Vaccinex Reports Second Quarter 2022 Results and Provides Corporate Update; Excellent Progress in Pepinemab Clinical Programs

August 15, 2022

Promising initial responses in continuing Phase 1b/2 KEYNOTE B84 study of pepinemab with KEYTRUDA® in Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma

Phase 2 SIGNAL-HD Study Published in Nature Medicine

Patient enrollment continues in the Phase 1/2a SIGNAL-AD Alzheimer's study

ROCHESTER, N.Y., Aug. 15, 2022 (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, 2022 and provided a corporate update on key events since April, 2022 (the last 5 months).

"Vaccinex has made excellent progress this year in its clinical programs to evaluate the potential use of our proprietary SEMA4D inhibitor, pepinemab, in oncology and neurodegenerative disease," said Maurice Zauderer, Ph.D., President and Chief Executive Officer of Vaccinex. "We have previously reported several promising responses in the open label, Phase 1b/2 KEYNOTE oncology B84 trial to evaluate pepinemab and KEYTRUDA® (pembrolizumab, a PD-1 inhibitor) in patients with advanced recurrent or metastatic head and neck cancer (R/M HNSCC). An expanded interim analysis of study data is planned in Q4 2022. With continued positive results, we are hopeful that this combination could be a promising treatment option for patients with R/M HNSCC who have limited treatment choices,"

Dr. Zauderer continued, "Vaccinex is also very pleased to announce the recent publication of the results of the Phase 2 SIGNAL study of pepinemab in Huntington's Disease (HD) in *Nature Medicine*. This is an important milestone for the neurodegenerative disease program. While, as previously reported, the study did not meet its pre-specified primary endpoints, we believe the results provide compelling signals of cognitive benefit, evidenced by multiple exploratory and post-hoc efficacy assessments, and support further development in HD and other neurodegenerative indications including Alzheimer's disease. Importantly, treatment resulted in a statistically significant increase in brain metabolic activity (measured by FDG-PET) in 15 of 26 brain regions of patients with Early Manifest HD. Multiple studies have shown that reduced FDG-PET signal correlates with cognitive decline and clinical progression in Alzheimer's Disease (AD). Based on these observations, we are excited to have initiated the randomized, double-blind, Phase 1/2a SIGNAL-AD study in 40 subjects with early AD. We expect this study will complete enrollment by Q1 2023."

Dr. Zauderer continued, "Vaccinex's clinical programs in oncology and neurodegenerative disease are poised to yield important data over the next twelve to eighteen months. We look forward to updating the clinical community and investors on our progress and thank all of the patients, caregivers, and participating clinical sites and investigators for their continued support of these promising clinical programs."

Recent Milestones:

Oncology:

- Initial data from the ongoing Phase 1b/2 KEYNOTE-B84 study in R/M HNSCC was published in the ASCO proceedings (May 26, 2022) and at the American Association for Cancer Research (AACR 2022) (April 11, 2022)

Neurodegenerative Disease:

- Results of the Phase 2 SIGNAL-HD study were published in *Nature Medicine* (Feigin et al., August 2022)
- Posters related to the ongoing Phase 1/2a SIGNAL-AD study was presented at the 2022 American Academy of Neurology (AAN) Annual Meeting (April 2022) and at the Alzheimer's Association International Conference (July 2022)

ActivMAb Platform Technology:

- Advances in use of the ActivMAb® platform to select antibodies against difficult multi-pass membrane targets (e.g. GPCR and ion channels) were reported at the PEGS Boston Conference & Expo (May 2022)
- The company is engaged in multiple biopharmaceutical collaborations employing this technology for drug discovery. An IND for the first such clinical product is expected to be filed in 2023.

Upcoming Milestones:

Head and Neck Cancer: **Phase 1b/2 KEYNOTE B84 study**

- Interim analysis: Expected Q4 2022
- Completion of enrollment: Expected by H1 2023

Alzheimer's Disease: Phase 1/2a SIGNAL-AD study

- Completion of enrollment: Expected by Q1 2023
- Topline data: Expected H2 2023

Pepinemab Program Overview:

Oncology: Head and Neck Cancer

Rationale: 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, there is strong rationale for development in this indication.

Status: Enrollment is underway in the Phase 1b/2 KEYNOTE B84 clinical study evaluating pepinemab in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in recurrent or metastatic head and neck cancer. The study was designed to enroll up to 65 subjects across 18 U.S. trial sites to assess safety and efficacy of the combination pepinemab/pembrolizumab. Key endpoints of the study will include objective response, duration of response and overall survival.

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., a subsidiary of Merck & Co. Inc., Kenilworth, NJ, USA.

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" biomarker studies of head and neck cancer and melanoma.

Neurodegenerative Disease:

Rationale: SEMA4D appears to be upregulated on damaged neurons in the brains of people with either Huntington's Disease (HD) or Alzheimer's Disease (AD), leading to physiological changes in the structure and function of the major inflammatory cells of the brain, astrocytes and microglia, that express receptors for SEMA4D. Preclinical studies conducted by Vaccinex have shown that pepinemab can inhibit SEMA4D and reverse neuroinflammation and restore normal functions associated with astrocytes.

