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Novartis announces positive clinical trial results for novel H7N9 vaccine

- *85% of subjects immunologically protected after receiving second dose of investigational cell culture vaccine when combined with proven MF59[®] adjuvant*
- *Vaccine now in large scale production highlighting rapid response capability of novel FDA licensed cell culture technology*
- *135 confirmed cases and 45 deaths from H7N9 virus since emergence in March according to the World Health Organization¹*

Basel, Switzerland, November 14, 2013 – Novartis announced today interim results from a Phase 1 clinical trial with its proprietary cell culture vaccine for the H7N9 avian influenza virus involving 400 healthy volunteers (18-64 years of age). The data shows 85% of subjects achieved a protective immune response after two doses of the 15 ug MF59 adjuvanted vaccine. Only 6% of subjects achieved a protective response when given two doses of the 15ug un-adjuvanted vaccine. The full data set from the trial will be submitted to a peer-reviewed journal for publication in the near future.

The vaccine was produced utilizing full-scale cell-culture manufacturing technology, an alternative technology that can significantly accelerate vaccine production versus traditional egg-based methods.² Cell-culture technology utilizes a well-characterized mammalian cell line rather than chicken eggs to grow virus strains.³

“This rapid response underscores our leadership position in pandemic preparedness” said Andrin Oswald, Division Head, Novartis Vaccines. “Thanks to our investments into innovative production technologies and adjuvants, we are now able to offer a protective solution for a potentially deadly pandemic virus within a few months after the emergence of the H7N9 virus.”

Reports of H7N9 infection first emerged in China in March 2013. Novartis, along with its partners at the Craig Venter Institute, first synthesized the viral strain several days after it was shared with global researchers by the Chinese Centers for Disease Control. Novartis then produced clinical trial lots, began clinical trials in August, and initiated large-scale production in its Holly Springs (NC), USA and Marburg, Germany facilities in October.

This project has been funded in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO1002012000141

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as “will be, investigative, interim” or similar terms, or by express or implied discussions regarding potential efficacy for Novartis H7N9 avian influenza vaccine, or regarding potential future revenues from Novartis H7N9 avian influenza vaccine. You should not place undue reliance on these statements. Such forward-looking statements

are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that Novartis H7N9 avian influenza vaccine will receive regulatory approval or be commercially successful in the future. In particular, management's expectations regarding Novartis H7N9 avian influenza vaccine could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing issues, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 133,000 full-time equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

Novartis is on Twitter. Sign up to follow @Novartis at <http://twitter.com/novartis>.

References

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New England Journal of Medicine Publishes Positive Data From Clinical Trial of Novavax' Vaccine Against H7N9 Avian Flu

- *Data are industry's first from clinical trial of vaccine against A(H7N9) strain of influenza*
- *81% of 5ug adjuvanted vaccine recipients had protective HAI levels*
- *97% of 5ug adjuvanted vaccine recipients had anti-neuraminidase antibody responses*
- *Protective levels achieved from vaccinations within 116 days of the announced outbreak of novel lethal H7N9 virus*
- *Dose-sparing formulation shows significant potential utility in the event of a pandemic*
- *Vaccine safety consistent with previously tested adjuvanted pandemic vaccines*

Rockville, MD (November 13, 2013)—/GlobeNewswire, Inc./-Novavax, Inc. (NASDAQ: NVAX) today announced that positive clinical data for the company's virus-like particle (VLP) vaccine candidate against A(H7N9) influenza were published online in the Correspondence section of *The New England Journal of Medicine*. The correspondence can be found at: <http://www.nejm.org/doi/full/10.1056/NEJMc1313186> and will appear in the December 26, 2013 print edition.

The study, conducted in 284 adult male and female subjects, examined the safety and immunogenicity of two administrations of Novavax' A(H7N9) VLP vaccine candidate on day 0 and day 21. Subjects were administered either placebo, 15 or 45 µg of vaccine alone, or 5 or 15µg of vaccine with either 30 or 60 ISCO[®] units of the saponin-based ISCOMATRIX[®] adjuvant, developed by CSL Limited in Australia. Serology was assessed at Days 0, 21 and 35 post-first immunization.

The Novavax A(H7N9) VLP vaccine candidate was generally well tolerated, and the safety was in line with the company's previous findings with its influenza VLP antigens using ISCOMATRIX[®] adjuvant. Overall, as with other adjuvanted influenza vaccines, there was an increase in transient local and systemic reactions in the adjuvanted in contrast to the non-adjuvanted formulations, but there were no treatment-related SAEs in the active groups. The A(H7N9) VLP vaccine candidate induced hemagglutination-inhibition (HAI) antibody titers of ≥1:40 (seroprotection) and a four-fold HAI antibody rise (serconversion) against H7N9 in 81%

of subjects at the 5µg dose of A(H7N9) antigen with 60 ISCO[®] units of adjuvant, and 73% of subjects receiving 5µg dose of A(H7N9) antigen with either adjuvant dose level. The vaccine also elicited anti-neuraminidase (NA) antibodies against N9 in 92 to 97% of subjects receiving 5µg with either adjuvant dose level.

