Vaccinex Reports First Quarter 2022 Results and Provides Corporate Update

05/16/22

Excellent Progress in Pepinemab Clinical Programs

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);
Phase 2 enrollment underway

Enrollment underway in Phase 1/2a study of pepinemab in Alzheimer's disease

ROCHESTER, N.Y., May 16, 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 first quarter ended March 31, 2022, and provided a corporate update on key events since the start of 2022.

"I am pleased to report that Vaccinex's clinical programs for oncology and neurodegenerative disease have made substantial progress this year. In oncology, we were gratified to report promising Phase Ib safety results and to observe two complete responses (CRs) in the first three patients enrolled in the open label, Phase 1b/2 KEYNOTE-B84 trial. The trial is evaluating the use of pepinemab in combination with KEYTRUDA® (pembrolizumab) as first-line treatment for patients with advanced recurrent or metastatic head and neck cancer. We are hopeful that, with continued positive results, this combination may represent a novel option for patients with head and neck cancer, including those whose tumors express low levels of the PD-L1 biomarker and who have limited treatment choices," said Maurice Zauderer, Ph.D., President and Chief Executive Officer of Vaccinex.

Dr. Zauderer continued, "In neurodegenerative disease, enrollment in the Phase 1/2a SIGNAL-AD trial in mild Alzheimer's Disease continues to progress, and we plan to soon publish the results of the SIGNAL Huntington's Disease study that we believe showed promise of slowing or preventing cognitive decline."

Dr. Zauderer continued, "Looking ahead, we expect to complete enrollment in the KEYNOTE-B84 and SIGNAL-AD trials in 2022. Data read outs are planned from the KEYNOTE-B84 during H2:2022 and topline data from the SIGNAL-AD trial are expected in H2:2023. These data will help to guide the regulatory and product development path for pepinemab. We look forward to continue to update the clinical community and investors on our progress."

Pepinemab Clinical Updates and Upcoming Milestones:

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 immune checkpoint therapy KEYTRUDA (pembrolizumab) in recurrent or metastatic head and neck cancer.

Multiple prior studies[1-3] 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.

In January 2022, Vaccinex reported two complete responses in the first three patients enrolled. Vaccinex reported further details of these patient responses (Abstract CT-11) at the American Association for Cancer Research (AACR 2022) on Monday, April 11, 2022.

The KEYNOTE-B84 study is planned to enroll up to 65 subjects across 18 U.S. trial sites and will assess whether combination immunotherapy with pepinemab and pembrolizumab can improve responses in this population. Key endpoints of the study will include objective response, progression free survival and overall survival.

Next Data and Trial Completion: Data read-outs are expected in H2:2022. Enrollment is expected to be completed and topline data presented in H1:2023.

ASCO Abstract Publication: An abstract of the Phase 1b segment of the study of pepinemab, an inhibitor of semaphorin 4D, in combination with pembrolizumab as first-line treatment of recurrent or metastatic head and neck cancer (KEYNOTE-B84) will be published with the ASCO proceedings on May 26, 2022.

Vaccinex has exclusive global commercial and development rights to pepinemab and is 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. Additional information about the study is available: here.

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:

Alzheimer's Disease. Enrollment continues in the Phase 1/2a SIGNAL-AD trial of pepinemab in early Alzheimer's disease which is being funded in part by the Alzheimer's Drug Discovery Foundation and by a grant from the Alzheimer's Association under its 2020 Part the Cloud Program. Additional

information about this study is available here.

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.

Next Data and Trial Completion: Enrollment is expected to be completed by year-end 2022 and topline data are expected in H2:2023.

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

While the Phase 2 study did not meet the prespecified primary endpoints, pre-specified exploratory and post-hoc analyses 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
- Significant benefit in reducing apathy severity (p=0.017, 1-sided)
- Reduced atrophy (p=0.017) in caudate region of striatum
- A striking increase in brain metabolic activity as measured by FDG-PET in most brain regions

Next Steps: The company intends to publish the results of the SIGNAL study in mid-2022. In addition, Vaccinex is in ongoing discussions with potential partners on plans to advance pepinemab into a Phase 3 HD 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) and ion channels known to be strongly associated with diseases.

In April, 2022, Vaccinex announced presentation of an abstract at the 18th Annual PEGS Boston Conference & Expo, May 2-3, 2022, related to ActivMAb's successful expression and selection of antibodies against multi-pass receptors and its potential application as a tool for drug discovery and development projects.

