Vaccinex Reports 2022 Financial Results and Provides Corporate Update of Continued Progress in Neurology and Oncology Clinical Programs

April 3, 2023

Expect to complete patient enrollment in the randomized Phase 1/2a SIGNAL-AD Alzheimer's study in April 2023 with topline data anticipated mid-2024

Completed enrollment of 36 patients required for a pre-planned interim analysis of KEYNOTE B84 phase 1b/2 study in Head and Neck Squamous Cell Carcinoma

ROCHESTER, N.Y., April 03, 2023 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology company pioneering a differentiated approach to treating neurodegenerative disease and cancer through the inhibition of SEMA4D today announced financial results for the fourth quarter ended December 31, 2022 and provided a corporate update on key programs.

In 2022 and continuing in Q1 2023, Vaccinex has made important clinical progress in its major neurology and oncology programs. This month the company will complete enrollment in its ongoing phase 1/2a SIGNAL-AD clinical trial of pepinemab in Alzheimer's disease (AD), with topline data for this randomized, double-blind study anticipated in mid-2024 after the last enrolled patients will have received 12 months of treatment. Investors will recall that this study builds on exciting data obtained in the randomized phase 2 SIGNAL study of pepinemab in Huntington's disease (HD), another neurodegenerative disease with many similarities in pathology to AD. As published in *Nature Medicine (2022)*, Vaccinex employed the Huntington's Disease-Cognitive Assessment Battery (HD-CAB), a set of 6 assessments in different cognitive domains, to generate evidence of cognitive benefit and also demonstrated significantly reduced atrophy in the caudate region of brain and increased brain metabolic activity in multiple brain regions of patients treated with pepinemab. Recent failures of other HD treatment strategies, including Roche's large phase 3 study of tominersen, a huntingtin lowering agent, makes the further evaluation of our novel and independent therapeutic strategy even more compelling. We are exploring partnering/financing opportunities for a pivotal phase 3 study in HD while we continue our ongoing high priority SIGNAL-AD study in Alzheimer's disease.

In parallel, the company continues its clinical collaboration with Merck Sharp & Dohme in a phase 2 study testing Vaccinex's pepinemab SEMA4D blocking antibody in combination with Merck's anti-PD-1 checkpoint inhibitor, KEYTRUDA®, for first-line treatment of patients with head and neck cancer. As previously reported, we believe a key observation has been an apparently increased frequency of response to our combination immunotherapy in the heretofore more difficult to treat population of patients whose tumors express low levels of PD-L1 (CPS<20) relative to those that express high levels (CPS≥20). We believe the mechanistic bbasis for this effect include pepinemab-induced increases in the infiltration of cytotoxic T cells, reduced frequency of myeloid suppressor cells, and increased formation of efficient lymphoid structures in the tumor. We have now completed enrollment of 36 patients required for a pre-planned interim analysis of tumor responses which we expect will be completed in mid-May. We plan to publicize results by early June after meeting with Merck to discuss the next steps in clinical development of this novel combination of pepinemab with KEYTRUDA® for improved cancer immunotherapy.

Recent Milestones:
Neurodegenerative Disease:

- A commentary summarizing the learnings from the SIGNAL HD study and their implications for other slowly progressive neurodegenerative diseases such as Alzheimer's was published in *Clinical and Translational Medicine* (January, 2023).

Oncology:

- The Phase 1b/2 KEYNOTE B-84 study reached required enrollment of 36 patients for a pre-planned interim analysis.
- Data from two investigator-sponsored studies in melanoma and metastatic breast cancer were presented at the Society for Immunotherapy in Cancer 2022 Annual Meeting (SITC 2022).

  Investigators from the *Winship Cancer Institute of Emory University* presented data from a study evaluating neoadjuvant treatment with pepinemab in combination with nivolumab and/or ipilimumab in resectable Stage III melanoma followed by surgical resection and adjuvant treatment with nivolumab alone (NCT03769155). 100% of patients who received neoadjuvant treatment with the triple combination of pepinemab, nivolumab and ipilimumab were recurrence free at 24 months. This contrasted with recurrence free survival of less than 40% in patients who received neoadjuvant treatment with the dual combination of pepinemab and nivolumab or pepinemab and ipilimumab. Importantly, tumors from patients receiving pepinemab combination treatments exhibited organized tertiary lymphoid structures, which facilitate productive immunity and correlated with improved recurrence free survival.

