Vaxart Doses First Subject in the Phase 2 Clinical Trial of its Bivalent Norovirus Candidate

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Study to evaluate safety and immunogenicity of oral norovirus vaccine in healthy adults

SOUTH SAN FRANCISCO, Calif., Feb. 14, 2023 (GLOBE NEWSWIRE) -- Vaxart, Inc. (NASDAQ: VXRT) today announced that it has dosed the first subject in the Phase 2 clinical trial of its oral tablet bivalent norovirus candidate. The dose-ranging study is designed to identify a vaccine dose for a potential Phase 3 clinical trial.

“Initiating the Phase 2 clinical trial of this candidate is an important achievement toward our goal of developing an oral tablet vaccine that may reduce the significant global health threat that norovirus poses to children and seniors,” said Dr. James F. Cummings, MD, Chief Medical Officer at Vaxart. “Results from the Phase 1b clinical trial in healthy adults demonstrate that this candidate stimulates robust IgA antibody secreting cells against the prevalent strains of two norovirus genotypes that cause the majority of norovirus disease. Data from the Phase 2 trial will inform our further clinical development strategy for this promising vaccine candidate targeting a market estimated at more than $10 billion in the United States alone.”

As previously reported, Vaxart’s bivalent vaccine candidate demonstrated robust immunogenicity, with an IgA ASC response rate of 78% for the GI.1 strain and 93% for the GII.4 strain, with no interference observed.

This Phase 2 clinical trial is expected to enroll approximately 135 healthy adults at three sites in the United States. The first 10 subjects will receive open label high-dose vaccine and the remaining subjects will be randomized to high- or low-dose vaccine (N=50 for each arm) or placebo (N=25). The primary endpoints are safety and immunogenicity with the objective of determining dose levels for Phase 3 development.

Vaxart expects to report topline data from the Phase 2 study in mid-2023.

Norovirus imposes significant health and economic burdens, with an estimated global impact of $60 billion.[1] In the United States, norovirus causes 21 million illnesses each year, infecting 15% of all children under the age of five years and resulting in illness — which frequently requires hospitalization — in 7.5% of people over the age of 65 years. Approximately 3 million sets of parents need to take an average of 2 days off from work to care for children with norovirus illness.[2]

Vaxart’s bivalent norovirus oral tablet candidate is differentiated from other norovirus vaccines in development because it generates both systemic and mucosal immunity, is delivered through the mouth and is stable at room temperature, making it much easier to distribute and administer than injected vaccines.

References

[1] Global Economic Burden of Norovirus, Bartsch S et al., PLOS ONE 2016.

[2] Incidence of Norovirus and Other Viral Pathogens That Cause Acute Gastroenteritis (AGE) among Kaiser Permanente Member Populations in the United States, 2012–2013, Grytdal et al, PLOS 1, 2016.

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, 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 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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