



Vaxart Announces Additional Preclinical COVID-19 Oral Vaccine Data and Publication

January 26, 2021

New pre-clinical histology data show that Vaxart's oral vaccine protected against lung inflammation in hamster models

An article published in Nature Medicine reports data from a collaboration with Stanford University researchers on in vitro activity of Vaxart's COVID-19 vaccine

Data from Vaxart's Phase I COVID-19 trial expected to be released next week

SOUTH SAN FRANCISCO, Calif., Jan. 26, 2021 (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 additional results from its SARS-CoV-2 Hamster Challenge Study, as well as a peer-reviewed publication in Nature Medicine resulting from a collaboration with prominent Stanford University scientists on COVID-19 vaccine candidates.

"The latest data from the SARS-CoV-2 Hamster Challenge Study reinforces our belief that our oral COVID-19 vaccine candidate shows great promise," said Andrei Floroiu, chief executive officer of Vaxart. "Our oral vaccine could help fight the COVID-19 epidemic globally because it is stable at room-temperature making it easier to transport, store, and administer than injectables. It may also appeal to those uncomfortable with injections."

New histology data from Vaxart's SARS-CoV-2 Hamster Challenge Study showed that hamsters that received two doses of the oral tablet vaccine had a substantial reduction in lung inflammation as compared to unvaccinated hamsters.

Vaxart announced earlier results of its Hamster Challenge Study. These findings included:

- A 4- to 5-fold log reduction in lung viral load in hamsters that received two oral vaccine doses, as compared to non-vaccinated animals.
- Potent induction of antibody response, with serum IgG antibody titers above 10,000 in hamsters that received two oral vaccine doses.
- Oral vaccination protected as well as intranasal vaccination against intranasal challenge with respect to key indicators: protection from weight loss, protection from increase in lung weight, viral load reduction, and induction of serum IgG antibodies, demonstrating that mucosal protection by both routes of administration was comparable.

The company expects to submit the Hamster Challenge Study results to a peer-reviewed journal this quarter.

In early 2020, Vaxart established a collaboration with researchers from Stanford University School of Medicine to assess its COVID-19 vaccine candidates in human lymphoid organoid culture. A portion of the results were published in [Nature Medicine](#) on Monday, January 11, 2021.

"Stanford's advanced in vitro human organoid system generated immune responses to three of our candidate vaccines," said Sean Tucker, chief scientific officer of Vaxart. "The data helped us narrow our selection of a vaccine construct." Senior authors of the paper included Dr. Mark M. Davis, Director of the Stanford Institute for Immunology, Transplantation and Infection; and Dr. Peter S. Kim, Professor of Biochemistry and former President of Merck Research Laboratories.

The vaccine candidate that was selected for clinical trials was designed to express not only the SARS-CoV-2 S protein, but also the nucleocapsid (or N) protein. The N protein was included because it would generate specific anti-viral T-cell responses against a more conserved protein than the S protein, providing for potentially better cross-protection.

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. 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 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 studies or 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. 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.

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