  Investigators from the *Moffitt Cancer Center* presented data from a study evaluating pepinemab in combination with adoptive cell therapy in patients with HER2+ metastatic breast cancer (NCT05378464). Preclinical studies previously showed that SEMA4D antibody blockade, in combination with a dendritic cell vaccine, improved trafficking of dendritic cells to tumors, stimulating expansion of tumor-specific B and T cells and resulting in improved regression of primary and distant tumors. A Phase 1/2 trial evaluating the combination of pepinemab and trastuzumab with a dendritic cell vaccine, followed

by adoptive transfer of expanded autologous CD4+ T cells, continues to enroll patients with HER2+ metastatic breast cancer at the Moffitt Cancer Center.

- Enrollment was initiated in the Phase 1b/2 single-arm, open label study to evaluate pepinemab in combination with avelumab (Bavencio®) as second line combination therapy for patients with metastatic pancreatic adenocarcinoma (PDAC, NCT05102721). Preclinical studies in PDAC models as well as prior clinical studies suggest that treatment with the semaphorin 4D (SEMA4D) blocking antibody, pepinemab, promotes the infiltration and activation of dendritic cells and CD8+ cells in the tumor microenvironment, rendering "cold" tumors such as PDAC to become "hot", leading to enhanced efficacy of checkpoint inhibitors such as avelumab.

Vaccinex has exclusive global commercial and development rights to pepinemab and is a sponsor of the KEYNOTE-B84 study which is being performed in collaboration with Merck Sharp & Dohme Corp, a subsidiary of Merck and Co, Inc. Kenilworth, NJ, USA. KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp.
Avelumab is being provided by Merck KGaA, Darmstadt, Germany and Pfizer, Inc. for the PDAC NCT05102721 study. Avelumab is co-developed and co-commercialized by Merck KGaA, Darmstadt, Germany and Pfizer Inc.

ActivMAb Platform Technology:

- The company is engaged in multiple biopharmaceutical collaborations employing this enabling technology for drug discovery. Vaccinex's partner, Surface Oncology, announced the initiation of a Phase 1/2 study for SRF114, a fully human monoclonal antibody targeting CCR8 selected by Vaccinex, for the potential treatment of solid tumors. SRF114 is the first clinical candidate to be selected employing the ActivMAb platform and initiation of this clinical study triggered a milestone payment.

Financial Results for the Year Ended December 31, 2022:

Cash and Cash Equivalents and Marketable Securities. Cash and cash equivalents and marketable securities on December 31, 2022 were $6.4 million, as compared to $8.6 million as of December 31, 2021. During the year ended December 31, 2022 the Company completed private placements of our common stock to various investors for gross proceeds of $13.5 million. No warrants, derivatives or financial covenants are associated with the stock purchase agreements. Additionally, the Company sold 3,189,411 shares of the Company's common stock through the Open Market Sale Agreement in 2022, for total net proceeds of $3.6 million.
Research and Development Expenses. Research and development expenses for the year ended December 31, 2022 were $14.0 million as compared to $17.2 million for the comparable period in 2021.

The decline in research and development expenses reflects completion of the final analysis of the SIGNAL HD study along with consistent clinical trial costs to support the pepinemab Phase 1b/2 KEYNOTE B84 study in R/M HNSCC and Phase 1/2a study in Alzheimer's Disease and continued careful cost control measures.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2022 were $6.2 million as compared to $6.2 million for the comparable period in 2021. Essentially flat level of general and administrative expenses reflects careful cost control measures.

Comprehensive loss/Net loss per share. The Comprehensive Loss and Net loss per share for the quarter ended December 31, 2022 was $19.8 million and $(0.47) compared to $22.4 million and $(0.78) for the comparable period in 2021.

Full financial tables are included below. For further details on Vaccinex's financials, refer to its Form 10-K filed March 31, 2023 with the SEC.

