Vaxart to Test Cross-Reactivity of its COVID-19 Oral Tablet Vaccine Against Omicron

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Cross-reactivity will be assessed using samples from Phase II clinical participants and in a parallel animal challenge study

Oral tablet's immunogenicity profile suggests it may provide cross-protection against SARS-CoV-2 variants, including Omicron

SOUTH SAN FRANCISCO, Calif., Dec. 16, 2021 (GLOBE NEWSWIRE) -- Vaxart, Inc. (NASDAQ: VXRT) said today it plans to test the cross-reactivity of its oral tablet COVID-19 vaccine candidate against the Omicron SARS-CoV-2 variant in two different studies expected to begin next month.

In the first study, Vaxart will test the activity of its Phase II COVID-19 oral vaccine candidate against Omicron by analyzing mucosal and serum samples from subjects to whom the vaccine was administered in Vaxart's current COVID-19 vaccine Phase II trials, Dr. Sean Tucker, Vaxart's Chief Scientific Officer and founder, said.

In the second study, Vaxart will conduct an animal Omicron challenge study to assess how its current Phase II COVID-19 vaccine candidate performs in comparison to an Omicron-specific vaccine candidate that Vaxart is developing, Dr. Tucker said.

Vaxart deliberately engineered its COVID-19 vaccine candidate to be cross-reactive against emerging variants based on Vaxart scientists' early recognition of the risk of emerging variants of SARS-CoV-2. In May 2021, the Company announced Phase I clinical test results demonstrating that its vaccine candidate, VXA-CoV2-1, produced broad cross-reactive T cell and IgA responses against other, non-COVID coronaviruses.

"We expect that our COVID-19 vaccine candidates would be less affected by mutations in the receptor-binding domain of the S protein than vaccines that rely on a serum IgG response," Dr. Tucker said.

Dr. Tucker also said that results from Vaxart's Phase I clinical testing and earlier preclinical testing support Vaxart's belief that its vaccine candidates should be reactive against Omicron.

"Our Phase I vaccine candidate was highly cross-reactive in human subjects against coronaviruses much more divergent than SARS-CoV-2 variants, and our preclinical research showed that our current Phase II vaccine candidate induced substantial cross-reactivity against multiple SARS-CoV-2 variants," he said. "As a result, we expect that this vaccine candidate should also be able to respond to the Omicron variant."

"As new variants have emerged it has become clear that we cannot win the fight against this pandemic with only the current generation injectable vaccines," said Vaxart Chief Executive Officer Andrei Floroiu. "To win this fight we need better, next-generation vaccines that provide broader, cross-variant protection, which our vaccine has the potential to do by leveraging the power of mucosal immunity."

Injectable vaccines primarily stimulate serum IgG responses, but Vaxart's COVID-19 vaccine candidate has been shown to trigger mucosal IgA in the nose, mouth and lungs, where SARS-CoV-2 infection occurs.

"We believe these differences in immunogenicity profile may provide cross-protection against SARS-CoV-2 variants as they emerge," Dr. Tucker said.

Mucosal IgA antibodies contain four or more antigen-binding sites, while IgG antibodies contain only two.

"This multimeric binding allows IgA to functionally attack viruses in different ways such as by immune exclusion and by steric hindrance, rather than relying on direct neutralization. These mechanisms should make it more difficult for viral variants to escape an IgA-mediated immune response compared to an IgG response," he added.

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

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