Vaccinex Reports Improved Immunity Correlating with Clinical Benefit of Pepinemab Combination Treatment at Society for Immunotherapy of Cancer's Annual Meeting

11/05/24

Pepinemab appears to enhance clinical activity of immune checkpoint inhibitors via induction of mature tertiary lymphoid structures in tumors of patients with HPV-negative head and neck cancer.

ROCHESTER, N.Y., Nov. 05, 2024 (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 new biomarker data that neoadjuvant treatment with pepinemab enhanced the clinical activity of immune checkpoint inhibitors in poorly immunogenic, HPV-negative, head and neck cancer (HNSCC). **In a presentation at Society for Immunotherapy of Cancer's Annual Meeting (SITC) on November 8th**, Vaccinex will present data from the Phase 2 KEYNOTE-B84 study (NCT04815720) for treatment of recurrent and metastatic disease as well as an independent study evaluating neoadjuvant treatment of resectable HNSCC (NCT03690986) showing that pepinemab combination treatments appear to induce mature lymphoid aggregates correlating with clinical benefit within immunotherapy resistant tumor populations, including HPV-negative and PD-L1 low HNSCC.

"Major advances beyond immune checkpoint therapies to expand and extend treatment benefits are needed for cancers whose activity may be limited by other resistance mechanisms, including expression of semaphorin 4D (SEMA4D), which binds receptors on myeloid cells to inhibit the migration and maturation of dendritic cells (DC) that are crucial for priming and expanding T cells in adaptive immune responses." said Maurice Zauderer, CEO at Vaccinex. "We are very excited to see that pepinemab treatment induced the formation of productive lymphoid structures within treated tumors and that this is associated with enhanced immune interactions and durable responses. We believe that novel modalities such as pepinemab can overcome limitations of ICI, particularly in patients who would not typically benefit from immune checkpoint monotherapy. We look forward to ongoing development of pepinemab combination therapies in metastatic and neoadjuvant settings."

Meeting:	SITC 39th Annual Meeting
Date:	November 8, 2024
Poster Number:	747
Poster Title:	**Pepinemab a Semaphorin 4D blockade antibody in combination with immune checkpoint therapies induces mature lymphoid aggregates correlating with clinical outcomes**
Presenter	Crystal Mallow, Vaccinex, Rochester, NY, USA

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. Over 600 patients have been enrolled in clinical trials of pepinemab in different indications and pepinemab appears to be well-tolerated and to have a favorable safety profile.

About Vaccinex Inc.

Vaccinex, Inc. is pioneering a differentiated approach to treating cancer and slowly progressive neurodegenerative diseases through the inhibition of semaphorin 4D (SEMA4D). The Company's lead drug candidate, pepinemab, blocks SEMA4D, a potent biological effector that it believes prevents immune infiltration into tumors and triggers damaging inflammation in chronic diseases of the brain. 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.

Vaccinex has global commercial and development rights to pepinemab and is the sponsor of the KEYNOTE-B84 study which is being performed in collaboration with Merck Sharp & Dohme Corp, a subsidiary of Merck and Co, Inc. Kenilworth, NJ, USA. Additional information about the study is available at: clinicaltrials.gov.

KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co. Inc., Kenilworth, NJ, USA. 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.

Vaccinex's ActivMAb ® Technology is a proprietary poxvirus-based antibody discovery platform. The technology has multiple applications, including discovery of antibodies specific for complex membrane antigens, discovery of antibodies with optimized developability, and protein optimization for expression and activity. Its novel capabilities enable selection of unique antibody drugs against difficult, high-value targets, including multi-pass membrane proteins against which small molecule drugs have demonstrated low efficacy or high toxicity. ActivMAb® 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.

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 expectations and objectives with respect to the results and timing of the SIGNAL-AD clinical trial; our plans, expectations and objectives with respect to the results and timing of the KEYNOTE-B84 clinical trial; the use and potential benefits of pepinemab in R/M HNSCC, lung cancer, metastatic pancreatic adenocarcinoma (PDAC) and other indications; the potential for benefits as compared to single agent KEYTRUDA® or BAVENCIO®; expectations with respect to the collaboration of Merck; the potential to initiate a Phase 3 trial in Huntington's Disease; and other statements identified by words such as "believe," "being," "will," "appears," "expect," "ongoing," "potential," "suggest", 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 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 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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