## Novavax Statement on U.S. Availability of the Novavax COVID-19 Vaccine, Adjuvanted

July 22, 2022

Following Tuesday's <u>U.S. Centers for Disease Control and Prevention (CDC) endorsement</u> of the Novavax COVID-19 Vaccine, Adjuvanted (NVX-CoV2373) as a two-dose primary series in individuals 18 years of age and older, Novavax is pleased to announce that doses have shipped from its warehouse and have been received by the U.S. government's designated distribution centers today.

The CDC will now allocate doses to the states – including state and local distribution centers, federal pharmacy partners, and federally-qualified health centers – and they will have the ability to order doses starting on Monday, July 25. Doses are expected to be available to consumers for vaccinations shortly thereafter.

Information about where to access the Novavax COVID-19 Vaccine, Adjuvanted will be available on <u>Vaccines.gov</u> in the coming days. Importantly, consumers should work with their healthcare providers and local pharmacies to share requests for the vaccine in areas where it is not yet available to help inform additional allocation decisions by the CDC. Novavax is committed to making the first protein-based COVID-19 vaccine option available to the U.S. population and will be working closely with the U.S. Government to ensure consumers have access.

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

The Novavax COVID-19 Vaccine, Adjuvanted 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 provide a two-dose primary series to individuals 18 years of age and older to prevent Coronavirus Disease 2019 (COVID-19).

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.

## **Authorized Use**

The Novavax COVID-19 Vaccine, Adjuvanted is authorized for use under an Emergency Use Authorization (EUA) to provide a two-dose primary series for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.