The A(H7N9) influenza strain has emerged recently as a potential pandemic concern. Less than ten (10) days after the Chinese Health authorities announced an outbreak of this novel avian influenza in humans (137 total confirmed cases, including 45 deaths, to date), Novavax obtained the genetic sequence of the strain and commenced production of a recombinant vaccine. Clinical trial material was manufactured and released in late June 2013 with the first doses injected in humans in early July 2013. Less than four months after the novel A(H7N9) virus had been identified and sequenced, Novavax' H7N9 VLP vaccine, with the higher-dose of ISCOMATRIX[®] adjuvant, has achieved immune responses likely to be protective in 81% of recipient subjects with as little as 5µg of antigen.

“The production and testing of a vaccine for a novel, lethal influenza virus in such a short time period validates the agility of Novavax' technology in addressing pandemic threats,” said Dr. Lou Fries, the company's Vice President of Clinical and Medical Affairs. “The performance of our vaccine candidate is particularly important in light of the speed with which pandemic outbreaks can unfold. Often, an initial outbreak of a novel influenza virus is followed by a more severe and widespread outbreak at the onset of the next fall and winter respiratory virus season, as seen in 2009 with H1N1. Unfortunately, vaccine makers in 2009 were unable to produce vaccine in advance of the second wave and there was little impact of vaccine upon H1N1 disease in the first year. Past H7-based vaccine candidates have been poorly immunogenic and thus could not be advanced as viable vaccine candidates. This risk appears to have been overcome by our H7N9 adjuvanted VLP vaccine.”

Stanley C. Erck, President and Chief Executive Officer of Novavax, added, “As evidenced by our correspondence in *The New England Journal of Medicine*, this is a critical accomplishment for pandemic preparedness. Building on the positive clinical results with our H5N1 VLP vaccine candidate from last October, these recently gathered data from our A(H7N9) influenza vaccine give further confirmation that the Novavax vaccine platform deserves to play a key role in addressing evolving pandemic threats. We have used recombinant VLP technology to demonstrate that timely responses are possible, and we are proud to be the first company to produce a viable H7N9 vaccine. Furthermore, we are pleased that HHS-BARDA has recognized this achievement and asked us to focus our pandemic vaccine development under our HHS-BARDA contract on our H7N9 vaccine candidate.”

About H7N9 Avian Flu

Following recognition of the first human infections with avian-origin influenza A(H7N9) and their attendant severity in March 2013, public health officials from around the world called for immediate and preemptive development of surveillance, diagnostic and clinical intervention tools in the event that the A(H7N9) virus becomes transmissible among humans. According to Keiji Fukuda of the WHO, there is high concern over potential for A(H7N9) to gain sustainable person-to-person transmissibility. He noted that over a two-month period in China, as many H7N9 cases occurred as caused by H5N1 cases over 10 years. Additionally, molecular genetic changes occurred, suggesting adaptation of the virus to humans. After a quiescent period during

the summer months, four new cases of human A(H7N9) disease have been reported since October 7, prompting concerns and expectations over the virus reemerging in human populations in the coming winter season.

About Novavax

Novavax, Inc. (Nasdaq: NVAX) is a clinical-stage biopharmaceutical company creating novel vaccines and vaccine adjuvants to address a broad range of infectious diseases worldwide. Using innovative proprietary recombinant protein nanoparticle vaccine technology, the company produces vaccine candidates to efficiently and effectively respond to both known and newly emergent diseases. Novavax is involved in several international partnerships, including collaborations with Cadila Pharmaceuticals of India, LG Life Sciences of Korea, PATH and recently acquired Isconova AB, a leading vaccine adjuvant company located in Sweden. Together, Novavax' network supports its global commercialization strategy to create real and lasting change in the biopharmaceutical and vaccinology fields. Additional information about Novavax is available on the company's website, novavax.com.

About ISCOMATRIX[®] adjuvant

ISCOMATRIX[®] adjuvant is made from saponin, cholesterol and phospholipid which, under defined conditions, form cage-like structures typically 40-50nm in diameter. The optimized ISCOMATRIX[®] adjuvant is well defined, has minimal impurities and does not use any materials of animal origin. Additionally, improvements have been made to the manufacturing processes to ensure it can be reproduced on a large scale. ISCOMATRIX[®] adjuvant is currently manufactured at commercial scale at CSL's facility in Kankakee, Illinois.

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, 2012, and Form 10-Q for the period ended June 30, 2013, both 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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