



Vaccinex Reports Second Quarter 2021 Financial Results and Provides Corporate Update

August 16, 2021

Patients are currently being screened and enrolled in two studies of pepinemab as monotherapy in Alzheimer's disease and in combination with KEYTRUDA® in Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC)

Ended the second quarter with cash and cash equivalents of \$22.4 million

ROCHESTER, N.Y., Aug. 16, 2021 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology company pioneering a differentiated approach to treating cancer and neurodegenerative disease through the inhibition of SEMA4D, today announced financial results for the second quarter ended June 30, 2021 and provided a corporate update.

"During the second quarter and subsequent period, we achieved significant milestones by initiating clinical trials in both Alzheimer's disease (AD) and metastatic head and neck cancer (HNSCC). We believe that successfully advancing these programs will demonstrate the versatility of pepinemab's mechanism of action in serious diseases in which SEMA4D overexpression is implicated," stated Maurice Zauderer, Ph.D., president and chief executive officer.

"With respect to our Huntington's disease (HD) program, we believe the results of our completed Phase 2 SIGNAL study support potential cognitive benefit of treatment with pepinemab. 1) treatment with pepinemab significantly improved cognition as reflected in the HD-Cognitive Assessment Battery Composite score ($p=0.007$). 2) Patients demonstrated significant improvement ($p=0.029$) in a measure of apathy severity that has previously been reported to correlate with cognition in HD as well as in Alzheimer's and Parkinson's disease. 3) FDG-PET, a measure of brain metabolic activity, indicated significant positive treatment effect in the majority of brain regions examined in patients with HD. Multiple clinical studies in AD have shown that decline in FDG-PET correlates with cognitive decline and FDG-PET is accepted as a biomarker of clinical progression in AD. As previously indicated, we are actively engaged in partnering discussions to initiate a definitive Phase 3 study in HD.

Pepinemab Clinical Updates:

- **Alzheimer's Disease.** We announced activation of clinical sites and dosing of the first patient in our Phase 1/2 clinical trial of pepinemab in Alzheimer's disease. This program is funded in part by a \$3 million award from the Alzheimer's Drug Discovery Foundation as well as a \$750,000 development grant from the Alzheimer's Association under its 2020 "Part the Cloud" program.

This randomized, placebo-controlled, multi-center study is expected to enroll at least 40 subjects across 13 U.S. trial sites. We anticipate topline data in late 2022 or early 2023.

- **Head and Neck Cancer.** Subsequent to the end of the first quarter, Vaccinex announced that it initiated screening to enroll patients in its Phase 2 clinical trial evaluating pepinemab in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in metastatic head and neck cancer.

Multiple prior studies suggest that inhibition of SEMA4D increases immune infiltration and alters the balance of cytotoxic and immunosuppressive cells in the tumor microenvironment. As SEMA4D is highly expressed in head and neck cancer, we believe there is strong rationale for development in this indication.

The study is expected to enroll up to 65 subjects across 18 U.S. trial sites and is designed to assess whether combination therapy can improve responses in this population. Key endpoints of the study will include objective response, progression free survival and overall survival. Vaccinex anticipates early data from this study in second half of 2022.

- **Other Trials.** Pepinemab is also being evaluated in multiple investigator-sponsored trials (ISTs) being conducted by the Winship Cancer Institute of Emory University to evaluate pepinemab in combination with checkpoint inhibitors in "Window of Opportunity" studies in colorectal, pancreatic, head and neck cancer and melanoma.

Other Second Quarter and Recent Accomplishments:

- Elizabeth Evans, PhD, Senior Vice President and Chief Operating Officer, chaired a panel and Q&A session, entitled, *Targeting glial cell activation for treatment of neurodegenerative disease* at the XV European Meeting on Glial Cells in Health and Disease, which was held July 5-9. Dr. Evans shared a presentation and an accompanying poster describing the mechanism of action of pepinemab and findings from the Company's Phase 2 clinical trial of pepinemab in Huntington's Disease as well as the design of the now active Phase 1b/2a clinical trial of pepinemab in Alzheimer's Disease.
- Vaccinex announced the publication of results from the CLASSICAL-Lung phase 1b/2 clinical trial in non-small cell lung cancer in the peer-reviewed journal *Clinical Cancer Research*. The paper presents data showing that pepinemab is

clinically active when combined with BAVENCIO[®], a checkpoint inhibitor, and was well tolerated with no major safety signals identified. The combination appeared to halt or reverse tumor progression (partial response or stable disease) in select patients with primary or acquired resistance to anti-PD-1/L1 therapy.

Upcoming Anticipated Milestones:

- **H2 2022** – Meaningful data from open label head and neck cancer trial
- **Late 2022/Early 2023** – Topline data from randomized Alzheimer's trial

Financial Results for the Three Months Ended June 30, 2021:

Research and Development Expenses. Research and development expenses for the three months ended June 30, 2021 were \$4.1 million as compared to \$4.6 million for the comparable period in 2020.

General and Administrative Expenses. General and administrative expenses for the three months ended June 30, 2021 were \$1.6 million as compared to \$1.9 million for the comparable period in 2020.

Cash and Cash Equivalents and Marketable Securities. Cash and cash equivalents and marketable securities on June 30, 2021 were \$22.4 million, as compared to \$10.6 million as of December 31, 2020.

About Vaccinex, Inc.

Vaccinex, Inc. is pioneering a differentiated approach to treating cancer and slowly progressive neurodegenerative diseases through the inhibition of semaphorin 4D (SEMA4D). The company's lead drug candidate, pepinemab, blocks SEMA4D, a potent biological effector that prevents immune infiltration into tumors and triggers chronic inflammation in the brain. The company additionally intends to leverage its proprietary drug discovery platform, ActivMAB[®], to create opportunities for future pipeline expansion and strategic collaborations, particularly by exploiting its unique capability to select high value antibodies against important multi-pass membrane receptors including GPCR and ion channels.

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 Company's plans, expectations and objectives with respect to the results and timing of clinical trials of pepinemab in various indications, the use and potential benefits of pepinemab in Huntington's disease Alzheimer's disease, cancer and other indications, and other statements identified by words such as "may," "will," "appears," "expect," "planned," "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 the outcome of the Company's 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 the Company's dependence on its lead product candidate pepinemab, the ability to leverage its ActivMAB[®] platform, the impact of the COVID-19 pandemic, and other matters that could affect its development plans or the commercial potential of its product candidates. Except as required by law, the Company assumes 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 the Company's periodic reports filed with the Securities and Exchange Commission ("SEC") and the other risks and uncertainties described in the Company's Form 10-K for year-end December 31, 2021 and subsequent filings with the SEC.

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Source: Vaccinex, Inc.