

# New England Journal of Medicine Publishes Novavax' NanoFlu Clinical Trial Data

June 13, 2018

GAITHERSBURG, Md., June 13, 2018 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq:NVAX) today announced that *The New England Journal of Medicine* (NEJM) published a peer-reviewed letter to the editor detailing the positive results from Novavax' Phase 1/2 clinical trial in older adults comparing its Matrix-M<sup>TM</sup> adjuvanted nanoparticle seasonal influenza vaccine candidate (NanoFlu) to the leading licensed egg-based, high-dose influenza vaccine (IIV3-HD). The letter is available online at [www.nejm.org/doi/full/10.1056/NEJMc1803554](http://www.nejm.org/doi/full/10.1056/NEJMc1803554).

"We are pleased to be able to share the detailed data from the NanoFlu Phase 1/2 clinical trial with the broader scientific community," said Stanley C. Erck, President and Chief Executive Officer of Novavax, Inc. "The low effectiveness of seasonal influenza vaccines, and in particular the A(H3N2) component of the vaccine, during the 2017-2018 season emphasizes the need for a more effective vaccine. Our non-egg-based, recombinant nanoparticle vaccine, when coupled with Matrix-M, potentially offers broader protection against rapidly evolving drift strain variants. We believe this addresses important public health challenges caused by influenza and offers a significant advantage over current influenza vaccines."

In February 2018, Novavax reported the positive top-line results from the NanoFlu Phase 1/2 clinical trial in older adults. Details of the data, as published in this letter, include that NanoFlu in comparison to IIV3-HD induced:

- Hemagglutination inhibition (HAI) immune responses that were 28 to 64% greater against the homologous and four generations of drifted wild-type A(H3N2) influenza strains; and
- Higher HAI responses against the homologous A(H1N1) strain and comparable responses against the homologous B/Brisbane strain.

"These results showcase the potential benefit NanoFlu could have for older adults, a population challenged by poor immune responses. This population faces an urgent unmet medical need for a more effective flu vaccine, as highlighted by the severe flu season of 2017-2018," said Dr. Vivek Shinde, Executive Director, Clinical Development at Novavax and lead author of the letter. "We look forward to advancing this vaccine into the planned Phase 2 clinical trial of quadrivalent NanoFlu in the third quarter of 2018."

## About the Phase 1/2 Clinical Trial

Novavax, Inc. conducted a randomized, observer-blind, comparator-controlled trial of NanoFlu (in two trivalent formulations: 45µg or 180µg total HA) against IIV3-HD in 330 healthy adults aged 60 years or older. Immunogenicity was measured by HAI and neutralization antibody responses against a panel of vaccine-homologous, and historically and forward-drifted, influenza virus strains.

## About NanoFlu<sup>TM</sup> and Matrix M<sup>TM</sup>

NanoFlu is a recombinant hemagglutinin (HA) protein nanoparticle influenza vaccine candidate produced by Novavax in its SF9 insect cell baculovirus system. NanoFlu uses HA amino acid protein sequences that are substantially the same as wild-type circulating virus HA sequences. NanoFlu contains Novavax' patented saponin-based Matrix-M adjuvant, which 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.

## About Novavax

Novavax, Inc. is a clinical-stage biotechnology company committed to delivering novel products to prevent infectious diseases. Its RSV and NanoFlu vaccine candidates are Novavax' most advanced clinical programs and are at the forefront of its efforts to improve global health. For more information, please visit [www.novavax.com](http://www.novavax.com).

## Forward-Looking Statements

Statements herein relating to the future of Novavax and the ongoing development of its vaccine and adjuvant products are forward-looking statements. Novavax cautions that these forward looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include those identified under the heading "Risk Factors" in the Novavax Annual Report on Form 10-

K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at [sec.gov](http://sec.gov), 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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