Vaxart Announces Positive Top-line Phase II Clinical Study Data Demonstrating Safety and Immunogenicity of Its Wuhan S-Only COVID-19 Pill Vaccine Candidate

September 1, 2022

—Study met primary safety and secondary immunogenicity endpoints —

—Boosted serum neutralizing antibodies in both naive and previously mRNA vaccinated subjects —

—Elicited cross-reactive mucosal responses in approximately 50% of subjects —

—Company to host conference call at 8:30 a.m. ET today —

SOUTH SAN FRANCISCO, Calif., Sept. 01, 2022 (GLOBE NEWSWIRE) -- Vaxart, Inc. (NASDAQ: VXRT) today reported positive top-line data from the first part of a planned two-part Phase II study of its Wuhan S-only oral pill COVID-19 vaccine candidate, VXA-CoV2-1.1-S. The data demonstrate that the trial met its primary safety and secondary immunogenicity endpoints and will inform ongoing development of new Omicron-based vaccine constructs.

Serum neutralizing antibodies rose after oral vaccination, and the increases were particularly notable in subjects who had previously received an mRNA vaccine. Additionally, all subjects who had a mucosal immune response to the Wuhan-based vaccine had mucosal immune responses that cross-reacted with the Omicron variants, including BA 4/5, as well as other coronaviruses. Vaxart is the first company to advance an oral pill COVID-19 vaccine to Phase II clinical development.

“These Phase II data represent a very important milestone in the development of the world’s first COVID-19 pill vaccine,” said Dr. James F. Cummings, Vaxart’s Chief Medical Officer. “These data also demonstrate that a pill vaccine can induce strong serum antibody responses as well as mucosal and T cell responses. Unfortunately, for the past two years the emergence of new variants has outpaced the ability to update the currently approved injectable vaccines. We believe that activating multiple mechanisms of the immune system that can address emerging variants may help the global community get ahead of the immunologic curve of protection. It could transform how we fight this and future pandemics.”

"The results reported today clearly indicate that the S-only construct improved antibody responses compared with the data we previously generated for the S+N construct (VXA-CoV2-1), and also boosted immune responses in subjects who previously received an mRNA vaccine. These are the critical data we sought when this trial was initiated in October 2021,” said Dr. Sean Tucker, Vaxart's Founder and Chief Scientific Officer. “Additionally, the observed increase in mucosal IgA is very encouraging, and we believe that the positive findings for multiple immunologic responses may ultimately translate to enhanced protection against infection with, and/or transmission of, SARS-CoV-2.”

Study Key Findings

- The VXA-CoV2-1.1-S vaccine construct was safe and well-tolerated. No vaccine-related solicited grade 3 adverse events (AEs) and no vaccine-related serious adverse events (SAEs) were reported.
- Vaccination with VXA-CoV2-1.1-S increased levels of SARS-CoV-2-specific serum IgG and IgA antibodies at Days 29 and 57.
- The geometric mean titer (GMT) increase of SARS-CoV-2-specific serum neutralizing antibodies from Day 1 to Day 57 ranged by cohort between 1.2- and 2-fold, with higher increases for higher doses.
- Among 18-55 year-old subjects previously vaccinated with mRNA vaccines, the geometric mean titer (GMT) of SARS-CoV-2-specific serum neutralizing antibodies increased 1.6-fold, from 481 AU/ml at Day 1 to 778 AU/ml at Day 57. The subjects who had lower starting titers showed greater increases after oral boosting.
- Approximately 50% of all subjects, as well as 50% of subjects that previously received an mRNA vaccine, had at least a 1.5-fold increase in mucosal IgA antibodies.
- All subjects who had a mucosal response to Wuhan S from VXA-CoV2-1.1-S (a Wuhan-based vaccine) also had mucosal immune responses that cross-reacted with the Omicron variants, including BA 4/5, as well as other coronaviruses. This includes subjects that had previously received an mRNA-based vaccine.
- SARS-CoV-2-specific T cell responses were observed in the majority of subjects after the second dose of VXA-CoV2-1.1-S.

“These very exciting data support the great potential of our platform,” said Andrei Floroiu, Vaxart’s Chief Executive Officer. “We are now a step closer to the day when we could get vaccinated against COVID-19 with an oral pill vaccine that offers broad protection against current and future variants by harnessing multiple immune system mechanisms. I believe this is what transformative innovation looks like. We will continue working toward the promise of vaccinating more people around the world, faster, with more protective vaccines, with just a pill and a glass of water."

Clinical Trial Next Steps

As previously announced, Vaxart is evaluating new Omicron-based constructs as Omicron-only monovalent vaccine candidates and as bivalent candidates in combination with the Company’s Wuhan constructs. Vaxart will also compare the clinical results of its S-only and S+N constructs to determine the best path forward in developing a vaccine that can hinder viral infection and transmission for current and emerging variants. These constructs are expected to be evaluated in preclinical models this year and to advance to clinical trials in the first half of 2023. The Company expects to move forward with the best possible vaccine constructs for its planned COVID-19 Omicron challenge in the second half of 2023 with hVIVO, as well as larger trials in the U.S. and internationally.

Clinical Study Design
Part 1 of the open-label, Phase II study enrolled 66 healthy adult volunteers, including subjects who had or had not received prior mRNA COVID-19 vaccination, ages 18-55 years and 56-75 years. Subjects were randomized into six cohorts stratified by age, vaccination history and dose. Subjects received either a high or a low dose of VXA-CoV2-1.1-S on Day 1 and Day 29, and immune responses were assessed prior to vaccine administration on Day 1, Day 29 and on Day 57.

Conference Call Information
The Vaxart senior management team will host a conference call today, beginning at 8:30 a.m. ET.

The conference call can be accessed using the following information:
Webcast: Click here
Date: Thursday, September 1, 2022 – 8:30 a.m. ET
Domestic: 877-407-0832
International: 201-689-8433
Conference ID: 13732510

Investors may submit written questions in advance of the conference call to ir@vaxart.com. A replay of the webcast will be available on the Company's website at www.vaxart.com following the conclusion of the event.

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.

Please also refer to the 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.

Contacts

Vaxart Media Relations:
Mark Herr
Vaxart, Inc.
mherr@vaxart.com
(203) 517-8957

Investor Relations:
Andrew Blazier
Finn Partners
IR@Vaxart.com
(646) 871-8486

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