Vaccinex Reports Third Quarter 2021 Financial Results and Provides Corporate Update

11/08/21

Enrollment underway in combination Phase 1b/2 *study of pepinemab with KEYTRUDA® in Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC)*

Patient screening and enrollment underway in Phase 1/2a study of pepinemab in Alzheimer's disease

Engaged in partnering discussions for a randomized Phase 3 trial in Huntington's disease

ROCHESTER, N.Y., Nov. 08, 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 financial results for the third quarter ended September 30, 2021 and provided a corporate update.

"We made steady progress on our pepinemab clinical programs since our last quarterly update. Enrollment is now underway in the Phase 1b/2 head and neck cancer trial and the Phase 1/2a Alzheimer's disease trial, two of the serious indications in which SEMA4D is overexpressed and is believed to contribute to disease pathology," stated Maurice Zauderer, Ph.D., President and Chief Executive Officer.

"As presented at the September European Huntington's Disease Network meeting, we believe post-hoc analysis of the Phase 2, SIGNAL trial of pepinemab in patients with early manifest Huntington's disease (HD) supports the potential cognitive benefit of treatment with pepinemab in HD patients, particularly those with mild advanced disease. We are engaged in discussions with potential partners for the advancement of this important program."

Pepinemab Clinical Updates:

Head and Neck Cancer. Enrollment is underway in the Phase 1b/2 clinical trial evaluating pepinemab in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in advanced recurrent or metastatic head and neck cancer.

The study will enroll up to 65 subjects across 18 U.S. trial sites and will assess whether combination therapy can improve responses in this population. Key endpoints of the study will include objective response, progression free survival and overall survival. Vaccinex anticipates data from this study in the second half of 2022.

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.

- **Alzheimer's Disease.** Patient screening and enrollment have been initiated in the Phase 1/2a clinical trial of pepinemab in Alzheimer's disease. The Alzheimer's trial is being funded in part by the Alzheimer's Drug Discovery Foundation by the Alzheimer's Association under the 2020 Part the Cloud Program.

  The randomized, double-blind, placebo-controlled, multi-center safety and biomarker study of pepinemab in early AD is planned to enroll 40 subjects across 14 U.S. trial sites. Vaccinex anticipates topline data from this study in late 2022 or early 2023.

- **Huntington's disease.** We believe that post-hoc analysis of the Phase 2, double-blind, placebo-controlled SIGNAL trial of pepinemab in patients with early manifest Huntington's disease (HD) supports the potential cognitive benefit of treatment with pepinemab in HD patients, particularly those with mild cognitive deficits.
  - Highly significant improvement (p=0.007) in the (Huntington's Disease Cognitive Assessment Battery (HD-CAB) Composite score, a widely employed measure comprised of 6 different cognitive assessments.
  - Significant benefit in reducing apathy severity (p=0.017, 1-sided), a problem behavior that has previously been correlated with cognition in both HD and AD.
  - Striking increase in brain metabolic activity as measured by FDG-PET in most brain regions. Decline in FDG-PET signal has been reported to correlate with cognitive decline in several studies of AD.

  The company continues to actively explore advancing pepinemab into a Phase 3 HD trial in collaboration with a biopharmaceutical partner; discussions are ongoing.

- **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" studies in head and neck cancer and melanoma.

Upcoming Anticipated Milestones:

- **H2:2022–** Meaningful data from open label head and neck cancer trial

- **Late 2022/Early 2023 –** Topline data from randomized Alzheimer's trial

ActivMAb® Updates:

As previously announced, we have entered into several collaborations with pharmaceutical and biotechnology companies employing the unique capabilities of our ActivMAb® antibody discovery platform to address difficult to drug G-protein Coupled Receptors (GPCRs) known to be strongly associated with diseases. "We believe this enabling technology will allow us and our collaborators to address significant market opportunities," said Ernest S. Smith, Ph.D., Chief Scientific Officer.

Financial Results for the Three Months Ended September 30, 2021:

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2021 were $3.6 million as compared to $7.3 million for the comparable period in 2020.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2021 were $1.5 million as compared to $1.9 million for the comparable period in 2020.

Cash and Cash Equivalents and Marketable Securities. Cash and cash equivalents and marketable securities on September 30, 2021 were $13.8 million, as compared to $10.6 million as of December 31, 2020.

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 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," "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 Form 10-K for year end December 31, 2021 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 September 30, 2021	As of December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,741	$ 10,596
Accounts receivable	50	157
Prepaid expenses and other current assets	1,071	533
Total current assets	14,862	11,286
Property and equipment, net	327	416
TOTAL ASSETS	$ 15,189	$ 11,702
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 957	$ 3,169

Accrued expenses	1,208	1,937
Senior secured convertible debt, net	-	8,074
Total current liabilities	2,165	13,180
Long-term debt	1,134	1,134
TOTAL LIABILITIES	3,299	14,314
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, 2021, and December 31, 2020; 30,801,962 and 22,388,027 shares issued as of September 30, 2021 and December 31, 2020, respectively; 30,801,110 and 22,387,175 shares outstanding as of September 30, 2021 and December 31, 2020, respectively	3	3
Additional paid-in capital	307,128	250,914
Treasury stock, at cost; 852 shares of common stock as of September 30, 2021 and December 31, 2020, respectively	(11)	(11)
Accumulated deficit	(295,230)	(277,481)
Total Vaccinex, Inc. stockholders' equity (deficit)	11,890	(26,575)
Noncontrolling interests	-	23,963
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	11,890	(2,612)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 15,189	$ 11,702

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,	
	2021	2020	2021	2020
Revenue	$ 50	$ 625	$ 900	$ 625
Costs and expenses:				
Cost of revenue	-	2	-	2
Research and development	3,629	7,334	13,206	17,300
General and administrative	1,484	1,872	4,666	5,565
Total costs and expenses	5,113	9,208	17,872	22,867
Loss from operations	(5,063)	(8,583)	(16,972)	(22,242)
Interest expense	(142)	(148)	(825)	(150)
Other income (expense), net	(1)	(23)	48	(14)
Loss before provision for income taxes	(5,206)	(8,754)	(17,749)	(22,406)
Provision for income taxes	-	-	-	-
Net loss	(5,206)	(8,754)	(17,749)	(22,406)
Net loss attributable to noncontrolling interests	-	-	-	-
Net loss attributable to Vaccinex, Inc. common stockholders	$ (5,206)	$ (8,754)	$ (17,749)	$ (22,406)
Comprehensive loss	$ (5,206)	$ (8,754)	$ (17,749)	$ (22,406)
Net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (0.17)	$ (0.44)	$ (0.63)	$ (1.27)
Weighted-average shares used in computing net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	30,801,110	20,074,726	28,198,559	17,587,219

Source: Vaccinex, Inc.