Results from Novavax NanoFlu Influenza Vaccine Phase 3 Clinical Trial Published in The Lancet Infectious Diseases

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GAITHERSBURG, Md., Sept. 23, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced publication of complete results from a pivotal Phase 3 clinical trial of NanoFlu™, its recombinant quadrivalent seasonal influenza vaccine candidate with Matrix-M™ adjuvant, in *The Lancet Infectious Diseases (Lancet ID*).

The trial evaluated the immunogenicity and safety of NanoFlu in older adults compared to a leading U.S.-licensed quadrivalent influenza vaccine. In the complete analysis, NanoFlu was well-tolerated and produced significantly enhanced humoral and cellular immune responses versus the comparator vaccine.

"Despite high vaccination rates, limitations in the effectiveness of existing influenza vaccines leave significant disease burden unaddressed, particularly in older adults," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "These encouraging results reflect NanoFlu's promise, especially as we currently have a combination COVID-19-influenza vaccine under evaluation for protection against two life-threatening diseases simultaneously."

Novavax previously announced that NanoFlu achieved the trial's primary endpoints, demonstrating non-inferior immunogenicity to Fluzone® Quadrivalent against all four influenza virus strains included in the vaccine, while also showing both enhanced wild-type hemagglutination-inhibiting antibody responses against homologous strains (22-66% increased) and six heterologous A/H3N2 strains (34-46% increased) as compared to Fluzone Quadrivalent.

Additionally, NanoFlu showed potent induction of polyfunctional antigen-specific CD4+ T-cells against A/H3N2 and B/Victoria strains, with a 126–189% increase in various post-vaccination cell-mediated immunity markers as compared to Fluzone Quadrivalent.

The paper, 'Comparison of the safety and immunogenicity of a novel Matrix-M-adjuvanted nanoparticle influenza vaccine with a quadrivalent seasonal influenza vaccine in older adults: a phase 3 randomised controlled trial,' may be accessed here. The manuscript was previously posted to the medRxiv preprint server in August 2020.

About NanoFlu™
NanoFlu™ is a quadrivalent recombinant hemagglutinin (HA) protein nanoparticle influenza vaccine produced in Novavax' SF9 insect cell baculovirus system. NanoFlu uses HA amino acid protein sequences that are the same as the recommended wild-type circulating virus HA sequences and contains Novavax' patented saponin-based Matrix-M™ adjuvant.

About Matrix-M™ Adjuvant
Novavax' patented saponin-based Matrix-M™ adjuvant has demonstrated a potent and well-tolerated effect by stimulating the entry of antigen-presenting cells into the injection site and enhancing antigen presentation in local lymph nodes, boosting immune response.

About Novavax
Novavax, Inc. (Nasdaq: NVAX) is a biotechnology company that promotes improved health globally through the discovery, development and commercialization of innovative vaccines to prevent serious infectious diseases. The company's proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles designed to address urgent global health needs. Novavax is conducting late-stage clinical trials for NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Both vaccine candidates incorporate Novavax' proprietary saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies.

For more information, visit www.novavax.com and connect with us on Twitter and LinkedIn.

Forward-Looking Statements
Statements herein relating to the future of Novavax, its operating plans and prospects, the ongoing development of NanoFlu™ and its partnerships, and other Novavax vaccine product candidates, the efficacy, safety and intended utilization of our product candidates, the timing of results from clinical trials, and the potential for a combination NanoFlu™ and NVX-

CoV2373 vaccine to lead to greater efficiencies for the healthcare system and achieve high levels of protection against COVID-19 and influenza 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 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; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities; 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' Annual Report on Form 10-K for the year ended December 31, 2020 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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