



## Vaxart Receives BARDA-Funded Project NextGen Award Valued Up to \$453 Million to Conduct a Phase 2b Study Evaluating Its COVID-19 Oral Pill Vaccine Candidate

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— 10,000-subject Phase 2b study will evaluate Vaxart's next generation oral pill COVID-19 vaccine against an approved mRNA vaccine comparator

— Vaxart anticipates initiating enrollment as early as summer 2024 —

SOUTH SAN FRANCISCO, Calif., June 13, 2024 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) announced today that it received a project award valued at up to \$453 million through the Rapid Response Partnership Vehicle (RRPV). The RRPV is a Consortium funded 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).

The funds will be used to conduct a Phase 2b comparative study evaluating Vaxart's oral pill COVID-19 vaccine candidate against a U.S. Food and Drug Administration (FDA)-approved mRNA vaccine comparator. In preparation for the trial, Vaxart created and manufactured under Good Manufacturing Practice (GMP) standards a next-generation oral COVID-19 vaccine tablet candidate that — based on preclinical data — is more potent than Vaxart's prior COVID-19 vaccine constructs.

Funding under the award will be provided in two parts with approximately \$65.7 million available immediately to continue study start-up activities, and the remainder of approximately \$387.2 million provided when Vaxart and BARDA have determined that the study may further proceed and paid over the course of the study. Currently, Vaxart anticipates initiating enrollment as early as summer 2024. An interim analysis for vaccine efficacy compared to an approved mRNA comparator may occur as early as the first quarter of 2025.

"We are grateful to BARDA for this funding, which will enable Vaxart to conduct a Phase 2b trial for our COVID-19 oral pill vaccine candidate. This trial will evaluate whether our oral pill vaccine candidate compares favorably against an approved mRNA injectable vaccine," said Dr. James F. Cummings, Vaxart's Chief Medical Officer. "We are excited to explore the results of this head-to-head comparison. Previous research showed that our earlier COVID-19 vaccine constructs triggered long-lasting immune responses and induced a cross-reactive immunogenic response against all tested SARS-CoV-2 variants."

"Vaccine delivery has relied primarily on injection for more than 150 years. This funding from BARDA will assist us in determining whether we can bring a transformational, next-generation approach to global vaccination," said Steven Lo, Vaxart's Chief Executive Officer. "We believe our oral pill vaccine platform can better meet societal needs not just for COVID-19, which is now in the endemic phase, but for other infectious diseases that present significant endemic and pandemic threats."

Vaxart was the first U.S. company to complete a Phase 2 clinical trial of an oral vaccine for COVID-19. In earlier clinical trials, Vaxart demonstrated its COVID-19 vaccine candidates generated robust cross-reactive mucosal IgA responses, boosted immune responses to existing COVID-19 vaccines, increased neutralizing antibodies against Omicron 4/5, and had a benign tolerability profile.

Funding for this award was received under [Project NextGen](#), a \$5 billion initiative by HHS to develop new, innovative vaccines and therapeutics that provide broader and more durable protection against COVID-19 than the first generation COVID-19 vaccines and medicines. This project has been funded with federal funds from HHS; ASPR; BARDA, under Other Transaction (OT) number 75A50123D00005.

### About the COVID-19 Phase 2b Trial

The Phase 2b trial is a double-blind, multi-center, randomized, comparator-controlled study to determine the relative efficacy, safety, and immunogenicity of Vaxart's oral pill COVID-19 vaccine candidate against an approved mRNA COVID-19 injectable vaccine in adults previously immunized against COVID-19 infection. The study design anticipates enrolling approximately 10,000 healthy adults 18 years and older in the United States with 5,000 receiving Vaxart's COVID-19 vaccine candidate and 5,000 receiving an approved mRNA comparator. At least 25% of the participants should be at least 65 years old.

The study will measure efficacy for symptomatic and asymptomatic disease, systemic and mucosal immune induction, and the incidence of adverse events. The primary endpoint is relative efficacy of Vaxart's COVID-19 vaccine candidate compared to an approved mRNA comparator for the prevention of symptomatic disease. Primary efficacy analysis will be performed when all participants have either discontinued or completed a study visit 12 months post-vaccination.

An independent Data and Safety Monitoring Board (DSMB) will review safety data of the participants.

Execution of this Phase 2b study will be funded by BARDA through the RRPV.

### 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 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, receipt of funding from BARDA for the Phase 2b study, results from preclinical and clinical trials and the timing of such trials and results, 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," "anticipate," "plan," and other words and terms of similar meaning. Examples of such statements include, but are not limited to, statements relating to Vaxart's receipt of funding from BARDA for the Phase 2b study (or for any other purpose), 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 the timing of receiving and reporting such clinical results and trial data; Vaxart's expectations regarding timing of enrollment in studies; 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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