Vaccinex Announces Clinical Collaboration with Merck to Evaluate Pepinemab in Combination with KEYTRUDA® in Advanced, Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma

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ROCHESTER, N.Y., Sept. 17, 2020 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology company pioneering a novel approach to treating cancer and neurodegenerative disease through the inhibition of SEMA4D, today announced that it has entered into a clinical collaboration agreement with Merck (known as MSD outside the US and Canada), through a subsidiary, to evaluate the combination of Vaccinex's investigational SEMA4D inhibitor, pepinemab, and Merck's anti-PD-1 therapy, KEYTRUDA ® (pembrolizumab), in the treatment of patients with advanced, recurrent or metastatic head and neck squamous cell carcinoma (HNSCC).

"We are pleased to be working with Merck to evaluate the potential of pepinemab in combination with KEYTRUDA® to further improve the efficacy of cancer immunotherapy," said Maurice Zauderer, Ph.D., President and Chief Executive Officer of Vaccinex. "Several prior studies suggest that inhibition of SEMA4D increases immune infiltration and alters the balance of cytotoxic and immunosuppressive cells in the tumor microenvironment. SEMA4D is highly expressed in HNSCC and is believed to promote correspondingly high levels of myeloid derived suppressor cells. This collaboration provides an opportunity to evaluate this innovative approach in combination with anti-PD-1 therapy."

The planned clinical collaboration with pepinemab and pembrolizumab will consist of a dose escalation phase followed by an expansion phase that will enroll up to 65 HNSCC 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, and a major goal of this study is to determine whether combination therapy can improve response in these populations. Key endpoints of the study include objective response, progression free survival and overall survival.

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

About Pepinemab

Pepinemab, also known as VX15/2503, is a humanized monoclonal antibody that binds and blocks the activity of semaphorin 4D (SEMA4D) which is an extracellular signaling molecule that regulates the migration and function of immune and inflammatory cells. Preclinical studies have demonstrated that the biological activities associated with antibody blockade of SEMA4D promote immune cell infiltration into tumors and prevent neurological damage in neuroinflammatory and neurodegenerative disease models. Vaccinex is focused on the development of pepinemab for the treatment of cancer and neurodegenerative diseases including Huntington's disease. Pepinemab is an investigational new drug that has not yet been approved by the U.S. Food and Drug Administration (FDA) or other regulatory authorities for any indication.

About Vaccinex, Inc.

Vaccinex, Inc. is pioneering a differentiated approach to treating cancer and neurodegenerative disease through the inhibition of semaphorin 4D (SEMA4D), a key driver of immune infiltration and neuroinflammation. The company's lead drug candidate, pepinemab, blocks SEMA4D and has potential as an immune enhancing therapy in cancer and a disease-modifying treatment for Huntington's, Alzheimer's and other neurodegenerative diseases. The company additionally intends to leverage its proprietary drug discovery platform, ActivMAb®, to create opportunities for future pipeline expansion and strategic collaborations.

Forward Looking Statements

To the extent that statements contained in this press release 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 our plans, expectations and objectives with respect to the Huntington's, Alzheimer's disease and cancer clinical trials, the use of pepinemab, and other statements identified by words such as "may," "will," "appears," "expect," "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 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 and clinical trials, uncertainties related to regulatory approval, uncertainties with respect to whether the FDA will agree that the SIGNAL trial qualifies as a pivotal trial, risks related to our dependence on our lead product candidate pepinemab (VX15/2503), 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 our Form 10-K dated March 9, 2020 and subsequent filings with the SEC.

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