Vaxart Publishes Positive Data for its Oral Bivalent Norovirus Candidate in Lactating Women and Their Infants

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Vaccine was safe and well-tolerated and led to a significant increase in norovirus-specific antibodies in serum and breast milk

Norovirus-specific IgA in infant stool correlated with breast milk IgA, suggesting passive transfer of immunity to breastfed infants and the potential for a new approach to confer mucosal anti-norovirus immunity to a vulnerable population

SOUTH SAN FRANCISCO, Calif., Jan. 15, 2026 (GLOBE NEWSWIRE) -- Vaxart, Inc. (OTCQX: VXRT) ("Vaxart" or the "Company"), a clinical-stage biotechnology company developing a range of oral vaccines based on its proprietary delivery platform, today announced the publication in *npj Vaccines* of data from a double-blind, placebo-controlled Phase 1 trial evaluating a single-dose, oral bivalent vaccine candidate in post-partum, breastfeeding women (NCT07254728). Topline safety and immunogenicity results in lactating women were initially reported in April 2024; the newly published study additionally shows vaccine-induced functional norovirus-specific antibodies in breastmilk and serum from vaccinated women, and norovirus-specific IgA in the stool of their breastfed infants. A positive correlation between levels of breast milk IgA and infant stool IgA was observed.

"These findings demonstrate that oral vaccination of lactating women led to passive transfer of norovirus-specific antibodies to their infants via breastmilk consumption," said Sean N. Tucker, Vaxart's Chief Scientific Officer. "This promising finding could be especially important given that children under the age of five years can experience severe disease from norovirus infection, particularly in under-resourced areas. The passive immunity generated by our oral norovirus vaccine candidate has the potential to protect this highly vulnerable population from infection and illness at a time when their immune systems are still developing."

There is no approved vaccine against norovirus, which sickens approximately 21 million people in the United States each year, including the 15% of children under age 5 who 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 United States 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 more common in the developing world.

About the Trial
The Phase 1, multicenter, randomized, double-blind, placebo-controlled single dose, dose-ranging study was designed to evaluate the safety, tolerability, and immunogenicity of an orally administered bivalent GI.1/GII.4 norovirus vaccine in healthy lactating women. The primary outcomes of the study were safety and reactogenicity, and breast milk and serum norovirus-specific IgA; passive transfer of IgA to infants was an exploratory outcome. The Bill & Melinda Gates Foundation provided partial funding for the study.

The study enrolled 76 women 18-43 years of age at five sites in South Africa. Participants were randomized into high- or medium-dose vaccine (n=30 per group) or placebo (n=16). As previously reported, the vaccine was safe and well tolerated, and reports of mild or moderate adverse events (AEs) were similar between the placebo group and each of the vaccine groups; no AEs beyond grade 2 were reported. Results for serum and breastmilk IgA at Day 29 post vaccination were consistent with the prior report. Serum norovirus-specific IgA rose an average of 5.6-fold in response to GI.1 and 4.7 fold in response to GII.4 in the high dose group. Breastmilk norovirus-specific IgA rose on average 4.0 fold in response to G1.1 and 6.0 fold in response to GII.4 in the high dose group (p=0.018 and p=0.004, respectively).

Newly reported data show:

- Elevated levels of GI.1 and GII.4-specific breastmilk IgA in the high dose group compared with placebo were maintained through day 180.
- A consistent trend of increased GI.1 and GII.4-specific IgA was observed in the stool from paired infants of vaccinated women at days 29 and 60.
- A positive association between levels of IgA in maternal breast milk and infant stool, supporting the hypothesis of passive transfer of mucosal immunity.
- Oral vaccination induced functional breast milk and serum antibody responses as assessed with norovirus blocking antibody assays.
- Oral vaccination generated GI.1 and GII.4-specific IgA in saliva and nasal lining fluid in lactating women.

"These findings add to the growing body of evidence supporting the safety and efficacy of our oral pill norovirus vaccine candidate," said James F. Cummings, Vaxart's Chief Medical Officer. "In June, we reported positive Phase 1 data demonstrating that our second-generation norovirus constructs produced statistically significant increases in GI.1 and GII.4 norovirus blocking antibodies compared with first-generation constructs, supporting their potential for improved protection against infection. In September, we reported data demonstrating that these constructs induced robust increases in fecal IgA, which was shown to be correlated with protection against infection in our previous Phase 2b challenge study. The increased immunogenicity shown by second-generation vaccines may improve the passive transfer of norovirus-specific antibodies to breastfed infants in future studies."

Pending a partnership or other funding, Vaxart expects to initiate the next clinical trial of its norovirus oral vaccine candidate in 2026.

[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 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, 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; Vaxart's expectations regarding clinical results and trial data, and the timing of receiving and reporting such clinical results and trial data; Vaxart’s expected timing for future clinical trials; 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, 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 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; 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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