# Vaxart Announces First Subject Enrolled in Phase 1b Norovirus Boosting Regimen Study

May 4, 2021

Study will evaluate safety and immunogenicity of multiple distinct dosing regimens of norovirus oral vaccine candidate

Norovirus infects 15% of U.S. children under age five every year

Study results may inform the COVID-19 oral vaccine program

SOUTH SAN FRANCISCO, Calif., May 04, 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 boosting regimen trial of its norovirus vaccine candidate. This study is designed to evaluate the safety and immunogenicity of various dosing intervals for Vaxart's candidate, which is the only clinical stage norovirus oral tablet vaccine actively being developed.

In a health economic study published in the *American Journal of Preventative Medicine* in January 2021, the negative economic impact to the U.S. of norovirus was estimated to be approximately $10.5 billion* annually. Annual vaccine costs with an efficacy of 75% were cost effective and cost saving at ≤$1,600 and ≤$1,300 per year, respectively, for preschool-aged children, and ≤$165 and ≤$100 per year, respectively, for older adults.

"Norovirus is a potentially fatal illness that affects around 20 million Americans annually. It has an enormous impact on young families with 15% of children under age five being infected every year in the United States," said Andrei Floroiu, Vaxart's chief executive officer. "The WHO designated norovirus as a priority disease for vaccine development, as it is a major public health problem with no approved vaccine available, having a multi-billion dollar annual impact in the US alone and significantly more globally."

Sean Tucker, Ph.D., chief scientific officer of Vaxart commented, "This study will provide insight into the optimal booster timing to maximize immunogenicity and total response of our oral norovirus vaccine candidate. Additionally, the findings may provide important information into the overall dynamics of our platform technology that could guide future protocols for our other vaccine candidates, including our oral COVID-19 tablet vaccine candidate, which is estimated to enter Phase 2 clinical trials around mid-year."

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.

The booster regimen trial is the second of four Vaxart norovirus trials that are ongoing or are planned for 2021. Vaxart is currently administering a second booster dose to a subset of subjects who had participated in the prior Phase 1b bivalent study. The Company is also scheduled to initiate an age escalation trial in subjects over 65 years old and plans to launch a Phase 2 challenge study later this year.

**VXA-NVV-105 Phase Booster Regimen 1b Trial Design**

The Phase 1b study is designed to enroll 30 subjects aged 18 to 55 years old. Subjects will be randomized into 3 cohorts: Cohort 1 will receive the vaccine candidate on day 1 and week 4 of the study; Cohort 2 will receive the vaccine candidate on day 1 and week 8 of the study; Cohort 3 will receive the vaccine candidate on day 1 and week 12 of the study. The endpoints are safety and immunogenicity. For more information, refer to ClinicalTrials.gov.

* Note: The $10.5 Billion annual economic impact of norovirus infections in the US includes both direct medical costs and indirect costs such as time off work, school, etc.

**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 analogs 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, potential insights from Vaxart's Phase 1b norovirus study, the potential role of Vaxart's platform technology 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.

Contacts


Media Relations:
Gloria Gasaatura
LifeSci Communications
(646) 970- 4688
ggasaatura@lifescicomms.com

Investor Relations:
David R. Holmes
LifeSci Advisors, LLC
(646) 970-4995
dholmes@lifesciadvisors.com


Source: Vaxart, Inc.