Vaxart Publishes Clinical Data Suggesting its Oral COVID-19 Pill Vaccine Candidate Induces Long-Lasting Mucosal Immune Responses that are Highly Cross-Reactive

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Vaccine-induced mucosal IgA antibody responses persisted for up to 1 year and had a higher neutralizing activity compared with convalescent samples

Vaxart will leverage data gained from trial as it develops additional vaccine candidates

SOUTH SAN FRANCISCO, Calif., July 20, 2022 (GLOBE NEWSWIRE) -- Vaxart (NASDAQ: VXRT) today reported additional phase 1 clinical data published on medRxiv.org, indicating that its Spike/Nucleocapsid (S+N) oral tablet COVID-19 vaccine induced long-lasting mucosal IgA antibodies against SARS-CoV-2 the virus that causes COVID-19, and all tested coronaviruses. The neutralizing activity of these IgA antibodies in responders was higher than that measured in convalescent samples.

Vaxart had previously disclosed results from this study showing its vaccine candidate was well-tolerated and immunogenic. This additional data supports its potential to improve immune responses at mucosal surfaces and improve public health responses to the COVID-19 pandemic. Vaxart intends to publish the complete data from the study in a peer-reviewed journal.

“One of the most important challenges with current COVID-19 vaccine strategies is that injected vaccines stimulate robust serum antibody responses against the Wuhan strain of SARS-CoV-2, but these responses quickly decline, and they are not as effective against the currently circulating viral variants. This has resulted in breakthrough infections in many people who have received injected vaccines,” said the article’s lead author, Dr. Sean Tucker, Vaxart’s SVP and Chief Scientific Officer.

“Our clinical study results showed that our vaccine candidate stimulates broadly cross-reactive mucosal IgA responses that persist for at least 6 months in most responders, and up to a year in a subset of them following just a single dose. Two key observations in this study were that vaccination induced a similar mucosal IgA response as seen in convalescent subjects, and that the vaccinated subjects appeared to have better neutralizing antibody potential in the mucosa than infected subjects. We are excited to explore these aspects in depth in future studies,” he said.

“These findings support our view that the cross-reactivity of our vaccine candidates’ mucosal immune responses could have a significant impact in the fight against evolving SARS-CoV-2 variants,” Dr. James Cummings, Vaxart’s SVP and Chief Medical Officer said. “We will continue to evaluate our vaccine candidates in order to choose the best way forward for our COVID-19 vaccine development program in the face of emerging variant strains.”

About the Data

The data reported today are from a phase 1 dose-ranging, open-label clinical trial (NCT04563702) in which the S+N vaccine candidate was evaluated in 35 healthy adult volunteers who tested negative for SARS-CoV-2 by PCR and rapid antigen tests. Subjects received a low dose with a boost at Day 29 or a single low or high dose of the S+N oral tablet vaccine candidate.

Nasal samples were collected and analyzed for SARS-CoV-2-specific IgA. In the study, 46% of subjects had at least a 1.5-fold increase in SARS-CoV-2-specific secretory IgA compared with pre-vaccination levels. In a separate study, nasal and saliva samples were collected from individuals with prior SARS-CoV-2 infection. Analysis of nasal and saliva samples for neutralizing activity (sVNT) against SARS-CoV-2 showed that 50% of the vaccinated subjects had more neutralizing activity than those with prior infections, and this enhanced neutralizing capacity persisted 6 months post vaccination.

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 pills that can be stored and shipped without refrigeration and eliminate the risk of needle-stick injury. Vaxart believes that its proprietary pill 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 pill 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

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