Vaccinex Presents Updated Interim Data from a Phase 1b/2 Study of Pepinemab (VX15/2503) in Combination with Avelumab (BAVENCIO®) in Non-Small Cell Lung Cancer at the 34th Annual Meeting of the Society for Immunotherapy of Cancer (SITC)

November 9, 2019

ROCHESTER, N.Y., Nov. 09, 2019 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology company pioneering novel investigational antibody therapies in cancer and Huntington's disease, today announced that updated interim data of the Phase 1b/2 study of pepinemab in combination with anti-PD-L1 checkpoint inhibitor, BAVENCIO® (avelumab), in non-small cell lung cancer (NSCLC) is being reported during a poster presentation on Saturday, November 9 at the 34th Annual Meeting of The Society for Immunotherapy of Cancer ("SITC"). Below is a summary of updated interim data from the poster presentation.

Updated Interim Data

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. In the interim data presented at SITC, 59% of patients (17/29) whose tumors had progressed during or following treatment with FDA-approved checkpoint inhibitors appeared to benefit from switching to the combination of pepinemab + avelumab, which appeared to induce a halt or reversal of tumor progression. Notably, half of these patients who benefited from the combination of pepinemab + avelumab had been treated with Keytruda® and 25% had been treated with Opdivo® prior to enrolling in this clinical trial. Two patients had partial responses (PR) with 63% and 52% tumor reductions on combination therapy after progression on Keytruda®, and 15 patients experienced stable disease (SD) , including 3 who had been refractory to prior anti-PDx therapy. To date, 1 subject (PR) has been on study for one year, 4 subjects (1PR+3SD) have been on study for at least 26 weeks and an additional 5 subjects with stable disease for at least 16 weeks.

Among 21 evaluable immunotherapy naïve patients enrolled, 5 subjects experienced a partial response following treatment with pepinemab plus avelumab. A total of 3 subjects have experienced durable clinical benefit for > 1 year at data cutoff and an additional 5 subjects have been on study for at least 26 weeks. The Disease Control Rate (PR+SD) is 81%.

Importantly, comparative analysis of available pre-treatment and on-treatment biopsies in a subset of subjects indicate that there is increased CD8+ T cell influx into tumors following combination therapy in patients experiencing a partial response (5/5) or stable disease (4/5), suggesting a favorable treatment-related change in the tumor micro-environment. Tumor was absent or greatly reduced in on-treatment biopsies from these subjects.

No concerning safety signals with the combination of pepinemab and avelumab have been identified by investigators to date. One dose limiting toxicity (DLT), a grade 3 pulmonary embolism, occurred. This resolved and did not recur in that same subject or additional subjects in any cohort. In addition, there have been no dropouts or discontinuations due to toxicity.

Dr. Maurice Zauderer, President and CEO of Vaccinex, commented, "We are very pleased that patients appear to be experiencing durable clinical benefit from the combination of pepinemab plus avelumab, in many cases even after progression on prior immune checkpoint inhibitor therapy. The many patients who do not respond to single agent immunotherapy and others who relapse following single agent immunotherapy represent important unmet needs for NSCLC, and our data suggest that the combination treatment may overcome inherent or acquired resistance to anti-PD-1/PD-L1 therapy."

The poster presentation is 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. Enrollment is complete and 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). The primary objective was 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 a clinical-stage immunotherapy company engaged in the discovery and development of targeted biotherapeutics to treat serious diseases and conditions with unmet medical needs, including cancer, neurodegenerative diseases, and autoimmune disorders, with currently active clinical trials in non-small cell lung cancer and Huntington's disease. Vaccinex is based in Rochester, New York.

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 indicated in the US for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

The US Food and Drug Administration (FDA) also 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 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. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," "potential," "advance," and similar expressions or their negatives (as well as other words and expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. Forward-looking statements may 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, our ability to continue as a going concern, 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, uncertainties regarding the development of our commercialization capabilities and degree of market acceptance of any of our product candidates, our ability to establish and maintain intellectual property protection covering our technology, 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 filed with the SEC on March 13, 2019.

Investor Contact
Jeremy Feffer
LifeSci Advisors, LLC
212-915-2568
jeremy@lifesciadvisors.com

Source: Vaccinex, Inc.