# Vaxart Announces FDA Clearance of IND Application for Oral COVID-19 Vaccine and Provides Update on COVID-19 Program

September 14, 2020

*Recruitment for Phase 1 clinical study expected to start this month*

*Data from ongoing hamster challenge study expected in October*

SOUTH SAN FRANCISCO, Calif., Sept. 14, 2020 (GLOBE NEWSWIRE) -- Vaxart, Inc., a clinical-stage biotechnology company developing oral vaccines that are administered by tablet rather than by injection, today announced that the U.S. Food and Drug Administration (FDA) has completed its review of the Company's Investigational New Drug (IND) application for its Phase 1 clinical trial evaluating its oral COVID-19 vaccine candidate. The Company also provided an update on its COVID-19 program.

"Our goal is to deliver the best, most elegant solution for conferring mass protection against COVID-19. Our oral tablet vaccine offers a much more attractive mode of administration than injectables and may confer superior protection against COVID-19 due to activation of mucosal immunity. Importantly, our room-temperature stable tablet is significantly easier and cheaper to store and distribute to the farthest corners of the US and the globe, as it does not require the very costly and complex refrigerated cold chain needed for injectable vaccines.," said Andrei Floroiu, chief executive officer of Vaxart. "The IND clearance and the initiation of our Phase 1 clinical trial moves us a step closer to proving the superiority of our convenient oral COVID-19 solution in the clinic. We are thus excited to start enrollment for our Phase 1 this month."

**COVID-19 Program Updates:**

- **IND Clearance for Phase 1 Clinical Trial Evaluating Oral COVID-19 Vaccine**
  The Phase 1, open-label, dose-ranging study will be conducted in healthy adults ages 18 to 55 years old. The study's primary objective is to examine the safety and reactogenicity of two-doses of the vaccine. Secondary objectives include immunogenicity, duration of immune response and occurrence of symptomatic COVID-19.

- **Data from Two Ongoing Animal Challenge Studies expected starting with mid-October**
  Vaxart is conducting a SARS-CoV-2 challenge study in hamsters to provide efficacy data and insights into the optimal dose regimen of our vaccine candidate. Results from this study, which began in early August, are expected mid-October.

In addition, and as previously disclosed, Vaxart is awaiting results from a non-human primate (NHP) challenge study that is testing its vaccine in a harmonized protocol as part of Operation Warp Speed. This preclinical program is being conducted in collaboration with the Biomedical Advanced Research and Development Authority (BARDA) and other entities working with Operation Warp Speed.

Sean Tucker Ph.D., chief scientific officer added, "In addition to our clinical program progress, we have a hamster challenge study underway with our COVID-19 vaccine candidate to assess the potential contribution of inducing mucosal immunity to overall efficacy. We are also awaiting the results from a non-human primate study. Both hamsters and monkeys are susceptible to SARS-CoV-2 infection and these models may be capable of providing a deeper understanding of the immune responses and correlates of protection elicited by our oral vaccine candidate."

**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 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 and 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 our 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; that if we fail to comply with the policies, rules and regulations governing Operation Warp Speed, or do not ultimately receive funding or complete our planned non-human primate challenge study for any other reason, our business and operations would be materially and adversely impacted; 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.