



Vaxart Begins Recruiting in Global Phase II COVID-19 Oral Tablet Vaccine Clinical Trial

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Start of US Phase II of S-Only Vaccine Candidate Expected Later This Month Ex-US Clinical Trials to Begin Later This Year with India Study

SOUTH SAN FRANCISCO, Calif., Oct. 6, 2021 /PRNewswire/ -- Vaxart, Inc. (NASDAQ: VXRT) today announced that it has begun recruiting subjects for its Phase II COVID-19 oral tablet vaccine clinical trial.



Vaxart expects to begin dosing the first of 96 U.S. subjects, split evenly between COVID-19 naïve and mRNA vaccinated subjects, later this month.

The company's Phase II COVID-19 program will also include countries outside of the United States, starting with a trial in India that is expected to begin later this year.

"Phase II is an extremely important milestone in the development of the first and only COVID-19 oral tablet vaccine that has reached this phase of development," said Vaxart Chief Executive Officer, Andrei Floroiu.

"An oral vaccine has the potential to dramatically impact the world's response to the COVID-19 pandemic and to improve global public health. It can be easier and faster to administer than injectables and can help mitigate vaccine hesitancy, as many of those unwilling to get vaccinated by needle would take an oral tablet vaccine," Floroiu said.

"We're very excited to start Phase II trials of our S-only vaccine candidate because in our nonhuman primate studies, our S-only vaccine produced much higher serum antibody levels than the S+N construct did," said Dr. Sean Tucker, Vaxart's founder and Chief Scientific Officer.

"Vaxart's new trials will generate key data that will allow us to compare the S-only and S+N vaccine candidates and help us decide on the best development path forward for our COVID-19 vaccine program, particularly in the face of emerging variant strains," added Dr. Tucker.

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 the receipt by 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.

Contacts

Vaxart Media Relations: **Investor Relations:**

Mark Herr

Vaxart, Inc.

mherr@vaxart.com

(203) 517-8957

IR@Vaxart.com

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