Vaccinex Reports Phase Ib KEYNOTE B84 Combination Study of Keytruda® and Pepinemab in Patients with Advanced, Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC) Passes Planned Interim Safety Analysis

January 4, 2022

Phase 1b segment evaluated safety and tolerability of the combination

Paves the way to expand and accelerate enrollment in the Phase 2 segment of the study

ROCHESTER, N.Y., Jan. 04, 2022 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX, Vaccinex, the Company), a clinical-stage biotechnology company pioneering a differentiated approach to treating cancer and neurodegenerative disease through the inhibition of SEMA4D, today reported positive interim safety data in the Phase Ib "safety run-in" segment of the KEYNOTE B84 combination study of Keytruda ® (Merck, NYSE: MRK, known as MSD outside of the United States and Canada) and pepinemab (Vaccinex) in patients with advanced, recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC). The Phase 2 segment of the study is now expected to begin enrollment and is expected to accelerate patient accrual.

The Phase Ib "safety run-in" segment of the trial (NCT04815720) was intended to evaluate the safety and tolerability of pepinemab (20 mg/kg) in combination with Keytruda (Merck's anti-PD-1 therapy, pembrolizumab, 200 mg Q3W/every three weeks) to determine a recommended Phase 2 dose (RP2D) for the dose expansion phase of the study enrolling patients with R/M HNSCC. The interim safety analysis was completed by the Data Safety Monitoring Board and signals initiation of the Phase 2 expansion segment.

"We are very pleased that the interim KEYNOTE B84 safety data indicated that the combination of pepinemab and Keytruda appears to be well tolerated," stated Maurice Zauderer, Ph.D., President and Chief Executive Officer. "Vaccinex hopes that the combination of pepinemab and an anti-PD-1 therapy for the treatment of advanced R/M HSNCC may result in improved patient benefits. There is strong rationale for development in HNSCC because these tumors express very high levels of SEMA4D and we believe that preclinical data indicated that this contributes to disease pathology. We look forward to progressing with the recruitment of the Phase 2 segment of the trial."

About the KEYNOTE B84 Study:

The KEYNOTE B84 combination study of Keytruda® (Merck's anti-PD-1 therapy, pembrolizumab) and pepinemab (Vaccinex's monoclonal antibody inhibitor of SEMA4D) is being conducted for first line treatment of patients with advanced, recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC). The study has two segments:

- **Segment 1**: The completed Phase 1b "safety run-in" segment assessed the safety and tolerability of the combination and defined a Recommended Phase 2 Dose (RP2D) in 3-6 subjects. After enrolling the first three subjects, the Data Safety Monitoring Board determined that the RP2D dose of pepinemab (20 mg/kg) and Keytruda (200 mg Q3W) was safe and well tolerated.
- **Segment 2**: The Phase 2 "expansion" segment is now expected to proceed to enroll up to 62 subjects across 19 U.S. trial sites. The primary objective of this segment is to evaluate Objective Response Rate (ORR) per Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 of the combination in immunotherapy naïve patients with advanced R/M HNSCC.

Secondary objectives of the study are to evaluate Progression-Free Survival (PFS) by RECIST 1.1, Overall Survival (OS), and Duration of Response (DOR).

The study is also expected to evaluate a number of exploratory measures including the pharmacokinetics (PK), pharmacodynamics (PD) and immunogenicity of the combination and a number of biomarkers and genomic tumor signatures.

Additional information about the study is available at: the KEYNOTE B84 clinicaltrials.gov link. Vaccinex anticipates interim results for the primary efficacy endpoint, ORR, in the second half of 2022.

Vaccinex will sponsor the study which is being performed in collaboration with Merck Sharp & Dohme Corp, a subsidiary of Merck and Co, Inc.

Vaccinex has global commercial and development rights to pepinemab.

Keytruda® is a trademark of Merck.

About Pepinemab
Pepinemab is a humanized IgG4 monoclonal antibody that inhibits SEMA4D, which regulates chronic inflammation in the tumor microenvironment. Preclinical/clinical data show that pepinemab promotes infiltration/activation of dendritic cells/ CD8+ T-cells and reverses immunosuppression within the tumor.

Results of a Phase 1b/2 study to evaluate the combination of pepinemab with checkpoint inhibitor, BAVENCIO®, (with Merck KGaA) were presented by Dr. Shafique, MD, Assistant Professor Thoracic Oncology, Moffitt Cancer Center, in an oral poster and discussion section at ASCO 2020 and were highlighted in the July 2021 publication of Clinical Cancer Research. Vaccinex reported that results of the Phase 1b/2 CLASSICAL-Lung trial showed a 25-33% Overall Response Rate (ORR) for patients with difficult to treat PD-L1 low/negative tumors treated with the combination, while reported ORR

for similar patients treated with anti-PD-L1 monotherapy is ~10-15%. The study report also indicated that pepinemab did not increase immune-related toxicities of BAVENCIO but increased penetration of cytotoxic T cells. The publication is available electronically at: Clinical Cancer Research.

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 it believes 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 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," "hope", "planned," "anticipate," "estimate," "intend," "hypothesis," "potential," "suggest", "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 the Company's most recent annual year end Annual Report on Form 10-K and subsequent filings with the SEC.

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Source: Vaccinex, Inc.