Vaccinex Announces Full Enrollment Achieved in Ongoing CLASSICAL-Lung Phase 1b/2 Trial of Pepinemab in Combination with BAVENCIO® (avelumab) in Advanced Non-Small Cell Lung Cancer

August 13, 2019

63% of evaluable subjects whose tumors had progressed during prior checkpoint inhibitor therapy benefited from treatment with the combination of pepinemab and avelumab

Primary completion anticipated in second half of 2019

ROCHESTER, N.Y., Aug. 13, 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 full enrollment has been achieved in the ongoing CLASSICAL-Lung Phase 1b/2 clinical trial evaluating the company's lead clinical candidate, pepinemab (VX15/2503), in combination with anti-PD-L1 checkpoint inhibitor, BAVENCIO® (avelumab), for the treatment of advanced non-small cell lung cancer (NSCLC). The clinical trial is being conducted in collaboration with Merck KGaA, Darmstadt, Germany and Pfizer.

This multi-center, open-label study is designed to evaluate the safety and potential efficacy of the combination of pepinemab and avelumab in patients with advanced NSCLC (n=62) who are either immunotherapy naïve or who failed prior immunotherapy with approved checkpoint inhibitors.

Interim results presented June 3, 2019 at the 2019 annual meeting of the American Society of Clinical Oncology (ASCO), showed that 63% or 10 of 16 evaluable subjects whose tumors had progressed during prior treatment with a checkpoint inhibitor benefited from the combination of pepinemab and avelumab through either halting or reversing tumor progression.

Maurice Zauderer, Ph.D., president and chief executive officer of Vaccinex, commented, "With the important milestone of full enrollment achieved, we anticipate the study's primary completion by the end of 2019, with top-line results expected in the first half of 2020."

He added, "We believe the study's interim results, although early, are very encouraging, showing that the combination of our lead therapeutic candidate, pepinemab, together with avelumab checkpoint inhibitor, had promising anti-tumor activity in lung cancer patients who were either immunotherapy treatment naïve or had failed prior single agent anti-PD-1/PD-L1 immunotherapy. We were also very pleased to see signs of positive changes in the tumor microenvironment that may potentiate the effectiveness of checkpoint therapy. We believe this early data with a 63% positive response suggests synergy between our drug candidate and avelumab in potentially treating certain patients whose tumors progress on approved first or second line immunotherapies. We anticipate issuing another interim update later this year."

Recap of Interim Results Presented at the June 2019 ASCO Annual Meeting

The CLASSICAL-Lung trial 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. 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 primary objective of the dose expansion phase 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.

In the interim data presented at ASCO, the overall average combination treatment benefit to subjects was approximately 13 weeks at data cutoff with 6 of these 16 subjects continuing treatment. Among the 10 responders, all of whom had failed prior treatment with FDA-approved checkpoint inhibitors (most frequently pembrolizumab), two had partial responses with 49% and 37% tumor reductions and eight experienced stable disease.

Importantly, comparative analysis of available pre-treatment and on-treatment biopsies demonstrated increased CD8+ T cell influx into tumors and an increased ratio of T effector/T regulatory cells (Teff/Treg) following combination therapy, indicating a favorable treatment-related change in the tumor micro-environment. Tumor was absent or reduced in biopsies from the 2 subjects who had partial responses, and no tumor was evident in available biopsies from 3 of 4 subjects with stable disease.

No concerning safety signals with the combination of pepinemab and avelumab have been identified to date. One dose limiting toxicity (DLT), a grade 3 pulmonary embolism, occurred in the 10mg/kg pepinemab + 10mg/kg avelumab escalation cohort, 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.

The ASCO poster is available for review on the Presentations page of the Company's website, www.vaccinex.com.

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.

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.

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 CLASSICAL-Lung clinical trial, the combination of pepinemab and avelumab, and other statements identified by 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). 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 13, 2019 and subsequent filings with the SEC.

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

Source: Vaccinex, Inc.