Vaxart Doses First Subject in Phase 1 Trial of Its Norovirus Vaccine Candidate in Lactating Mothers

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Trial evaluating the ability of oral vaccine tablets to induce breast milk antibodies and transfer of antibodies to young infants

SOUTH SAN FRANCISCO, Calif., Nov. 02, 2023 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) today announced it has dosed the first subject in its Phase 1 clinical trial evaluating Vaxart's oral pill bivalent norovirus vaccine candidate focused on lactating mothers.

"Initiating this study is an important step toward Vaxart's goal of developing a vaccine that may reduce the significant global health threat norovirus poses to children under 5 years of age," said Dr. James F. Cummings, Vaxart's Chief Medical Officer. "We believe an oral norovirus vaccine pill may make it possible for mothers to protect their infants against this highly contagious virus for which there currently is no approved vaccine."

Norovirus sickens approximately 21 million people in the United States each year, and 15% of children under age 5 contract norovirus annually. This would translate into about 3 million sets of parents needing to take time from work (approximately 2.2 days on average) to care for their children.

Globally, in countries that have adopted a rotavirus vaccine program, norovirus has become the leading cause of pediatric gastroenteritis in health care settings.[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 and their breast-feeding infants (aged 30 days to 11 months). The study is expected to enroll approximately 76 subjects at seven sites in South Africa. Subjects will be 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).

[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 coronavirus, norovirus, 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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