Vaccinex Reports 2023 Financial Results and Provides Corporate Update

04/02/24

Expect Topline Data for Phase 1/2a Randomized SIGNAL-AD Study of Pepinemab for Alzheimer's Disease in Q3 2024

Company raised $17.9 million of new financing during Q4 2023 and Q1 2024

ROCHESTER, N.Y., April 02, 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 SEMA4D, today announced financial results for the fourth quarter ended December 31, 2023 and provided a corporate update on key programs.

Vaccinex achieved several important clinical milestones for pepinemab in both Alzheimer's disease and Head and Neck Cancer.

Alzheimer's Disease (AD):

- In June 2024, anticipate completing planned 12-months treatment of patients with mild Alzheimer's disease in the randomized, double-blind, **Phase 1b/2a SIGNAL-AD trial of pepinemab vs placebo** (NCT04381468). This study was funded in part by the Alzheimer's Drug Discovery Foundation and by a grant from the Alzheimer's Association. Topline data is expected in Q3 2024.
- Following last patient last visit we will evaluate the impact of treatment on brain metabolic activity, a key biomarker of clinical progression in AD, together with other biomarkers of disease progression and initial assessment of treatment effects on cognition employing several validated, clinically meaningful cognitive scales for AD.
- An improving AD-drug development environment, based on FDA's recent full approval of LEQEMBI ®, enables the pathway to reimbursement and supports partnering and further investment in Alzheimer's Disease drug development.
- As previously reported, pepinemab has a differentiated mechanism of action, blocking SEMA4D, which is upregulated in neurons during stress of Alzheimer's and Huntington's disease and triggers the transformation of astrocytes and microglia from normal homeostatic functions to neuroinflammatory activity. Blockade of SEMA4D is believed to reduce neuroinflammation and to protect and restore healthy astrocyte and neuronal functions (Nature Medicine 2022, https://doi.org/10.1038/s41591-022-01919-8).
- We believe that the prevalence of AD (6 million people diagnosed with AD in the US alone) and current concerns about the limitations of anti-Aβ amyloid antibodies would make pepinemab attractive as a potential alternative to anti-Aβ antibodies or possibly for use in combination with anti-Aβ for greater efficacy.

Head and Neck Cancer:

- As previously reported, analysis of interim data from the first 36 patients in the single-arm, **Phase 2 KEYNOTE-B84 study** (NCT04815720) evaluating pepinemab in combination with KEYTRUDA™ in patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) suggests that the combination treatment resulted in an approximately 2X increase in objective responses (ORR) and progression free survival (PFS) in the subset of patients with hard-to-treat PD-L1-low tumors compared to historical response rates for checkpoint monotherapy in this population.
- Biomarker data indicate that treatment induced the formation of highly organized lymphoid aggregates in tumor that correlate with disease control and have previously been shown to be predictive of positive response to checkpoint inhibitors.
- Further research has suggested strategies to exploit this unique feature of pepinemab treatment in combination with KEYTRUDA so as to further enhance and expand treatment benefit. This will be the focus of continuing development.

Financial Results for the Year Ended December 31, 2023:

Cash and Cash Equivalents and Marketable Securities. Cash and cash equivalents and marketable securities on December 31, 2023 were $1.5 million, as compared to $6.4 million as of December 31, 2022.

In October 2023, the Company raised gross proceeds of $9.6 million from the sale of common stock and 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, President and CEO of Vaccinex. Subsequently, on February 8, 2024, the Company completed a private placement of common stock and warrants to purchase common stock for gross proceeds of $3.7 million and on March 28, 2024 raised $1.5 million in a public offering and an additional $1.24 million on similar terms in a parallel private placement of common stock and warrants to purchase common stock. The Company was very pleased to also receive a $1.75 million investment from the Alzheimer's Drug Discovery Foundation (ADDF) on March 29, 2024 in a private placement of preferred stock together with a common warrant 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 (S.E.C.).

Research and Development Expenses. Research and development expenses for the year ended December 31, 2023, were $16.6 million as compared to $14.0 million for the comparable period in 2022.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2023 were $6.9 million as compared to $6.2 million for the comparable period in 2022.

Comprehensive loss/Net loss per share. The Comprehensive Loss and Net loss per share for the year ended December 31, 2023, was $20.3 million and $(43.68) compared to $19.8 million and $(98.05) for the comparable period in 2022.

Full financial tables are included below. The Company effected a 1-for-15 reverse stock split in Q3 2023 and 1-for-14 reverse stock split in Q1 2024. All share and share amounts have been retro-actively restated to give effect to the reverse stock splits. For further details on Vaccinex's financials and the reverse stock splits, refer to its Form 10-K filed April 2, 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 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 and to have 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. In neurodegenerative diseases, 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 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 expectations and objectives with respect to the results and timing of the SIGNAL-AD clinical trial; 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 "believe," "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 we are 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, 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 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.

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

	As of December 31, 2023	As of December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,535	$ 6,391
Accounts receivable	961	175
Prepaid expenses and other current assets	853	912
Total current assets	3,349	7,478
Property and equipment, net	136	189
Operating lease right-of-use asset	146	310
TOTAL ASSETS	$ 3,631	$ 7,977
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,039	$ 1,518
Accrued expenses	1,242	781
Deferred revenue	63	-
Current portion of long-term debt	75	74
Operating lease liability	146	164
Warrant liability	2,351	-
Total current liabilities	5,916	2,537
Long-term debt	26	101
Operating lease liability, net of current portion	-	146
TOTAL LIABILITIES	5,942	2,784
Commitments and contingencies (Note 6)		
Stockholders' equity (deficit):		
Common stock, par value of $0.0001 per share; 100,000,000 shares authorized as of December 31, 2023, and December 31, 2022; 892,622 and 237,532 shares issued as of December 31, 2023 and December 31, 2022, respectively; 892,617 and 237,527 shares outstanding as of December 31, 2023 and December 31, 2022, respectively	-	-
Additional paid-in capital	337,627	324,880
Treasury stock, at cost; 5 shares of common stock as of December 31, 2023 and December 31, 2022, respectively	(11)	(11)
Accumulated deficit	(339,927)	(319,676)
TOTAL STOCKHOLDERS' EQUITY/(DEFICIT)	(2,311)	5,193
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 3,631	$ 7,977

VACCINEX, INC.

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

	Year Ended December 31,	
	2023	2022
Revenue	$ 570	$ 275
Costs and expenses:		
Research and development	16,574	13,979
General and administrative	6,881	6,202
Total costs and expenses	23,455	20,181
Loss from operations	(22,885)	(19,906)
Interest expense	(1)	(2)
Financing costs - warrant liabilities	(383)	-
Change in fair value of warrant liabilities	2,106	-
Other income (expense), net	912	93
Loss before provision for income taxes	(20,251)	(19,815)
Provision for income taxes	-	-
Net loss attributable to Vaccinex, Inc. common stockholders	$ (20,251)	$ (19,815)
Comprehensive loss	$ (20,251)	$ (19,815)
Net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (43.68)	$ (98.05)

Weighted-average shares used in computing net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	463,653	202,082

Source: Vaccinex, Inc.