Vaccinex Reports 2021 Financial Results and Provides Corporate Update

March 31, 2022

Promising responses in Phase 1b segment of the open-label KEYNOTE B84 study of pepinemab with KEYTRUDA® in Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma (R/M HNSCC);

Enrollment in Phase 2 expansion underway

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

ROCHESTER, N.Y., March 31, 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 year ended December 31, 2021 and provided a corporate update on key events since the start of 2021.

"I am pleased to report that the last 15 months have been extremely productive for Vaccinex. We are advancing the development of pepinemab for oncology and neurodegenerative disease and have made good progress in each of the clinical programs in these diseases. These programs build on a comprehensive body of prior preclinical and clinical studies that provide a strong foundation of understanding of the mechanism of action of this novel immunomodulator," said Maurice Zauderer, Ph.D., President and Chief Executive Officer of Vaccinex.

Dr. Zauderer continued, "In the open label, Phase 1b/2 KEYNOTE-B84 trial of pepinemab in combination with KEYTRUDA® (pembrolizumab) as first-line treatment for recurrent or metastatic head and neck cancer, we observed two complete responses (CRs) in the first three patients enrolled. We will review details of those responses and promising Phase 1b safety results that opened enrollment into the Phase 2 expansion of this study at the American Society for Cancer Research (AACR 2022) on Monday, April 11, 2022."

"In addition, phase 1 has been completed and enrollment is underway in Phase 2a expansion of the SIGNAL-AD trial in early Alzheimer's Disease. Looking ahead to 2022 and early 2023, we expect to complete enrollment in the KEYNOTE-B84 and SIGNAL-AD trials. Data from these studies will help to guide the regulatory and product development path for the pepinemab programs. We look forward to continue to update the clinical community and investors on our progress at other medical conferences in 2022."

Pepinemab Clinical Updates:

Oncology: 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) for first-line treatment in recurrent or metastatic head and neck cancer.

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 and has been shown to promotes immunosuppression in head and neck cancer, there is strong rationale for development in this indication.

In January 2022, Vaccinex reported that, based on data from the phase 1b segment, the Data Safety Monitoring Board approved the recommended phase 2 dose and initiation of enrollment into the Phase 2 expansion segment of the trial. Importantly, two complete responses were observed among the three patients enrolled in phase 1b.

Vaccinex expects to report further data from this study (Abstract CT-111) at the AACR 2022 on Monday, April 11, 2022 in the Phase II Clinical Trials session.

The KEYNOTE-B84 study is expected to enroll up to 65 subjects across 18 U.S. trial sites and will assess whether immunotherapy with pepinemab in combination with pembrolizumab can improve responses in the front-line setting. The primary outcome of the study is objective response, and additional outcomes include progression free survival and overall survival.

Vaccinex anticipates that study enrollment will conclude in 2023. The Company expects to continue to provide additional updates from this open label trial at medical conferences in 2022 and results for the primary outcome in 2023.

Other Oncology Trials. Pepinemab is also being evaluated in multiple investigator-sponsored trials (ISTs) in pancreatic and breast cancer and in "window of opportunity" studies, including head and neck cancer and melanoma to evaluate pepinemab in several combination treatments.

Neurodegenerative Disease:

Alzheimer's Disease. Enrollment continues in the Phase 1/2a SIGNAL-AD trial of pepinemab as a single agent in early Alzheimer's disease. This trial is being funded in part by the Alzheimer's Drug Discovery Foundation and 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 15 U.S. trial sites. Vaccinex anticipates topline data from this study in 2023.

Huntington's disease. The Phase 2 double-blind, placebo-controlled SIGNAL trial of pepinemab in patients with early Huntington's disease (HD) has been completed, and Vaccinex believes the program is Phase-3 ready.

While the Phase 2 study did not meet the prespecified primary endpoints, we believe that multiple exploratory and post-hoc analyses support the potential cognitive benefit of treatment with pepinemab in early manifest HD patients, particularly those with evidence of mild cognitive or functional

deficits at baseline including:

- Highly significant improvement (p=0.007) in the Huntington's Disease Cognitive Assessment Battery (HD-CAB) Composite score, a measure comprised of 6 different cognitive assessments that has also been employed in other HD trials.
- 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.
- Reduced atrophy (p=0.017) in caudate region of striatum, a brain region known to degenerate early in HD progression, along with a 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 and clinical progression in several studies of AD.

The Company continues to actively explore advancing pepinemab into a Phase 3 HD trial in collaboration with biopharmaceutical partners.

Upcoming Anticipated Milestones:

Oncology:

- **Phase 1b/2 Keynote B84 Trial:** Open label head and neck cancer trial of pepinemab in combination with KEYTRUDA**/**pembrolizumab. Multiple interim data read-outs expected in 2022. Enrollment is expected to be completed and primary outcome data presented in 2023.
- **AACR Presentation:** Monday, April 11 in the Phase II Clinical Trials 1 between 9:00 a.m. and 12:30 p.m. CST.

Neurodegenerative Disease:

- **Phase 1/2a Alzheimer's Disease Trial:** Topline data are expected in 2023.

ActivMAb® Updates:

As previously announced, the Company has entered into several collaborations with pharmaceutical and biotechnology companies employing the unique capabilities of our ActivMAb® antibody discovery platform to address difficult to drug multi-pass membrane receptors including G-protein Coupled Receptors (GPCRs) and ion channels known to be strongly associated with diseases.

