19 Vaccine, Adjuvanted in the U.S.

The Novavax COVID-19 Vaccine, Adjuvanted vaccine has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) as a primary series in individuals 12 years of age and older. The Novavax COVID-19 Vaccine, Adjuvanted vaccine is also authorized to provide a first booster dose at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine to individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.