Vaccinex Provides Update of Potentially Pivotal SIGNAL Clinical Trial in Huntington's Disease

July 7, 2020

Topline data anticipated in October 2020 as previously guided

ROCHESTER, N.Y., July 07, 2020 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology company pioneering novel investigational antibody therapies in Huntington's disease (HD) and cancer, today announced that, notwithstanding the challenges posed by the ongoing COVID-19 pandemic, it remains on track to complete the potentially pivotal SIGNAL trial in HD within the anticipated time frame. Primary efficacy data has been collected from all subjects who completed the study except for 2 subjects whose assessments were delayed by the COVID-19 pandemic, but whose clinical sites have now reopened and who are expected to complete efficacy assessments later this month. The Company continues to anticipate that database lock will be completed by September and that topline data may be released by early October as previously guided.

The Company has also completed productive interactions with the FDA Division of Neurology and has identified primary and secondary endpoints for the two randomized arms of the SIGNAL trial as detailed below.

Efficacy Analysis

The efficacy results for the 265 subjects enrolled in the SIGNAL study, all of whom were confirmed to carry the Huntington's mutation, will be analyzed in two groups: a first group comprising 179 subjects diagnosed with early manifest disease defined by Total Functional Capacity (TFC) ≥ 11, and a second group comprised of all 265 subjects enrolled in the study that represents the continuum of disease before and after conversion to manifest symptoms. In addition to the 179 subjects with early manifest disease, this latter group includes 86 subjects deemed to be at an earlier stage of underlying disease progression, late prodromal (DCL 2 or 3). Co-primary endpoints for the first group are Clinical Global Impression of Change (CGIC) from baseline through 18 months of treatment and a family of selected cognitive assessments from the Huntington's Disease Cognitive Assessment Battery (HD-CAB). Secondary endpoints for this group include Quantitative Motor assessments (Q-Motor) and TFC. For the consolidated group, the single primary endpoint will be TFC and secondary endpoints are Q-Motor and the selected family of HD-CAB cognitive assessments. A number of brain imaging assessments will be reported including changes in volumetric MRI, a measure of brain atrophy, and changes in FDG-PET, a measure of metabolic activity in major brain regions.

"We are very pleased with continued progress in our potentially pivotal effort to make a disease modifying therapy available to people at risk of this debilitating disease," said Maurice Zauderer, Ph.D., President and Chief Executive Officer of Vaccinex. "The data from Cohort A suggest that pepinemab can improve metabolic activity in the brain as detected by FDG-PET imaging, a biomarker that correlates with cognitive decline in other neurodegenerative diseases. At this time, we believe the Vaccinex HD program is two or more years in advance of other programs employing alternative technologies that have not yet achieved clinical proof of concept. Because the Vaccinex strategy addresses a pathogenic mechanism common to different neurodegenerative diseases, we believe pepinemab also has potential application in Alzheimer's disease (AD), progressive multiple sclerosis, and ALS. A phase 1/2 trial in AD supported by the Alzheimer's Association and the Alzheimer's Drug Discovery Foundation is expected to begin enrolling patients in September 2020."

About the SIGNAL trial

SIGNAL is a multi-center, double-blind, placebo-controlled study to evaluate the safety and efficacy of pepinemab as a potential treatment for people with Huntington's disease, a devastating neurodegenerative disease with currently no effective treatment. The study had two sequential Cohorts. The primary outcome of Cohort A was safety and pepinemab was found to be well-tolerated. Additional data from SIGNAL Cohort A demonstrated that pepinemab treatment results in an increase in FDG-PET signal, a measure of brain metabolic activity, in contrast to the decrease observed in the placebo group and in the natural history of this and other neurodegenerative diseases. The design of the subsequent Cohort B was informed by the results of Cohort A and enrolled 265 subjects for treatment of 18 months duration.

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. Pepinemab is an investigational new drug that has not yet been approved by the U.S. Food and Drug Administration (FDA) or other regulatory authorities for any indication.

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 and new trials pending in Alzheimer's disease and Head & Neck cancer. 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 Huntington's, Alzheimer's disease and cancer 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, uncertainties with respect to whether the FDA will agree that the SIGNAL trial qualifies as a pivotal trial, 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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