Vaccinex Announces Publication of Results from CLASSICAL-Lung Phase 1b/2 Clinical Trial in Non-Small Cell Lung Cancer in the Peer-Reviewed Journal Clinical Cancer Research

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CLASSICAL-Lung study evaluated pepinemab in combination with the checkpoint inhibitor BAVENCIO® for the treatment of non-small cell lung cancer

ROCHESTER, N.Y., April 21, 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 the publication of results from the company's CLASSICAL-Lung clinical trial in the journal *Clinical Cancer Research*, a publication of the American Association for Cancer Research (AACR). CLASSICAL-Lung was a Phase 1b/2 trial evaluating the company's lead clinical candidate, pepinemab, in combination with the immune checkpoint inhibitor BAVENCIO® (avelumab) for the treatment of non-small cell lung cancer (NSCLC).

The paper, entitled, "A Phase 1b/2 Study of Pepinemab in Combination with Avelumab in Advanced Non-Small Cell Lung Cancer," presents data showing that pepinemab is clinically active when combined with BAVENCIO® and was well tolerated, with no identified safety concerns. The combination appeared to halt or reverse tumor progression (partial response or stable disease) in a subset of both immunotherapy naïve patients, including patients with often difficult to treat PD-L1–negative or PD-L1–low tumors, and some patients with primary or acquired resistance to prior single-agent anti-PD-1/L1 therapy.

Among 21 evaluable immunotherapy naïve patients, most of whom had negative or low tumoral expression of the PD-L1 biomarker, five patients experienced partial responses, four patients evidenced clinical benefit at or greater than one year, and the disease control rate (DCR) was 81%. Notably, the objective response rate (ORR) with the combination therapy was higher than previously reported for single agent avelumab in the PD-L1 negative / low population. Among 29 evaluable patients who previously experienced disease progression during or following anti-PD-1/L1 immunotherapy, the subsequent combination treatment resulted in a DCR of 59%, including two partial responses and seven patients with durable clinical benefit of at least 23 weeks. Finally, exploratory biomarker analysis from biopsies demonstrated improved penetration of killer CD8+ T cells into the tumor.

Dr. Maurice Zauderer, President and CEO of Vaccinex, stated, "The results of the CLASSICAL-Lung study support our hypothesis that adding pepinemab to a checkpoint inhibitor for the treatment of NSCLC can shift the tumor microenvironment toward anti-tumor immunity and away from immunosuppression. This appears to enhance the efficacy of checkpoint inhibition, even in some patients who did not respond to prior anti-PD-1/L1 therapies. We are very pleased to have the full data set published in this prestigious peer-reviewed medical journal and look forward to the continued development of this promising combination for the treatment of NSCLC. We are particularly pleased to shortly begin a new study of the combination of pepinemab and Keytruda® (pembrolizumab) in front-line Head & Neck cancer."

The publication is now available electronically at: https://clincancerres.aacrjournals.org/content/early/2021/04/06/1078-0432.CCR-20-4792

About the CLASSICAL – Lung Clinical Trial

The design of the trial consisted of a 12-subject dose escalation phase to determine the recommended Phase 2 dose of pepinemab in combination with avelumab, followed by a 50-subject dose expansion phase. The study included a total of 21 evaluable patients who were immunotherapy naïve and 32 patients who were refractory or resistant to prior treatment with immune checkpoint inhibitors (predominantly anti–PD-1). The primary objective was to assess safety and tolerability. Secondary objectives included evaluation of efficacy, immunogenicity, and PK/PD. An exploratory objective was to identify candidate biomarkers of activity.

For more information: NCT03268057

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 our plans, expectations and objectives with respect to the results and timing of our clinical trials of pepinemab in various indications, the use and potential benefits of pepinemab in Huntington's and Alzheimer's disease 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 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, the impact of the COVID-19 pandemic, 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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