Novavax Continues to Partner with the U.S. FDA on Review of 2024-2025 Formula COVID-19 Vaccine

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Novavax and the U.S. Food and Drug Administration (FDA) are working together productively as the U.S. FDA continues its review of data in consideration of an Emergency Use Authorization (EUA) of Novavax's 2024-2025 formula COVID-19 vaccine (NVX-CoV2705).

"Novavax is working expeditiously to provide the additional information the U.S. FDA requires to complete its review and we are grateful for their ongoing efforts and strong partnership," said John C. Jacobs, President and Chief Executive Officer, Novavax. "Novavax's intent is to provide access to our vaccine as a choice for consumers this season."

The U.S. FDA has committed to moving swiftly on regulatory action once their review of the expected data is completed.

Upon expected authorization in the U.S., product will be supplied in pre-filled syringes and will be available in thousands of locations across the country, including retailers, regional grocers and independent pharmacies.

Novavax's 2024-2025 formula COVID-19 vaccine targets JN.1, the "parent strain" of currently circulating variants and has demonstrated cross-reactivity against JN.1 lineage viruses, including KP.2.3, KP.3, KP.3.1.1 and LB.1.[1] Upon expected authorization, Novavax's vaccine will be the only protein-based option available in the U.S. for use in individuals aged 12 and older to prevent COVID-19.

References:

1. U.S. Centers for Disease Control and Prevention. Variant Proportions [Data set]. In COVID Data Tracker. 2024. Available at: https://covid.cdc.gov/covid-data-tracker/#variant-proportions.