Vaxart Announces Agreement with hVIVO to Develop World's First Human Omicron Challenge Model

June 30, 2022

Model will be used in Vaxart's Phase II Omicron Challenge Trial

Open Orphan subsidiary hVIVO to manufacture challenge virus and conduct characterization study

SOUTH SAN FRANCISCO, Calif., June 30, 2022 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) today announced an agreement with hVIVO Services Limited, a subsidiary of Open Orphan plc (AIM: ORPH) under which hVIVO will conduct a characterization study and, if successful, develop a human challenge model based on the Omicron variant of SARS-CoV-2 with the intent to conduct a subsequent Phase II Human Challenge Trial (HCT) of Vaxart's oral COVID-19 vaccine pill candidate.

Vaxart is developing an oral COVID-19 vaccine pill and is the first company to progress to a Phase II clinical trial with an oral candidate. Vaxart is now also the first company to announce the intent to test a vaccine candidate through a COVID-19 human challenge study using the now prevalent Omicron variant, rather than the original Wuhan strain.

hVIVO is a specialist contract research organization (CRO) and global leader in testing infectious and respiratory disease products using HCTs.

"We are excited at the prospect of testing our vaccine candidates in a human Omicron challenge model particularly given the preclinical data we reported earlier this month that showed two of our COVID-19 vaccine constructs could protect against the Omicron BA.1 variant. A human challenge study of our oral COVID-19 vaccine pill candidate against the Omicron variant of SARS-CoV-2 is the most rapid and direct way to assess the efficacy of this candidate against a highly prevalent viral strain," said Dr. James Cummings, Vaxart's Chief Medical Officer.

"hVIVO has pioneered COVID-19 characterization and the Omicron human challenge model, and the use of this model in our planned Phase II HCT can rapidly generate robust, controlled data on the ability of our COVID-19 vaccine candidate to prevent infection and the development of symptomatic disease, as well as its effect on viral shedding, which plays a critical role in the spread of infection from one person to another. The results of this study will inform the next steps in the development of our COVID-19 vaccine candidate, which we believe has the potential to transform personal and public health approaches to controlling the global pandemic," added Dr. Cummings.

"We are proud to be developing the world's first Omicron human challenge model and to welcome Vaxart as the first client of this program," said Yamin 'Mo' Khan, Chief Executive Officer of Open Orphan. "The successful completion of the world's first COVID-19 characterization, which was published in Nature Medicine earlier this year, has given our customers the confidence to move forward with the less severe yet more infective Omicron challenge model."

Following manufacture of the challenge virus, hVIVO will conduct a characterization study to establish a dose of the Omicron challenge virus that will cause a safe and reliable infection in healthy volunteers. The study will enroll healthy male and female volunteers who have previously been vaccinated against or infected with SARS-CoV-2, with no known risk factors for severe COVID-19 and low levels of serum neutralizing antibodies (and therefore still likely to become infected following inoculation). Subject to the successful completion of the characterization study and receipt of relevant regulatory approvals, the Omicron human challenge trial is expected to begin in 2023.

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, 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.

About hVIVO

A subsidiary of Open Orphan plc (AIM: ORPH), hVIVO is an industry leading partner providing end-to-end human challenge trial services to help accelerate drug and vaccine development in respiratory and infectious disease. With a leading portfolio of human challenge models, hVIVO has decades of experience and expertise in conducting human challenge trials as well as challenge agent manufacture and clinical characterization across a range of respiratory viruses including various strains of influenza, respiratory syncytial virus (RSV), human rhinovirus (hRV – common cold virus), as well as the initial circulating SARS-CoV-2 virus and variants which have since emerged. hVIVO leads the Challenge Agent Manufacture Consortium, which has developed international standards that pertain to challenge agent manufacture and storage, to ensure safety, quality and consistency. hVIVO runs its studies from its state-of-the-art quarantine facilities in London with specialized on-site virology and immunology laboratories, the Company leverages its unique FluCamp clinical trial recruitment capacity to recruit volunteers / patients for its studies.

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.