Vaxart Announces Favorable DSMB Review of Sentinel Cohort from COVID-19 Phase 2b Clinical Trial

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Independent Data Safety Monitoring Board (DSMB) recommends study to proceed without modifications based on initial safety assessment of 400 participant 30-day data

The company plans to progress the trial to enrollment of 10,000 participants, upon favorable review from the U.S. Food and Drug Administration (FDA) and upon Biomedical Advanced Research and Development Authority (BARDA) approval

SOUTH SAN FRANCISCO, Calif., Jan. 13, 2025 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) today announced that an independent DSMB, which conducted a planned review of the 30-day safety data from a sentinel cohort of 400 participants in its COVID-19 Phase 2b trial, has recommended that the study continue without any modifications.

“We are pleased with the DSMB recommendation, an important step forward in conducting our head-to-head study versus an mRNA comparator,” said Dr. James F. Cummings, Vaxart’s Chief Medical Officer. “We look forward to the next steps of review of the safety data by the FDA and approval from BARDA before advancing the Phase 2b trial to the second part that will measure both safety and efficacy.”

The FDA is reviewing the 30-day safety data from the sentinel cohort, and, upon favorable review as well as BARDA’s approval, the study will progress by enrolling approximately 10,000 participants. The trial will strive to enroll participants in line with U.S. demographics, as well as including at least 25% over the age of 65.

The Phase 2b trial is a double-blind, multi-center, randomized, comparator-controlled study to determine the relative efficacy, safety, and immunogenicity of Vaxart’s oral pill COVID-19 vaccine candidate compared to an approved mRNA COVID-19 injectable vaccine, in adults previously immunized against COVID-19 infection.

Funding for this award was received under Project NextGen, a $5 billion initiative led by BARDA and the National Institute of Allergy and Infectious Diseases (NIAID) to accelerate and streamline the development of the next generation of innovative COVID-19 vaccines, therapeutics, and enablers. Vaxart’s project award through the Rapid Response Partnership Vehicle (RRPV) is valued at up to $460.7 million. This project has been funded with federal funds from the U.S. Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); BARDA, under Other Transaction (OT) number 75A50123D00005.

As a pioneer of oral vaccines, Vaxart was the first U.S. company to complete a Phase 2 clinical trial of an oral vaccine for COVID-19.

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, receipt of funding from BARDA, results from preclinical and clinical trials and the timing of such results as well as the outcome of the review of such results by regulatory authorities, 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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