Vaxart Reports Boosting Immune Responses in Subjects Previously Vaccinated by a Vaxart Vaccine

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First booster clinical study by Vaxart shows boosted immune responses similar to original responses with Vaxart vaccine

Findings have potential implications for Vaxart's COVID-19 oral vaccine program

SOUTH SAN FRANCISCO, Calif., July 29, 2021 /PRNewswire/ -- Vaxart, Inc. (Nasdaq: VXRT) today announced that it has shown for the first time in clinical trials that its oral tablet vaccine platform successfully boosted immune responses in subjects previously vaccinated with a Vaxart oral vaccine more than a year earlier.

Vaxart is a clinical-stage biotechnology company developing oral vaccines that are administered by tablet rather than by injection. Vaxart's programs are based on its proprietary oral vaccine platform called VAAST.

"These results are very important because they support our belief that our oral tablet vaccines have the potential to be used repeatedly for indications that may require an annual boost, such as flu, COVID-19, or norovirus," said Andrei Floroiu, Vaxart's Chief Executive Officer. "We are excited by these findings and by the implications for all of our vaccines."

"Using our oral norovirus vaccine candidate, we successfully boosted the immune responses of those previously vaccinated with our platform," said Dr. Sean Tucker, Vaxart's founder and Chief Scientific Officer. "We believe these results could have implications for the other vaccines we are developing, including our oral COVID-19 vaccine tablet, because they are all based on the same platform and use the same vector.

"Moreover," Dr. Tucker said, "this clinical evidence has the potential to differentiate our vaccines from injectable vector-based vaccines. Typically, when you inject viral vector-based vaccines, they generate immune responses against the against the viral vector as well as the intended antigens.

"Anti-vector antibodies from the injected vaccine immune response may prevent the viral vector from serving as a boosting agent. Our norovirus trial results suggest that Vaxart's vaccines may not be hampered by certain antibody response challenges that can occur with injectable viral vector-based vaccines."

The data came from Vaxart's 12-subject Phase 1b blinded study evaluating the ability of its norovirus vaccine to boost immunogenicity. Study participants were initially vaccinated with Vaxart's oral norovirus vaccine in late 2019 and were vaccinated again between February and April 2021.

All seven participants who had been previously immunized with the oral norovirus vaccine elicited a similar broad range of immune responses to norovirus as the five subjects that had not received a prior oral vaccine dose.

"We will continue to evaluate the capability of our norovirus and COVID-19 vaccine candidates to be used repeatedly as boosters to extend protection in those previously vaccinated with Vaxart candidate vaccines."

Key metrics identified in the boosting study were as follows:

- Serum antibody blocking titer 50, a surrogate neutralizing antibody measurement, increased in both previously vaccinated and unvaccinated subjects by similar amounts.
- Antibody secreting B cell (ASC) responses to norovirus VP1 measured seven days post-boost were no different than those in subjects receiving the vaccine for the first time.
- Serum IgG and IgA antibody responses were significantly elevated 29 days post-boost immunization, with no difference in titer between subjects that had received a prior oral norovirus vaccine and those who had not previously been vaccinated.

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 immuno-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 the receipt by 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 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; 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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