Results from Influenza Challenge Study Published in Lancet Infectious Diseases

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Efficacy of Oral Tablet Vaccine Compares Favorably to Market-Leading Fluzone®

SOUTH SAN FRANCISCO, Calif., Jan. 22, 2020 (GLOBE NEWSWIRE) -- Vaxart, Inc. (VXRT), a clinical-stage biotechnology company developing oral recombinant vaccines administered by tablet rather than by injection, announced today that the results from its H1 influenza oral tablet vaccine challenge study were published in the *Lancet Infectious Diseases,* January 21, 2020 and currently available at *doi.org/10.1016 /S1473-3099(19)30584-5.* Topline results had been reported previously.

The study demonstrated a single dose with the Vaxart oral tablet H1 influenza vaccine was well tolerated and provided statistically significant protection against H1 influenza infection in the human challenge model. Efficacy results trended favorably when compared to Fluzone, an injectable quadrivalent influenza vaccine (QIV) and the active comparator in the study.

“If the results of the oral H1N1 influenza vaccine in this clinical trial can be reproduced with a quadrivalent mixture of strains this would revolutionize immunization against influenza, which after all is a mucosal disease,” said Stanley Plotkin, MD.

Dr. Stanley A. Plotkin is Emeritus Professor of the University of Pennsylvania and Adjunct Professor of the Johns Hopkins University. Dr. Plotkin has developed several vaccines including the rubella vaccine now in standard use throughout the world and a recently licensed pentavalent rotavirus vaccine. He has also been involved in other vaccine development programs including anthrax, oral polio, rabies, varicella, and cytomegalovirus.

“These results provide clinical proof-of-concept for Vaxart’s proprietary technology being able to make an oral vaccine that is at least as protective as Sanofi’s Fluzone,” said Sean Tucker, Ph.D., chief scientific officer of Vaxart. “The results of the clinical study also demonstrated that our oral tablet vaccine primarily protects through mucosal immunity, a potential key factor for improving influenza vaccine performance.”

Data from the Phase 2 influenza A challenge study demonstrated that Vaxart’s oral tablet influenza vaccine generated a 39 percent reduction in clinical disease relative to placebo, compared to a 27 percent reduction by Fluzone. It also reduced infection rates by 47 percent, compared to 43 percent by Fluzone. The tablet vaccine showed a favorable safety profile, similar to placebo.

“Influenza continues to be a serious public health problem affecting all age groups and causing severe illness and sometimes death in high-risk populations. A convenient and effective tablet vaccine may significantly increase current vaccination rates, generating important public health benefits for at-risk groups and the population as a whole,” said Wouter Latour, M.D., M.B.A., chief executive officer of Vaxart. “These results also confirm the value of our oral vaccine platform, particularly for mucosal pathogens such as flu, norovirus, RSV, as well as coronaviruses such as SARS, MERS and the virus that recently emerged in China.”

The Phase 2 influenza A challenge trial was a randomized, double-blind study consisting of three groups. Subjects received either a single dose of the Vaxart oral tablet vaccine and a placebo intramuscular injection, a QIV injection and a placebo tablet, or a double placebo. Subjects were challenged intranasally with homologous A strain influenza virus 90-132 days after vaccination. The main objective of the study was to evaluate the percentage of subjects protected by the Vaxart oral tablet vaccine against influenza illness, measured as a reduction in clinical symptoms and laboratory-confirmed homologous influenza A infections, compared to QIV and placebo.

The Phase 2 study was completed with support from the Office of Biomedical Advanced Research and Development Authority (BARDA). Vaxart received a total of $15.7 million under a contract from BARDA to support the advanced development of more effective influenza vaccines to ultimately improve seasonal and pandemic influenza preparedness.

This project has been funded in whole or in part with federal funds from the Department of Health and Human Services’ Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority under Contract No. HHSO100201500034C.

About Influenza

The flu is a contagious respiratory illness caused by influenza viruses that infect the nose, throat and sometimes the lungs. It can cause mild to severe illness, and at times, can lead to death. The best way to prevent the flu is by getting a flu vaccine each year. While the impact of flu varies, it places a substantial burden on the health of people in the United States. The U.S. Centers for Disease Control and Prevention (CDC) estimates that influenza has resulted in between 9.2 million and 60.8 million illnesses, between 140,000 and 710,000 hospitalizations and between 12,000 and 56,000 deaths annually since 2010.

For further information on influenza, its burden on human health and vaccine development, please visit the CDC website at www.cdc.gov/flu/.

About Vaxart

Vaxart is a clinical-stage biotechnology company focused on developing oral recombinant protein vaccines based on its proprietary oral vaccine platform. Vaxart’s vaccines are designed to generate broad and durable immune responses that protect against a wide range of infectious diseases and may also be useful for the treatment of chronic viral infections and cancer. Vaxart’s vaccines are administered using a convenient room temperature-stable tablet, rather than by injection. Vaxart believes that tablet vaccines are easier to distribute and administer than injectable vaccines and have the potential to significantly increase vaccination rates. Vaxart’s development programs include oral tablet vaccines that are designed to protect against norovirus, seasonal influenza and respiratory syncytial virus (RSV), as well as a therapeutic vaccine for human papillomavirus (HPV). For more information, please visit www.vaxart.com.

Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding our strategy, prospects, plans and objectives, results from preclinical and clinical trials, commercialization agreements and licenses, beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as “believe,” “could,” “potential,” “will” and other words and terms of similar meaning. Examples of such statements include, but are not limited to, statements relating to the Vaxart’s ability to develop and commercialize its product candidates and clinical results and trial data; Vaxart’s intention to continue its efforts to advance its oral tablet seasonal flu vaccine; and Vaxart’s expectations with respect to the important advantages it believes its oral vaccine platform can offer over injectable alternatives, particularly for mucosal pathogens such as norovirus, flu and RSV, as well as coronaviruses such as SARS, MERS and the virus that recently emerged in China. Vaxart may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our forward-looking statements and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Vaxart makes, that Vaxart’s product candidates may not be approved by the FDA or non-U.S. regulatory authorities; that, even if approved by the FDA or non-U.S. regulatory authorities, Vaxart’s product candidates may not achieve broad market acceptance; that Vaxart may experience manufacturing issues and delays; and other risks described in the “Risk Factors” sections of Vaxart’s Quarterly and Annual Reports filed with the SEC. Vaxart does not assume any obligation to update any forward-looking statements, except as required by law.

CONTACT:

Brant Biehn
Vaxart, Inc.
(650) 550-3500
bbiehn@vaxart.com

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