Vaxart Doses First Patient in Randomized Cohort of Bivalent Norovirus Vaccine Phase 1b Clinical Trial

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 16, 2019-- Vaxart, Inc., a clinical-stage biotechnology company developing oral recombinant vaccines that are administered by tablet rather than by injection, today announced it has started dosing subjects in the randomized cohort of the Phase 1b bivalent norovirus vaccine clinical trial.

“We are delighted to start the randomized portion of the bivalent norovirus phase 1b trial,” said David Taylor, M.D., chief medical officer of Vaxart. “The monovalent GII.4 vaccine tablets performed as expected in the lead-in cohort we just completed, and we look forward to building on the excellent results we observed previously with our monovalent GI.1 vaccine. Norovirus is the leading cause of foodborne illness in the United States and causes significant morbidity and mortality in older adults and the very young. Our oral norovirus vaccine could provide a significant public health benefit for these vulnerable populations in the United States and beyond.”

The Vaxart bivalent norovirus vaccine consists of an oral norovirus GI.1 vaccine tablet and an oral norovirus GII.4 vaccine tablet administered concurrently. The bivalent norovirus Phase 1b trial includes two stages, an open-label lead-in phase which was completed successfully earlier this month, and a randomized, double-blind, placebo-controlled phase which has now started. Both portions of the trial are designed to evaluate safety and immunogenicity. The Company expects to receive topline data from the trial in the second half of 2019.

About Norovirus

Norovirus is recognized as the leading cause of acute gastroenteritis in the United States. It is a common intestinal infection that typically lasts three to five days and is marked by diarrhea, vomiting, abdominal cramps, nausea and sometimes fever. Symptoms can be more severe in older adults and young children and may lead to serious complications including death. Norovirus causes frequent and widespread outbreaks in the military, food industry, travel industry, child care facilities, elderly homes and healthcare facilities.

The U.S. Centers for Disease Control and Prevention (CDC) estimates that norovirus causes approximately 19 to 21 million illnesses in the United States each year, resulting in 56,000 to 71,000 hospitalizations and 570 to 800 deaths, mostly among young children and older adults.

In a recent study by Johns Hopkins University and the CDC, researchers estimated global economic impact of norovirus disease at $60 billion, $34 billion of which occurred in high income countries, including the United States, Europe and Japan.

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 tableted 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).

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; the expected timing of the initiation of the Phase 1 bivalent study and Phase 2 monovalent challenge study; and Vaxart’s expectations with respect to the advantages it believes its oral vaccine platform can offer over injectable alternatives, particularly for mucosal pathogens such as norovirus, flu and RSV. 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 factors could cause actual results or events to differ materially from these forward-looking statements, including Vaxart’s ability to raise sufficient capital to fund the continued development of its product candidates and complete its planned studies and trials, 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.

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