Vaxart Announces Positive Preliminary Data from Phase 1 Clinical Trial Evaluating Its Oral COVID-19 Tablet Vaccine Candidate

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- *Study reached primary and secondary endpoints of safety and immunogenicity, respectively*
- *VXA-CoV2-1 induced potent CD8$^+$ T-cell responses*
- *VXA-CoV2-1 potentially protective against new and emerging COVID-19 strains*
- *Data to be presented today at the New York Academy of Sciences Symposium "The Quest for a COVID-19 Vaccine"*

SOUTH SAN FRANCISCO, Calif., Feb. 03, 2021 (GLOBE NEWSWIRE) -- Vaxart, Inc., (NASDAQ: VXRT), a clinical-stage biotechnology company developing oral vaccines administered by tablet, today announced preliminary data from its Phase 1 study of VXA-CoV2-1 showing that its oral COVID-19 tablet vaccine candidate was generally well-tolerated, and immunogenic as measured by multiple markers of immune response to SARS-CoV-2 antigens.

"Our Phase I results highlight the importance of our differentiated vaccine design, as they suggest VXA-CoV2-1 could have broad activity against existing and future coronavirus strains. These results are timely, as we are seeing the emergence of new variants less responsive to first generation vaccines, thus making potential cross-reactivity another important advantage of next-generation vaccines," said Andrei Floroiu, Vaxart's Chief Executive Officer.

Vaxart's scientists recognized early the risk of variants of SARS-CoV-2 emerging and they designed a vaccine with the potential to be protective not only against the prevalent strain, but also against emerging mutations of the Spike (S) protein, by including both the S and N proteins. Virtually all other COVID-19 vaccines include just the S protein.

"These results, together with recent data from our peers, further raise our confidence in the success of VXA-CoV2-1 and the broad potential of our platform," continued Floroiu.

"We previously showed that our oral tablet vaccine technology worked to protect against flu – another airborne virus – as well as the leading injectable, but through a different mechanism, in a Phase II trial sponsored by BARDA. With COVID-19, we have now seen that many vaccine approaches—mRNA, protein, and viral vector, including three adenovirus vaccines – are protective, and that all available positive COVID-19 hamster challenge studies such as ours have translated into protection against COVID-19 in human trials," Floroiu said.

"These clinical data further differentiate our COVID-19 vaccine and enable us to meaningfully advance discussions with healthcare officials in the U.S. and around the world about how Vaxart may be able to help them fight back against COVID-19 with a transformative solution - a room-temperature stable oral vaccine that is not only easier to distribute and administer, but may also be more broadly protective," Floroiu added.

Sean Tucker, Ph.D., Vaxart's Chief Scientific Officer, will present the Phase 1 data as part of a clinical trial update at the New York Academy of Sciences Symposium "The Quest for a COVID-19 Vaccine" today at 1:15 p.m. ET. Register here to attend the symposium.

Preliminary Phase 1 trial results from a pooled analysis of all cohorts include:

VXA-CoV2-1 was generally well-tolerated:

- No severe adverse events were reported
- Adverse events were generally mild and primarily gastrointestinal in nature
- Including this study, a total of 495 subjects have now been dosed with our platform, with no serious adverse events reported

VXA-CoV2-1 triggered multiple immune responses against SARS-CoV-2 antigens, including:

- CD8$^+$ cytotoxic T-cell response to the viral Spike (S) protein, necessary for long-lasting cross-reactive immunity, higher than we have seen in any previous Vaxart clinical trial
- An increase in plasmablast cell number and an upregulation of the mucosal homing receptor, indicating activation of B cells that will home to the mucosa
- An increase in proinflammatory Th1 cytokines, responsible for orchestrating the immune response to viral infection
- IgA responses in serum and/or nasal swab samples in 100% of 2 dose subjects; neutralizing antibodies were not detected in serum and IgG responses were not detected in most subjects

“Viral variants with altered S proteins are becoming established in the population before the majority of people can be vaccinated. To end the pandemic, the world needs a vaccine that can provide long-lasting protection from emerging strains,” Dr. Tucker said.

“T-cells can provide long-lasting cross-reactive protection against current and emerging strains of the virus. Our vaccine induced a high percentage of responding $CD8^+$ T cells against both Spike (S) and Nucleoprotein (N) proteins, which may provide protection against variants with alterations in the faster-changing S protein. We expect that our vaccine will be less impacted by new variants than injectable vaccines,” Dr. Tucker added.

Vaxart expects to broaden its COVID-19 vaccine development plans, with efforts that could include:

- VXA-CoV2-1 in COVID-19 naïve subjects: Phase II studies to evaluate optimal dosing schedule, and to then assess efficacy against COVID-19
- VXA-CoV2-1 in previously vaccinated or exposed subjects: investigating single dose boosting protocol to broaden and strengthen immune responses

Clinical Trial design

The Phase I study (NCT04563702) was designed to evaluate the safety and immunogenicity of VXA-CoV2-1 vaccine with multiple dosing schedules. Subjects were divided into three cohorts. The first cohort (5 subjects) received two low doses of vaccine 29 days apart. The remaining cohorts (15 subjects each) received a single low or high dose of the vaccine. Safety and tolerability were monitored following vaccination as well as signs of immunogenicity, including general and SARs-CoV-2 specific immune responses.

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 has 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 (including enrolling a sufficient number of subjects and manufacturing sufficient quantities of its product candidates) 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, 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 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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