Vaxart's Oral COVID-19 Vaccine Candidate Induces Potent Systemic and Mucosal Immune Responses in Preclinical Studies

September 8, 2020

Triggering mucosal immunity may be crucial for effective protection against SARS-CoV-2 infection and transmission

Vaxart's oral tablet vaccine can overcome major challenges of injectable vaccines

SOUTH SAN FRANCISCO, Calif., Sept. 08, 2020 (GLOBE NEWSWIRE) -- Vaxart, Inc. (NASDAQ: VXRT), a clinical-stage biotechnology company developing oral recombinant vaccines that are administered by tablet rather than by injection, today announced pre-publication of a manuscript titled "Preclinical studies of a recombinant adenoviral mucosal vaccine to prevent SARS-CoV-2 infection." The manuscript describes the pre-clinical development of a SARS-CoV-2 (COVID-19) vaccine based on Vaxart's oral adenovirus platform and is available on an online preprint server at https://biorxiv.org/cgi/content/short/2020.09.04.283853v1.

"Vaxart is developing an oral COVID-19 vaccine that will address many of the key challenges of injectable vaccines," said Andrei Floroiu, chief executive officer of Vaxart. "Cold storage distribution and the need for medical personnel as well as having to travel to vaccination sites and dislike of needles pose significant barriers to the vaccine uptake required for successful mass vaccination campaigns. We believe our room temperature stable, easy to administer oral vaccine provides a unique solution that overcomes these important difficulties. We look forward to advancing our COVID-19 vaccine candidate into the clinic."

Key Findings:

- Immunization with the vaccine candidate induced IgA response in the lungs of animals, which is indicative of a mucosal immune response. Of particular note, neutralizing antibodies in the lungs were observed at a very high percentage of the total antibody response.
- Immunization with our vaccine candidate expressing full length S and N proteins induced IgG responses in a dose-dependent manner.
- Antigen-specific CD4+ and CD8+ T cells were induced at both low and high doses.
- Vaccine administration induced only low levels of IL-4 production, suggesting little risk of vaccine- dependent disease enhancement.

Sean Tucker, Ph.D., chief scientific officer of Vaxart, commented, "The data from these studies suggest that our vaccine candidate is capable of inducing immunogenicity on three levels: first, to induce potent serum neutralizing antibodies to the viral S protein, second to induce a mucosal immune response, and third to induce T cell responses. As we continue to learn more about COVID-19, there is a growing body of evidence that mucosal immunity may become a key factor for the development of an efficacious vaccine. Both mucosal IgA and mucosal T cells have been shown to contribute to sterilizing immunity in other respiratory diseases. Importantly, while systemic immunity is important for controlling the development of illness, it has been suggested that mucosal immunity may be essential for blocking transmission which will be crucial for an effective vaccine campaign. We believe this will be essential in reducing infection rates and eventually eradicating COVID-19 globally."

Study Design

The study was designed to assess the relative immunogenicity of four candidate vaccines expressing multiple combinations of the spike (S) and nucleocapsid (N) proteins of the SARS-CoV-2 virus in a standard mouse model. While all candidates demonstrated the ability to elicit a strong immune response, the most successful candidate contained the full length S and N proteins. While the S protein is responsible for receptor binding, membrane fusion, and tissue tropism and a major target for neutralizing antibodies, targeting full length S protein in combination with N protein may prevent future vaccine-driven escape due to the accumulation of mutations in the S protein. The inclusion of N protein in the vaccine candidate provides additional conserved T epitopes. Further, the induction of polymeric IgA at mucosal surfaces may be superior for generating neutralizing antibodies against divergent viruses.

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 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 and commercialize its

product candidates 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; 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 a mouse model 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, 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, 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.

References and Links to websites have been provided for convenience, and the information contained on any such website is not a part of, or incorporated by reference into, this press release. Vaxart is not responsible for the contents of third-party websites.

Contacts:

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

Investor Relations
Joyce Allaire
LifeSci Advisors, LLC
617 435 6602
jallaire@lifesciadvisors.com

Source: Vaxart, Inc.