Vaxart Announces Positive Preliminary Topline Data from Dose-Ranging Phase 2 Study of its Bivalent Norovirus Vaccine Candidate

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Met all primary endpoints: *Vaccine was well-tolerated with robust immunogenicity*

Continue to expect topline data from Phase 2 GI.1 challenge study in Q3 2023

SOUTH SAN FRANCISCO, Calif., July 06, 2023 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) today announced positive topline data from the dose-ranging Phase 2 clinical trial of its oral pill bivalent norovirus vaccine candidate.

Preliminary results of the trial (NCT05626803) showed robust serum immune responses across all doses at Day 29 relative to Day 1. Both doses showed a similar increase in serum antibody responses with no statistical difference between the medium and high dose arms. At Day 29, increases in serum IgA, IgG, and BT50, for both the GII.4 and GI.1 strains in the vaccine arms, were similar to those seen in previous norovirus studies conducted by Vaxart. Mucosal and cell-based assay data will be available at a later date.

Mean Fold Rise Summary (Day 1 to Day 29) Preliminary Data

	G1.1			GII.4		
Serum antibodies	IgA	IgG	BT50	IgA	IgG	BT50
Medium Dose (n=50)	5.9	4.8	3.0	9.3	6.1	4.3
High Dose (n=59)	6.4	4.2	2.3	8.6	5.1	7.8
Placebo (n=25)	1.0	1.0	1.1	1.1*	1.0	1.0*

*excluding subject with confirmed gastroenteritis.

Results from this Phase 2 dose-ranging study also demonstrated that the bivalent norovirus vaccine candidate was well tolerated, with a favorable safety profile that included no vaccine-related serious adverse events (SAEs) and no dose limiting toxicity. Adverse event rates for both doses were similar to placebo.

“Topline data reported today further validate the potential of our norovirus vaccine candidate and, more broadly, our oral vaccine platform,” said Dr. James F. Cummings, Vaxart’s Chief Medical Officer. “These data, additional forthcoming data from this study, and the data we expect from our norovirus challenge study will help inform our selection of dosage levels in a larger Phase 2b study and support an End-of-Phase 2 meeting with the U.S. Food and Drug Administration.

“Our bivalent vaccine is designed to target the most important genogroups, GI and GII, and specifically to cover the important strains, GI.1 and GII.4. GII.4 currently causes the majority of norovirus disease in humans.”

The study enrolled 135 healthy adults at three sites in the United States. The first 10 subjects received open label high-dose vaccine and the remaining subjects were randomized to high- or medium-dose vaccine (N=50 for each arm) or placebo (N=25).

This is the seventh clinical trial completed in Vaxart’s norovirus program, and it supports previous findings of robust immunogenicity and benign tolerability. Collectively, the data from these completed trials have shown immune responses from Vaxart’s oral norovirus vaccine constructs to be strong, long-lasting, and comparable to natural infection. Final results could vary slightly from these preliminary data, and additional timepoint measures and mucosal data from this study are expected in the second half of 2023.

“The results take us one important step forward in our clinical development,” said Andrei Floroiu, Vaxart’s Chief Executive Officer. “Our norovirus vaccine candidates are the only ones formulated for oral administration and optimized for delivery to the gastrointestinal system, the site at which norovirus enters the body. Today’s results add to the evidence supporting the potential of this approach in addressing the unmet and critical need for an approved norovirus vaccine.”

Vaxart’s Norovirus Program Next Steps

The data reported today support the continued development of Vaxart’s oral norovirus vaccine candidate in adult populations and add to the growing body of evidence supporting its clinical utility. These data, along with upcoming topline data from the ongoing Phase 2 G1.1 challenge study, will inform dosage amounts for a bivalent norovirus Phase 2b study, the next step in progressing the vaccine candidate.

The Phase 2b study is expected to add safety data that, if successful, will then enable Vaxart to schedule an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (the “FDA”), potentially in 2024. Data from the Phase 2 study announced today, along with a future Phase 3 study, are required for a Biologics License Applications submission to the FDA as the Company pursues a commercial pathway for its bivalent norovirus candidate.

Norovirus is the leading cause of acute viral gastroenteritis in all age groups in the U.S. There are no approved vaccines for noroviruses. In the U.S. alone, the annual disease burden from norovirus is $10.6 billion, as norovirus causes 19 to 21 million cases of acute gastroenteritis, (AGE), infecting

15% of all children under the age of 5, and leads to 465,000 emergency department visits, 109,000 hospitalizations, and 900 deaths on average each year.

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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