Vaxart Reports Positive Clinical Data Demonstrating that its Second-Generation Vaccine Technology Produces Much Stronger Antibody Responses than its First-Generation Technology

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- Second-generation norovirus constructs produce statistically significant increases in GI.1 and GII.4 norovirus blocking antibodies (141% and 94%, respectively) compared with first-generation constructs, supporting potential for improved protection against infection -

- Vaccine candidates were safe and well-tolerated across all dose groups with no vaccine-related serious adverse events reported -

- Conference call today at 8:30 a.m. ET -

SOUTH SAN FRANCISCO, Calif., June 11, 2025 (GLOBE NEWSWIRE) -- Vaxart, Inc. (NASDAQ: VXRT), a clinical-stage biotechnology company developing a range of oral recombinant pill vaccines based on its proprietary delivery platform, today reported positive topline results from the Phase 1 clinical trial evaluating its second-generation oral pill norovirus vaccine constructs head-to-head against its first-generation constructs.

The open-label, Phase 1 trial was conducted in 60 healthy volunteers who were randomized to receive the first-generation constructs, an equivalent dose of the second-generation GI.1 and GII.4 constructs, or a lower dose of the second-generation constructs (n=20 for each group). The primary immunological endpoint was norovirus blocking antibody assay (NBAA) titer at Day 0 and Day 28. In a Phase 2 challenge trial of the first-generation vaccine constructs, these functional NBAA titers correlated with protection against norovirus infection. Although the study was not powered to determine superiority by statistical methods, the increase in NBAA titers with the second-generation constructs was sufficiently large (141% for the GI.1 construct and 94% for the GII.4 construct) to demonstrate statistical significance at the higher dose.

“Consistent with what we previously demonstrated in animal models, these clinical data prove that our second-generation constructs increased antibody titers in humans, providing additional compelling evidence of the potential of our oral pill vaccine candidates,” said Sean Tucker, PhD, Vaxart’s Founder and Chief Scientific Officer. “We previously demonstrated that our first-generation construct for the norovirus GI.1 genotype protected against infection and that protection correlated with increased antibody levels detected by our proprietary NBAA assay. The significant increases in NBAA titers reported today give us high confidence that our second-generation constructs will provide even greater protection against infection.”

Key findings from the study show:

- Significantly increased GI.1 NBAA titers in the cohort receiving the high dose of the second-generation constructs compared with an equivalent dose of the first-generation constructs.
  - A 141% increase in GI.1 NBAA titers was observed, which corresponds to a 3.2 increase in Geometric Fold Response (GMFR) from 2.2 to 5.4.
- Significantly increased GII.4 NBAA titers in the cohort receiving the high dose of the second-generation constructs compared with an equivalent dose of the first-generation constructs.
  - A 94% increase in NBAA titers was observed, which corresponds to a 1.8 increase in GMFR from 1.9 to 3.7.
- The low dose of the second-generation constructs produced a numerical increase in NBAA titers compared with the first-generation constructs.
  - 129% increase in NBAA titers for GI.1 was observed, which corresponds to a 2.9 increase in GMFR from 2.2 to 5.1.
  - 84% increase in NBAA titers for GII.4 was observed, which corresponds to a 1.6 increase in GMFR from 1.9 to 3.5.
- With respect to safety, all norovirus vaccine candidates evaluated in this study were well-tolerated, with no vaccine-related serious adverse events.

Vaxart intends to publish the complete results of this study in a peer-reviewed journal.

“We are very pleased with these results, which exceeded our expectations. With no currently approved vaccine, norovirus causes millions of infections globally resulting in billions of dollars of economic burden,” said Steven Lo, Chief Executive Officer of Vaxart. “We believe that our second-generation norovirus oral pill vaccine candidate has the potential to provide first-in-class or best-in-class protection against this highly contagious virus where there is significant unmet need. We intend to incorporate these compelling new data into our ongoing discussions with potential partners.”

Assuming a partnership or other funding, Vaxart expects to conduct a Phase 2b safety and immunogenicity study that could potentially begin as early as the second half of 2025 followed by an End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA). A Phase 3 trial could then begin as early as 2026.

Vaxart’s oral pill technology works by inducing expression of antigen proteins in the cells of humans’ intestines. Vaxart’s second-generation technology was developed in 2023 and 2024 to achieve two purposes: first, to increase expression levels of the antigen proteins, and thus to greatly increase antibody titers; and second, to improve manufacturability. In pre-clinical experiments, the second-generation constructs substantially improved antibody responses in animal models. The trial reported today, for the updated norovirus vaccine candidate, is the first test in humans of the new technology. Vaxart has also adopted the new technology in its latest COVID-19 vaccine candidate and implemented these improvements throughout its portfolio.

There is no approved vaccine against norovirus, a leading cause of acute gastroenteritis (AGE) worldwide that is responsible for outbreaks of infection

and illness globally. Each year there are approximately 685 million norovirus infections globally, with 20 million infections occurring annually in the United States. Due to these high rates of infection, norovirus is believed to cause nearly 20% of diarrheal disease globally. Additionally, the economic burden associated with norovirus infection and AGE is estimated at $60 billion worldwide and $10 billion in the United States.

Conference Call
The Vaxart senior management team will host a conference call to discuss the topline data from the norovirus Phase I trial today, beginning at 8:30 a.m. ET.

The conference call can be accessed using the following information:

Webcast: Click here
Date: Wednesday, June 11, 2025 – 8:30 a.m. ET
Domestic: (877) 407-0832
International: (201) 689-8433
Conference ID: 13754315

Investors may submit written questions in advance of the conference call to ir@vaxart.com.

A replay of the webcast will be available on the Company'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 coronavirus, norovirus and influenza, 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, funding milestones, any partnership or other funding, the results of the FDA's review of any trials, studies, or data, results from clinical trials and the timing of such results and such trials, 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 complete ongoing clinical trials; Vaxart's ability to develop and commercialize its product candidates, including its vaccine booster products; Vaxart's expectations regarding clinical results and trial data, including their design, and the timing of such trials and of receiving and reporting such clinical results and trial data; Vaxart's expectations regarding timing of enrollment in studies; and Vaxart's expectations with respect to the effectiveness of its product candidates and the potential of its vaccine pill platform. 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 U.S. Securities and Exchange Commission. Vaxart does not assume any obligation to update any forward-looking statements, except as required by law.

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