Vaxart Announces Positive Topline Results for its Oral Tablet Vaccine in Phase 2 Influenza Challenge Study

Reduction in Disease Comparable to Market-Leading Injectable Quadrivalent Influenza Vaccine

SOUTH SAN FRANCISCO, Calif., October 26, 2017 – Vaxart, Inc., a privately-held, clinical-stage biotechnology company developing oral recombinant vaccines administered by tablet rather than by injection, announced today that its H1 influenza oral tablet vaccine demonstrated similar protection against influenza virus as the market-leading injectable quadrivalent influenza vaccine (QIV) in a clinical trial. These results met the efficacy objectives of the Phase 2 influenza A clinical study. The oral tablet vaccine also demonstrated a favorable safety and tolerability profile.

“Influenza virus continues to be a serious public health problem affecting all age groups and causing severe illness and sometimes death in high-risk populations. While immunization campaigns have grown in efficacy and scale, there remains potential to improve this public health measure,” said Dave Liebowitz, M.D., Ph.D., chief medical officer of Vaxart. “The results of the clinical study suggest that our oral tablet vaccine could address unmet needs given its ease of distribution and administration.”

Data from the Phase 2 influenza A challenge study demonstrated that Vaxart’s influenza oral tablet vaccine provided a 39 percent reduction in clinical disease relative to placebo, compared to a 27 percent reduction by the injectable QIV. The tablet vaccine also showed a favorable safety profile, similar to placebo.

“These results provide clinical proof-of-concept for Vaxart’s groundbreaking oral tablet vaccine technology,” said Wouter Latour, M.D., M.B.A., chief executive officer of Vaxart. “Currently less than half of the approximately 320 million eligible Americans are vaccinated against influenza each year. A convenient and effective tablet vaccine could significantly increase current vaccination rates and generate important public health benefits for at-risk groups and the population as a whole.”

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 90-120 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 $13.9 million contract from BARDA in September 2015 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 company developing a range of oral recombinant vaccines based on its proprietary delivery platform. Vaxart vaccines are administered using convenient room temperature-stable tablets that can be stored and shipped without refrigeration and eliminate risk of needle-stick injury. Its development programs are oral tablet vaccines designed to protect against norovirus, seasonal influenza and respiratory syncytial virus (RSV), as well as a therapeutic vaccine for human papillomavirus (HPV), Vaxart’s first immuno-oncology indication. For more information, please visit www.vaxart.com.

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