Vaxart Announces Publication of Complete Data from Preclinical COVID-19 Oral Vaccine Hamster Challenge Study in Journal of Infectious Diseases

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Study demonstrates oral vaccination significantly reduces viral titers in the lung and protects against COVID-19 in animal model

SOUTH SAN FRANCISCO, Calif., Nov. 16, 2021 (GLOBE NEWSWIRE) -- Vaxart, Inc. (NASDAQ: VXRT) announced today the Journal of Infectious Diseases has published complete data from Vaxart's preclinical Hamster Challenge Study. The study shows Vaxart's COVID-19 oral vaccine candidate's potential efficacy in preventing SARS-CoV-2 infection.

"The complete data from the Hamster Challenge Study, together with Vaxart's other preclinical and clinical data, reinforce our belief that Vaxart's vaccine could have a major impact on the fight against COVID-19." said Dr. Sean Tucker, Vaxart's Chief Scientific Officer and founder, as well as a co-author of the study.

The Hamster Challenge Study adds to the significant body of preclinical and clinical evidence Vaxart has amassed during the last two years supporting its belief that Vaxart's room temperature oral tablet COVID-19 vaccine candidate, can be effective against SARS-CoV-2:

- A Hamster Transmission Study, conducted by Duke University and published in bioRxiv last month, demonstrated that the COVID-19 vaccine reduced the airborne transmission of SARS-CoV-2 virus in a hamster model.
- These results are consistent with those from Vaxart's Phase II human flu challenge study, which showed that Vaxart's oral tablet flu vaccine was better at reducing shedding than the injectable flu vaccine comparator.
- Vaxart's Phase I results, released earlier this year, showed that the vaccine triggered multiple immune responses against SARS-CoV-2 antigens, including strong T-cell and IgA responses.
- Vaxart anticipates its Phase II clinical study to provide additional evidence regarding the potential impact and efficacy of the oral tablet COVID-19 vaccine. Initial data from that study is expected in Q1 2022.

Vaxart Senior Scientist Dr. Susan Johnson, the Hamster Challenge Study's lead author, said, "An oral room temperature vaccine that protects against COVID-19 and reduces airborne transmission of SARS-CoV-2 would significantly improve our ability to fight the COVID-19 pandemic not only in the developed world, but could give us a major public heath advantage in less developed countries that do not have the infrastructure to easily transport, store, and administer existing vaccines."

Key Findings of the Hamster Challenge Study

Key findings from the study include:

- All hamsters that received two doses of the oral vaccine demonstrated protection from COVID-19.
- Vaccinated hamsters had no significant loss of weight over the five days post challenge, while unvaccinated hamsters lost up to 10% of their body weight.
- Lung weight, which can be an indirect measure of lung inflammation, was significantly lower in double-vaccinated hamsters compared with unvaccinated animals.
- Five days post challenge, double-vaccinated hamsters had a greater than 4 log reduction in viral load and had no detectable infectious virus in their lungs.

About the Study

The study evaluated Vaxart's recombinant adenoviral vaccine, with doses administered at 0 and 4 weeks. Animals were challenged with SARS-CoV-2 at week 8. Hamsters are considered an excellent model for assessing COVID-19 infection because they can be infected via the intranasal route and, if infected, they demonstrate clinical symptoms such as weight loss, labored breathing and ruffled fur. Furthermore, images of hamsters infected with SARS-CoV-2 reveal severe lung injury comparable to what has been observed in infected human lungs, including severe, multi-lobular ground glass opacity and regions of lung inflammation.

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 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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