Vaccinex to Present Updated Results from CLASSICAL-Lung, Phase 1b/2 Study of Pepinemab (VX15/2503) in Combination with Avelumab (BAVENCIO®) in Non-Small Cell Lung Cancer at the American Society of Clinical Oncology (ASCO) 2020 Annual Meeting

May 13, 2020

Data continue to demonstrate durable response in patients as trial nears completion

ROCHESTER, N.Y., May 13, 2020 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology company pioneering a differentiated approach to treating cancer and neurodegenerative disease through the inhibition of SEMA4D, today announced a poster presentation highlighting interim results from CLASSICAL-Lung, the Company's Phase 1b/2 study of pepinemab in combination with the anti-PD-L1 checkpoint inhibitor BAVENCIO® (avelumab) in non-small cell lung cancer (NSCLC), at the American Society of Clinical Oncology (ASCO) 2020 Annual Meeting, being held virtually May 29-31, 2020.

"We are pleased to announce that updated data from the CLASSICAL-Lung trial of combination treatment with pepinemab and avelumab confirms earlier signs of anti-tumor activity, most notably in patients for whom previous treatment with anti–PD-1/PD-L1 therapies failed and those who have PD-L1–negative or –low tumors," said Dr. Maurice Zauderer, President and CEO of Vaccinex. "We believe this uniquely positions pepinemab to help the many patients with NSCLC who do not respond to PDx therapies, and we are looking forward to continuing to advance pepinemab through development."

Details on Vaccinex's poster discussion presentation at ASCO:

Abstract Number: 3011
Title: *Interim subgroup analysis for response by PD-L1 status of CLASSICAL-Lung, a phase 1b/2 study of pepinemab (VX15/2503) in combination with avelumab in advanced NSCLC*
Session: Developmental Therapeutics – Immunotherapy
Presenter: Michael Rahman Shafique, M.D., Department of Thoracic Oncology, Moffitt Cancer Center and Research Institute
Date: Available on demand beginning May 29 at 8:00 a.m. EDT.

The CLASSICAL-Lung trial is being conducted in collaboration with Merck KGaA, Darmstadt, Germany. It is a multi-center, open-label study designed to evaluate the safety and potential efficacy of the combination of pepinemab and avelumab in subjects with advanced NSCLC. Avelumab is co-developed and co-commercialized by Merck KGaA, Darmstadt, Germany and Pfizer Inc. The data to be presented at ASCO demonstrate that 59% (17/29) of patients who were either refractory (3/17) or whose tumors progressed (14/17) during or following treatment with single agent checkpoint inhibitor benefited from switching to the combination therapy, demonstrating that adding pepinemab to an immunotherapy (IO) treatment regimen has the potential to halt or reverse tumor progression. Additionally, 81% of immunotherapy-naïve patients (17/21) have experienced disease control, either a partial response (5 patients) or stable disease (12 patients), while receiving the combination. Six IO naïve and 4 IO failure patients have experienced durable clinical benefit of greater than six months. Tumor biopsies show increased T cell infiltration and reduced tumor burden in both patients who experienced a partial response or stable disease. Notably, 97% of patients who demonstrated a partial response or stable disease had negative or low PD-L1 expression in the tumor, demonstrating that adding pepinemab to an immunotherapy treatment regimen has the potential to expand the patient population for whom immunotherapy could be beneficial. The combination of pepinemab and avelumab has been demonstrated to be well-tolerated at all dose levels tested.

The presentation will also be available for review on the Presentations page in the Investors section of the Company's website, www.vaccinex.com.

About the CLASSICAL – Lung Clinical Trial

The design of the trial consists of a 12-subject dose escalation phase to determine the recommended Phase 2 dose of pepinemab in combination with avelumab, followed by a 50-subject dose expansion phase. The study includes a total of 21 evaluable patients who were immunotherapy naïve and 32 patients who were refractory or resistant to prior treatment with immune checkpoint inhibitors (predominantly anti–PD-1). 4 patients remain on study of whom two so far have responses of duration greater than 18 months. The primary objective is to assess safety and tolerability. Secondary objectives include evaluation of efficacy, immunogenicity, and PK/PD. An exploratory objective is to identify candidate biomarkers of activity.

About Vaccinex, Inc.

Vaccinex, Inc. is pioneering a differentiated approach to treating neurodegenerative disease through the inhibition of semaphorin 4D (SEMA4D), a key driver of neuroinflammation. The company's lead drug candidate, pepinemab, blocks SEMA4D and has potential as a disease-modifying treatment for Huntington's, Alzheimer's and other neurodegenerative diseases. Beyond neurology, Vaccinex has determined that, in combination with checkpoint inhibitors, pepinemab has potential to increase objective responses in oncology. The company additionally intends to leverage its proprietary drug discovery platform, ActivMAb®, to create opportunities for future pipeline expansion and strategic collaborations.

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.

Avelumab Approved Indications

Avelumab (BAVENCIO®) in combination with axitinib is approved in the US for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

The US Food and Drug Administration (FDA) granted accelerated approval for avelumab (BAVENCIO®) for the treatment of (i) adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (mMCC) and (ii) patients with locally advanced or metastatic urothelial carcinoma (mUC) who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. These indications are approved under accelerated approval based on tumor response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Avelumab is also currently approved for patients with MCC in more than 45 countries globally, with the majority of these approvals in a broad indication that is not limited to a specific line of treatment.

Avelumab Important Safety Information from the US FDA-Approved Label

The warnings and precautions for avelumab (BAVENCIO®) include immune-mediated adverse reactions (such as pneumonitis and hepatitis [including fatal cases], colitis, endocrinopathies, nephritis and renal dysfunction and other adverse reactions [which can be severe and have included fatal cases]), infusion-related reactions, hepatotoxicity, major adverse cardiovascular events (MACE) [which can be severe and have included fatal cases], and embryo-fetal toxicity.

Common adverse reactions (reported in at least 20% of patients) in patients treated with BAVENCIO® include fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, peripheral edema, decreased appetite/hypophagia, urinary tract infection and rash. Common adverse reactions (reported in at least 20% of patients) in patients receiving BAVENCIO® in combination with axitinib include diarrhea, fatigue, hypertension, musculoskeletal pain, nausea, mucositis, palmar-plantar erythrodysesthesia, dysphonia, decreased appetite, hypothyroidism, rash, hepatotoxicity, cough, dyspnea, abdominal pain and headache. Grade 3-4 clinical chemistry and hematology laboratory value abnormalities reported in at least 10% of patients across studies include hyponatremia, lymphopenia, GGT increased, blood triglycerides increased and lipase increased.

For full Prescribing Information and Medication Guide for BAVENCIO®, please see www.BAVENCIO.com.

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 and Alzheimer's disease 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, 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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