Vaxart Reports Topline 12-Month Safety Data From the 400-Participant Sentinel Safety Cohort of the Phase 2b Clinical Trial of Its Oral Pill COVID-19 Vaccine

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No vaccine-related serious adverse events (SAEs) or sustained Grade 3 or higher adverse events related to the vaccine reported

SOUTH SAN FRANCISCO, Calif., July 06, 2026 (GLOBE NEWSWIRE) -- Vaxart, Inc. (OTCQX: VXRT) today announced topline data from the approximately 400-participant sentinel safety cohort of its Phase 2b clinical trial evaluating the Company's oral pill COVID-19 vaccine candidate against an approved mRNA vaccine comparator. Participants in this safety cohort received Vaxart's oral pill vaccine (201 participants dosed) or an approved mRNA vaccine (199 participants dosed) targeting the XBB strain of SARS-CoV-2, the virus that causes COVID-19. No vaccine-related serious adverse events (SAEs) or sustained Grade 3 or higher adverse events (AEs) were reported in either arm of the study. Data from the complete study, comprising the 400 dosed participants in the sentinel safety cohort and approximately 5,000 dosed participants in the main cohort, are currently anticipated in 2027. Participants in the main cohort received vaccines targeting the KP.2 viral strain prevalent at the time cohort dosing was initiated.

"These topline safety data are encouraging and are consistent with the safety profile observed to date in other studies of our oral pill vaccine constructs," said James Cummings, MD, Chief Medical Officer at Vaxart. "We know that safety and tolerability are critical factors in successful vaccine development, and we are pleased with how our investigational vaccine performed in this cohort."

What did the topline 12-month results from the sentinel safety cohort show?
Key topline 12-month results from the 400-participant sentinel safety cohort (201 oral vaccinees and 199 mRNA vaccinees) include:

- No vaccine-related serious adverse events (SAEs) or sustained Grade 3 or higher AEs were reported in either the oral pill vaccine or mRNA arms of the trial.
- The most common AEs in participants receiving the oral pill vaccine were malaise/fatigue (20.9%), headache (18.9%) and anorexia (10.0%). Fewer than 10% of participants experienced any other AE.
- The most common AEs in participants receiving the mRNA vaccine were injection site pain (60.3%), injection site tenderness (40.2%), malaise/fatigue (35.2%), myalgia/muscle pain (33.2%), and headache (28.6%). Arthralgia, chills, anorexia, nausea, diarrhea, and induration/swelling at the injection site were experienced by between 10-15% of participants. Fewer than 10% of participants experienced any other AE.
- With respect to the efficacy measure of symptomatic COVID, 33 participants in Vaxart's oral pill vaccine arm and 30 participants in the injectable mRNA vaccine arm had symptomatic disease. Asymptomatic COVID cases were reported in 12 participants in the Vaxart oral pill arm and 12 in the mRNA vaccine arm.
    - It should be noted that this 400-participant sentinel safety cohort was not powered to determine comparative efficacy between the two arms.
    - Topline data from the complete study, comprising the 400 participants in the sentinel safety cohort and approximately 5,000 participants in the main cohort, are anticipated in 2027. The main cohort is designed and powered to support the planned statistical comparison of safety and relative efficacy outcomes between the two arms.

"These first cohort topline data are an important advancement for our COVID-19 program and for our oral pill vaccine platform overall," said Steven Lo, Chief Executive Officer at Vaxart. "This study adds to the body of evidence supporting the safety profile of our vaccine constructs as we look to demonstrate the potential of our proprietary oral delivery technology. We believe more insights into our oral COVID program are important and will be further analyzing this cohort as we eagerly await the readout from the main cohort of this trial, which is expected to provide more robust information on safety and efficacy."

Funding for this award was received under Project NextGen, an initiative by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS), and the National Institute of Allergy and Infectious Diseases (NIAID) to accelerate and streamline the development of the next generation of innovative COVID-19 vaccines, therapeutics, and enablers. Vaxart's project award through the Rapid Response Partnership Vehicle (RRPV) Consortium is valued at up to $344.8 million. This project has been funded in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under Other Transaction Number: 75A50123D00005.

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 pills that can be stored and shipped without refrigeration and eliminate the risk of needle-stick injury. Vaxart believes that its proprietary pill 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 pill vaccines designed to protect against coronavirus, norovirus and influenza, 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 within the meaning of the Private Securities Litigation Reform Act of 1995 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 preclinical and clinical trials and the timing of such results, and beliefs and expectations of management,

including statements regarding Vaxart's Phase 2b clinical trial of its oral pill COVID-19 vaccine candidate, the 400-participant sentinel safety cohort, the approximately 5,000-participant main cohort, further analyses of trial data, anticipated timing of complete study data, and funding under Project NextGen and the RRPV Consortium, are forward-looking statements. These forward-looking statements may be accompanied by such words as "should," "believe," "could," "potential," "will," "expected," "anticipate," "plan," "intend," "may," "estimate," "approximately," "designed," "powered," "subject to," 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 its product candidates and oral pill vaccine platform; Vaxart's expectations regarding clinical results and trial data, and the timing of receiving and reporting such clinical results and trial data, including further analyses of the sentinel safety cohort and complete study data anticipated in 2027; Vaxart's expectations regarding the design, powering, conduct, completion and analysis of its Phase 2b COVID-19 trial and main cohort; and Vaxart's expectations with respect to the safety, tolerability, efficacy, relative efficacy, immunogenicity and potential regulatory significance of its product candidates, as well as the availability, permitted uses and sufficiency of funding under the Project NextGen/BARDA/RRPV award. These forward-looking statements are based on Vaxart's current expectations and assumptions as of the date of this press release. 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, retain participants, collect follow-up data, generate sufficient evaluable cases and events, and complete, unblind, analyze and report data from the Phase 2b trial, including the main cohort, in the expected timeframes, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data, including analyses that may differ from or not confirm the topline data from the sentinel safety cohort or may not support conclusions regarding safety, tolerability, immunogenicity, efficacy or relative efficacy; the risk that clinical trial data, including data from the sentinel safety cohort and main cohort, are subject to differing interpretations and assessments by Vaxart, investigators, independent safety reviewers, funding agencies, regulatory authorities and other third parties; whether regulatory authorities will be satisfied with the design of and results from the clinical studies, including the study's comparator, endpoints, statistical assumptions, strain selection, safety database and efficacy analyses; 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, authorized or licensed by the FDA or non-U.S. regulatory authorities; and that results from the Phase 2b trial may not be sufficient to support regulatory submissions, regulatory interactions, approval, authorization, licensure or commercialization of Vaxart's oral pill COVID-19 vaccine candidate; risks related to government funding for the Phase 2b trial, including whether amounts under the Project NextGen/BARDA/RRPV award will be available, released, reimbursed or sufficient in the amounts or at the times expected, and whether the award may be modified, reduced, delayed, suspended or terminated or subject to conditions, audits or other compliance requirements; that Vaxart or its partners may experience manufacturing, supply, storage, shipment, stability, quality control or quality assurance 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; Vaxart's ability to obtain sufficient capital to fund its operations on terms acceptable to Vaxart, if at all, including expenses not covered by government funding; the impact of changes in government public-health, procurement and funding priorities; changes in COVID-19 incidence, circulating variants, vaccination recommendations and market demand; and competition from approved and investigational COVID-19 vaccines and other vaccine technologies; and other risks described in the "Risk Factors" sections of Vaxart's most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other filings filed with or furnished to the SEC. Vaxart does not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Contact
Vaxart Media and Investor Relations:
FINN Partners
IR@vaxart.com