Vaccinex Announces Activation of Clinical Sites to Enroll Patients in Studies of Pepinemab as Single Agent in Alzheimer's Disease and in Combination with KEYTRUDA® in Advanced, Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC)

June 8, 2021

Company plans to activate at least 13 clinical sites for Alzheimer's study and 18 clinical sites for head and neck cancer across the United States

ROCHESTER, N.Y., June 08, 2021 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology Company pioneering a differentiated approach to treating neurodegenerative disease and cancer through the inhibition of SEMA4D, today announced that the first clinical sites have been activated to screen and enroll patients in its Phase 1/2 study evaluating pepinemab as a single agent in Alzheimer's disease (AD) and in its phase 2 study in of pepinemab combination with Merck's anti-PD-1 therapy KEYTRUDA ® (pembrolizumab) as front-line treatment for advanced, recurrent or metastatic head and neck squamous cell carcinoma (HNSCC). The Company plans to activate at least 13 U.S. sites for the Alzheimer study and 18 U.S. sites for HNSCC.

The Alzheimer's proof-of-concept study is expected to enroll at least 40 patients with key efficacy endpoints that include measures of cognition and brain imaging. This study has received funding support from the Alzheimer's Drug Discovery Foundation and the Alzheimer's Association. The HNSCC study will enroll up to 65 patients allocated to different levels of combined positive score (The HNSCC study is expected to enroll up to 65 patients allocated to different levels of combined positive score (CPS) of PD-L1 expression. CPS is a biomarker associated with benefit in response to immunotherapy. Efficacy endpoints will focus on objective response rate (ORR) per RECIST 1.1 criteria, as well as progression-free survival (PFS), overall survival (OS) and duration of response (DOR).

Dr. Maurice Zauderer, chief executive officer of Vaccinex, stated, "With this Alzheimer's study, we are building on prior data from our SIGNAL phase 2 study in Huntington's disease that we believe indicated cognitive benefit to patients at an early stage of this devastating neurodegenerative disease. It was particularly encouraging that this was accompanied by evidence of increased brain metabolic activity which has been shown in several independent studies to correlate with cognitive change in AD as well. AD patients are in urgent need of new therapies to effectively slow or halt disease progression, and we are looking forward to results from this important study.

"In addition, we recently published results of a prior phase 2 study of pepinemab in combination with a checkpoint inhibitor, EMD Serono's Bavencio ®, that we believe indicated treatment benefit to patients with non-small cell lung cancer. We are pleased to have now initiated this new trial in HNSCC in collaboration with Merck, a global immunotherapy leader. We and others have shown that SEMA4D is highly expressed in head and neck cancer and triggers increased levels of myeloid-derived suppressor cells that inhibit immune responses to tumor, providing a compelling scientific rationale for this study," Dr. Zauderer concluded.

Multiple prior preclinical studies suggested that inhibition of SEMA4D has unique mechanisms of action that reduce activation of inflammatory glial cells in brain but increases immune infiltration and alters the balance of cytotoxic and immunosuppressive cells in a tumor microenvironment. The Company is pleased and excited to have the opportunity to develop this potentially promising therapy in multiple important indications.

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

Bavencio® is a registered trademark of EMD Serono, Inc., the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany.

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 Company's plans, expectations and objectives with respect to the results and timing of clinical trials of pepinemab in various indications, the use and potential benefits of pepinemab in Huntington's and Alzheimer's disease and other indications, and other statements identified by words such as "may," "will," "appears," "expect," "planned," "anticipate," "estimate," "intend," "hypothesis," "potential," "advance," 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 the Company's 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 and clinical trials, uncertainties related to regulatory approval, risks related to the Company's dependence on its lead product candidate pepinemab, the ability to leverage its ActivMAb® platform, the impact of the COVID-19 pandemic, and other matters that could affect its development plans or the commercial potential of its product candidates. Except as required by law, the Company assumes 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 the Company's periodic reports filed with the Securities and Exchange Commission ("SEC") and the other risks and uncertainties described in the Company's Form 10-K for year end December 31, 2021 and subsequent filings with the SEC.

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