



Vaxart Announces IND Filed for COVID-19 Vaccine

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SOUTH SAN FRANCISCO, Calif., Aug. 10, 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 its COVID-19 Investigational New Drug (IND) application has been filed with the US Food and Drug Administration (FDA).

"We are very excited to reach this important milestone in advancing our oral COVID-19 vaccine candidate towards the clinic," said Andrei Floroiu, chief executive officer of Vaxart. "We expect our upcoming Phase I study to generate data that will further differentiate our oral vaccine from injectable vaccines by substantiating the importance of activating both systemic and mucosal immunity in protecting against COVID-19. We believe that this mechanistic benefit combined with the significant advantages of oral administration to the patient while eliminating the need for cold chain distribution, could make our COVID-19 vaccine an ideal candidate for successful mass vaccination campaigns globally."

"Filing the IND is the first major step of many we are taking to advance our oral vaccine in the prevention of COVID-19," said Sean Tucker, Ph.D., chief scientific officer of Vaxart. "We are excited to be moving this project toward clinical trials, and potentially demonstrating similarly potent mucosal and systemic immune responses like we have seen with our other vaccine candidates using the same oral tablet vaccine platform."

About Vaxart

Vaxart is a clinical-stage biotechnology company focused on developing oral tablet vaccines designed to generate mucosal and systemic immune responses that protect against a wide range of infectious diseases and have the potential to provide sterilizing immunity for diseases such as COVID-19. Vaxart believes that a room temperature stable tablet is easier to distribute, store and administer than injectable vaccines and may provide a significantly faster response to a pandemic than injectable vaccines, enabling a greater portion of the population to be protected. 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 regarding the timing and nature of future announcements including, those related to clinical trials and Vaxart's expectations with respect to the important advantages it believes its oral vaccine platform can offer over injectable alternatives, particularly for coronaviruses. 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 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 Operation Warp Speed may not result in a positive financial impact on Vaxart's financial results; 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 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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