Novavax Continues Phase 3 Trial of the RSV F Vaccine for Infants via Maternal Immunization and Provides Update on Phase 1/2 Trial of the NanoFlu™ Vaccine

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GAITHERSBURG, Md., Dec. 18, 2017 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq:NVAX) today announced the Phase 3 trial of its RSV F protein recombinant nanoparticle vaccine (RSV F Vaccine) for infants via maternal immunization will continue. Novavax also provided an update on its nanoparticle influenza vaccine candidate with proprietary Matrix-M™ adjuvant (NanoFlu™).

RSV F Vaccine for Infants via Maternal Immunization

“Novavax has completed an informational analysis of our Phase 3 trial of the RSV F Vaccine for infants via maternal immunization using threshold criteria for a commercial product. As a result, we are accelerating our Phase 3 trial enrollment into 2018. Our maternal immunization program is supported by an $89 million grant from the Bill and Melinda Gates Foundation and has also been granted Fast Track designation by the U.S. Food and Drug Administration,” said Stanley C. Erck, President and CEO. “We have enrolled over 3,000 volunteers to date and anticipate that the current pace of enrollment would trigger an interim analysis in mid-2018, with an expected Phase 3 primary endpoint readout in early 2019. This timing would allow us to submit a biologics license application (BLA) by the end of 2019.”

NanoFlu Vaccine

A number of key scientific developments regarding influenza vaccines for the current season have occurred and relate to our NanoFlu program, including:

- A November 29, 2017, editorial in the *New England Journal of Medicine*1 detailed public health concerns related to the poor efficacy of existing seasonal influenza vaccines that is due, in part, to genetic changes or drift in the hemagglutinin (HA) protein, leading to low vaccine efficacy
- Based on analyses from the Southern Hemisphere, the effectiveness of the seasonal influenza vaccine was as low as 10% for the A(H3N2) strain2
- A November 6, 2017, *Proceedings of the National Academy of Sciences*3 publication identified that the circulating influenza A(H3N2) virus contains an HA structure that has been lost in the corresponding vaccine strain during adaptation to be grown in eggs (“egg-adapted”) as part of the typical seasonal influenza vaccine manufacturing process, which, in turn, affects vaccine efficacy for egg-based vaccines
- Novavax’ NanoFlu vaccine candidate is designed specifically to address these challenges
- The wild-type viruses necessary to assess immunogenicity of the vaccines to circulating strains have been difficult to obtain, grow and maintain genetic stability
- Therefore, a complete Phase 1/2 data package expected in February 2018

“Recent information published presents both an opportunity and a challenge for our NanoFlu Vaccine program. First, we have the unique opportunity to determine whether our recombinant, adjuvanted NanoFlu vaccine can address egg-adapted virus mismatch. We can also observe whether our vaccine-induced antibodies can neutralize circulating viruses with antigenic drift in humans, as we demonstrated in our ferret study earlier this year,” said Greg Glenn, M.D., President, R&D. “Our team has been able to optimize our assays to address this challenge and we expect to present NanoFlu immunogenicity data that includes HA inhibition and microneutralization assays comparing wild-type virus and egg-based reagents.”

About RSV

Respiratory syncytial virus (RSV) is the most common cause of lower respiratory tract infections and the leading viral cause of severe lower respiratory tract disease in infants and young children worldwide, with estimated annual infection and mortality rates of 64 million and 160,000, respectively4. In the US, RSV is the leading cause of hospitalization of infants5. Despite the induction of post-infection immunity, repeat infection and lifelong susceptibility to RSV is common6,7. Currently, there is no approved RSV vaccine available.

About Influenza

Influenza is a world-wide infectious disease that causes illness in humans with symptoms ranging from mild to life-threatening or even death. Serious illness occurs not only in susceptible populations such as pediatrics and older adults, but also in the general population largely because of infection by unique strains of influenza for which most humans have not developed protective antibodies. An estimated one million deaths each year are attributed to influenza8. Current estimates for seasonal influenza vaccine growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show a potential increase from approximately $3.2 billion in the 2012-2013 season to $5.3 billion by the 2021-2022 season9.

About Fast Track

The Fast Track Drug Development Program was established under the FDA Modernization Act of 1997. A Fast Track designation is intended for products that treat serious or life-threatening diseases or conditions, and that demonstrate the potential to address unmet medical needs for such diseases or conditions. The program is intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously. Specifically, Fast Track designation facilitates meetings to discuss all aspects of development to support licensure and it provides the opportunity to submit sections of a Biologics License Application (BLA) on a rolling basis as data become available, which permits the FDA to review modules of the BLA as they are received instead of waiting for the entire BLA submission. In addition, priority review (6 month review versus standard 10 month review) is a potential benefit that may be available to Novavax' RSV F vaccine in the future.

About Novavax

Novavax, Inc. (Nasdaq:NVAX) is a clinical-stage biotechnology company committed to delivering novel products to prevent a broad range of infectious diseases. Our recombinant nanoparticles and Matrix-M™ adjuvant technology are the foundation for groundbreaking innovation that improves global health through safe and effective vaccines. Additional information about Novavax is available on the Company's website, novavax.com.

References

1. Paules, C. I. *et al*. Chasing seasonal influenza – The need for a universal influenza vaccine. *NEJM*, 2017. DOI: 10.1056/NEJMp1714916.
2. Sullivan, S. G. *et al*. Low interim influenza vaccines effectiveness, Australia, 1 May to 24 September 2017, *Eurosurveillance*, 2017, 22(43): pii=17-00707. https://doi.org/10.2807/1560-7917.ES.2017.22.43.17-00707
3. Zost, S.J., *et al*. Contemporary H3N2 influenza viruses have a glycosylation site that alters binding of antibodies elicited by egg-adapted vaccine strains. *PNAS*, 2017, 12578-12583, doi: 10.1073/pnas.1712377114.
4. Nair, H. et al. Global burden of acute lower respiratory infections due to respiratory syncytial virus in young children: a systematic review and meta-analysis. Lancet, 2010; 375: 1545-1555.
5. Hall, C.B. et al. Respiratory Syncytial Virus-Associated hospitalizations Among Children Less Than 24 Months of Age. Pediatrics, 2013; 132(2): E341-348.
6. Glezen, W.P. et al. Risk of primary infection and reinfection with respiratory syncytial virus. Am J Dis Child, 1986; 140:543-546.
7. Glenn GM, et al. Modeling maternal fetal RSV F vaccine induced antibody transfer in guinea pigs. Vaccine, 2015, http://dx.doi.org/10.1016/j.vaccine.2015.08.039.
8. Resolution of the World Health Assembly. (2003) WHA56.19.28
9. Influenza Vaccines Forecasts. Datamonitor (2013)

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, 2016 and the Quarterly Report on Form 10-Q for the period ended September 30, 2017, both 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, 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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