Vaxart Doses First Subject in Phase II COVID-19 Oral Tablet Vaccine Clinical Trial

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Study Will Evaluate Safety, Immunogenicity and Efficacy of the Only Oral Tablet COVID-19 Vaccine in Phase II
Vaxart Now Operates Two Manufacturing Facilities To Support Timely Progress of Multiple Clinical Programs

SOUTH SAN FRANCISCO, Calif., Oct. 26, 2021 /PRNewswire/ -- Vaxart, Inc. (NASDAQ: VXRT) today announced that it has dosed the first subject in its Phase II COVID-19 oral tablet vaccine clinical trial, the only Phase II trial of an oral tablet COVID-19 vaccine underway in the world.

Vaxart expects to enroll 96 subjects at four sites in the United States in the first part of its Phase II trial. The U.S. trial will be followed by an international trial involving a larger pool of subjects. The U.S. portion of the trial will be a randomized open-label dose and age escalation lead-in segment in naïve and previously vaccinated subjects, to be followed by an international placebo-controlled efficacy trial. The full data set from the U.S. trial is expected in Q1 2022.

"Dosing the first subjects with the most advanced oral tablet COVID-19 vaccine candidate marks another important step forward toward developing a transformative solution to the SARS-CoV-2 global pandemic," said Andrei Floroiu, Vaxart's Chief Executive Officer.

"Vaxart's oral vaccine has the potential to transform public health both in the United States and globally by getting more people vaccinated faster while also offering broader protection by triggering mucosal immunity. This could help us fight emerging strains, break through the barriers to herd immunity and move toward domestic and global vaccine equity," Floroiu said.

"A vaccine that can inhibit infection in the mucosal surfaces provides potentially better protection against airborne viruses because the mucosa is the body's first line of defense against these pathogens," said Dr. Sean Tucker, Vaxart's founder and Chief Scientific Officer. "The mucosa is where the virus invades, and if we can stop it there, we can keep people healthier and fight off this virus and its variants."

Manufacturing Update

Vaxart has recently brought online its own GMP manufacturing facility and is now producing vaccines at two GMP plants in parallel. This allowed the company to manufacture all of the COVID-19 vaccine oral tablets for the clinical trials planned to start in 2021, and to start manufacturing vaccines for its upcoming norovirus Phase II trials.

Recent Pre-clinical Data

A Duke University-led study published earlier this month showed that Vaxart's vaccine candidate reduced the airborne transmission of SARS-CoV-2 virus in an animal model and suggested the vaccine candidate would support superior mucosal protection.

The study's findings, published by bioRxiv, are consistent with those from Vaxart's Phase II human flu challenge study published in 2020. The flu study showed Vaxart's oral tablet flu vaccine was better at reducing shedding than the injectable flu vaccine competitor. The Duke and flu studies' data support the thesis that mucosal vaccines may offer better protection than injectable vaccines against airborne viruses.

VXA-COV2-1.1-S Phase II Trial Design
The Phase II study is designed to enroll 96 subjects aged 18-55 years old, and then enroll subjects aged 56-75 years old, in eight subgroups. Subjects will be randomized into eight cohorts stratified by age, vaccination history, dose size and placebo. The study drug will be an oral tablet administered on Days 1 and 29. The endpoints are safety, immunogenicity and efficacy. For more information, refer to ClinicalTrials.gov (NCT 05067933).

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 pre-clinical 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," "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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