FDA Clears Vaxart's IND Application for S-Only Oral Tablet COVID-19 Vaccine Candidate

August 2, 2021

Vaccine candidate expressing S-only protein produced higher serum antibodies than construct expressing both S and N in NHP study

Phase II clinical trial with S-only candidate to begin in 2H21

Development of this and other S-only constructs will proceed in parallel with that of S+N construct, as previously announced

SOUTH SAN FRANCISCO, Calif., Aug. 2, 2021 /PRNewswire/ -- Vaxart, Inc., (NASDAQ: VXRT), a clinical-stage biotechnology company developing oral vaccines administered by tablet, announced today that the U.S. Food and Drug Administration has cleared Vaxart's Investigational New Drug application for an S-only oral tablet SARS-CoV-2 vaccine candidate.

"This is great news because it allows us to move forward with our first S-only vaccine construct," said Andrei Floroiu, Vaxart's Chief Executive Officer. "As we said at the end of the first quarter, we will explore multiple S-only constructs in clinical trials alongside the S+N construct that has already completed its Phase I trial.

"Together, the S-only and S+N constructs are part of our unique oral tablet COVID-19 vaccine candidate portfolio, which we believe could make a significant contribution to the fight against COVID-19 globally."

"Preliminary data from our current Non-Human Primate study indicates that the S-only vaccine produced much higher serum antibodies than the one expressing both S and N proteins," said Dr. Sean Tucker, Vaxart's Chief Scientific Officer. "Our Phase I results from the S+N vaccine candidate showed remarkable T-cell responses and a mucosal antibody response, but not as strong serum antibody responses.

"This new clinical trial will allow us to compare the S-only and S+N vaccine candidates and put us in a position to decide which approach offers the best way forward for our COVID-19 vaccine development program, particularly in the face of emerging variant strains."

Vaxart announced in February that it had completed a Phase 1 clinical trial for its oral S+N COVID-19 vaccine. The results from that study found that the investigational oral vaccine triggered multiple immune responses against SARS-CoV-2 antigens, while reaching primary and secondary endpoints of safety and immunogenicity, respectively.

The Phase II clinical trial with the S-only construct is expected to start in 2H21.

About Vaxart

Vaxart (www.vaxart.com) 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. 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 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; Vaxart's expectations with respect to the important advantages it believes its oral vaccine platform can offer over injectable alternatives for SARS-CoV-2; expectations regarding Vaxart's ability to develop effective vaccines against new and emerging variant strains; and Vaxart's expectations with respect to the effectiveness of its product candidates, including Vaxart's potential role in mitigating the impact of Covid-19. 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 , 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 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 resolve pending legal matters; 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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