Vaxart Announces Topline Data from the Phase 2 Challenge Study of its Monovalent Norovirus Vaccine Candidate

September 6, 2023

Study met 5 of 6 primary endpoints

Vaccine was safe and well tolerated with no vaccine-related serious adverse events (SAEs)

Vaccination led to a statistically significant reduction in infection rate, a non-statistically significant reduction in norovirus acute gastroenteritis (AGE), and a substantial reduction in viral shedding

Conference call today at 5:00 p.m. ET

SOUTH SAN FRANCISCO, Calif., Sept. 06, 2023 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) today announced top-line data from the Phase 2 challenge study of its oral tablet monovalent norovirus vaccine candidate (NCT05212168).

The Phase 2 challenge study enrolled 165 healthy adults, who were randomized 1:1 to receive Vaxart's monovalent oral tablet vaccine targeting the norovirus GI.1 genotype or placebo. Four weeks after vaccination, subjects were challenged with GI.1 norovirus. The study achieved its primary endpoints of a statistically significant 29% reduction in the rate of norovirus infection between the vaccinated and placebo arms through Day 8 post challenge, a strong induction of norovirus-specific immunoglobulin A (IgA) and immunoglobulin G (IgG) antibodies, and other immune response endpoints. Vaccination also led to a reduction in norovirus AGE in the vaccine arm compared to placebo, but this was not statistically significant. In a prespecified analysis, the study also showed an 85% decrease in viral shedding in the vaccine arm compared with placebo.

"Challenge studies use higher quantities of virus than an individual may encounter during a naturally occurring infection, yet our vaccine candidate demonstrated a significant effect on infection and viral shedding, even though it did not achieve a statistically significant reduction in norovirus AGE," said Dr. James F. Cummings, Vaxart's Chief Medical Officer. "The magnitude of the reduction in shedding could have an impact on transmission and may have important public health benefits, as norovirus spreads rapidly among people gathering in large numbers, including settings such as daycare centers, nursing homes, and workplaces, and may reduce the potential spread of the infection to families at home."

Key Study Findings:

- **Primary Endpoints:**
  - 29% reduction in the rate of infection in the vaccinated cohort compared with placebo (82% vs. 58%) (p=0.003)
  - 21% reduction in the rate of norovirus AGE in the vaccinated cohort compared with placebo (45% vs. 57%) that was not statistically significant (p=0.149)
  - Significant increase in the induction of norovirus-specific IgA antibody-secreting cells (ASC) in the vaccinated cohort, with a 79% response rate in the vaccinated cohort, compared with 2.5% in the placebo cohort (p<0.001) on Day 8 post-vaccination; mean response was 375 ASC per million cells for the vaccinated cohort, compared with 26 ASC per million cells for placebo
  - Significant increase in the induction of HBGA blocking anti-bodies in the vaccinated cohort (GMFR 3.23) compared with the placebo cohort (GMFR 1.0) on Day 29 post-vaccination (p<0.001)
  - Significant increases in norovirus-specific serum IgA (GMFR 7.14) and IgG (GMFR 4.64) in the vaccinated cohort compared with placebo from baseline to Day 29 post-vaccination (p<0.001)
  - No vaccine-related SAEs or dose-limiting toxicities were reported, consistent with the safety profile observed in all of Vaxart's norovirus trials

- **Pre-specified Analysis**:
  - 85% decrease in viral shedding in the vaccinated cohort compared with placebo
  - No statistically significant difference in disease severity in the vaccinated cohort compared with placebo

"The results of this study highlight the potentially distinctive profile of mucosal vaccination and the potential that our oral pill vaccines may have in protecting against infection and blocking transmission – potential benefits that have also been seen with our influenza vaccine. We are excited to further our understanding of these data and determine the optimal path forward for our norovirus program," added Dr. Cummings.

Norovirus is the leading cause of acute viral gastroenteritis in all age groups in the U.S. However, there are no approved vaccines for noroviruses. In the U.S. alone, the annual disease burden from norovirus is $10.6 billion, as on average norovirus causes 19 to 21 million cases of AGE, infects 15% of all children under the age of 5, and leads to 465,000 emergency department visits, 109,000 hospitalizations and 900 deaths.

Next Steps
Vaxart believes the reduction in the rate of infection and increases in multiple immunologic endpoints in this challenge study support the potential for its norovirus vaccine program to provide significant public health benefit. The Company also believes that the numeric reduction in rate of AGE, while not statistically significant, is encouraging, especially given the high dose of challenge virus used in the study, compared with what would occur in a natural infection.

Vaxart is currently conducting additional analyses of the data from this challenge study and its prior norovirus trials with the objectives of defining the timing of a larger phase 2b study, and identifying ways to reduce the size and duration of a subsequent Phase 3 registration study.

Conference Call
The Vaxart senior management team will host a conference call to discuss the data, beginning at 5:00 p.m. ET today.

The conference call can be accessed using the following information:

Webcast: Click here
Date: Wednesday, September 6, 2023 – 5:00 p.m. ET
Domestic: 877-407-6184
International: 201-389-0877
Conference ID: 13740946

A replay of the webcast will be available for 30 days on Vaxart's website at www.vaxart.com following the conclusion of the event.

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 pills that can be stored and shipped without refrigeration and eliminate the risk of needle-stick injury. Vaxart believes that its proprietary pill 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. Vaxart's development programs currently include pill vaccines designed to protect against norovirus, coronavirus, seasonal influenza, and respiratory syncytial virus (RSV), as well as a therapeutic vaccine for human papillomavirus (HPV), Vaxart's first immune-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 preclinical and clinical trials and the timing of such results, commercialization agreements and licenses, and 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," "anticipate," "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, including its vaccine booster products; Vaxart's expectations regarding clinical results and trial data, and the timing of receiving and reporting such clinical results and trial data; 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 trials, 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; 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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