Vaccinex Reports First Quarter 2020 Financial Results and Provides Corporate Update

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Approaching key topline data in non-small cell lung cancer and Huntington's disease

Advancing plans to expand pepinemab development to include Alzheimer's disease

ROCHESTER, N.Y., May 14, 2020 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology company pioneering novel investigational antibody therapies in cancer and Huntington's disease, today announced financial results for the first quarter ended March 31, 2020 and provided a corporate update.

First Quarter and Recent Accomplishments:

- Presented updated interim data from the CLASSICAL-Lung Phase 1b/2 study of the company's lead product candidate, pepinemab, in combination with avelumab (BAVENCIO®) in non-small cell lung cancer (NSCLC) at the American Association for Cancer Research Virtual Annual Meeting.
- Delivered three oral presentations highlighting Semaphorin 4D (SEMA4D) as an emerging and important cancer target at the American Society of Clinical Oncology (ASCO)-Society for Immunotherapy of Cancer (SITC) Clinical Immuno-Oncology Symposium. Pepinemab is a monoclonal antibody that targets SEMA4D.
- Delivered a virtual presentation at the Advances in Alzheimer's and Parkinson's Therapies AAT-AD/PD™ Focus Meeting 2020 highlighting the potential of the company's lead candidate, the anti-Semaphorin 4D (SEMA4D) antibody pepinemab to regulate glial cell activation and neurodegeneration in Alzheimer's and Huntington's diseases.
- Announced financing agreements for an open market sale agreement with Jefferies LLC, including a related prospectus supplement for "at the market" sales of up to $11.5 million, and for an equity purchase agreement of up to $5 million with Keystone Capital Partners, LLC. Execution of these agreements depends on share price and market conditions.
- Raised gross proceeds of approximately $7.5 million through a private placement of 1,468,563 shares of the company's common stock in January 2020.

Pepinemab Clinical Updates:

- **Non-Small Cell Lung Cancer - CLASSICAL-Lung Clinical Trial**. The company's ongoing CLASSICAL-Lung study is evaluating pepinemab in combination with avelumab for the treatment of advanced (stage IIIB/IV) NSCLC. Of the 62 subjects enrolled in this phase 2 trial, four remain on study with continuing objective response or stable disease. Vaccinex has been invited to present near topline data at the virtual ASCO conference in late May 2020.
- **Huntington's Disease – SIGNAL Clinical Trial** . The company's ongoing, potentially pivotal, SIGNAL clinical trial is evaluating pepinemab for the treatment of Huntington's disease. As of March 31, 2020, 37 of the 265 study subjects enrolled in cohort B have not yet completed the planned 18 months of treatment. The majority (32/37) have completed 16 of the 18 monthly visits specified in the trial protocol. The company is working with clinical investigators and sites to safely complete remaining visits and assessments and to use statistical projections as necessary for what we estimate may be up to 10% of the remaining subjects who are unable to compete the final one or two visits due to the COVID-19 pandemic.
- **Alzheimer's Disease** . As announced in November 2019, the pepinemab development program has been expanded to include Alzheimer's disease based on findings from cohort A of the SIGNAL trial. The company had previously anticipated initiating a trial of pepinemab in Alzheimer's disease in mid-2020, but the initial enrollment date is now delayed. The extent of the delay is subject to evaluating further developments and risks related to the COVID-19 pandemic.
- In addition, the company's lead drug candidate, pepinemab is being evaluated in multiple investigator-sponsored trials (ISTs) in additional indications:
    - **Melanoma -** The UCLA School of Medicine, in collaboration with Bristol-Myers Squibb, is evaluating pepinemab in combination with the checkpoint inhibitors nivolumab and ipilimumab in a small cohort of patients with advanced melanoma whose tumors progressed during or following initial treatment with immunotherapy.
    - **Other Cancers -** Multiple "window of opportunity" trials are being conducted by the Winship Cancer Institute of Emory University to evaluate pepinemab in combination with checkpoint inhibitors in colorectal, pancreatic, head and neck cancer and melanoma.

"During the first quarter and subsequent period, we took significant steps that we believe strengthen our balance sheet as we look to conclusion of important trials of our lead clinical candidate pepinemab in both Huntington's disease and non-small cell lung cancer," said Maurice Zauderer, Ph.D., President and Chief Executive Officer of Vaccinex. "And while the COVID-19 pandemic has created unprecedented disruptions and uncertainty affecting clinical development timelines around the world, we continue to engage with our trial sites and, given the advanced stage of both trials, we do not currently anticipate that these trials will be materially impacted by the pandemic.

“In parallel, we continue to advance plans to leverage our work in Huntington’s disease and initiate a formal study of pepinemab in Alzheimer’s disease when trial sites are again permitted to safely enroll patients. Both Huntington’s and Alzheimer’s are slowly progressive neurodegenerative diseases characterized by the activation of inflammatory cells in the brain. As we recently presented at this year’s AAT-AD/PD™ Focus Meeting 2020, we believe pepinemab can block the upregulation of SEMA4D and the activation of glial cells in HD and AD patients, leading to a reduction in disease progression and improved long-term patient outcomes. We look forward to initiating our work in AD as soon as practicable,” Dr. Zauderer concluded.

Upcoming Expected Milestones:

- **May 2020 -** Near topline data from the CLASSICAL-Lung non-small cell lung cancer study to be presented at the virtual ASCO conference
- **May 2020 (ASCO) -** Interim analysis of combination Window-of-Opportunity studies at Emory University (melanoma, head and neck squamous cell carcinoma, colorectal and pancreatic cancer) expected.
- **Second half 2020 -** Anticipated publication of data from Cohort A of the SIGNAL Huntington’s disease trial.
- **Second half 2020 -** Anticipated enrollment of first patient in Alzheimer’s disease Phase 1 study, subject to effects of the COVID-19 pandemic.
- **October 2020 -** Topline data from Cohort B of SIGNAL Huntington’s disease study expected.

Financial Results for the Three Months Ended March 31, 2020:

Research and Development Expenses. Research and development expenses for the three months ended March 31, 2020 were $5.5 million as compared to $7.4 million for the comparable period in 2019. This decrease was attributable to fewer subjects enrolled in active clinical trials during the three months ended March 31, 2020.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2020 were $1.7 million, essentially flat with the comparable period in 2019.

Cash and Cash Equivalents and Marketable Securities. Cash and cash equivalents and marketable securities on March 31, 2020 were $2.5 million, as compared to $2.8 million on December 31, 2019. On March 27, 2020, Vaccinex announced an agreement with Jefferies and a related prospectus supplement pursuant to which the company may sell up to $11.5 million shares of its common stock from time to time through Jefferies as sales agent, and its agreement with Keystone, pursuant to which Keystone has agreed to purchase up to $5 million of shares of Vaccinex common stock at the company’s direction from time to time. Execution of these agreements depends on share price and market conditions.

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. Examples of forward-looking statements in this press release include, among others, statements about the expected timing and results of our ongoing clinical trials, our expectations regarding the impacts of the COVID-19 pandemic on our clinical trials and clinical data, and our expectations regarding the potential benefits, activity and effectiveness of our product candidates. 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, our ability to continue as a going concern, the impact on our operations and clinical trials of the current COVID-19 pandemic, uncertainties inherent in the execution, cost and completion of preclinical and clinical trials, uncertainties related to regulatory approval, our history of operating losses and need to raise additional capital, risks related to our dependence on our lead product candidate, pepinemab, 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 and the other risks and uncertainties described in our Form 10-K filed with the SEC on March 9, 2020 and subsequent periodic reports.

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