Vaccinex Reports Third Quarter 2022 Results and Provides Corporate Update

November 14, 2022

Continued Progress in Pepinemab Oncology and Neurology Clinical Programs

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

Patient enrollment continues in the Phase 1b/2 KEYNOTE B84 oncology and Phase 1/2a SIGNAL-AD Alzheimer's studies

Several posters and presentations expected at November Medical Meetings, the Society for Immunotherapy of Cancer (SITC 2022) and Huntington's Study Group (HSG 2022)

ROCHESTER, N.Y., Nov. 14, 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 third quarter ended September 30, 2022 and provided a corporate update on key programs.

"Vaccinex continues to advance clinical development of our proprietary product candidate, pepinemab, a SEMA4D inhibitor, in oncology and neurodegenerative disease," said Maurice Zauderer, Ph.D., President and Chief Executive Officer of Vaccinex. "In the open label, Phase 1b/2 KEYNOTE B84 trial (NCT04815720) to evaluate immunotherapy with pepinemab and KEYTRUDA® (pembrolizumab, a PD-1 inhibitor) in patients with recurrent or metastatic head and neck cancer (R/M HNSCC), we initially reported 2 confirmed complete responses (CRs) in patients whose tumors expressed low levels of PD-L1 biomarker (CPS<20), a subset of HNSCC patients who have had historically low response rates to anti-PD-1/L1 antibodies administered as single agents. We continue to observe a pattern of improved responses in this difficult to treat patient population and expect to report results of interim analysis from this study in 1Q 2023."

Dr. Zauderer continued, "Vaccinex is also very pleased to publish the full results of the SIGNAL phase 2 study of pepinemab treatment in Huntington's disease (HD) in Nature Medicine (available here). While multiple prior clinical interventions in HD, including several recent trials of genetic interventions that aimed to inhibit expression of mutant huntingtin protein, were widely reported to have failed to provide benefit to patients, we believe pepinemab is the only clinical intervention to date that shows promise of preventing or reducing cognitive decline in HD patients. A major challenge in HD drug development has been that, in contrast to Alzheimer's disease, there is currently no established measure of cognition in HD that is accepted as intrinsically meaningful by US and European regulators. We believe the SIGNAL study provided compelling evidence that the Huntington's Disease-Cognitive Assessment Battery (HD-CAB) can be a useful measure of the ability to learn, which we believe is intrinsically meaningful to patients. We are currently preparing briefing materials and a request for a meeting with FDA in early 2023 to discuss (i) use of HD-CAB as a surrogate endpoint likely to predict clinical benefit, and that could potentially support accelerated approval, and (ii) incorporation of HD-CAB in the design of a larger confirmatory pivotal study to support regular approval. Separately, we expect to complete enrollment of patients in the randomized, double-blind, Phase 1/2a SIGNAL-AD clinical trial in Alzheimer's Disease (NCT04381468) in 1H 2023 with topline results of 12-months treatment with pepinemab expected in 2024."

Recent Milestones:
Oncology:

- Data from an investigator-sponsored study at The Winship Cancer Institute of Emory University 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) was presented at the 2022 European Society for Medical Oncology (September 2022). 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.

Neurodegenerative Disease:

- Full results of the Phase 2 SIGNAL-HD study were published in *Nature Medicine* (Feigin et al., August 2022)
- Results of detailed pepinemab mechanism of action studies in neurodegenerative disease were published in the *Journal of Neuroinflammation* (Evans et al., August 2022)
- Posters related to the ongoing Phase 1/2a SIGNAL-AD study were presented at the Alzheimer's Association International Conference (July 2022)
- Poster related to the Phase 2 SIGNAL study of pepinemab as a treatment for early HD was presented at the European Huntington's Disease Network 2022 (September 2022)

ActivMAb Platform Technology:

- The company is engaged in multiple biopharmaceutical collaborations employing this enabling 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 and Oncology updates**

- Presentation of biomarker data from the investigator-sponsored study evaluating neoadjuvant pepinemab in combination with nivolumab and/or ipilimumab in resectable Stage III melanoma to be presented at the Society for Immunotherapy of Cancer (SITC) 2022: November 11, 2022
- Poster related to "Phase I Study of Adoptive T Cell Therapy Following HER2-Pulsed Dendritic Cell Vaccine and Pepinemab/Trastuzumab in Patients with Metastatic HER2-Positive Breast Cancer (MBC)" presented at SITC 2022: November 10-11, 2022
- Interim analysis of KEYNOTE B84: Expected Q1 2023

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

- Completion of enrollment: Expected in H1 2023 with topline results of 12-months treatment with pepinemab expected in 2024.