Corporate Update:

In January 2022, the Company sold 8,747,744 shares of the Company's common stock at a purchase price of $1.11 per share raising aggregate gross proceeds of approximately $9.7 million. In addition, during the first quarter, the company received $3.5 million of net proceeds from the Open Market Sale Agreement by selling 3,115,197 shares of the Company's common stock at a weighted average price of $1.16 per share.

Financial Results for the Three Months Ended March 31, 2022:
Cash and Cash Equivalents and Marketable Securities. Cash and cash equivalents and marketable securities on March 31, 2022 were $16.8 million, as compared to $8.6 million as of December 31, 2021.

Research and Development Expenses. Research and development expenses for the quarter ended March 31, 2022 were $3.0 million as compared to $5.5 million for the comparable period in 2021.

Research and Development expenses are lower in 2022 compared to 2021 primarily attributed to reduced clinical trial costs as a result of the completion of the CLASSICAL-Lung and SIGNAL studies, partially offset by setup expenses for the KEYNOTE B84 and SIGNAL-AD studies as well as a large production run of pepinemab completed in Q1:21.

General and Administrative Expenses. General and administrative expenses for the quarter ended March 31, 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 in light of inflationary pressures.

Comprehensive loss/Net loss per share. The Comprehensive Loss and Net loss per share for the quarter ended March 31, 2022 was $4.6 million and $0.12, respectively, compared to $6.6 million and $0.26 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 May 16, 2022, with the Securities and Exchange Commission

REFERENCES:

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2. Clavijo PE, Friedman J, Robbins Y, Moore EC, Smith ES, Zauderer M, Evans EE, Allen CT. Semaphorin4D inhibition improves response to immune checkpoint blockade via attenuation of MDSC recruitment and function. Cancer Immunol Res. 2019 Feb;7(2):282-291
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blockade of semaphorin 4D promotes immune infiltration into tumor and enhances response to other immunomodulatory therapies. Cancer Immunol Res. 2015 Jun;3(6): 689-701. http://www.ncbi.nlm.nih.gov/pubmed/25614511

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 cell interactions in the brain. Preclinical and clinical data show that pepinemab promotes infiltration/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 major pharmas utilizing this technology. Vaccinex seeks partnering opportunities for co-development or licensing of existing antibodies in our pipeline, discovery of new antibodies and/or applications for this powerful 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 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," "hope", "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 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
(in thousands, except share and per share data)

	As of March 31, 2022	As of December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,803	$ 8,589
Accounts receivable	-	-
Prepaid expenses and other current assets	963	816
Total current assets	17,766	9,405
Property and equipment, net	256	297
Operating lease right-of-use asset	99	141

TOTAL ASSETS	$ 18,121	$ 9,843
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 589	$ 1,061
Accrued expenses	1,015	980
Senior secured convertible debt, net	-	-
Current portion of long-term debt	74	74
Operating lease right-of-use liability	99	141
Total current liabilities	1,777	2,256
Long-term debt	156	175
TOTAL LIABILITIES	1,933	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 March 31, 2022, and December 31, 2021; 42,664,903 and 30,801,962 shares issued as of March 31, 2022 and December 31, 2021, respectively; 42,664,051 and 30,801,110 shares outstanding as of March 31, 2022 and December 31, 2021, respectively	4	3
Additional paid-in capital	320,651	307,281
Treasury stock, at cost; 852 shares of common stock as of March 31, 2022 and December 31, 2021, respectively	(11)	(11)
Accumulated deficit	(304,456)	(299,861)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	16,188	7,412
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 18,121	$ 9,843

VACCINEX, INC.

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

	Three Months Ended March 31,	
	2022	**2021**
Revenue	$ -	$ 850
Costs and expenses:		
Cost of revenue	-	-
Research and development	2,966	5,513
General and administrative	1,628	1,577
Total costs and expenses	4,594	7,090
Loss from operations	(4,594)	(6,240)
Interest expense	(1)	(332)
Gain on forgiveness of PPP loan	-	-
Other income (expense), net	(0)	(2)
Loss before provision for income taxes	(4,595)	(6,574)
Provision for income taxes	-	-
Net loss	(4,595)	(6,574)
Net loss attributable to noncontrolling interests	-	-
Net loss attributable to Vaccinex, Inc. common stockholders	$ (4,595)	$ (6,574)
Comprehensive loss	$ (4,595)	$ (6,574)
Net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (0.12)	$ (0.26)
Weighted-average shares used in computing net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	38,758,283	25,216,788

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

Source: Vaccinex, Inc.