# Vaccinex, Inc. Announces the First Patient Treated in a Phase Ib/II Combination Study with Anti-Semaphorin 4D Antibody, VX15/2503, and Avelumab in Non-Small Cell Lung Cancer Patients (CLASSICAL – Lung)

October 26, 2017

October 26, 2017. Rochester, New York – Vaccinex Inc. today announced the dosing of the first patient in a Phase Ib/II study of VX15/2503, an investigational humanized anti-semaphorin 4D IgG4 monoclonal antibody, in combination with avelumab*, a human anti-PD-L1 IgG1 monoclonal antibody, in patients with advanced non-small cell lung cancer (NSCLC). The trial is being conducted under a clinical collaboration agreement announced last year 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 of VX15/2503 and avelumab in patients with advanced NSCLC who have not previously received immunotherapy. The design of the trial consists of a dose escalation phase to determine the recommended Phase II dose of VX15/2503 in combination with avelumab, followed by an expansion phase to enroll up to a total of 40 patients with NSCLC.

In preclinical studies conducted by Vaccinex, anti-semaphorin 4D antibodies have been shown to increase infiltration of tumoricidal immune cells while simultaneously reducing multiple types of immunosuppressive cells in tumors. In these studies, anti-semaphorin 4D antibody was found to synergize with a checkpoint inhibitor antibody to promote tumor eradication. The CLASSICAL – Lung study marks the first clinical trial to evaluate VX15/2503 in combination with a checkpoint inhibitor.

"We are very excited to begin this collaborative study to determine whether combination therapy with anti-semaphorin 4D antibody and avelumab in NSCLC will realize the potential for synergy in eradicating tumors that has been observed in prior preclinical studies," said Dr. Maurice Zauderer, President and CEO of Vaccinex.

*Avelumab is jointly developed by Merck KGaA, Darmstadt, Germany, and Pfizer. Avelumab is under clinical investigation for the treatment of advanced NSCLC and has not been demonstrated to be safe and effective for this indication. There is no guarantee that avelumab will be approved for advanced NSCLC by any health authority worldwide.

**About Avelumab**

Avelumab is a human programmed death ligand-1 (PD-L1) blocking antibody. Avelumab is designed to potentially engage both the adaptive and innate immune systems. By binding to PD-L1, avelumab is thought to prevent tumor cells from using PD-L1 for protection against white blood cells, such as T cells, exposing them to anti-tumor responses. Avelumab has been shown to induce antibody-dependent cell-mediated cytotoxicity in vitro. In November 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

**Approved Indications in the US**
The US Food and Drug Administration (FDA) granted accelerated approval for avelumab (BAVENCIO®) for the treatment of (i) metastatic Merkel cell carcinoma (mMCC) in adults and pediatric patients 12 years and older and (ii) patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy, or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. These indications were 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.

**Important Safety Information from the US FDA Approved Label**
The warnings and precautions for avelumab (BAVENCIO) include immune-mediated adverse reactions (such as pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction and other adverse reactions), infusion-related reactions and embryo-fetal toxicity.

Common adverse reactions (reported in at least 20% of patients) in patients treated with avelumab for metastatic mMCC and patients with locally advanced or metastatic UC include fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, peripheral edema, decreased appetite/hypophagia, urinary tract infection and rash.

**About Vaccinex, Inc.**

Vaccinex, Inc. is a privately held clinical-stage immunotherapy company engaged in the discovery and development of human therapeutic monoclonal antibodies to treat cancer and neurodegenerative diseases, including Huntington's disease. Vaccinex utilizes its proprietary ActivMAb® Antibody Discovery Technology for rapid, mammalian cell-based antibody selection to build its antibody pipeline and in service to its biopharmaceutical partners. ActivMAb® combines the advantages of rapid and sensitive selection by virus panning and cell sorting in one technology, with intrinsic selection of antibodies that are efficiently expressed and stable in mammalian cells. We believe that recent advances have made this technology very efficient for selection of antibodies against membrane associated proteins, an important class of target molecules for pharmaceutical development. Vaccinex is based in Rochester, New York. For more information and to contact Vaccinex (info@vaccinex.com) or visit www.vaccinex.com.

**Cautionary Note on Forward-Looking Statements**

This press release contains forward-looking statements reflecting the current beliefs and expectations of management. Words such as "may," "believe," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions, as well as other words or expressions referencing future events, conditions or circumstances, are intended to identify forward-looking statements. Forward-looking statements contained in this press release include statements about expectations related to a Phase Ib/II clinical trial for the Company's lead monoclonal antibody, VX15/2503. Forward-looking statements in this press release involve substantial risks and uncertainties that could cause our performance or achievements to differ significantly from those expressed or implied by the forward-looking statements, including as a result of the inherent challenges in clinical development. All forward-looking statements are based on Vaccinex's expectations and assumptions as of the date of this press release, and actual results may differ materially. Except as required by law, Vaccinex expressly disclaims any responsibility to update any forward-looking statement contained herein, whether as a result of new information, future events or otherwise.

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