Financial Results for the Three Months Ended September 30, 2022:
Cash and Cash Equivalents and Marketable Securities. Cash and cash equivalents and marketable securities on September 30, 2022 were $7.2 million, as compared to $8.6 million as of December 31, 2021.

Research and Development Expenses. Research and development expenses for the quarter ended September 30, 2022 were $3.4 million as compared to $3.6 million for the comparable period in 2021.

The essentially flat level of research and development expenses reflects 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 study along with continued careful cost control measures.

General and Administrative Expenses. General and administrative expenses for the quarter ended September 30, 2022 were $1.4 million as compared to $1.5 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 September 30, 2022 was $4.8 million and $(0.11) compared to $5.2 million and $(0.17) for the comparable period in 2021.

Full financial tables are included below. For further details on Vaccinex's financials, refer to its Form 10Q filed November 14, 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 of 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 pharmaceutical companies 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 diseases and other indications, and other statements identified by words such as "may," "will," "appears," "expect," "hope", "planned," "poised," "promising," "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, our ability to continue as a going concern, our ability to maintain the listing of our common stock on Nasdaq, the impact of inflation on our expenses and business, 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.

Investor Contact: John Mullaly
LifeSci Advisors, LLC
617-429-3548
jmullaly@lifesciadvisors.com

VACCINEX, INC.

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

	As of September 30, 2022	As of December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,186	$ 8,589
Accounts receivable	50	-
Prepaid expenses and other current assets	789	816
Total current assets	8,025	9,405
Property and equipment, net	236	297
Operating lease right-of-use asset	351	141
TOTAL ASSETS	$ 8,612	$ 9,843
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities:		
Accounts payable	$ 494	$ 1,061
Accrued expenses	1,256	980
Current portion of long-term debt	74	74
Operating lease liability	163	141
Total current liabilities	1,987	2,256
Long-term debt	119	175
Operating lease liability, net of current portion	188	-
TOTAL LIABILITIES	2,294	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 September 30, 2022, and December 31, 2021; 42,664,903 and 30,801,962 shares issued as of September 30, 2022 and December 31, 2021, respectively; 42,664,051 and 30,801,110 shares outstanding as of September 30, 2022 and December 31, 2021, respectively	4	3
Additional paid-in capital	320,923	307,281
Treasury stock, at cost; 852 shares of common stock as of September 30, 2022 and December 31, 2021, respectively	(11)	(11)
Accumulated deficit	(314,598)	(299,861)
TOTAL STOCKHOLDERS’ EQUITY	6,318	7,412
TOTAL LIABILITIES AND STOCKHOLDERS’ EQUITY	$ 8,612	$ 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	$ 50	$ 50	$ 50	$ 900
Costs and expenses:				
Research and development	3,429	3,629	10,238	13,206
General and administrative	1,413	1,484	4,599	4,666
Total costs and expenses	4,842	5,113	14,837	17,872

Loss from operations	(4,792)	(5,063)	(14,787)	(16,972)
Interest expense	(1)	(142)	(2)	(825)
Other income (expense), net	34	(1)	52	48
Loss before provision for income taxes	(4,759)	(5,206)	(14,737)	(17,749)
Provision for income taxes	-	-	-	-
Net loss	(4,759)	(5,206)	(14,737)	(17,749)
Net loss attributable to noncontrolling interests	-	-	-	-
Net loss attributable to Vaccinex, Inc. common stockholders	$ (4,759)	$ (5,206)	$ (14,737)	$ (17,749)
Comprehensive loss	$ (4,759)	$ (5,206)	$ (14,737)	$ (17,749)
Net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (0.11)	$ (0.17)	$ (0.36)	$ (0.63)
Weighted-average shares used in computing net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	42,664,051	30,801,110	41,362,128	28,198,559

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

Source: Vaccinex, Inc.