Novavax Announces Topline RSV F Vaccine Data from Two Clinical Trials in Older Adults

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GAITHERSBURG, Md., Sept. 15, 2016 (GLOBE NEWSWIRE) -- Novavax, Inc., (Nasdaq:NVAX) today announced topline data from two clinical trials of its RSV F-protein recombinant nanoparticle vaccine candidate (RSV F Vaccine) in older adults. The Resolve™ trial, a Phase 3 trial of our RSV F Vaccine in 11,856 older adults (60 years of age and older), did not meet the pre-specified primary or the secondary efficacy objectives, and did not demonstrate vaccine efficacy. Consistent with our previous clinical experience, the vaccine was well tolerated.

Phase 3 Resolve™ Trial

The trial was a randomized, observer-blinded, placebo-controlled trial conducted at 60 sites in the United States. The primary objective of the Resolve trial was to demonstrate efficacy in the prevention of moderate-severe RSV-associated lower respiratory tract disease (RSV msLRTD), as defined by the presence of multiple lower respiratory tract symptoms. The secondary objective of the trial was to demonstrate efficacy of the RSV F Vaccine in reducing the incidence of all symptomatic respiratory disease due to RSV (RSV ARD). Finally, the trial also evaluated the safety of the unadjuvanted, 135 microgram dose of the RSV F Vaccine compared to placebo.

Topline efficacy results of the trial are shown in the following table:

Summary of Primary and Secondary Objectives – Vaccine Efficacy

	Number of Participants - ITT Population (11,856)			
Primary and Secondary Objectives	Placebo (5,935)	Vaccine (5,921)	Vaccine Efficacy (CI)	P-Value
Primary: RSV msLRTD, N(%)	26 (0.44%)	28 (0.47%)	-7.9 % (-84, 37)	0.78
Secondary: RSV ARD, N(%)	117 (1.97%)	102 (1.72%)	12.6 % (-14, 33)	0.32

“We are both surprised and disappointed by the outcome of the Resolve trial, which we recently unblinded. Our initial analyses and review of the key aspects of the trial do not indicate issues with trial execution, data collection, data integrity, or drug product quality. We expect to have preliminary immunogenicity data in the coming weeks to further our understanding of the trial results,” said Gregory Glenn M.D., President, Research and Development. “Historically, annual seasonal RSV ARD attack rates between 3% and 7% have been observed in older adults1. In our Phase 2 trial, we observed an RSV ARD attack rate of 4.9% and an RSV msLRTD attack rate of 1.8%. In contrast, we observed an RSV ARD attack rate of 2.0% and an msLRTD attack rate of 0.4% in our Phase 3 trial. These attack rates indicate a mild RSV season in older adults this year. We are continuing to investigate potential root causes that could have impacted the outcome of this trial. We continue to believe that there is a path forward for our RSV vaccine and that there is an important unmet need for an RSV vaccine in older adults.”

Phase 2 Rollover Trial

Novavax also reported topline results from the Phase 2 rollover clinical trial of its RSV F Vaccine in older adults.

The trial was a randomized, observer-blinded, placebo-controlled rollover trial which enrolled 1,329 older adults from the prior Phase 2 trial, conducted at the same 10 sites in the United States. The primary objectives of the trial evaluated safety and serum anti-F IgG antibody concentrations in response to immunization with the RSV F Vaccine. The exploratory objectives of the trial evaluated the efficacy of a second annual dose of the RSV F Vaccine in the prevention of RSV ARD and RSV msLRTD. Participants previously randomized to receive 135 microgram RSV F Vaccine or placebo were re-enrolled and re-randomized in the current trial to receive either 135 microgram RSV F Vaccine or placebo. This resulted in analysis of four separate trial arms: a) participants receiving a placebo in both the first trial and second trial; b) participants receiving RSV F Vaccine in the first trial and placebo in the second trial (Vaccine-Placebo); c) participants receiving placebo in the first trial and RSV F Vaccine in the second trial (Placebo-Vaccine); and d) participants receiving RSV F Vaccine in both the first trial and second trial (Vaccine-Vaccine).

Topline results of the trial are shown in the following tables:

Summary of Geometric Mean Titer for Anti-F by Visit – ITT Population

	Number of Participants (1,329)			
	Placebo (2014/15) Placebo (2015/16) (N = 333)	Vaccine (2014/15) Placebo (2015/16) (N = 328)	Placebo (2014/15) Vaccine (2015/16) (N = 337)	Vaccine (2014/15) Vaccine (2015/16) (N = 331)
Day 0 (baseline) N	333	327	336	329
GMEU	1012.8	2293.6	962.9	2267.3
95% CI	(922.0,1112.5)	(2091.8, 2514.9)	(869.0,1067.0)	(2076.4, 2475.8)
Day 28 N	332	325	333	327
GMEU	1019.3	2188.7	6071.2	4489.3
95% CI	(928.6, 1119.0)	(2005.0, 2389.2)	(5526.9, 6669.0)	(4137.7, 4870.7)