Financial Results for the Twelve Months Ended December 31, 2021:

Cash and Cash Equivalents and Marketable Securities. Cash and cash equivalents and marketable securities on December 31, 2021 were $8.6 million, as compared to $10.6 million as of December 31, 2020. In January, 2022, the Company sold 3,115,197 shares of its common stock at a weighted average price of $1.16 through the Open Market Sale Agreement, and 8,747,744 shares of the Company's common stock at a price of $1.11 through a private placement sale.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2021 were $17.2 million as compared to $21.5 million for the comparable period in 2020.

Research and Development expenses are lower in 2021 compared to 2020 primarily attributed to a smaller number of patients enrolled in clinical trials, especially the CLASSICAL-Lung and SIGNAL studies.

General and Administrative Expenses. General and administrative expenses for the year ended December 2021 were $6.2 million as compared to $7.4 million for the comparable period in 2020.

The difference in general and administrative expenses is primarily attributable to planned cost reductions, as part of cost control measures.

Comprehensive loss/Net loss per share. The Comprehensive Loss and Net loss per share for the year ended December 31, 2021 was $22.4 million and $0.78 compared to $28.9 million and $1.54 for the comparable period in 2020.

Financial results are included below. For further details on Vaccinex's financials, refer to its Form 10-K filed March 31, 2022 with the Securities and Exchange Commission.

About Pepinemab
Pepinemab is a humanized IgG4 monoclonal antibody that inhibits SEMA4D, which regulates chronic inflammation in the tumor microenvironment. Preclinical and clinical data show that pepinemab promotes infiltration of activated immune cells while reducing immune suppression in tumors and repair or prevention of neurological damage in neuroinflammatory and neurodegenerative diseases.

Results of a Phase 1b/2 study were presented at ASCO 2020 and were highlighted in the July 2021 publication of Clinical Cancer Research. The Company believes that results of this Phase 1b/2 CLASSICAL-Lung trial supports increased benefit of combination immunotherapy relative to historical results for checkpoint inhibitor alone as a treatment for immunotherapy naïve patients with PD-L1 low non-small cell lung cancer (NSCLC). In addition, the Company believes that its recently completed phase 2 study of single agent pepinemab in Huntington's disease indicated both cognitive benefit and a reduction in brain atrophy and reversal of disease-associated loss of brain metabolic activity. Topline data for the SIGNAL Phase 2 trial was reported in September 2020 and more detailed analysis of the data was presented at medical conferences in April and September of 2021.

Vaccinex has global commercial and development rights to pepinemab and is the sponsor of SIGNAL trials for HD and AD, as well as 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. Additional information about the study is available at: clinicaltrials.gov link.

KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co. Inc., Kenilworth, NJ, USA.

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.

Pepinemab is being evaluated in studies in oncology and neurodegenerative disease. In oncology, pepinemab is being evaluated in the Phase 1b/2 open label KEYNOTE-B84 study, in combination with KEYTRUDA/pembrolizumab, in patients with recurrent or metastatic head and neck squamous cell carcinoma (R/M HSNCC). In neurodegenerative disease, pepinemab is being evaluated in a Phase 1/2a randomized, double-blinded, placebo-controlled trial in people with early 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 intends to use 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, our history of operating losses and our need and ability to raise additional capital to continue as a going concern, 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 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)

	As of December 31, 2021	As of December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,589	$ 10,596
Accounts receivable	-	157
Prepaid expenses and other current assets	816	533
Total current assets	9,405	11,286
Property and equipment, net	297	416
Operating lease right-of-use asset	141	-
TOTAL ASSETS	$ 9,843	$ 11,702
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,061	$ 3,169
Accrued expenses	980	1,937
Senior secured convertible debt, net	-	8,074
Current portion of long-term debt	74	-
Operating lease right-of-use liability	141	-
Total current liabilities	2,256	13,180
Long-term debt	175	1,134
TOTAL LIABILITIES	2,431	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 December 31, 2021, and December 31, 2020; 30,801,962 and 22,388,027 shares issued as of December 31, 2021 and December 31, 2020, respectively; 30,801,110 and 22,387,175 shares outstanding as of December 31, 2021 and December 31, 2020, respectively	3	3
Additional paid-in capital	307,281	250,914
Treasury stock, at cost; 852 shares of common stock as of December 31, 2021 and December 31, 2020, respectively	(11)	(11)
Accumulated deficit	(299,861)	(277,481)
Total Vaccinex, Inc. stockholders' equity (deficit)	7,412	(26,575)
Noncontrolling interests	-	23,963
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	7,412	(2,612)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 9,843	$ 11,702

VACCINEX, INC.

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

	Year Ended December 31,	
	2021	**2020**
Revenue	$ 900	$ 625
Costs and expenses:		
Cost of revenue	-	2
Research and development	17,160	21,549
General and administrative	6,230	7,405
Total costs and expenses	23,390	28,956
Loss from operations	(22,490)	(28,331)
Interest expense	(809)	(489)
Gain on forgiveness of PPP loan	876	-
Other income (expense), net	43	(31)
Loss before provision for income taxes	(22,380)	(28,851)
Provision for income taxes	-	-
Net loss	(22,380)	(28,851)
Net loss attributable to noncontrolling interests	-	-
Net loss attributable to Vaccinex, Inc. common stockholders	$ (22,380)	$ (28,851)
Comprehensive loss	$ (22,380)	$ (28,851)
Net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (0.78)	$ (1.54)
Weighted-average shares used in computing net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	28,849,197	18,786,768

Source: Vaccinex, Inc.