Vaxart Announces First Subject Enrolled in Phase 1b Norovirus Dose-Ranging Trial in Elderly Adults

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Study will evaluate safety and immunogenicity of oral norovirus vaccine in elderly population

Norovirus represents a significant unmet need in the elderly — there currently is no approved vaccine

Safety and immunogenicity data to also inform oral COVID-19 vaccine program in older population

SOUTH SAN FRANCISCO, Calif., May 07, 2021 (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 that it has enrolled the first subject in a Phase 1b placebo-controlled, dose-ranging, repeat dose trial investigating its oral norovirus vaccine candidate in elderly subjects aged 55 – 80 years. This study is designed to evaluate the safety and immunogenicity of Vaxart's candidate, which is the only clinical stage norovirus oral tablet vaccine actively being developed.

Norovirus is the leading cause of vomiting and diarrhea from acute gastroenteritis among people of all ages. In the United States, this virus contributes to 56,000 to 71,000 hospitalizations and 570 to 800 deaths annually.

"Many think norovirus is just a virus that may infect those who go on cruises, when in fact it is a potentially fatal illness that affects around 20 million Americans every year, primarily young children or the elderly," said Andrei Floroiu, Vaxart's chief executive officer. "Norovirus is the most common viral cause of epidemic gastroenteritis and is a major public health problem with no approved vaccine available."

In a health economic study published in *The Journal of Infectious Diseases* in July 2020, the negative economic impact of norovirus to the U.S. was estimated to be $10.5 billion annually. The burden of disease is concentrated in two groups: 1) approximately 7.5% of the population aged 65 and above are infected annually, with most hospitalizations occurring in this group; and 2) approximately 15% of children under age 5 are infected annually. The World Health Organization's (WHO) Product Development for Vaccines Advisory Committee has identified norovirus as a priority disease for vaccine development.

"The norovirus program is part of our broader strategy to develop prophylactic vaccines that target a range of pathogens," Floroiu said. "We believe we have the capabilities to develop a new generation of orally administered vaccines, with the potential to benefit public health by protecting at-risk populations against infectious diseases."

"Our norovirus vaccine candidate, developed using our proprietary oral tablet vaccine platform, is being evaluated in a comprehensive clinical program that is currently scheduled to include at least four clinical trials in 2021. These efforts put Vaxart at the forefront of norovirus research," said Dr. Sean Tucker, Vaxart's founder and chief science officer. "It is well-established that the elderly population is at a higher risk of infection and severe illness from norovirus. The vast majority of norovirus-associated deaths in the U.S. occur in patients aged 65 or over. This placebo-controlled, dose ranging study in older adults will help us understand safety and immunogenicity of the norovirus vaccine candidate in this population. Importantly, the results may give us insight as to what doses of our investigational COVID vaccine might be most effective in a dosing study of the elderly using our COVID-19 vaccine candidate."

Norovirus is an enteric pathogen that infects epithelial cells of the small intestine. Vaxart's VP1- based bivalent oral tablet vaccine candidate targets the norovirus GI.1 Norwalk and GII.4 Sydney strains, which are the predominant strains affecting humans. Vaxart's oral tablet vaccine candidate is designed to produce antibodies against norovirus locally in the intestine.

Vaxart has already performed and reported on three previous clinical trials with a norovirus vaccine candidate:

- In a Phase 1 bivalent study the vaccine showed no interference with the monovalent arms of the study performing as well as the bivalent arm.
    - The study met all primary endpoints for safety and demonstrated robust immunogenicity, with 78% - 93% of subjects responding by eliciting IgA antibody secreting cells, a key marker for mucosal immunity and a potential correlate of protection for norovirus disease.
- In an earlier Phase 1 monovalent study more than 80% of recipients of the high dose vaccine developed mucosally-primed norovirus specific circulating antibody secreting cells, IgA memory and effector B cells expressing the α4β7 gut homing receptor, and a greater than tenfold increase in fecal IgA antibodies.
- In the high dose group of another Phase 1 dose optimization monovalent study, 100 percent of adults responded as measured by a significant increase in IgA and IgG antibody secreting cells after 2 doses.

The dose ranging trial in the elderly is the third of four Vaxart norovirus trials that are being conducted currently or are planned for 2021. Vaxart currently is administering a second booster dose to a subset of subjects who had participated in the prior Phase 1b bivalent study and recently began a study designed to evaluate different boosting regimens.

Vaxart also expects to launch a Phase 2 norovirus human challenge study later this year.

VXA-NVV-104 Phase 1b Trial Design

The Phase 1b study is designed to enroll 48 subjects aged 55 to 80 years old. Subjects will be randomized into two cohorts stratified by age: Cohort 1 will receive either low dose vaccine candidate (1e10 I.U. n=16) or placebo (n=8); Cohort 2 will receive high dose vaccine candidate (1e11 I.U. n=16) or placebo (n=8). The study drug will be an oral tablet administered on Days 1 and 29. The endpoints are safety and immunogenicity. For more information, refer to ClinicalTrials.gov. (NCT04854746).

About Vaxart

Vaxart is a clinical-stage biotechnology company developing a range of oral recombinant vaccines based on its proprietary delivery platform. Vaxart vaccines are designed to be administered using tablets that can be stored and shipped without refrigeration and eliminate the risk of needle-stick injury. Vaxart believes that its proprietary tablet vaccine delivery platform is suitable to deliver recombinant vaccines, positioning the company to develop oral versions of currently marketed vaccines and to design recombinant vaccines for new indications. Its development programs currently include tablet vaccines designed to protect against coronavirus, norovirus, seasonal influenza and respiratory syncytial virus (RSV), as well as a therapeutic vaccine for human papillomavirus (HPV), Vaxart's first immuno-oncology indication. Vaxart has filed broad domestic and international patent applications covering its proprietary technology and creations for oral vaccination using adenovirus and TLR3 agonists.

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 Vaxart's strategy, prospects, plans and objectives, results from pre-clinical 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 "should," "believe," "could," "potential," "will," "expected," "plan" and other words and terms of similar meaning. Examples of such statements include, but are not limited to, statements relating to Vaxart's ability to develop and commercialize its product candidates and clinical results and trial data (including its Phase 1b dose-ranging, repeat dose trial investigating its norovirus vaccine candidate (VXA-NVV-104) in elderly subjects); expectations regarding Vaxart's ability to develop effective vaccines against new and emerging variant strains; expectations regarding the timing and nature of future developments and announcements, including those related to trials and studies; the potential applicability of results seen in our preclinical studies or trials to those that may be seen in humans or clinical trials; and Vaxart's expectations with respect to the effectiveness of its product candidates. Vaxart may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the 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, including uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; decisions by regulatory authorities impacting labeling, manufacturing processes and safety that could affect the availability or commercial potential of any product candidate, including the possibility 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 a Vaxart collaborator may not attain development and commercial milestones; that Vaxart or its partners may experience manufacturing issues and delays due to events within, or outside of, Vaxart's or its partners' control, including the recent outbreak of COVID-19; difficulties in production, particularly in scaling up initial production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel or key raw materials, and compliance with strictly enforced federal, state and foreign regulations; that Vaxart may not be able to obtain, maintain and enforce necessary patent and other intellectual property protection; that Vaxart's capital resources may be inadequate; Vaxart's ability to resolve pending legal matters; Vaxart's ability to obtain sufficient capital to fund its operations on terms acceptable to Vaxart, if at all; the impact of government healthcare proposals and policies; competitive factors; 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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