Vaxart Announces Initiation of Sentinel Cohort for Phase 2b Study Evaluating Its COVID-19 Oral Pill Vaccine Candidate

September 30, 2024

— 400 subject sentinel portion of Phase 2b study will evaluate the safety, immunogenicity and efficacy of Vaxart's next generation oral pill COVID-19 vaccine compared to an approved mRNA vaccine comparator —

—The sentinel cohort is being funded as part of the Phase 2b NextGen COVID-19 clinical trial, valued at up to $456 million through the Rapid Response Partnership Vehicle under the U.S. government's Project NextGen —

SOUTH SAN FRANCISCO, Calif., Sept. 30, 2024 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) today announced the initiation of the sentinel cohort of its Phase 2b clinical trial evaluating Vaxart's oral pill COVID-19 vaccine candidate against an approved mRNA vaccine comparator.

"Initiating the sentinel cohort is a strong step toward Vaxart's goal of developing a vaccine that may bring us closer to a sustainable solution to the persistent threat of COVID-19," said Dr. James F. Cummings, Vaxart's Chief Medical Officer. "We continue to progress toward our goal of conducting the Phase 2b study and look forward to the results of our mucosal technology's first head-to-head comparison against an approved mRNA vaccine for this virus."

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 against an approved mRNA COVID-19 injectable vaccine in adults previously immunized against COVID-19 infection.

The trial consists of two parts and will enroll healthy adults 18 years and older in the United States. The first part, for which funding is now approved, is a sentinel cohort comprised of 400 participants, with 200 receiving Vaxart's COVID-19 vaccine candidate and 200 receiving an approved mRNA vaccine comparator. Once an independent Data and Safety Monitoring Board (DSMB) and FDA review the 30-day safety data of the 400 participants, the second part of the trial will proceed to enroll 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 full Phase 2b trial will measure efficacy for symptomatic and asymptomatic disease, systemic and mucosal immune induction, and the incidence of adverse events. The primary endpoint is relative efficacy of Vaxart's COVID-19 vaccine candidate compared to an approved mRNA comparator for the prevention of symptomatic disease. Primary efficacy analysis will be performed when all participants have either discontinued or completed a study visit 12 months post-vaccination.

Funding for this award was received under Project NextGen, a $5 billion initiative led by the Biomedical Advanced Research and Development Authority (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. 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, 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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Source: Vaxart, Inc.