About Pepinemab
Pepinemab is a humanized IgG4 monoclonal antibody that inhibits SEMA4D, which regulates the actin cytoskeleton of cells that plays an important role in inflammatory reactions in the brain as well as in tumor immune evasion. Data show that by preventing deleterious inflammatory gliosis during disease progression, pepinemab preserves normal function of astrocytes and microglia, two types of glial cells that play a crucial role in the development and maintenance of neurons in the brain. Additional preclinical and clinical data show that pepinemab promotes infiltration and activation of dendritic cells and CD8+ T-cells and reverses immunosuppression within the tumor microenvironment. Pepinemab is being evaluated in several studies in neurodegenerative disease and oncology.

About ActivMAb®
Vaccinex has developed a proprietary mammalian cell-based antibody discovery platform with unique multi-pass membrane target capabilities. The ActivMAb technology now has four main applications: native presentation of complex membrane antigens including GPCRs and ion channels, antibody and antigen discovery, and protein optimization. Vaccinex has entered into an antibody license with Surface Oncology (Cambridge, MA) and the company is engaged in multiple biopharmaceutical collaborations employing this enabling technology for drug discovery, including Material Transfer Agreements for drug discovery or process development with pharmaceutical and biotech companies.

About Vaccinex, Inc.

Vaccinex, Inc. is pioneering a differentiated approach to treating slowly progressive neurodegenerative diseases (NDD) and cancer through the inhibition of semaphorin 4D (SEMA4D). The Company's lead drug candidate, pepinemab, blocks SEMA4D, a potent biological effector that it believes triggers inflammation and loss of function in chronic diseases of the brain and prevents immune infiltration into tumors. In NDD, pepinemab is being studied as a monotherapy in a Phase 1/2a study in the 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 B-84 study in recurrent or metastatic head and neck cancer (R/M 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 and melanoma. The Company has also developed a proprietary drug discovery platform, ActivMAb, that it is leveraging through strategic collaborations, particularly by applying its unique capability to select high value antibodies against important multi-pass membrane receptors.

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 the KEYNOTE-B84 clinical trial, planned interim analysis, the use and potential benefits of pepinemab in R/M HNSCC, lung cancer, metastatic pancreatic adenocarcinoma and other indications, the potential for benefits as compared to single agent KEYTRUDA or BAVENCIO, the expected timeline for publication and disclosure of trial results, and other statements identified by words such as "may," "will," "expect," "planned," "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 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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VACCINEX, INC.

Consolidated Balance Sheets
(in thousands, except share and per share data)

ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,391	$ 8,589
Accounts receivable	175	-
Prepaid expenses and other current assets	912	816
Total current assets	7,478	9,405
Property and equipment, net	189	297
Operating lease right-of-use asset	310	141
TOTAL ASSETS	$ 7,977	$ 9,843
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,518	$ 1,061
Accrued expenses	781	980
Current portion of long-term debt	74	74
Operating lease liability	164	141
Total current liabilities	2,537	2,256
Long-term debt	101	175
Operating lease liability, net of current portion	146	-
TOTAL LIABILITIES	2,784	2,431
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit):		
Common stock, par value of $0.0001 per share; 100,000,000 shares authorized as of December 31, 2022, and December 31, 2021; 49,881,613 and 30,801,962 shares issued as of December 31, 2022 and December 31, 2021, respectively; 49,880,761 and 30,801,110 shares outstanding as of December 31, 2022 and December 31, 2021, respectively	5	3
Additional paid-in capital	324,875	307,281
Treasury stock, at cost; 852 shares of common stock as of December 31, 2022 and 2021, respectively	(11)	(11)
Accumulated deficit	(319,676)	(299,861)
TOTAL STOCKHOLDERS' EQUITY	5,193	7,412

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 7,977	$ 9,843

VACCINEX, INC.

Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,	
	2022	**2021**
Revenue	$ 275	$ 900
Costs and expenses:		
Research and development	13,979	17,160
General and administrative	6,202	6,230
Total costs and expenses	20,181	23,390
Loss from operations	(19,906)	(22,490)
Interest expense	(2)	(809)
Gain on forgiveness of PPP loan	-	876
Other income (expense), net	93	43
Loss before provision for income taxes	(19,815)	(22,380)
Provision for income taxes	-	-
Comprehensive loss	$ (19,815)	$ (22,380)
Net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (0.47)	$ (0.78)
Weighted-average shares used in computing net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	42,437,225	28,849,197

Source: Vaccinex, Inc.