Vaccinex Reports Positive Effect of Pepinemab Treatment on New Biomarker of Brain Inflammation in Neurodegenerative Diseases

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Pepinemab, anti-SEMA4D blocking antibody, appears to inhibit astrocyte activation and brain inflammation as evidenced by significantly reduced levels of GFAP in patient blood

ROCHESTER, N.Y., Oct. 26, 2023 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology company, today reports novel findings for its lead product, pepinemab, in a highlighted podium presentation at the Clinical Trials on Alzheimer's Disease (CTAD) Conference in Boston, MA. Vaccinex has previously reported results of a phase 2 trial in Huntington's disease (HD) that suggest pepinemab treatment prevents decline in glucose uptake associated with astrocyte activation and significantly slows cognitive decline as measured by the Huntington's Disease Cognitive Assessment Battery (HD-CAB). The company now reports data indicating that pepinemab treatment significantly reduced blood levels of GFAP, a biomarker of reactive astrocytes, providing further evidence of the drug's potential to reverse harmful astrocyte activation and brain inflammation.

Astrocytes are key regulatory cells in the brain that, under conditions of brain injury or disease, switch from their normal supportive physiological functions to inflammatory activity that is believed to aggravate damage to brain tissue. This transition is marked by release of glial fibrillary acidic protein (GFAP), a characteristic astrocyte protein, into blood. Importantly, results from a highly sensitive S-PLEX GFAP immunoassay demonstrated a significant reduction in plasma GFAP levels in HD patients treated with pepinemab compared to those receiving placebo. Elevated GFAP levels in blood have also been found to correlate with Aβ amyloid deposits in brain and to be associated with higher risk of dementia and faster rates of cognitive decline in AD. A committee convened by the Alzheimer's Association has recently recommended GFAP as a leading blood-based biomarker of astrocytic activation and brain inflammation in AD.

Given the many physiological parallels between neurodegenerative processes in HD and AD, we believe that similar biological effects of pepinemab treatment are likely in the two indications. This is being tested in an ongoing randomized, placebo-controlled trial, SIGNAL-AD, supported by awards from the Alzheimer's Drug Discovery Foundation and the Alzheimer's Association, for which it is anticipated that the last patient will complete 12 months of treatment by June 2024. Early evidence of limited benefit to AD patients treated with antibodies to Aβ amyloid has stimulated a search for differentiated treatments that could further improve responses. It has been known for some time that beta amyloid deposits can also be present in the brain of elderly subjects who do not progress to Alzheimer's. As noted by Howard Fillit, MD, Chief Science Officer for the Alzheimer's Drug Discovery Foundation, "If there's no strong immune reaction to the buildup, there's no inflammation and no progression of disease." We believe that preventing astrocyte activation and reducing brain inflammation with pepinemab treatment could be an attractive alternative or complement to anti-Aβ antibodies with potential for greater efficacy.

About Pepinemab
Pepinemab is a humanized IgG4 monoclonal antibody designed to block SEMA4D, which can trigger collapse of the actin cytoskeleton and loss of homeostatic functions of astrocytes and glial cells in the brain and dendritic cells in immune tissue. Pepinemab has been administered to more than 400 patients and appears to be well-tolerated and to have a favorable safety profile.

About Vaccinex Inc.
Vaccinex, Inc. is pioneering a differentiated approach to treating slowly progressive neurodegenerative diseases and cancer through the inhibition of semaphorin 4D (SEMA4D). The Company's lead drug candidate, pepinemab, is designed to block SEMA4D, a potent biological effector that is believed to trigger damaging inflammation in chronic diseases of the brain and inhibit immune infiltration and activation in tumors. In neurodegenerative diseases, pepinemab is being studied as a monotherapy in the Phase 1/2a SIGNAL-AD study in Alzheimer's Disease, with ongoing exploration of potential Phase 3 development in Huntington's disease. In oncology, pepinemab is being evaluated in combination with KEYTRUDA® in the Phase 1b/2 KEYNOTE-B84 study in recurrent or metastatic head and neck cancer (HNSCC) and in combination with BAVENCIO® in a Phase 1b/2 study in patients with metastatic pancreatic adenocarcinoma (PDAC). The oncology clinical program also includes several investigator-sponsored studies in solid tumors including breast cancer and melanoma.

Forward Looking Statements
To the extent that statements contained in this presentation 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 the use and potential benefits of pepinemab in neurodegenerative diseases like AD and HD, and cancer, and other statements identified by words such as "anticipate," "believes," "appears," 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 the outcome of 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 studies and clinical trials, that interim and preliminary data may not be predictive of final results and does not ensure success in later clinical trials, uncertainties related to regulatory approval, risks related to our dependence on our lead product candidate pepinemab, the impact of the COVID-19 pandemic, the possible delisting of our common stock from Nasdaq if we are unable to regain compliance with the Nasdaq listing standards, 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 the Company's annual year-end Form 10-K and subsequent filings with the SEC.

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