Vaxart's Tableted Oral Bivalent Norovirus Vaccine Meets Primary and Secondary Endpoints in Phase 1b Study

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Both norovirus vaccines induced substantial immune responses with no indication of immunological interference when administered concurrently

Phase 2-ready oral norovirus vaccine targets potential $3B+ market opportunity

SOUTH SAN FRANCISCO, Calif., Sept. 25, 2019 (GLOBE NEWSWIRE) -- Vaxart, Inc. (NASDAQ: VXRT), a clinical-stage biotechnology company developing oral recombinant vaccines that are administered by tablet rather than by injection, today announced positive topline results from the randomized, double-blind, placebo-controlled Phase 1b safety, immunogenicity and interference study with its oral tableted bivalent norovirus vaccine in healthy adults. The study met all primary endpoints for safety and demonstrated robust immunogenicity, with 78% - 93% of subjects responding by eliciting IgA antibody secreting cells (ASC), a key marker for mucosal immunity and a potential correlate of protection for norovirus disease.

"Norovirus is a very contagious disease which can be especially harmful to children under age 5 as well as to older adults," said William Schaffner, MD, medical director of the National Foundation for Infectious Diseases (NFID) and Professor of preventive medicine and infectious diseases at Vanderbilt University School of Medicine. "An effective and safe vaccine would be critical to protecting high-risk populations against serious illness caused by norovirus, especially if it could be administered orally."

"These results are in line with the robust immune response profile seen in previous studies with our noro-GI.1 tablet vaccine, while the immunogenicity of our new noro-GII.4 tablet vaccine trended even higher with an IgA ASC response rate of 90% or greater," said Wouter Latour, M.D., chief executive officer of Vaxart. "Norovirus infection causes $60 billion in global healthcare-related costs annually, and there is no licensed vaccine available. We believe these favorable results put us on track to develop a vaccine with the potential to become the product of choice for policy makers and health care professionals in a $3+ billion market. We are now forging ahead with the Phase 2 dose confirmation study planned for 2020."

Both the oral norovirus GI.1 and GII.4 vaccines were well tolerated, with no treatment-related serious adverse events reported. Most solicited and unsolicited adverse events were mild in severity and there were no significant differences observed between the vaccine and placebo treatment groups.

Vaxart's bivalent vaccine demonstrated robust immunogenicity, with an IgA ASC response rate of 78% for the GI.1 strain and 93% for the GII.4 strain for the bivalent cohort of the study, and 86% and 90%, respectively, for the two monovalent cohorts of the study. There was no interference observed in the bivalent arm of the study.

The Phase 1b norovirus bivalent vaccine trial enrolled a total of 80 subjects. After enrollment of an open-label sentinel GII.4 group of 5 subjects, the remaining 75 subjects were randomized in a blinded manner to one of 4 treatment groups: 15 subjects in each monovalent group received an oral $5x10^{10}$ I.U. dose of either the norovirus GII.4 or GI.1 vaccine, 30 subjects in the bivalent group received a $5x10^{10}$ I.U. dose of both the norovirus GII.4 and GI.1 vaccine administered concurrently, and 15 subjects received placebo tablets. The trial was designed to evaluate safety, immunogenicity and interference of Vaxart's oral bivalent norovirus vaccine by comparing the bivalent vaccine group to the two monovalent vaccine groups, as well as the placebo group.

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 high-risk patients (older adults and young children) and may lead to serious complications, including death. Norovirus causes frequent, debilitating and widespread outbreaks in the military, food industry, travel industry, childcare 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; Vaxart's plans to start a Phase 2 study with its bivalent norovirus vaccine in 2020; 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. 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.

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