Vaxart Announces Positive Pre-Clinical Data for its Oral COVID-19 Vaccine Program

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Lead Vaccine Candidates Generate Anti-SARS CoV-2 Antibodies in All Tested Animals after First Dose

SOUTH SAN FRANCISCO, Calif., April 21, 2020 (GLOBE NEWSWIRE) -- Vaxart, Inc., a clinical-stage biotechnology company developing oral recombinant vaccines that are administered by tablet rather than by injection, today announced that it has obtained positive pre-clinical results for its COVID-19 vaccine candidates, with several of the vaccine candidates generating immune responses in all tested animals after a single dose.

“These early pre-clinical results are in line with those for our oral influenza vaccine which was protective in a clinical Phase 2 efficacy study,” said Sean Tucker, Ph.D., chief scientific officer of Vaxart. “Additional data will inform us on which candidate we will move forward into clinical trials. We are particularly interested in vaccine candidates that can generate mucosal immune responses in addition to serum antibody responses. That is a key feature of our oral vaccines and potentially significant for protection against SARS CoV-2, the virus that causes COVID-19.”

In January 2020, Vaxart initiated a program to develop a COVID-19 vaccine based on its VAAST^{TM} oral vaccines platform. The Company is currently evaluating multiple vaccine candidates in its preclinical models. In this first round of preclinical testing, all animals that received one of the Vaxart vaccines had IgG anti-SARS CoV-2 antibodies in serum two weeks after the first vaccination. Antibody responses in all vaccinated groups were statistically significant compared to the untreated controls. Vaxart plans to select one or more vaccine candidates for cGMP manufacturing and clinical testing based on the magnitude and the breadth of the immune response.

On March 18, 2020, Vaxart entered into an agreement with Emergent BioSolutions Inc. (“Emergent”) for development services to prepare for cGMP production of an oral COVID-19 vaccine. The first stage of the collaboration is underway and, provided Vaxart elects to proceed with cGMP manufacturing, Emergent is expected to produce bulk cGMP vaccine in time to allow the initiation of a Phase 1 clinical study during the second half of 2020.

“These results are extremely encouraging, and we should be in a position to select a lead development candidate for cGMP manufacturing and clinical testing in the coming weeks,” said Wouter Latour, MD, chief executive officer of Vaxart Inc. “Our oral vaccines have been shown to protect against respiratory infection based on mucosal immunity, the first line of defense for such infections, as recently published in the *Lancet Infectious Diseases*. This could be important for an effective vaccine that protects the global population from COVID-19. In addition, the Vaxart vaccine would be administered orally using a room temperature-stable tablet, an enormous logistical advantage over injectables in large vaccination campaigns.”

About Vaxart

Vaxart is a clinical-stage biotechnology company primarily focused on developing oral recombinant protein vaccines based on its proprietary oral vaccine platform. Vaxart’s vaccines are designed to generate broad and durable immune responses that protect against a wide range of infectious diseases and may also be useful for the treatment of chronic viral infections and cancer. Vaxart’s vaccines are administered using a convenient room temperature-stable tablet, rather than by injection. Vaxart believes that tablet vaccines are easier to distribute and administer than injectable vaccines and have the potential to significantly increase vaccination rates. Vaxart’s development programs include oral tablet vaccines that are designed to protect against coronavirus, norovirus, seasonal influenza and respiratory syncytial virus (“RSV”), as well as a therapeutic vaccine for human papillomavirus (“HPV”). For more information, please visit www.vaxart.com.

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, 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 clinical results and trial data (including plans with respect to the COVID-19 vaccine product candidates); expectations relating to Vaxart’s relationship with Emergent, including Emergent’s ability to produce bulk cGMP vaccine and the timing thereof; and Vaxart’s expectations with respect to the important advantages it believes its oral vaccine platform can offer over injectable alternatives, particularly for mucosal pathogens such as norovirus, flu and RSV, as well as coronaviruses such as SARS, MERS and SARS CoV-2. 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 may experience manufacturing issues and delays due to events within, or outside of, Vaxart’s control, including the recent outbreak of COVID-19; 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; 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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