# Vaxart Announces Dosing First Subject in Phase 1 Clinical Trial of Its Oral Tablet COVID-19 Vaccine

October 13, 2020

*Open-label, dose ranging study to examine safety and immunogenicity*

*First clinical data readouts in a few weeks*

SOUTH SAN FRANCISCO, Calif., Oct. 13, 2020 (GLOBE NEWSWIRE) -- Vaxart, Inc., (NASDAQ: VXRT), a clinical-stage biotechnology company developing oral vaccines that are administered by tablet rather than by injection, today announced that the first subject has been dosed in its Phase 1 study of VXA-CoV2-1, an oral tablet COVID-19 vaccine candidate.

"We are advancing VXA-CoV2-1 into clinical development based on the strength of pre-clinical data that showed that the vaccine is capable of inducing both a robust systemic immune response and a strong mucosal immune response, specifically in the lungs," said Sean Tucker, Ph.D., chief scientific officer and founder of Vaxart. "We are eager to explore the clinical profile of VXA-CoV2-1 for effective protection against SARS-CoV-2 infection and transmission in healthy adults."

The Phase 1, open-label, dose-ranging trial (NCT04563702) is designed to examine the safety and immunogenicity of two doses of VXA-CoV2-1 in up to 48 healthy adult volunteers aged 18 to 54 years old. Enrollment is expected to be completed by early November 2020, with participants receiving the low or high dose of the VXA-CoV2-1 oral tablet at days 1 and 29. Safety, reactogenicity and immunogenicity assessments will be performed at set times during the active phase.

"We are very excited about our oral tablet vaccine entering the clinic because we believe that the COVID-19 pandemic needs an oral alternative to injectable vaccines," said Andrei Floroiu, chief executive officer of Vaxart. "Our room temperature stable oral tablet vaccine has the potential to ease many of the problems associated with distribution and administration of cold chain dependent injectable vaccines and may make herd immunity more achievable by making it much easier to vaccinate more people faster. We are looking forward to receiving the first clinical data in the next few weeks."

**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 convenient room temperature-stable tablets that can be stored and shipped without refrigeration and eliminate the risk of needle-stick injury. Vaxart has demonstrated 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. Its 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 immuno-oncology indication. Vaxart has filed broad domestic and international patents 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, commercialization agreements and licenses, 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 (including enrolling a sufficient number of patients and manufacturing sufficient quantities of its product candidates) and commercialize its COVID-19 vaccine candidate; preclinical or clinical results and trial data (including plans with respect to the COVID-19 vaccine product candidates); expectations regarding the timing and nature of future announcements including, those related to clinical trials and results of preclinical studies; Vaxart's expectations with respect to the important advantages it believes its oral vaccine platform can offer over injectable alternatives, particularly for coronaviruses; the potential applicability of results seen in Vaxart's preclinical trials to those that may be seen in human studies or clinical trials; the expected role of mucosal immunity in blocking transmission of COVID-19; and Vaxart's expectations with respect to the effectiveness of its products or product candidates, including Vaxart's potential role in mitigating the impact of COVID-19 globally. 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 or preclinical studies, 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 and preclinical study 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, including the recent outbreak of COVID-19; 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 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.

References and Links to websites have been provided for convenience, and the information contained on any such website is not a part of, or incorporated by reference into, this press release. Vaxart is not responsible for the contents of third-party websites.

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