GMEU: geometric mean ELISA units

Gregory Glenn, M.D., said, “The rollover trial demonstrated immunogenicity in all active vaccine recipients. As shown in the table above, there was a 6-fold increase in anti-F IgG in the Placebo-Vaccine arm, consistent with the Phase 2 efficacy trial. There was higher anti-F IgG at baseline in the Vaccine-Vaccine arm compared to the Placebo-Vaccine arm. Further, the Vaccine-Vaccine arm showed a greater than 2-fold increase in anti-F IgG from the higher baseline. We observed similar low attack rates and absence of efficacy of a single immunization in this trial as was observed in Phase 3 Resolve trial, although we did observe that a second season immunization could provide efficacy. The event rate comparisons made to either placebo groups suggested that the second season immunization was protective, even in a year with a very low attack rate. Further understanding of these data may come forth with full evaluation of the immune responses.”

Summary of Exploratory Efficacy Objective+

	Number of Participants (1,329)			
	Placebo (2014/15) Placebo (2015/16) (N = 333)	Vaccine (2014/15) Placebo (2015/16) (N = 328)	Placebo (2014/15) Vaccine (2015/16) (N = 337)	Vaccine (2014/15) Vaccine (2015/16) (N = 331)
RSV ARD (%)	8 (2.4%)	7 (2.1%)	11 (3.3%)	2 (0.6%)*
RSV ARD Vaccine Efficacy		11 %	-36 %	75 %
msLRTD (%)	1 (0.3%)	2 (0.6%)	2 (0.6%)	0

*p-value = 0.079; msLRTD was not calculated due to low N value

+all data in table is not significant (p-value > 0.05); preliminary N

“While the results from the Resolve trial are unexpected, we continue to believe in our technology and product candidates based on the totality of the data from our RSV F Vaccine franchise,” said Stanley C. Erck, President and CEO. “We expect to gain a better understanding of the data from both the Phase 2 rollover and Phase 3 trials as we further analyze and review them internally, as well as with our investigators and potential partners. We intend to provide a more in-depth update at our investor and analyst meeting on October 11, 2016.”

Conference call

Novavax management will host a conference call at 5:00 p.m. ET. The dial-in number for the conference call is 877-212-6076 (U.S. or Canada) or 707-287-9331 (International), passcode 80163880. A webcast of the conference call can also be accessed via a link on the home page of the Novavax website (novavax.com) or through the "Investor Info"/"Events" tab on the Novavax website. Presentation slides will be available via the webcast link.

A replay of the conference call will be available starting at 7:30 p.m. on September 15, 2016 until midnight September 20, 2016. To access the replay by telephone, dial 855-859-2056 (Domestic) or 404-537-3406 (International) and use passcode 80163880. The replay will also be available as a webcast and can be found on the "Investor Info"/"Events" on the Novavax website.

About RSV

Respiratory syncytial virus, commonly referred to as RSV, is a respiratory infectious disease that causes serious infection of the respiratory tract, similar to influenza. For some, RSV may progress in severity, and lead to hospitalization or even death. The spread of RSV occurs annually, with an incidence rate of 2.5 million infections per year in the United States, RSV is increasingly being recognized as a significant cause of morbidity and mortality in the population of 64 million older adults.1,2 Each year, RSV is responsible for approximately 207,000 hospitalizations and 16,000 deaths among adults older than 65.3 Annually, there are approximately 900,000 medical interventions directly caused by RSV disease.4,5 Currently, there is no approved RSV vaccine available.

About Novavax

Novavax, Inc. (Nasdaq:NVAX) is a clinical-stage vaccine company committed to delivering novel products to prevent a broad range of infectious diseases. Its recombinant nanoparticles and Matrix-M™ adjuvant technology are the foundation for ground-breaking 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. A.R. Falsey et al. Respiratory syncytial virus infection in elderly and high-risk adults. *N Engl J Med*. 2005; 352:1749–59.

2. A.R. Falsey et al. Respiratory syncytial virus and influenza A infections in the hospitalized elderly. *J. Infect Dis.* 1995; 172:389-94.

3. K. Widmer et al. Rates of hospitalizations for respiratory syncytial virus, human metapneumovirus, and influenza virus in older adults. *J Infect Dis*. 2012; 206: 56-62.

4. K. Widmer et al. Respiratory syncytial virus & human metapneumovirus-associated emergency department and hospital burden in adults. *Influenza and Other Respiratory Viruses.* 2014; 8(3): 347-352.

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, 2015 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.

Contact:
Novavax, Inc.Barclay A. Phillips
SVP, Chief Financial Officer and Treasurer

Andrea N. Flynn, Ph.D.
Associate Director, Investor Relations

ir@novavax.com
240-268-2000

Russo Partners, LLCDavid SchullTodd Davenport, Ph.D.

david.schull@russopartnersllc.comtodd.davenport@russopartnersllc.com
212-845-4271