- *This Phase 2 trial is evaluating three vaccine candidates: COVID-Influenza Combination, stand-alone influenza and high-dose COVID*
- *Preliminary topline immune responses for all three vaccine candidates were robust versus authorized comparators*
- *For the stand-alone influenza vaccine candidate, HAI responses were 31 to 56% higher for all four influenza strains compared to Fluad®, and were 44 to 89% higher for A strains compared to Fluzone HD®*
- *For the COVID-Influenza Combination vaccine candidate, anti-S IgG and neutralization responses achieved levels seen in Phase 3 trial with Novavax's prototype vaccine, with HAI responses generally consistent with Fluad® and Fluzone HD®*
- *All three vaccine candidates were well-tolerated and demonstrated a reassuring preliminary safety profile, with reactogenicity comparable to authorized comparators*
- *These Phase 2 results support continued development for all three vaccine candidates*

GAITHERSBURG, Md., May 9, 2023 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its novel Matrix-M™ adjuvant, today announced that its COVID-Influenza Combination (CIC), stand-alone influenza and high-dose COVID vaccine candidates all showed a reassuring preliminary safety profile as well as comparable reactogenicity to individual Novavax influenza and COVID vaccine candidates or authorized influenza vaccine comparators. Additionally, all three vaccines demonstrated preliminary robust immune responses.

The primary endpoint evaluated the safety of different formulations of the CIC vaccine candidate and the quadrivalent influenza vaccine candidate compared to Fluad®* and Fluzone High-Dose Quadrivalent®** (Fluzone HD), as well as a high-dose COVID vaccine candidate in adults aged 50 through 80. All three vaccine candidates contained Novavax's patented Matrix-M adjuvant and showed reassuring preliminary safety profiles and reactogenicity that was comparable to Fluad and Fluzone HD. The reactogenicity profile remained consistent as the adjuvant or antigen dose was increased.

In all groups there were no adverse events (AE) of special interest, no potentially immune mediated medical conditions and no treatment-related serious AEs. Unsolicited AEs occurred in 25% or fewer of any group and were consistent with diagnoses in the older adult population. Local and systemic symptoms were mostly mild and moderate and occurred at rates comparable to Fluad and Fluzone HD.

"The reactogenicity results support our previous observations that this technology is well suited for combination vaccines because large amounts of antigen can be incorporated without impacting tolerability," said Filip Dubovsky President, Research and Development, Novavax. "The immune responses we observed were robust, and the data we have shared today significantly increase the probability of Phase 3 success."

The CIC vaccine candidate achieved both immunoglobulin G (IgG) and neutralizing levels comparable to Novavax's prototype COVID vaccine (NVX-CoV2373). In addition, several of the combination formulations achieved responses to both SARS-CoV-2 and to the four homologous influenza strains that were comparable to the reference comparators, supporting their prioritization for advanced development. The stand-alone influenza vaccine candidate achieved statistically significant hemagglutination inhibition (HAI) antibody responses 31 to 56% higher for all four strains compared to Fluad. Titers were 44 (H1N1) to 89% (H3N2) higher for A strains and statistically non-inferior for B-strains compared to Fluzone HD.

The highest dose stand-alone COVID vaccine candidate achieved statistically significant anti-S IgG and neutralization responses approximately 30% higher than Novavax's prototype COVID vaccine while maintaining comparable safety and reactogenicity to currently authorized dose level of Nuvaxovid.

"Today's positive data are encouraging and further validate the value of our technology platform and its potential to improve global public health," said John C. Jacobs, President and Chief Executive Officer, Novavax. "This is an important milestone in our journey to create additional value and diversify our portfolio of vaccines."

About the Phase 2 Trial for CIC, Stand-alone Influenza and High-Dose COVID Vaccine Candidates
The Phase 2 Trial is a dose-confirming, randomized, observer-blinded trial evaluating the safety and effectiveness (immunogenicity) of different formulations of the CIC and influenza vaccine candidates, and higher doses of Novavax's COVID vaccine in adults aged 50 through 80. The trial is assessing a CIC vaccine candidate comprised of Novavax's recombinant protein-based COVID vaccine, quadrivalent influenza vaccine candidate and patented saponin-based Matrix-M adjuvant. Primary and secondary objectives of the study are to assess the safety, tolerability and immune responses to various formulations of the CIC, influenza and high-dose COVID vaccine candidates. The Phase 2 dose-confirmation trial is being conducted in two parts.

About NVX-CoV2373

NVX-CoV2373 is a protein-based vaccine made by creating copies of the surface spike protein of SARS-CoV-2 that causes COVID. With Novavax's unique recombinant nanoparticle technology, the non-infectious spike protein serves as the antigen that primes the immune system to recognize the virus, while Novavax's Matrix-M adjuvant enhances and broadens the immune response. The vaccine is packaged as a ready-to-use liquid formulation and is stored at 2° to 8°C, enabling the use of existing vaccine supply and cold chain channels.

About Matrix-M™ Adjuvant
When added to vaccines, Novavax's patented saponin-based Matrix-M adjuvant enhances the immune system response, making it broader, and more durable. The Matrix-M adjuvant stimulates the entry of antigen-presenting cells at the injection site and enhances antigen presentation in local lymph nodes.

About Novavax
Novavax, Inc. (Nasdaq: NVAX) promotes improved health by discovering, developing and commercializing innovative vaccines to 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. Focused on the world's most urgent health challenges, Novavax is currently evaluating vaccines for COVID, influenza, and COVID and influenza combined. Please visit novavax.com and LinkedIn for more information.

Forward-Looking Statements
Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the timing of clinical trial results, the ongoing development of NVX-CoV2373, the CIC, the high-dose COVID vaccine candidates, the quadrivalent influenza investigational vaccine candidate, the potential impact and reach of Novavax and NVX-CoV2373 in improving public health, the efficacy, safety intended utilization, and the expected administration of NVX-CoV2373 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; difficulty obtaining scarce raw materials and supplies; resource constraints, including human capital and manufacturing capacity, on the ability of Novavax to pursue planned regulatory pathways; unanticipated challenges or delays in conducting clinical trials; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities; challenges in implementing our global restructuring and cost reduction plan; challenges in obtaining commercial adoption of NVX-CoV2373 or a COVID-19 variant strain-containing formulation; 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, 2022 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.

*Fluad® is a registered trademark of Seqirus UK Limited
**Fluzone High-Dose Quadrivalent®* is a registered trademark of Sanofi Pasteur Inc.

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https://ir.novavax.com/2023-05-09-Positive-Phase-2-Topline-Results-Show-Novavaxs-COVID-Influenza-Combination,-Stand-alone-Influenza-and-High-dose-COVID-Vaccine-Candidates-Demonstrate-Robust-Immune-Responses