Alzheimer's Disease: The Phase 1/2a SIGNAL-AD Study **.** Enrollment is underway in this randomized, double-blind, placebo-controlled, multi-center safety and biomarker study of pepinemab in early AD. The study is planned to enroll 40 subjects across 15 U.S. trial sites. The trial is being funded in part by the Alzheimer's Drug Discovery Foundation and by the Alzheimer's Association under their 2020 Part the Cloud Program.

Financial Results for the Three Months Ended June 30, 2022:
Cash and Cash Equivalents and Marketable Securities. Cash and cash equivalents and marketable securities on June 30, 2022 were $11.4 million, as compared to $8.6 million as of December 31, 2021.

Research and Development Expenses. Research and development expenses for the quarter ended June 30, 2021 were $3.8 million as compared to $4.1 million for the comparable period in 2021.

The slight reduction in Research and Development expenses in the period ended June 30, 2022 compared to 2021 is primarily attributed to reduced clinical trial costs as a result of the completion of the CLASSICAL-Lung and SIGNAL studies phase 2 trials, partially offset by setup expenses for the SIGNAL-AD and HNSCC KEYNOTE-B84 studies.

General and Administrative Expenses. General and administrative expenses for the quarter ended June 30, 2022 were $1.6 million as compared to $1.6 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 June 30, 2022 was $5.4 million and $(0.13) compared to $6.0 million and $(0.21) for the comparable period in 2021.

Full financial tables are included below. For further details on Vaccinex's financials, refer to its Form 10-Q filed August 15, 2022 with the S.E.C.

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 tumor immunity and in inflammatory reactions in the brain. Preclinical and clinical data show that by preventing inflammatory reactivity pepinemab 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 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 oncology and neurodegenerative disease.

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: complex membrane antigen presentation, antibody or antigen discovery, and protein optimization. Vaccinex has entered into an antibody license with Surface Oncology (Cambridge, MA) and into Material Transfer Agreements for drug discovery or process development with two major pharma utilizing this technology.

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 inflammation in chronic diseases of the brain. Pepinemab is being evaluated in a Phase 1b/2 study in recurrent or metastatic head and neck cancer and in a Phase 1/2a study in Alzheimer's Disease, with ongoing exploration of potential Phase 3

development in Huntington's disease. The Company has also developed a proprietary drug discovery platform, ActivMAb ®, that it is leveraging thru strategic collaborations, particularly by exploiting 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 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," "poised," "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 and 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, enrollment and completion of preclinical studies 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 year-end Annual Report on Form 10-K and subsequent filings with the SEC.

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VACCINEX, INC.

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

	As of June 30, 2022	As of December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,400	$ 8,589
Prepaid expenses and other current assets	861	816
Total current assets	12,261	9,405
Property and equipment, net	254	297
Operating lease right-of-use asset	57	141
TOTAL ASSETS	$ 12,572	$ 9,843
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 265	$ 1,061
Accrued expenses	1,095	980
Current portion of long-term debt	74	74
Operating lease liability	57	141
Total current liabilities	1,491	2,256
Long-term debt	138	175
TOTAL LIABILITIES	1,629	2,431
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, par value of $0.0001 per share; 100,000,000 shares authorized as of June 30, 2022, and December 31, 2021; 42,664,903 and 30,801,962 shares issued as of June 30, 2022 and December 31, 2021, respectively; 42,664,051 and 30,801,110 shares outstanding as of June 30, 2022 and December 31, 2021, respectively	4	3
Additional paid-in capital	320,789	307,281
Treasury stock, at cost; 852 shares of common stock as of June 30, 2022 and December 31, 2021, respectively	(11)	(11)
Accumulated deficit	(309,839)	(299,861)
TOTAL STOCKHOLDERS' EQUITY	10,943	7,412
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 12,572	$ 9,843

The accompanying notes are an integral part of these condensed consolidated financial statements.

VACCINEX, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenue	$ -	$ -	$ -	$ 850
Costs and expenses:				
Research and development	3,843	4,064	6,809	9,577
General and administrative	1,558	1,605	3,186	3,182
Total costs and expenses	5,401	5,669	9,995	12,759
Loss from operations	(5,401)	(5,669)	(9,995)	(11,909)
Interest expense	(1)	(351)	(2)	(683)
Other income, net	19	51	19	49
Loss before provision for income taxes	(5,383)	(5,969)	(9,978)	(12,543)
Provision for income taxes	-	-	-	-
Net loss	(5,383)	(5,969)	(9,978)	(12,543)
Net loss attributable to noncontrolling interests	-	-	-	-
Net loss attributable to Vaccinex, Inc. common stockholders	$ (5,383)	$ (5,969)	$ (9,978)	$ (12,543)
Comprehensive loss	$ (5,383)	$ (5,969)	$ (9,978)	$ (12,543)
Net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (0.13)	$ (0.21)	$ (0.25)	$ (0.47)
Weighted-average shares used in computing net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	42,664,051	28,577,779	40,711,167	26,897,283

The accompanying notes are an integral part of these condensed consolidated financial statements.

Source: Vaccinex, Inc.