Vaxart Reports Positive Preliminary Data from the Phase 1b Trial of its Oral Norovirus Vaccine Candidates in Elderly Adults

June 2, 2022

Results support safety and immunogenicity of the vaccine candidate in the highly vulnerable elderly population

Preliminary boost study data also reported

Norovirus has been estimated to cost the United States $10.6 billion annually

SOUTH SAN FRANCISCO, Calif., June 02, 2022 (GLOBE NEWSWIRE) -- Vaxart (NASDAQ: VXRT) today reported positive preliminary data from its recently completed Phase 1b trial of its oral vaccine candidate in subjects aged 55 – 80 years (NCT04854746).

Results of the trial show a robust immune response across all doses, with a dose-dependent production of IgA antibody secreting cells (ASCs), consistent with previous studies conducted in younger populations. The results also demonstrate that the vaccine candidate was well tolerated with a favorable safety profile.

These data support the continued development of Vaxart's oral norovirus vaccine candidate in adult populations, including elderly adults, and add to the growing body of evidence supporting its clinical utility. Vaxart is conducting a Phase 2 clinical challenge study of its norovirus vaccine candidate in adult volunteers.

Norovirus is the leading cause of acute gastroenteritis that produces vomiting and diarrhea among people of all ages. The World Health Organization's (WHO) Product Development for Vaccines Advisory Committee has identified norovirus as a priority disease for vaccine development.

The virus causes up to 21 million cases, 109,000 hospitalizations and 900 deaths annually in the United States. Adults over the age of 65 years are especially vulnerable to norovirus infection, with 7.5% of this population infected annually. Norovirus also has a negative health economic impact, which has been estimated to cost $10.6 billion annually in the United States alone.

"Our norovirus vaccine candidate, the only investigational norovirus vaccine formulated for oral administration, is optimized for delivery to the gastrointestinal system, which is the site at which norovirus enters the body," said James F. Cummings, MD, Chief Medical Officer at Vaxart. "The data reported today add to a growing body of preclinical and clinical evidence demonstrating the efficacy and safety of this approach in addressing the unmet and critical need for an approved norovirus vaccine."

Key findings from the Phase 1b study in elderly patients include:

- Robust immune response across all doses, with a dose dependent IgA ASC response
- IgA ASC responses were consistent with previous studies in younger subjects
- All solicited adverse events were mild or moderate with generally similar rates of events between the vaccine groups and placebo

Vaxart is also reporting preliminary data from a Phase 1 boosting regimen of its norovirus vaccine candidate. These data show that the candidate was able to successfully boost antibody responses, with antibody responses trending better with administration spread out over 3 months versus a shorter interval. Vaxart has previously reported that booster administration at a year post first dose was able to return antibody titers to levels similar to what was observed after the first dose.

"The results reported today support the potential of our Norovirus vaccine candidate in key patient populations and in a variety of boosting schedules," said Andrei Floroiu, Vaxart's Chief Executive Officer. "We are making progress in our Phase 2 trial, which is designed to provide additional evidence validating the safety and efficacy of our norovirus vaccine candidate. The data we have generated across our clinical program increases our confidence that our norovirus vaccine candidate may demonstrate first- and best-in-class potential."

References

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 tablets that can be stored and shipped without refrigeration and eliminate the risk of needle-stick injury. Vaxart believes that its proprietary tablet 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 tablet 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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Source: Vaxart, Inc.