Vaccinex Reports Clinical Benefit in Interim Analyses from two Phase 2 Studies of Pepinemab Combination Treatment at Society for Immunotherapy of Cancer's Annual Meeting

10/31/23

Pepinemab, anti-SEMA4D blocking antibody, appears to enhance clinical activity of immune checkpoint inhibitors via induction of highly organized tertiary immune structures in tumors of patients with head and neck cancer and melanoma

ROCHESTER, N.Y., Oct. 31, 2023 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology company, will be reporting novel findings for its lead product, pepinemab, in two presentations at the 38th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), being held in San Diego, CA November 1-5, 2023. Vaccinex reports consistent findings from two independent studies demonstrating novel activity of pepinemab antibody to induce the formation of lymphoid structures in tumors that promote efficient immune responses and are known to be associated with improved outcomes to immune checkpoint inhibitors (ICI). In a pre-specified interim analysis of the Phase 2 KEYNOTE-B84 study (NCT04815720) evaluating pepinemab in combination with Merck's anti-PD-1 therapy, KEYTRUDA ® (pembrolizumab) for immunotherapy of recurrent or metastatic head and neck squamous cell carcinoma (HNSCC), these structures were associated with an approximate **doubling of objective responses (ORR) and progression free survival (PFS)** relative to historical results with checkpoint monotherapy in patients with hard-to-treat tumors that express low levels of PD-L1 (CPS<20). Similarly, findings will be reported from a separate study with collaborators at Emory University indicating that pepinemab in combination with nivolumab and/or ipilimumab (BMS), appeared to induce tertiary lymphoid structures in tumors. Remarkably, patients receiving neoadjuvant treatment with the triple combination have not experienced tumor recurrence for more than 2 years following treatment (**ongoing response in 8/8 patients**) (NCT03769155).

The potential of immune checkpoint therapies to sustain cytotoxic T cells is limited by insufficient support from other immune cell interactions, including with myeloid cells and B cells. The tumor microenvironment creates barriers to efficient immune cell communication, including by 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. Preclinical and clinical studies have previously demonstrated improved trafficking of DC and T cells and reduction of immature myeloid derived suppressor cells in tumor following treatment with pepinemab SEMA4D blocking antibody. Data from two independent studies to be presented at SITC provide new evidence that **pepinemab induces the formation of lymphoid structures within treated tumors and that this is associated with enhanced immune interactions and durable responses**. These results highlight pepinemab's novel mechanisms to overcome limitations of ICI.

> "**Neoadjuvant SEMA4D inhibitor pepinemab combination with nivolumab increases crosstalk between B cell and CD26hi T cell in patients with resectable stage III melanoma**" will be presented by Dr. Ayana Ruffin of Emory University together with Vaccinex authors on Friday, November 3, 2023.
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> "**Pepinemab, anti semaphorin 4D antibody, in combination with pembrolizumab induced formation of organized lymphoid aggregates and enhanced response to treatment in CPS<20 R/M HNSCC tumors (KEYNOTE-B84)**" will be presented by Dr. Terrence Fisher together with Merck authors and study investigators on Saturday, November 4, 2023.

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 dendritic cells in immune tissue and of astrocytes and glial cells in the brain. Pepinemab has been administered to more than 400 patients and 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, is designed to block SEMA4D, a potent biological effector that is believed to inhibit immune infiltration and activation in tumors and to trigger 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 LLC, a subsidiary of Merck and Co., Inc., Rahway, NJ, USA. Additional information about the study is available at: clinicaltrials.gov.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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 use and potential benefits of pepinemab in neurodegenerative diseases like AD and HD, and cancer, and other statements identified by words such as "anticipate," "believes," "appears," 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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