Vaxart Announces the Publication of Studies in the Peer-Reviewed Journal Science Translational Medicine That Suggest Mucosal Immunization Could Decrease SARS-CoV-2 Transmission

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A preclinical study in hamsters showed both a decrease in infectious virus and in transmission

Phase 1 data measuring cross-reactivity also included in the publication

SOUTH SAN FRANCISCO, Calif., May 19, 2022 (GLOBE NEWSWIRE) -- *Science Translational Medicine* has published the results of a Duke University-led preclinical hamster transmission study that found that Vaxart's (NASDAQ: VXRT) S-only oral COVID-19 vaccine candidate inhibited the transmission of SARS-CoV-2. The report also described updated results from Vaxart's Phase I clinical trial that suggest Vaxart's other vaccine candidate, the one targeting both the S and N proteins, could be effective against a range of diverse coronaviruses.

The study compared various measures of immunity and viral shedding in hamster cohorts immunized with Vaxart's S-only vaccine candidate (administered orally and intranasally), an intramuscular protein vaccine control and placebo. The vaccinated hamsters were then infected with high doses of SARS-CoV-2 to create vaccine breakthrough and exposed to naïve animals during the breakthrough period. The study authors concluded that Vaxart's S-only construct "reduced disease and decreased airborne transmission in a hamster model."

The publication also reported results from the Phase I clinical study of Vaxart's S+N vaccine candidate showing that it stimulated SARS-CoV-2-specific IgA antibodies in saliva and nasal samples from human subjects and was cross-reactive to many different coronaviruses that are more divergent than circulating variants of SARS-CoV-2.

"The publication of these results in a highly respected, peer-reviewed journal such as *Science Translational Medicine* underscores the potential value of Vaxart's oral COVID-19 vaccine platform in solving multiple aspects of the COVID-19 pandemic," said Dr. Sean Tucker, Vaxart's Chief Scientific Officer and senior author on the publication.

The S-only data from the hamster transmission preclinical study was initially reported last October in the non-peer reviewed journal bioRxiv. Vaxart first reported the potential cross-reactive properties of its S+N vaccine candidate in May 2021. The new *Science Translational Medicine* publication includes additional detail regarding IgA antibody responses in human subjects.

Vaxart has moved to Phase II clinical trials with the S-only vaccine candidate and expects to report those results later this year. Vaxart has also completed and published preliminary Phase I results from its S+N vaccine candidate. As previously stated, the company plans to compare the S-only and S+N vaccine candidates and to decide which approach offers the best way forward for its COVID-19 vaccine development program, particularly in the face of emerging variant strains.

Hamster Study

The results from the preclinical study conducted by Duke University, Lovelace Biomedical and Vaxart demonstrated that Vaxart's S-only vaccine candidate stimulates mucosal IgA and serum IgG antibodies and can reduce both SARS-CoV-2 infection and airborne transmission. Decreased transmission is important for protecting unvaccinated individuals, including the nearly 34% of Americans who are not fully vaccinated.[1]

"The recent COVID-19 variant outbreaks have shown us that vaccinated individuals who become infected with SARS-CoV-2 can spread the virus to unvaccinated members of their family and community, significantly contributing to public health risk," said Dr. Stephanie Langel, Scientist and Medical Instructor at Duke University and first author on the publication. "A vaccine that protects against infection and reduces transmission would provide significant personal and public health benefits. Moreover, an oral vaccine has the potential to address vaccine hesitancy among individuals who are averse to injection, which could help increase overall vaccination rates.

Phase I Study

In the Phase I study, subjects with at least a two-fold increase in virus-specific IgA also showed an increase in IgA antibodies that cross-reacted with a variety of other coronaviruses. This broad cross-reactivity has the potential to provide enhanced protection against COVID-19 variants compared with injected vaccines that largely stimulate IgG responses in serum. Data from the Phase I study also demonstrated that Vaxart's S+N vaccine candidate stimulates robust T cell responses, particularly CD8+ T cells.

The Phase I clinical study was designed to evaluate the safety and immunogenicity of Vaxart's S+N oral COVID-19 vaccine candidate in 35 subjects. Participants received a single high dose (n=15), a single low dose (n=15) or two low doses (n=5) of the vaccine. IgA levels in saliva and nasal samples were assessed 29 days post-vaccination. More than half (54%) of subjects had at least a two-fold increase in IgA antibodies in either their saliva or nasal samples. Responses were similar for both S and N protein as well as for the receptor-binding domain. Subjects with at least a two-fold increase in virus-specific IgA in saliva or nasal samples also showed an increase in cross-reactive IgA that bound to spike proteins from the four endemic strains of coronavirus as well as Middle East respiratory syndrome coronavirus (MERS-CoV) and SARS-CoV-1. The observed responses did not differ among the various doses.

Reference

[1] U.S. Centers for Disease Control and Prevention. COVID-19 Vaccination in the United States. Available at: https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total

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 preclinical 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," "anticipate," "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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