Vaccinex to Present Update on PDAC/Pepinemab Study; New ActivMAb® Application

09/27/23

Phase 1b/2 pepinemab/PDAC study update to be presented on September 29 at special AACR meeting

New ActivMAb® application to be reviewed on September 28 at CHI's 20th Annual Discovery on Target (DOT) conference

ROCHESTER, N.Y., Sept. 27, 2023 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology company pioneering a differentiated approach to treating cancer and neurodegenerative disease (NDD) through the inhibition of SEMA4D, today announced that it will present data on a **new ActivMAb® application on September 28th** and an **update on the Phase 1b/2 pepinemab study in patients with PDAC on September 29th**.

Vaccinex will provide an overview of the design and enrollment for the pancreatic ductal adenocarcinoma (PDAC) study (NCT05102721). Currently, seven patients are enrolled. Treatment has been well-tolerated by these patients to date and a mixed response with some lesions showing radiologic partial and even complete response has been observed in one patient. The trial, which employs a Bayesian Optimal Interval (BOIN) Design in the Phase 1b segment and a Simon two stage assessment in the Phase 2 segment, is expected to enroll up to 40 patients. The study rationale builds on safety and efficacy data from the CLASSICAL-Lung study of pepinemab and avelumab and the observation that pepinemab appears to modulate the tumor microenvironment by increasing effector cell infiltration and reducing immune suppression, rendering “cold” tumors such as PDAC to become “hot”. The study is being conducted with grant support from the Gateway Discovery Award (Conquer Cancer Foundation / ASCO).

Update on Phase 1b/2 Pepinemab/PDAC Study (NCT05102721)

Meeting	AACR SPECIAL CONFERENCE IN CANCER RESEARCH: PANCREATIC CANCER
Date:	September 29, 2023
Poster Time:	4:40 p.m. to 6:40 p.m.
Session Title:	**A Phase 1b/2 trial of pepinemab and avelumab as second line immunotherapy for patients with chemotherapy refractory metastatic pancreatic adenocarcinoma**
Presenter	Luis Ruffolo, MD, University of Rochester Cancer Center & Wilmot Cancer Institute, Rochester, NY, USA
	Presentation will be available here

New ActivMAb® “Antigen Virus” Application

Meeting	CHI's 20th Annual DOT Conf: Antibodies Against Membrane Proteins
Date:	September 28, 2023
Time:	8:35 a.m. ET: GPCR Sessio
Session Title:	**Discovery of High-Affinity Functional Antibodies Specific for CXCR5 and Other Multi-Pass Membrane Proteins**
Presenter	Ernest Smith, Ph.D., Senior Vice President, Research
	Presentation will be available here

Vaccinex will describe use of the new “Antigen Virus” application, a potential tool to improve antibody development for high complexity, hard-to-drug targets, such as G-protein coupled receptors (GPCRs) and ion channels. This technology, a powerful complement to the existing ActivMAb platform, allows the direct incorporation of properly folded, complex multi-pass membrane proteins into specially designed poxviruses. We believe based on our rigorous evaluation that the ActivMab® system can readily generate functional and properly folded complex proteins that can be used for selection of novel, high value, antibody therapeutics. A new manuscript describing this technology was recently published in *mAbs*, a leading biotech journal.

About Pepinemab
Pepinemab is a humanized IgG4 monoclonal antibody designed to block SEMA4D, which can trigger collapse of the actin cytoskeleton and loss of homeostatic functions of astrocytes and glial cells in the brain and dendritic cells in immune tissue. Pepinemab has been administered to more than 400 patients and appears to be well-tolerated and to have a favorable safety profile.

Vaccinex has global commercial and development rights to pepinemab and is the sponsor of the NCT05102721 PDAC trial. BAVENCIO®/avelumab is provided by Merck KGaA, Darmstadt, Germany, previously as part of an alliance between the healthcare business of Merck KGaA, Darmstadt, Germany and Pfizer.

About ActivMAb®
ActivMAb is a proprietary mammalian cell-based antibody discovery platform developed by Vaccinex with unique capabilities for multi-pass membrane targets such as G-protein-coupled receptors (GPCRs). The ActivMAb® technology has multiple applications including: complex membrane antigen presentation and expression, antibody and antigen discovery, directed evolution and protein optimization.

The first clinical candidate selected through use of this technology (SRF114, a fully human monoclonal antibody targeting CCR8 for the potential treatment of solid tumors), entered development in a Phase 1/2 study sponsored by our licensee, Surface Oncology, recently acquired by Coherus Biosciences, Inc. The technology and its potential applications for drug discovery against complex membrane protein targets have been described in several publications and is the focus of collaborations with leading biopharmaceutical companies.

About Vaccinex Inc.
Vaccinex, Inc. is pioneering a differentiated approach to treating slowly progressive neurodegenerative diseases and cancer through the inhibition of semaphorin 4D (SEMA4D). The Company's lead drug candidate, pepinemab, is designed to block SEMA4D, a potent biological effector that is believed to trigger damaging inflammation in chronic diseases of the brain and inhibit immune infiltration and activation in tumors. In neurodegenerative diseases, pepinemab is being studied as a monotherapy in the Phase 1/2a SIGNAL-AD study in Alzheimer's Disease, with ongoing exploration of potential Phase 3 development in Huntington's disease. In oncology, pepinemab is being evaluated in combination with KEYTRUDA® in the Phase 1b/2 KEYNOTE-B84 study in recurrent or metastatic head and neck cancer (HNSCC) and in combination with BAVENCIO® in a Phase 1b/2 study in patients with metastatic pancreatic adenocarcinoma (PDAC). The oncology clinical program also includes several investigator-sponsored studies in solid tumors including breast cancer and melanoma.

Forward Looking Statements
To the extent that statements contained in this presentation are not descriptions of historical facts regarding Vaccinex, Inc. ("Vaccinex," "we," "us," or "our"), they are forward-looking statements reflecting management's current beliefs and expectations. Such statements include, but are not limited to, statements about the applicability and ability of the "Antigen Virus" application of the ActivMab ® platform, our plans, expectations and objectives with respect to the PDAC study, the expected timeline for disclosure of trial results at scientific conferences or through publications, and other statements identified by words such as "believes," "will," "appears," "expect," "ongoing," "potential,", and similar expressions or their negatives (as well as other words and expressions referencing future events, conditions, or circumstances). Forward-looking statements involve substantial risks and uncertainties that could cause the outcome of our research and pre-clinical development programs, clinical development programs, future results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, uncertainties inherent in the execution, cost and completion of preclinical studies and clinical trials, that interim and preliminary data may not be predictive of final results and does not ensure success in later clinical trials, uncertainties related to regulatory approval, risks related to our dependence on our lead product candidate pepinemab, the impact of the COVID-19 pandemic, the possible delisting of our common stock from Nasdaq if we are unable to regain compliance with the Nasdaq listing standards, and other matters that could affect our development plans or the commercial potential of our product candidates. Except as required by law, we assume no obligation to update these forward-looking statements. For a further discussion of these and other factors that could cause future results to differ materially from any forward-looking statement, see the section titled "Risk Factors" in our periodic reports filed with the Securities and Exchange Commission ("SEC") and the other risks and uncertainties described in the Company's annual year-end Form 10-K and subsequent filings with the SEC.

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Source: Vaccinex, Inc.