Vaccinex Presents Updated Interim Results from a Phase 1b/2 Study of Pepinemab in Combination with Avelumab in Non-Small Cell Lung Cancer at the 2019 ASCO Annual Meeting

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ROCHESTER, N.Y., June 03, 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 results of the Phase 1b/2 study of pepinemab in combination with avelumab in non-small cell lung cancer (NSCLC) subjects were reported during a poster session on Saturday, June 1 at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting. Michael Shafique, M.D., Assistant Professor of Thoracic Oncology at the H. Lee Moffitt Cancer Center and Research Institute and first author of the presentation, presented "Interim results from CLASSICAL-Lung, a phase 1b/2 study of pepinemab (VX15/2503) in combination with avelumab in advanced NSCLC" during the Developmental Immunotherapy and Tumor Immunobiology poster session.

Interim Results

This ongoing Phase 1b/2, open label, single arm, first-in-human combination study is designed to evaluate the safety, tolerability and efficacy of pepinemab in combination with avelumab in 62 subjects with advanced (stage IIIB/IV) NSCLC. The trial is split into dose escalation and dose expansion phases. The dose escalation phase, in which 12 subjects were enrolled, is complete and the recommended Phase 2 dose of the combination was selected as 10mg/kg pepinemab in combination with 10mg/kg avelumab, both administered intravenously once every two weeks. The dose expansion phase of the study is ongoing and includes two cohorts: (i) 17 subjects who are immunotherapy naïve; and (ii) up to 33 subjects whose tumors will have progressed during or following prior immunotherapy.

The combination of pepinemab and avelumab has been well-tolerated and no concerning safety signals have been identified to date. One DLT, a grade 3 pulmonary embolism, occurred in the 10mg/kg pepinemab + 10mg/kg avelumab escalation cohort, resolved and did not recur in that same subject or additional subjects in any cohort. In addition, there have been no drop-outs or discontinuations due to toxicity. It is particularly notable that among the 16 evaluable subjects to date who received prior immunotherapy, five had been treated with pembrolizumab or nivolumab for six to 18 months before progression, of whom 2 had partial responses and 2 had stable disease after receiving combination therapy with pepinemab and avelumab. An additional 9 subjects had prior immunotherapy for 3 to 6 months before progression, of whom 5 had stable disease and 4 continued progressing after receiving the combination of pepinemab and avelumab. Exploratory biomarker immunohistochemical analysis demonstrated increased CD8+ T cell influx into tumors and increased T effector / T regulatory (Teff / Treg) ratio following combination therapy, suggesting a favorable immuno-phenotype 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 biopsies from 3 of 4 subjects with stable disease, as defined by RECIST criteria.

Dr. Shafique commented, "Our team was pleased to find that pepinemab in combination with avelumab was well-tolerated by patients in this study and showed encouraging activity in patients who previously failed immunotherapy."

Dr. Maurice Zauderer, President and CEO of Vaccinex, commented, "We believe these interim results suggest that pepinemab in combination with a checkpoint inhibitor may contribute to the important and continuing effort to increase the benefit of immunotherapy to cancer patients. We are profoundly grateful to the many subject volunteers and clinicians involved in the CLASSICAL-Lung clinical trial with whom we share a hope for healing."

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

About Pepinemab

Pepinemab, also known as VX15/2503, is a humanized monoclonal antibody that binds and blocks the signaling 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 prevention of 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, major adverse cardiovascular events (MACE), 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. Additional common adverse reactions reported in patients receiving BAVENCIO® in combination with axitinib include hypertension, mucositis, palmar-plantar erythrodysesthesia, dysphonia, hypothyroidism, hepatotoxicity, cough, dyspnea, abdominal pain, and headache. Clinical chemistry and hematology laboratory value abnormalities have been reported including but not limited to grade 3-4 lymphopenia, anemia, elevated cholesterol and liver enzymes.

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.

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