Vaccinex Reports First Quarter 2024 Financial Results and Provides Corporate Update

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Last patient last visit in randomized, double-blind, SIGNAL-AD Phase 2a study of pepinemab treatment for Alzheimer's Disease is scheduled for early June 2024

ROCHESTER, N.Y., May 15, 2024 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology company pioneering a differentiated approach to treating neurodegenerative disease and cancer through the inhibition of Semaphorin 4D (SEMA4D), today announced financial results for the first quarter ended March 31, 2024, and provided a corporate update on its key program for Alzheimer's disease.

Treatment with pepinemab believed to halt or slow progression of neurodegenerative disease:

Vaccinex expects to complete the planned 12-months of treatment of the last patients enrolled in its randomized, double-blind, **Phase 2a SIGNAL-AD trial** of pepinemab anti-SEMA4D antibody for mild Alzheimer's disease (NCT04381468) in early June 2024. Database lock will follow by early July to enable final analysis of the major study outcomes.

Of interest to investors:

- Vaccinex's lead product, pepinemab, is designed to block astrocyte activation that is otherwise triggered by SEMA4D upregulation on stressed or damaged neurons in the brain during progression of Alzheimer's Disease (AD) and Huntington's Disease (HD) .
- Astrocytes, which are key brain cells that support the health and function of neurons, express high affinity receptors for SEMA4D and undergo substantial changes in morphology and gene expression when SEMA4D binds to these receptors. As a result, they switch from normal supportive functions to neurotoxic inflammatory activity that is believed to accelerate and aggravate progression of neurodegenerative diseases.
- The Company's hypothesis, which is being tested in the SIGNAL-AD study, is that treating with pepinemab antibody can block signaling by SEMA4D and prevent some or all damaging consequences of astrocyte activation.
- The Company has previously reported that antibody blockade of SEMA4D appears to protect and restore healthy astrocyte functions and, by some measures, also appears to slow or prevent cognitive decline in Huntington's disease.
- The Company believes that the prevalence of AD (6 million people diagnosed with AD in the US alone) and current concerns about the limitations of treatment with anti-Aβ amyloid antibodies could make pepinemab, if approved, attractive as a potential alternative treatment or possibly for use in combination with anti-Aβ to enhance the benefit to patients. Pepinemab has, to date, been well-tolerated in clinical trials that enrolled a total of more than 600 patients, with no evidence of amyloid-related imaging abnormalities (ARIA).

Of further interest to the medical and research communities:

- Deposition of Aβ amyloid in the brain is recognized as the earliest event in the pathologic cascade for AD. However, the observation that many elderly, cognitively normal subjects also evidence deposition of Aβ amyloid in their brains suggests that this is not of itself sufficient for disease progression and that a sequence of subsequent events, including astrocyte activation and formation of toxic tau tangles in neurons, is required. Others have recently shown that Aβ deposition in combination with astrocyte activation is associated with increased plasma levels of phosphorylated tau peptide (p-tau 217).
- Key outcomes of the SIGNAL-AD study will include impact of pepinemab treatment on brain metabolic activity, an important biomarker of clinical progression in AD, together with other biomarkers of disease progression including plasma levels of glial fibrillary acidic protein (GFAP) released by reactive astrocytes, and phosphorylated tau peptide. Exploratory evaluation of treatment effects on cognitive decline will employ several validated cognitive scales. Topline data will be presented at a major Alzheimer's medical conference.
- The SIGNAL-AD study was funded in part by two investments from the Alzheimer's Drug Discovery Foundation (ADDF) for a total of $4.75 million, and by an $0.75 million grant from the Alzheimer's Association.

Financial Results for the Quarter Ended March 31, 2024:

Cash and Cash Equivalents and Marketable Securities. Cash and cash equivalents and marketable securities on March 31, 2024, were $3.0 million, as compared to $1.5 million as of December 31, 2023.

