



Vaxart Announces Positive Hamster Challenge Study Data for its Oral COVID-19 Vaccine

October 14, 2020

Vaccinated Hamsters Show Protection from COVID-19 based on Prespecified Indicators of Clinical Outcomes

SOUTH SAN FRANCISCO, Calif., Oct. 14, 2020 (GLOBE NEWSWIRE) -- Vaxart, Inc., (NASDAQ: VXRT), a clinical-stage biotechnology company developing oral vaccines that are administered by tablet rather than by injection, announced today the topline results from its Hamster Challenge Study. The available results show that all hamsters that received two oral doses of COVID-19 vaccine candidate showed no systemic weight loss, a key indicator of protection against COVID-19 in this animal model.

"Our oral vaccine showed that 100% of hamsters receiving two oral doses of vaccine in the study were protected against systemic weight loss, as well as lung weight gain, which is a key indicator of lung damage due to infection," said Sean Tucker, Ph.D., chief scientific officer, and founder of Vaxart. "Given that the hamster is a great model for assessing severe infection, this study helps to validate our vaccine's potential to provide potent protection against COVID-19. These results increase our confidence as we move our vaccine candidate into human clinical trials."

The study evaluated Vaxart's recombinant adenoviral vaccine, with doses given at 0 and 4 weeks. Animals were challenged with SARS-CoV-2 at week 8. Topline data demonstrated that all unvaccinated animals lost at least 8% of their body weight, and all showed evidence of lung disease as measured by relative weight gain in the lungs. By contrast, all animals vaccinated with two doses of the oral vaccine maintained or gained body weight by the end of the experiment, a statistically significant result ($p < 0.001$). Additionally, these animals were protected against the lung weight gain seen in the unvaccinated animals ($p < 0.001$). For unvaccinated animals, lung weight as a percentage of body weight was approximately twice that of the animals that received two oral doses of the vaccine. The experiment was designed to monitor systemic weight for 5 days before animals were assessed for lung disease. N=8 per group. Hamsters receiving one oral dose had partial protection. Full results from the study will be published when data analysis is complete.

"We are happy that just as we dosed the first human subjects in our Phase 1 clinical trial, we showed indicators of protection against COVID-19 in an animal challenge study. These results support the efficacy potential of our oral COVID-19 vaccine candidate suggested by our earlier pre-clinical data," said Andrei Floroiu, chief executive officer of Vaxart. "We believe that our oral vaccine can be an important global solution for the COVID-19 pandemic, given its more convenient route of administration and supply chain distribution as compared to cold chain dependent injectable vaccines."

Hamsters provide a very sensitive model for assessing COVID-19 infection since they can be infected via the intranasal route, and, if infected, they demonstrate pronounced clinical symptoms such as weight loss. They can also show signs such as labored breathing and ruffled fur. They also develop lung issues similar to those seen in humans. Images of hamsters infected with SARS-CoV-2 reveal severe lung injury similar to that seen in infected human lungs, including severe, multi-lobular ground glass opacity, and regions of lung inflammation and consolidation.

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 subjects 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; 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:

Media Relations

Gloria Gasaatura
LifeSci Communications
Tel: (646) 970-4688
ggasaatura@lifescicomms.com

Investor Relations

David R. Holmes
LifeSci Advisors, LLC
Tel: (646) 970-4995
dholmes@lifesciadvisors.com



Source: Vaxart, Inc.