New Duke University-led Study Shows That Vaxart's Oral COVID-19 Vaccine Candidate Reduces Airborne Transmission of SARS-CoV-2 Infection in Animal Model

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Data published in bioRxiv confirmed previous findings suggesting mucosal vaccines could reduce transmission of airborne viruses such as COVID-19 and flu more than injectable vaccines

Study suggests mucosal vaccines may protect not only vaccinated, but also unvaccinated animals

SOUTH SAN FRANCISCO, Calif., Oct. 7, 2021 /PRNewswire/ -- A Duke University-led study published in bioRxiv showed that Vaxart, Inc.'s (NASDAQ: VXRT) investigational oral tablet vaccine reduced the airborne transmission of SARS-CoV-2 virus in an animal model.

These results are consistent with those from Vaxart's Phase II human flu challenge study, which showed that Vaxart's oral tablet vaccine was better at reducing shedding than the injectable flu vaccine comparator.

A limitation of the currently approved injected COVID-19 vaccines is that airborne transmission occurs in people who have received them. The preclinical study also demonstrated that Vaxart's oral vaccine platform induces robust systemic and mucosal responses.

Researchers vaccinated hamsters orally or intranasally with Vaxart's S-only vaccine candidate and then exposed them to significant levels of the COVID-19 virus to promote vaccine breakthrough. Vaccinated hamsters cleared infectious virus in the nose and lungs quickly. Before clearing the infection, the vaccinated hamsters were exposed to unvaccinated hamsters via aerosol. The mucosally vaccinated hamsters infected fewer hamsters and created less severe clinical symptoms than did unvaccinated hamsters.

"These findings show that our vaccine candidate can reduce transmission of SARS-CoV-2, even when there is infection breakthrough in vaccinated subjects," said Dr. Sean Tucker, the study's lead author and Chief Scientific Officer at Vaxart.

"Existing injected vaccines don't always protect against viral shedding and transmission to other people. A vaccine that reduces shedding and reduces the probability of infection could make a big difference in protecting lives and public health, particularly given the large number of unvaccinated individuals. This study used the same vaccine candidate Vaxart is using in its development of an oral tablet vaccine," added Dr. Tucker.

Earlier this week, Vaxart initiated recruiting for a global Phase II clinical trial of its oral tablet COVID-19 vaccine candidate, which targets the SARS-CoV-2 viral spike (S) protein.

"Vaxart previously published data from a human influenza challenge study that demonstrated our oral flu vaccine candidate inhibited shedding of viral RNA better than injectable vaccines. The data reported provides further evidence that our oral vaccine could offer both an easier, more attractive mode of administration and potentially superior protection against respiratory viruses," said Andrei Floroiu, Vaxart's Chief Executive Officer.

The mucosal surface of the upper respiratory tract is the initial site of SARS-CoV-2 replication and the primary site of infection. Vaccines that induce robust mucosal immune responses may have the greatest impact on reduction of SARS-CoV-2 transmission. Approved COVID-19 vaccines, all of which are administered via intramuscular injection, stimulate systemic immune responses but have minimal effects on mucosal immunity.

About the Study

The study used a hamster infection and aerosol transmission system to study the potential impact of oral vaccination on transmission of SARS-CoV-2 to uninfected individuals.

Animals received oral, intranasal or intramuscular vaccines targeting S protein, and a control group received a mock vaccination (four animals per group). These index hamsters were then infected intranasally with a high titer of SARS-CoV-2 to replicate a post-vaccination breakthrough infection.

One day after viral challenge, index hamsters were placed upstream of unvaccinated hamsters in a chamber that allowed aerosol movement but not direct contact with other animals or bedding or feeding receptacles used by other animals. Index animals were evaluated for antibodies for systemic (IgG) and mucosal (IgA) immunity; all animals were evaluated for viral titers and body weight and lung weight (indicators of SARS-CoV-2 infection).

Key Findings

Key findings from the study include:

- Oral and intranasal vaccination against S protein induced robust systemic and mucosal antibody responses.
    - Post-vaccination, the oral and intranasal groups had higher serum IgG and IgA, as well as higher bronchoalveolar

lavage (BAL) IgA compared to control animals.

- Oral and intranasal vaccination accelerated clearance of SARS-CoV-2 RNA and protected animals against disease.
  - Following intranasal delivery of SARS-CoV-2 and detection of substantial amounts of viral RNA in nasal swabs, vaccinated hamsters had decreased viral RNA and infectious virus in the nose and lungs and experienced less lung pathology (determined by lung weight) and lost less weight (a characteristic of SARS-CoV-2 disease in hamsters) compared to mock-vaccinated hamsters post challenge.
- Oral and intranasal vaccination limited transmission of SARS-CoV-2 to unvaccinated animals.
  - Unvaccinated animals exposed to animals vaccinated orally or intranasally shed lower nasal swab viral RNA than animals receiving intramuscular or mock vaccinations.
- Taken together, these data demonstrate that oral immunization against SARS-CoV-2 S protein resulted in reduced disease and decreased SARS-CoV-2 transmission in a hamster model.

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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