On February 8, 2024, and March 28, 2024, the Company completed private placements of common stock with accompanying warrants to purchase common stock to certain investors, including entities controlled by Albert D. Friedberg, the chairman of the Company's board of directors and Maurice Zauderer, the Company's President and CEO, for gross proceeds of $4.94 million. On March 29, 2024 the Company raised an additional $1.50 million

in a public offering and also received a $1.75 million investment from the ADDF in a private placement of preferred stock together with common warrants to purchase common stock. ADDF has been a leading and visionary supporter of research in AD for 25 years and this was the second such award received by Vaccinex from this distinguished foundation. Details of all these transactions are available in 8-K and other periodic reports filed with the Securities and Exchange Commission (SEC).

Research and Development Expenses. Research and development expenses for the quarter ended March 31, 2024, were $3.4 million as compared to $3.8 million for the comparable period in 2023.

General and Administrative Expenses. General and administrative expenses for the quarter ended March 31, 2024, were $1.8 million as compared to $1.7 million for the comparable period in 2023.

Comprehensive loss/Net loss per share. The Comprehensive Loss and Net loss per share for the quarter ended March 31, 2024, were $3.9 million and $(2.94) compared to $5.0 million and $(20.89) for the comparable period in 2023.

Total Stockholders' Equity. Stockholders' Equity as of March 31, 2024, was $2.7 million on March 31, 2024, as compared to a deficit of $(2.3) million on December 31, 2023. The 2023 discrepancy between the stockholder's equity balance and the Nasdaq listing requirement was largely due to a determination that the terms of warrants issued on October 3, 2023 did not meet all the requirements for classification as equity and were, therefore, classified as liabilities. The Company brought this matter to the attention of all Vaccinex warrant holders in March 2024, and the holders of 89% of all outstanding warrants agreed to modification of terms of their warrants resulting in the ability to classify the modified warrants as equity on our balance sheet as of March 31, 2024. On April 11, 2024, the Company received a letter from the Listing Qualifications staff of The Nasdaq Stock Market advising that based on the financial statements contained in its Form 10-K for the year-ended December 31, 2023, the Company no longer complied with the requirement to maintain a minimum of $2.5 million in stockholders' equity for continued listing on the Nasdaq Capital Market (the Equity Standard). The letter from Nasdaq was not a notice of delisting and had no immediate effect on the Company's listing on the Nasdaq Capital Market. However, Nasdaq required the Company to submit a plan by May 13, 2024, describing how it would regain compliance with the Equity Standard. The Company has submitted the required plan, and while the Company is confident that its plan is promising and feasible, the Company cannot provide assurances that Nasdaq will accept the plan or that the Company will maintain compliance with the Equity Standard.

Financial tables are included below. The Company effected a 1-for-14 reverse stock split on February 20 2024. All share and share amounts have been retroactively restated to give effect to the reverse stock split. For further details on Vaccinex's financials and the reverse stock split, please refer to its Form 10K filed April 1, 2024, with the SEC.

About Pepinemab
Pepinemab is a humanized IgG4 monoclonal antibody designed to block SEMA4D, which can trigger collapse of the actin cytoskeleton and loss of homeostatic functions of astrocytes and other glial cells in the brain and dendritic cells in immune tissue. Over 600 patients have been treated or enrolled in clinical trials of pepinemab in different indications and pepinemab appears to be well-tolerated with a favorable safety profile.

About Vaccinex Inc.
Vaccinex, Inc. is pioneering a differentiated approach to treating slowly progressive neurodegenerative diseases and cancer through the inhibition of semaphorin 4D (SEMA4D). The Company's lead drug candidate, pepinemab, blocks SEMA4D, a potent biological effector that it believes triggers damaging inflammation in chronic diseases of the brain and prevents immune infiltration into tumors. Pepinemab is being studied as a monotherapy in the Phase 1/2a SIGNAL-AD study in Alzheimer's Disease, with ongoing exploration of potential Phase 3 development in Huntington's disease. In oncology, pepinemab is being evaluated in combination with KEYTRUDA® in the Phase 1b/2 KEYNOTE-B84 study in recurrent or metastatic head and neck cancer (HNSCC) and in combination with BAVENCIO® in a Phase 1b/2 study in patients with metastatic pancreatic adenocarcinoma (PDAC). The oncology clinical program also includes several investigator-sponsored studies in solid tumors including breast cancer and melanoma.

Vaccinex has global commercial and development rights to pepinemab and is the 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. Additional information about the study is available at: clinicaltrials.gov.

KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co. Inc., Kenilworth, NJ, USA. BAVENCIO®/avelumab is provided by Merck KGaA, Darmstadt, Germany, previously as part of an alliance between the healthcare business of Merck KGaA, Darmstadt, Germany and Pfizer.

Forward Looking Statements
To the extent that statements contained in this press release 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 expectations and objectives with respect to the results and timing of the SIGNAL-AD clinical trial; expectations with respect to compliance with Nasdaq listing standards; our plans, expectations and objectives with respect to the results and timing of the KEYNOTE-B84 clinical trial; the use and potential benefits of pepinemab in R/M HNSCC, lung cancer, metastatic pancreatic adenocarcinoma (PDAC) and other indications; the potential for benefits as compared to single agent KEYTRUDA® or BAVENCIO®; expectations with respect to the collaboration of Merck, the potential to initiate a Phase 3 trial in Huntington's disease; and other statements identified by words such as "anticipate," "believe," "schedule," "being," "will," "appears," "expect," "ongoing," "potential," "suggest", 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 studies and clinical trials, that interim and preliminary data may not be predictive of final results and does not ensure success in later clinical trials, uncertainties related to regulatory approval, risks related to our dependence on our lead product candidate pepinemab, the possible delisting of our common stock from Nasdaq if the Company is unable to regain compliance with the Nasdaq listing standards, and other matters that could affect our development plans or the commercial potential of our product candidates. Except as required by law, the Company assumes 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 and the other risks and uncertainties described in the Company's annual year-end Form 10-K and subsequent filings with the SEC.

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VACCINEX, INC.

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

	As of March 31, 2024	As of December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,972	$ 1,535
Accounts receivable	2,775	961
Prepaid expenses and other current assets	1,312	853
Derivative asset	95	-
Total current assets	7,154	3,349
Property and equipment, net	110	136
Operating lease right-of-use asset	103	146
TOTAL ASSETS	$ 7,367	$ 3,631
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,329	$ 2,039
Accrued expenses	1,880	1,242
Deferred revenue	59	63
Current portion of long-term debt	76	75
Operating lease liability	103	146
Warrant liability	259	2,351
Total current liabilities	4,706	5,916
Long-term debt	6	26
TOTAL LIABILITIES	4,712	5,942
Commitments and contingencies (Note 6)		
Stockholders' equity (deficit):		
Convertible preferred stock (Series A), par value of $0.001 per share; 10,000,000 shares authorized, 10 shares issued and outstanding as of March 31, 2024, and no shares authorized, issued or outstanding as of December 31, 2023; with aggregate liquidation preference of $1,750,000 and $0 as of March 31, 2024 and December 31, 2023, respectively	1,236	-
Common stock, par value of $0.0001 per share; 100,000,000 shares authorized as of March 31, 2024, and December 31, 2023; 1,584,305 and 892,622 shares issued as of March 31, 2024 and December 31, 2023, respectively; 1,584,300 and 892,617 shares outstanding as of March 31, 2024 and December 31, 2023, respectively	1	-
Additional paid-in capital	345,253	337,627
Treasury stock, at cost; 5 shares of common stock as of March 31, 2024, and December 31, 2023, respectively	(11)	(11)
Accumulated deficit	(343,824)	(339,927)
TOTAL STOCKHOLDERS' EQUITY/(DEFICIT)	2,655	(2,311)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 7,367	$ 3,631

VACCINEX, INC.

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

	Three Months Ended March 31,	
	2024	2023
Revenue	$ 104	$ 550
Costs and expenses:		

Research and development	3,383	3,812
General and administrative	1,795	1,724
Total costs and expenses	5,178	5,536
Loss from operations	(5,074)	(4,986)
Financing costs - warrant liabilities	(28)	-
Change in fair value of warrant liabilities	1,206	-
Other income (expense), net	(1)	24
Loss before provision for income taxes	(3,897)	(4,962)
Provision for income taxes	-	-
Net loss attributable to Vaccinex, Inc. common stockholders	$ (3,897)	$ (4,962)
Comprehensive loss	$ (3,897)	$ (4,962)
Net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (2.94)	$ (20.89)
Weighted-average shares used in computing net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	1,327,257	237,527

Source: Vaccinex, Inc.