

Update on Novavax's COVID-19-Influenza Combination and Stand-alone Influenza Phase 3 Trial

October 16, 2024

GAITHERSBURG, Md., Oct. 16, 2024 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its Matrix-M™ adjuvant, today announced that the U.S. Food and Drug Administration (FDA) has placed a clinical hold on Novavax's Investigational New Drug (IND) application for its COVID-19-Influenza Combination (CIC) and stand-alone influenza vaccine candidates. The clinical hold is due to a spontaneous report of a serious adverse event (SAE) of motor neuropathy in a single CIC Phase 2 trial participant outside of the U.S. who received the vaccine in January 2023. The trial completed in July 2023 and the participant reported the SAE in September 2024.

"We are working closely with the FDA to provide the necessary information that will allow them to better understand this observation and resolve the clinical hold," said Robert Walker, MD, Chief Medical Officer, Novavax. "It is important to note that safety is our top priority, and while we do not believe causality has been established for this serious adverse event, we are committed to working expeditiously to fulfill requests for more information from the FDA. Our goal is to successfully resolve this matter and to start our Phase 3 trial as soon as possible."

Data from Novavax's previous COVID-19 and influenza trials have shown no signals for motor neuropathy. Investigators have been informed of this action. The COVID-19 IND for Novavax's COVID-19 vaccine is not impacted by the clinical hold.

About Novavax

Novavax, Inc. (Nasdaq: NVAX) promotes improved health by discovering, developing and commercializing innovative vaccines to help protect against serious infectious diseases. Novavax, a global company based in Gaithersburg, Md., U.S., offers a differentiated vaccine platform that combines a recombinant protein approach, innovative nanoparticle technology and Novavax's patented Matrix-M adjuvant to enhance the immune response. The Company's portfolio includes its COVID-19 vaccine and its pipeline includes its CIC and tNIV vaccine candidates. In addition, Novavax's adjuvant is included in the University of Oxford and Serum Institute of India's R21/Matrix-M malaria vaccine. Please visit [novavax.com](https://www.novavax.com) and [LinkedIn](#) for more information.

Forward-Looking Statements

Statements herein relating to the potential resolution of the clinical hold placed on Novavax's IND for its CIC and stand-alone influenza vaccine candidates and the timing of the initiation of the Phase 3 trial for Novavax's CIC and stand-alone influenza vaccine candidates are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, without limitation, challenges satisfying, alone or together with partners, various safety, efficacy and product characterization requirements, including those related to process qualification and assay validation, necessary to satisfy applicable regulatory authorities; resource constraints, including human capital and manufacturing capacity, on the ability of Novavax to pursue planned regulatory pathways; challenges or delays in clinical trials; manufacturing, distribution or export delays or challenges; Novavax's exclusive dependence on Serum Institute of India Pvt. Ltd. for co-formulation and filling and the impact of any delays or disruptions in their operations on the delivery of customer orders; and those other risk factors identified in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Novavax's Annual Report on Form 10-K for the year ended December 31, 2023, and subsequent Quarterly Reports on Form 10-Q, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at www.sec.gov and www.novavax.com, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of the statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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