Vaxart Announces Publication in Vaccines of Preclinical Data Supporting the Potential of its Mucosal Vaccine Technology Platform in Enabling Therapeutic Vaccination for HPV-Related Cervical Dysplasia

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- Data show that Vaxart's HPV vaccine constructs stimulate specific T cell immune responses, reduce tumor size, and increase survival in an animal model of human papillomavirus (HPV)-related tumorigenesis -

- Results suggest that Vaxart's mucosal vaccine platform holds promise in enabling a novel, non-invasive treatment for HPV-related cervical dysplasia -

SOUTH SAN FRANCISCO, Calif., Aug. 28, 2024 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) today announced the publication of preclinical data demonstrating the potential of its mucosal vaccine technology platform in enabling therapeutic vaccination against HPV-related cervical dysplasia. The data show that Vaxart's HPV vaccine constructs can stimulate a potent immune response against the HPV16 proteins E6 and E7 that are known to transform healthy cells into malignant cells. The data, reported in the current issue of *Vaccines*, also shows that administration of a mucosal vaccine against these proteins in mice with HPV-expressing tumors led to reductions in tumor size and increased survival.

Persistent HPV infection plays a causative role in most cases of cervical dysplasia, which leads to cervical cancers if left untreated. While prophylactic HPV vaccines are highly effective if administered prior to infection; they have not demonstrated a therapeutic effect on established infections.

"The preclinical data published in *Vaccines* demonstrate that our mucosal vaccines stimulate T cells to destroy HPV-expressing cells, reducing the size of HPV-derived tumors and increasing the survival of mice bearing these tumors," said Dr. Sean Tucker, Vaxart's Founder and Chief Scientific Officer. "While additional studies are needed to further characterize the immune stimulating and anti-tumor activity of our HPV-vaccine, these initial findings suggest that our mucosal vaccine platform could open the door to a non-invasive approach designed to prevent the progression to cervical cancer. As our mucosal vaccine candidates can be administered easily and are stable at room temperature, they also have potential to address global inequities associated with the treatment of HPV-related cancers."

In this study published in *Vaccines*, the therapeutic potential of this platform was assessed in mice bearing HPV-expressing tumors. Animals were treated with vaccine candidates expressing wildtype E6 and E7 antigens from HPV16, engineered E6 and E7 that disrupt their malignant transformation potential, and fragments of E6 and E7 predicted to stimulate an immune response. Key findings from the study include:

- All vaccines generated a specific T cell response to HPV16 E6 and E7 in mice.
- All vaccines caused significant reductions in tumor volume and increased survival compared to control groups.
- Concurrent administration of anti-PD-1 with vaccination further increased animal survival in small and large tumor models compared to vaccination alone.
- Vaccination led to significant increases in intra-tumoral T cells, including T cells that create a cytotoxic tumor environment, compared with an empty control vaccine.
- Vaccination led to the generation of antigen-specific cytotoxic T cells.

These results suggest that rAd5 vaccines delivered to a mucosal surface may have therapeutic potential in the treatment of HPV-derived cervical dysplasia and might be used to stimulate immune responses against other cancer-related proteins. Vaxart is continuing to evaluate its HPV vaccine candidates.

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 dsRNA 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 preclinical and clinical trials and the timing of such results, vaccine efficacy and safety, 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 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; 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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