Vaccinex, Inc. Announces Completion of Enrollment for Its “SIGNAL” Huntington’s Disease Trial

January 16, 2019

ROCHESTER, N.Y., Jan. 16, 2019 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX) announced today that it has completed subject enrollment for the SIGNAL trial. SIGNAL is a Phase 2, multi-center, randomized, double-blind, placebo controlled study in subjects with early manifest and late prodromal Huntington’s disease (HD) to assess the safety, tolerability, pharmacokinetics, and efficacy of VX15/2503 (pepinemab).

In June 2015, Vaccinex, the Huntington Study Group (HSG), and the University of Rochester's Clinical Trials Coordination Center (CTCC) launched SIGNAL, the first clinical trial to investigate a monoclonal antibody as a potential treatment for Huntington's disease (HD).

The SIGNAL study consists of two Cohorts, A and B. Cohort A was completed in February 2017 and consisted of 36 participants who were randomized to receive monthly infusions of either VX15/2503 (pepinemab) or placebo for six months in a double-blind fashion. All participants in Cohort A subsequently received open-label VX15/2503 (pepinemab) for another five months, followed by a three-month safety follow-up. No concerning safety signals were identified. VX15/2503 (pepinemab) treatment showed marked effects on FDG-PET imaging, a measure of brain metabolic activity. VX15/2503 (pepinemab) was favored in all brain regions examined, with median increase in FDG uptake from baseline of 8.6 percent (range: 0.5-20.4 percent) compared to placebo control achieving significance ($p<0.05$) in the majority of frontal and parietal brain regions analyzed. A number of prior studies have demonstrated that loss of FDG-PET signal correlates with cognitive decline in Alzheimer’s disease. SIGNAL is the first clinical study in HD to investigate potential correlation between FDG-PET and clinical outcomes.

Cohort B, now fully enrolled, includes two cohorts with a total of 265 HD subjects – 179 in group 1 (B1) who have early manifest disease and 86 in group 2 (B2) who are late prodromal. All subjects are randomized to receive monthly infusions of either VX15/2503 (pepinemab) or placebo for 18 months in double-blind fashion without crossover.

“We are gratified to have reached this important milestone of completing enrollment for the SIGNAL trial. Because of the efforts of HSG, CTCC, clinical site investigators and staff, and most importantly subject volunteers and their families, SIGNAL is several years ahead of any other ongoing advanced clinical trial testing possible disease modifying effects in Huntington’s disease. We are excited to be in the lead and hopeful of bringing relief to the patients and families who suffer this devastating disease,” said Maurice Zauderer, president & CEO, Vaccinex, Inc.

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. 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) are intended to identify forward-looking statements. Forward-looking statements may 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 prospectus for our initial public offering dated August 9, 2018, filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

Investor Contact
Michael Rice
LifeSci Advisors, LLC
Phone: (646) 597-6979
E-mail: mrice@lifesciadvisors.com

Media Contact
Jules Abraham
JQA Partners, Inc.
Phone: (917) 885-7378
E-mail: jabraham@jqapartners.com

Vaccinex, Inc.