U.S. Centers for Disease Control and Prevention Endorses Advisory Committee on Immunization Practices' Recommendation for Novavax COVID-19 Vaccine, Adjuvanted

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• U.S. CDC Advisory Committee unanimously recommended vaccination with Novavax COVID-19 Vaccine, Adjuvanted for individuals aged 18 and older earlier today
• Novavax' vaccine is the first protein-based vaccine to receive Emergency Use Authorization and CDC endorsement in the U.S.

Today the U.S. Centers for Disease Control and Prevention (CDC) endorsed the Novavax COVID-19 Vaccine, Adjuvanted (NVX-CoV2373) for active immunization against SARS-CoV-2, following the Advisory Committee on Immunization Practices' (ACIP) unanimous vote to recommend the vaccine as a two-dose primary series in individuals aged 18 and older. The CDC establishes its vaccine recommendations and schedules based on advice from ACIP.

The recommendation follows the Emergency Use Authorization (EUA) granted by the U.S. Food and Drug Administration (FDA). The FDA has determined that the first vaccine lot has met all release specifications and is acceptable for use under EUA. Novavax expects to ship doses to the U.S. Government-designated distribution center in the coming days.

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.