



Contact: Tricia J. Richardson
Senior Manager, Investor Relations
1 240-268-2031

NOVAVAX Announces Positive Preclinical Results for its Respiratory Syncytial Virus (RSV) Vaccine Candidate

- Recombinant F protein particle vaccine candidate protects cotton rats against live RSV
- No evidence of enhanced disease in lungs of vaccinated animals challenged with RSV
- Manufacturing process successfully scaled to produce cGMP material for toxicology study

Rockville, MD (January 12, 2010)–/PRNewswire-FirstCall/-Novavax, Inc. (NASDAQ:NVAX) announced today that it has successfully completed a pre-clinical safety and efficacy study of its RSV vaccine candidate in cotton rats. Results from this study are needed to support an Investigational New Drug (IND) application to advance this novel recombinant F protein particle based RSV (RSV-F) vaccine candidate into clinical development. This vaccine candidate is composed of recombinant ‘F’ or ‘fusion’ protein of RSV which is used by the virus to infect and fuse with cells in the respiratory tract and cause disease.

In the current study, Novavax tested its RSV-F vaccine candidate in cotton rats, a well accepted animal model for RSV infection and disease. The animals received two injections on days one and 21 with 1, 6 or 30 micrograms of RSV-F vaccine with or without an alum adjuvant. All dose groups produced antibodies that neutralize RSV, and with adjuvant, only a single injection of RSV-F was needed to induce high levels of neutralizing antibodies. The immunized cotton rats were challenged with live RSV to test if they were protected from infection. High levels of virus were measured in unimmunized control animals but no RSV was detected in the lungs of animals immunized with any dose of the Novavax RSV-F vaccine, with or without adjuvant.

RSV vaccines require a heightened evaluation of safety because of a failed study in children in the mid-1960s with a formalin-inactivated RSV vaccine candidate that caused enhancement of the disease. In the current study, the lungs of RSV challenged cotton rats were examined and there was no sign that immunization with the Novavax RSV-F vaccine candidate resulted in enhanced disease. However, RSV-induced pathology in the lungs was observed in animals immunized with a formalin-inactivated RSV control.

“We are excited to report steady progress towards the development of a vaccine against RSV, an important virus that is the leading cause of viral death in infants,” said Dr. Rahul Singhvi, President and CEO of Novavax. “A safe and effective vaccine against RSV is especially needed in very young children since RSV infection does not provoke lasting immunity. An effective vaccine would also be important in adults, especially the elderly, where RSV illness is common.

There is currently no approved vaccine for the prevention of RSV and the market potential for such a vaccine could exceed \$1 billion annually.”¹

In addition to completing this important preclinical study in cotton rats, Novavax today announced the successful scale up of the manufacturing process for the RSV-F vaccine candidate. Material produced with this process under current Good Manufacturing Practices (cGMP) is currently being used in a formal toxicology study in rabbits.

About Respiratory Syncytial Virus

RSV is the most commonly identified cause of lower respiratory tract illnesses in infants and young children. Repeated infections occur throughout life causing moderate to severe cold-like symptoms. More severe lower respiratory tract disease is also seen in elderly adults over age 65 years, similar to the severe illness witnessed in children. It is estimated that RSV infects more than 8.5 million adults annually, including the elderly over age 65 years. This virus is responsible for approximately 900,000 hospitalizations annually in the United States and major European countries. In the United States alone, RSV leads to 177,500 hospitalizations in high risk adults resulting in annual medical costs exceeding \$1 billion.

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. The company has formed 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.

Forward Looking Statement

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 seasonal influenza vaccine 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 the Company’s ability to progress the product candidate in preclinical or clinical trials; the scope, initiation, rate and progress of its preclinical studies and clinical trials and other research and development activities; animal results may not be predictive of human results; the Company cannot begin any clinical trial until all preclinical testing is completed and the IND is compiled and filed with the FDA; the FDA may request more information or changes to the IND or the clinical plans before human testing may begin; clinical trial results; even if the data from preclinical studies or clinical trials is positive, the product may not prove to be safe and efficacious; regulatory approval is needed before any vaccines can be sold in or outside the US; the rate and progress of manufacturing scale-up; the cost of filing,

¹ Datamonitor – December 2006

prosecuting, defending and enforcing any patent claims and other intellectual property rights; the company's ability to obtain rights to technology; competition for clinical resources and patient enrollment from drug candidates in development by other companies with greater resources and visibility; the company's ability to enter into future collaborations with industry partners and the terms, timing and success of any such collaboration; the cost, timing and success of regulatory filings and approvals; the company's ability to obtain adequate financing in the future through product licensing, co-promotional arrangements, public or private equity or debt financing or otherwise; general business conditions; competition; business abilities and judgment of personnel; 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. 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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