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## **Novavax Reports Positive Data for its Trivalent Seasonal Influenza (VLP) Vaccine Candidate in a Second Phase II Study**

- *Results Presented at 47<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America*
- *VLP vaccine induced robust hemagglutinin inhibition (HAI) antibody responses against all vaccine strains and a drifted strain*
- *First evidence of generation of functional anti-neuraminidase antibody by VLP vaccine*

**ROCKVILLE, MD** (November 2, 2009) – /PRNewswire-FirstCall/ - Novavax, Inc. (NASDAQ: NVAX) a clinical-stage vaccine company, announced today that the Company made a poster presentation on the “Safety and Immunogenicity of a Recombinant Trivalent Seasonal Influenza Virus-like Particle (VLP) Vaccine in Healthy Adults” on Saturday, October 31, 2009 at the 47<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America (IDSA).

This presentation included data from a study of Novavax’s trivalent seasonal influenza VLP vaccine that began in May of this year among healthy adults 18 to 49 years of age. The vaccine contained VLPs matched to the influenza strains recommended for the 2008-2009 influenza vaccine including H1N1 A/Brisbane/59/2007, H3N2 A/Brisbane/10/2007, and B/Florida/04/2006. The study enrolled 241 subjects in total, including 221 who were randomized to receive either VLP vaccine at 15 µg or 60 µg or a placebo and 20 subjects who received an inactivated influenza vaccine (TIV).

The trivalent seasonal influenza VLP vaccine was well tolerated and immunogenic. The incidence of adverse events was comparable in the VLP vaccine groups (10.6%) and the placebo group (11.8%). No serious vaccine-related adverse events have been reported to date. The VLP vaccine induced robust hemagglutination inhibition (HAI) antibody responses against all three strains in the vaccine and a drifted strain. Seroconversion ( $\geq 4$ -fold rise in titer from baseline) rates met the suggested FDA criteria for licensure of seasonal influenza vaccines for all three strains. For subjects in the 15 µg group, seroconversion rates (95% CIs) were 57% (44, 68), 86% (75, 93), and 62% (50,74) against the H1N1, H3N2, and B strains, respectively. Seroprotection (titer  $\geq 1:40$ ) rates met the FDA criteria for licensure for all strains except the H1N1 strain. For subjects in the 15 µg group, seroprotection rates (95% CIs) were 67% (54,78), 91% (82,97), and 84% (73,92) against the H1N1, H3N2, and B strains, respectively. Interestingly, the FDA seroconversion and seroprotection criteria were also met for a drifted H3N2 strain, A/Wisconsin/67/05, which was included in the 2006-2007 influenza vaccine. The seroconversion and seroprotection rates against this strain were 77% and 93%, respectively, among subjects in the 15 µg group.

Antibody responses were observationally compared among VLP vaccine and TIV recipients although the sample size for the TIV group was too small to support definitive conclusions. In this small study, HAI responses against the H1N1 and B strains were statistically indistinguishable and HAI responses against the H3N2 A/Brisbane strain appeared higher in VLP as compared with TIV recipients. These results support moving forward with a larger head-to-head study of the VLP vaccine as compared with TIV.

In addition to the HAI responses, although not presented in the poster, functional antibody against the Neuraminidase enzyme was measured in the sera of immunized subjects using a neuraminidase inhibition assay (NAI) developed by Novavax scientists. Inhibition of neuraminidase activity may be important in reducing the spread of influenza virus down the respiratory tract and severe influenza disease. Preliminary data indicate that the trivalent seasonal influenza VLP vaccine induced functional antibody that inhibits neuraminidase activity of Types A and B influenza viruses.

“We are pleased with the results of this study, which support continued development of novel VLP vaccines against influenza and moving forward with our head-to-head study in the elderly population this Fall,” said Dr. Rahul Singhvi, President and Chief Executive Officer of Novavax. “We believe that our VLP influenza vaccine has the potential to induce broad immunity against influenza including cross-reactivity against drifted strains which may emerge throughout an influenza season,” said Dr. Singhvi.

### **Seasonal Influenza**

Globally, seasonal flu infects between 5 percent and 20 percent of the population and kills between 250,000 and 500,000 people each year. In the US, the Centers for Disease Control and Prevention reports that 15 to 60 million people contract influenza each year leading to over 200,000 hospitalizations and 36,000 deaths. The Advisory Committee on Immunization Practices (“ACIP”) currently recommends seasonal influenza vaccination for children six months through 18 years of age, pregnant women, and adults over 50 years of age, and individuals of any age with chronic health conditions or who are at high risk of influenza disease. Based on the expanding recommendation of vaccination to new age groups, the growing worldwide population to be vaccinated, and the need of an improved influenza vaccine for the elderly, global market projections of seasonal influenza are estimated to increase from \$2.8 billion in 2007 to \$6.5 billion by 2013.

### **About VLPs**

Virus-like particles (VLPs) mimic the external structure of viruses but lack the live genetic material that causes viral replication and infection. VLPs can be designed quickly to match individual viral strains and be produced efficiently using portable cell-culture technology. Novavax VLP-based vaccine candidates are produced more rapidly than egg-based vaccines by using proprietary, portable, recombinant cell-culture technology.

### **About Novavax**

Novavax, Inc. is a clinical-stage biotechnology company, creating novel vaccines to address a broad range of infectious diseases worldwide, including H1N1, using advanced proprietary virus-like-particle (VLP) technology. The company produces potent VLP -based, recombinant

vaccines utilizing new and efficient manufacturing approaches. Novavax is committed to using its VLP technology to create country-specific vaccine solutions. It recently launched a joint venture with Cadila Pharmaceuticals, named CPL Biologicals, to develop and manufacture vaccines, biological therapeutics and diagnostics in India. Additional information about Novavax is available on the company's website: [www.novavax.com](http://www.novavax.com).

### **Forward-Looking Statements**

*Statements herein relating to future financial or business performance, conditions or strategies and other financial and business matters, including expectations regarding clinical trials and development of the 2009 H1N1 vaccine, the potential use of any data from clinical trials and other anticipated milestones are forward-looking statements within the meaning of the Private Securities Litigation Reform Act. Novavax cautions that these forward-looking statements are subject to numerous assumptions, risks and uncertainties, which change over time. Factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including clinical trial results, which may not be sufficient for regulatory approval or may indicate safety concerns not yet encountered; even if the results of the planned clinical trial are positive, the data may not be accepted by regulatory bodies in other countries or the 2009 H1N1 vaccine may not be approved by the Mexican government or additional clinical trials may be required; if approved, approval of the 2009 H1N1 vaccine may not be timely and thus may not be granted until after the 2009/2010 flu season has ended; sales of the 2009 H1N1 vaccine are not scheduled to begin until late in the 2009/2010 flu season which could result in poor sales; Avimex is expected to be responsible for sales of the 2009 H1N1 vaccine in Mexico, thus, the Company would be dependent on Avimex's sales effort; the Company has not yet manufactured, or relied on third parties to manufacture, any vaccines at a commercial scale; the 2009 H1N1 vaccine must be manufactured in a short period of time and will be subject to scale-up, validation and inspection; competition from already approved vaccines for the 2009 H1N1 flu; business abilities and judgment of personnel and corporate partners; and the availability of qualified personnel. Further information on the factors and risks that could affect Novavax's business, financial conditions and results of operations, is contained in Novavax's filings with the U.S. Securities and Exchange Commission, which are available at [www.sec.gov](http://www.sec.gov). These forward-looking statements speak only as of the date of this press release, and Novavax assumes no duty to update forward-looking statements.*

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