Vaccinex Announces Three Oral Presentations Highlighting Semaphorin 4D (SEMA4D) at the ASCO-SITC Clinical Immuno-Oncology Symposium

February 6, 2020

The multiple presentations in one ASCO-SITC meeting session spotlight the growing interest in SEMA4D as a clinically relevant target implicated in multiple cancer types and highlights the potential of pepinemab antibody to neutralize SEMA4D in the treatment of cancer

ROCHESTER, N.Y., Feb. 06, 2020 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology company pioneering novel investigational antibody therapies in cancer and neurodegenerative diseases, today announced that three oral presentations highlighting SEMA4D will be delivered at the American Society of Clinical Oncology (ASCO)-Society for Immunotherapy in Cancer (SITC) Clinical Immuno-Oncology Symposium, which is being held February 6-8 in Orlando, Florida.

“We believe these oral presentations at the prestigious ASCO-SITC Clinical Immuno-Oncology Symposium reflect growing interest in SEMA4D as an emerging and potentially important target for the treatment of cancer,” said Dr. Maurice Zauderer, President and Chief Executive Officer of Vaccinex. “We are currently evaluating our novel anti-SEMA4D antibody, pepinemab, in combination with avelumab, an anti-PD-L1 antibody co-developed and co-commercialized by Merck KGaA, Darmstadt, Germany and Pfizer, in a Phase 1b/2 study in patients with non-small cell lung cancer (NSCLC). Interim results that we recently presented at the 34th Annual Meeting of SITC in November demonstrated a robust effect, as 17 of 29 patients whose tumors had progressed during or following treatment with checkpoint inhibitors showed a halt or reversal of tumor progression. We look forward to final results from this important study while in parallel advancing our understanding of the potential role of SEMA4D in the treatment of other difficult to treat cancers.”

Below is the schedule for the SEMA4D-related presentations:

**Interim Results from a Phase Ib/II Study of Pepinemab in Combination with Avelumab in Advanced NSCLC Patients Following Progression on Prior Systemic and/or Anti-PDx Therapies**

Abstract # 75
First Author: Michael Rahman Shafique, MD
Oral Abstract Session A
Thursday, February 6, 2020
1:00-2:15pm EST

**Antibody Blockade of Semaphorin 4D to Sensitize Pancreatic Cancer to Immune Checkpoint Blockade**

Abstract # 26
First Author: Luis I. Ruffolo, MD
Oral Abstract Session A
Thursday, February 6, 2020
1:00-2:15pm EST

**Exploring New Immunologic Opportunities by Blocking Semaphorin 4D**

Timothy A Yap, MD, PhD, The University of Texas MD Anderson Cancer Center
Oral Abstract Session A
Thursday, February 6, 2020
1:00-2:15pm EST

Copies of the presentations may be found in the Presentations section of the Company’s website after the event. Visit the website at www.vaccinex.com.

About CLASSICAL – Lung

Vaccinex is currently evaluating its novel anti-SEMA4D antibody, pepinemab (VX15/2503), in combination with BAVENCIO® (avelumab), a human anti-PD-L1 IgG1 monoclonal antibody, in a Phase Ib/II study in patients with advanced (stage IIIIB/IV) non-small cell lung cancer (NSCLC). The trial is being conducted under a clinical collaboration agreement announced in 2016 between Vaccinex and Merck KGaA, Darmstadt, Germany. The clinical trial, short-named “CLASSICAL – Lung”, is a multi-center, open-label study designed to evaluate the safety and potential efficacy of the combination.

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 and Alzheimer'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.

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.

To receive Vaccinex news as it happens, please sign up for News Alerts on the Company’s Investor Services web page (Investors/Investor Services).

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 13, 2019 and subsequent filings with the SEC.

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Source: Vaccinex, Inc.