Vaxart Completes Enrollment in Phase 1 Trial for its Norovirus Oral Pill Vaccine Candidate

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- Topline data expected in mid-2025 -

SOUTH SAN FRANCISCO, Calif., April 30, 2025 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) today announced that it completed enrollment of its Phase 1 clinical trial evaluating its second-generation oral norovirus vaccine constructs head-to-head against its first-generation constructs.

“Completing enrollment in this trial bring us one step closer in our development of a norovirus vaccine, where there is a significant unmet need,” said Steven Lo, Chief Executive Officer of Vaxart. "We are excited about the potential of our second-generation oral norovirus vaccine constructs that we believe may be more potent than our first-generation constructs. We look forward to sharing the topline data in mid-2025.”

The Phase 1 trial is an open label, dose ranging clinical study designed to evaluate Vaxart's second-generation oral norovirus vaccine constructs head-to-head against its first-generation constructs. The study will measure safety and immune parameters that have correlated to protection in the completed norovirus challenge study. Norovirus is a leading cause of acute gastroenteritis worldwide, and Vaxart's oral vaccine candidate aims to provide a convenient and effective solution for this significant public health challenge.

An independent Data and Safety Monitoring Board (DSMB) conducted a pre-planned interim safety data review and recommended the study to continue without any modifications.

If the Phase 1 trial is successful, and assuming a partnership or other funding, Vaxart expects to conduct a Phase 2 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.

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, 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 the Phase 1 trial of its oral bivalent norovirus vaccine; 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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