# Vaxart Announces Last Subject Dosed in Phase 1 Trial of Its Norovirus Vaccine Candidate in Lactating Mothers

December 21, 2023

*On track to report topline data by the end of 2024*

SOUTH SAN FRANCISCO, Calif., Dec. 21, 2023 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) today announced that it has completed enrollment and dosing in the Phase 1 clinical trial evaluating Vaxart's oral pill bivalent norovirus vaccine candidate focused on lactating mothers.

"This is an important step forward as we drive toward a vaccine candidate that may make it possible for mothers to protect their children against this highly contagious – and potentially lethal -- virus. We look forward to announcing topline data from this study by the end of 2024," said Dr. James F. Cummings, Vaxart's Chief Medical Officer. "We are very proud of our clinical team for completing enrollment of this trial within our planned timeline."

There is no approved vaccine against norovirus, which sickens approximately 21 million people in the United States each year, and 15% of children under age 5 contract norovirus annually. Approximately 3 million sets of parents are forced by this virus to miss work -- approximately 2.2 days on average -- to care for their children. The annual disease burden from norovirus is $10.6 billion in the U.S. alone.

Globally, norovirus has become the leading cause of pediatric gastroenteritis in health care settings in countries that have adopted a rotavirus vaccine program.[1] Pediatric deaths in the United States due to norovirus are rare, but they are much more common in the developing world.

**About the VXA-NVV-108 Clinical Trial**

The Phase 1, multicenter, randomized, double-blind, placebo-controlled single dose, dose-ranging study is designed to evaluate the safety, tolerability, and immunogenicity of orally administered bivalent GI.1/GII.4 norovirus vaccine in healthy lactating females of at least 18 years of age. The study enrolled 76 subjects at five sites in South Africa. Subjects are randomized into high- or low-dose vaccine (N=30 for each arm) or placebo (N=16). The primary endpoints are:

- Frequency, duration and severity of solicited symptoms of reactogenicity (local and systemic) for one week following study drug dose;
- Frequency, duration and severity of unsolicited treatment-emergent adverse events (TEAEs), serious AEs (SAEs), adverse events of special interest (AESIs) and new onset of chronic illness (NOCIs) through the active period (four weeks post dose);
- Serum VP1-specific (GI.1 and GII.4) IgA on Day 1 (baseline), Day 8 and Day 29 (four weeks post last dose);
- Breastmilk VP1-specific (GI.1 and GII.4) IgA on Day 1 (baseline), Day 8 and Day 29 (four weeks post last dose).

Further information, including information about study funding, can be found in the Company's press release of December 1, 2022, as well as the Company's latest quarterly filing.

[1] Shah and Hall, Infect Dis Clin North Am. 2018 Mar; 32(1): 103-118.

**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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