U.S. FDA Removes Clinical Hold on Novavax's COVID-19-Influenza Combination and Stand-alone Influenza Phase 3 Trial

November 11, 2024

GAITHERSBURG, Md., Nov. 11, 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 removed the clinical hold on Novavax's Investigational New Drug (IND) application for its COVID-19-Influenza Combination (CIC) and stand-alone influenza vaccine candidates. The FDA has cleared the Company to begin enrolling the planned Phase 3 trial following the determination that Novavax satisfactorily addressed all clinical hold issues. Novavax will be working with the clinical trial investigators and other partners to resume trial activities as quickly as possible.

"We thank the FDA for their partnership and thorough review of the additional information provided as part of our response package," said Robert Walker, MD, Chief Medical Officer, Novavax. "The information provided to the FDA supported our assessment that the serious adverse event was not related to our vaccine. We plan to start our Phase 3 trial as soon as possible."

The clinical hold announced on October 16, 2024, resulted from a spontaneous report of a serious adverse event in a participant who received investigational CIC vaccine in a Phase 2 trial that completed in 2023. The FDA had requested additional information on this event, initially reported as motor neuropathy. The additional information included a change in the event term to amytrophic lateral sclerosis, a condition that is not known to be immune-mediated or associated with vaccination, which in this event was assessed as not related to vaccination.

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 stand-alone influenza 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 and LinkedIn for more information.

Forward-Looking Statements
Statements herein relating to 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, including the enrolment of trial participants; manufacturing, distribution or export delays or challenges; Novavax's exclusive dependence on Serum Institute of IndiaPvt. 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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