Updated Interim Results from CLASSICAL-Lung, Phase 1b/2 Study of Pepinemab (VX15/2503) in Combination with Avelumab (BAVENCIO®) in Non-Small Cell Lung Cancer Presented at the American Association for Cancer Research (AACR) Virtual Annual Meeting

April 27, 2020

Updated data continue to demonstrate a durable clinical benefit in both immunotherapy-naïve patients as well as those previously treated with an immunotherapy regimen

ROCHESTER, N.Y., April 27, 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 semaphorin 4D (SEMA4D), today announced the presentation of updated interim results from CLASSICAL-Lung, the Company's Phase 1b/2 study of pepinemab in combination with anti-PD-L1 checkpoint inhibitor avelumab (BAVENCIO®) in non-small cell lung cancer (NSCLC), at the American Association for Cancer Research (AACR) Virtual Annual Meeting I, being held April 27-28, 2020. The data will be presented in a virtual poster session, available on demand and free to anyone on the AACR website beginning April 27.

The CLASSICAL-Lung trial (NCT03268057) 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 presented at AACR, which build upon results presented at the 34th Annual Meeting of the Society for Immunotherapy of Cancer (SITC) in November 2019, show that 81% of immunotherapy-naïve patients (17/21) have experienced disease control, either a partial response (5/21 patients) or stable disease (12/21 patients), in response to combination immunotherapy. Of these, four patients have achieved a durable clinical benefit of greater than one year, and six have achieved a durable clinical benefit of greater than 6 months. Notably, in the cohort of evaluable patients whose tumors had progressed during or following treatment with anti-PD-x antibodies, 59% (17/29) benefited from switching to the combination therapy, suggesting that adding pepinemab to an immunotherapy treatment regimen has the potential to halt or reverse tumor progression. The combination of pepinemab and avelumab appears to be well-tolerated.

"We continue to be encouraged by data from the CLASSICAL-Lung trial and are pleased to see preliminary signals suggesting durable responses," said Dr. Maurice Zauderer, President and CEO of Vaccinex. "The combination of pepinemab and avelumab has potential to halt or reverse tumor progression, both in immunotherapy-naïve patients and those for whom prior single-agent immunotherapy treatments have failed. We look forward to continuing to advance pepinemab in additional cancer indications."

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 included 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. Results included 21 evaluable patients who were immunotherapy naïve and 32 patients whose disease was refractory or relapsed during 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 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.

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, EU, Japan and other countries 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 mMCC in 50 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® monotherapy 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 treated with BAVENCIO® monotherapy include hyponatremia, lymphopenia, GGT increased; in patients receiving BAVENCIO® in combination with axitinib, grade 3-4 clinical chemistry and hematology laboratory value abnormalities included blood triglyceride 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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