Vaccinex Reports First Quarter 2023 Financial Results and Provides Corporate Update

May 15, 2023

Significant YTD Progress in Neurology and Oncology Programs

New financing of $5MM closed without warrants, derivatives or other financial considerations

ROCHESTER, N.Y., May 15, 2023 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology company pioneering a differentiated approach to treating neurodegenerative disease (NDD) and cancer through the inhibition of SEMA4D today announced financial results for the first quarter ended March 31, 2023 and provided a corporate update on key programs and financing in the first five months of the year.

"Vaccinex continues to make important progress in our clinical programs to develop pepinemab, our proprietary immunotherapy product candidate, to improve patient outcomes in neurodegenerative disease and cancer," said Maurice Zauderer, Ph.D., President and Chief Executive Officer of Vaccinex. "We completed enrollment in the Phase 1b/2 SIGNAL-AD (Alzheimer's Disease) study, which we expect will read-out when all participants have completed 12 months of double-blind treatment in mid-2024. In parallel, we submitted a briefing document to the FDA with additional data to support use of the Huntington's Disease Cognitive Assessment Battery (HD-CAB) as a meaningful measure of cognitive benefit in a planned Phase 3 study intended to demonstrate evidence of treatment efficacy in Huntington's Disease (HD). FDA agreement on a study design that, if positive, could meet requirements for regulatory approval is an important issue to partner/finance such a study based on the promising data obtained in our completed phase 2 SIGNAL trial (Nature Medicine). FDA has advised that they expect to provide a written response later this month."

Dr. Zauderer continued, "In our oncology program, we reached the targeted enrollment of 36 patients specified for a pre-planned interim analysis of responses to treatment in the Phase 1b/2 KEYNOTE-B84 trial of pepinemab in combination with KEYTRUDA® for first-line head and neck cancer. We expect to meet with our collaborator, Merck, in early June to review the results and consider plans for continued development of this novel immunotherapy combination. Separately, we initiated enrollment in a Phase 1b/2 study to evaluate pepinemab in combination with BAVENCIO®/avelumab in patients with metastatic pancreatic cancer (PDAC). In addition, an innovative investigator sponsored trial combining pepinemab with adoptive cell therapy for breast cancer continues to enroll patients at the Moffitt Cancer Center. This trial is based on preclinical studies demonstrating that antibody blockade of SEMA4D increases tumor targeting and efficacy of a dendritic cell vaccine."

Summary of Recent Milestones and Upcoming News
Neurodegenerative Disease:

- **Huntington's Disease Program** : Submitted briefing documents along with a Type C meeting request to the FDA related to the proposed plan for a Phase 3 study of pepinemab in HD. **FDA has indicated that they expect to provide a written response later this month to the questions posed in the briefing package.**
- **Alzheimer's Disease Program** : Enrollment completed in the Phase 1b/2 SIGNAL-AD study evaluating pepinemab as a potential treatment for people with mild dementia due to Alzheimer's Disease (NCT04381468). The study builds on learnings from the previously completed Phase 2 SIGNAL study in HD. **Topline data from this SIGNAL-AD study are expected in mid-2024, after the last enrolled patients will have received 12 months of treatment.**

Oncology:

- **KEYNOTE B-84**: The Phase 1b/2 KEYNOTE B-84 study reached targeted enrollment of 36 patients for a pre-planned interim analysis. This open-label, Phase 1b/2 study (NCT04815720) is evaluating first line therapy of pepinemab in combination with KEYTRUDA®, Merck & Co. Inc's (MRK) anti-PD-1 therapy, in immunotherapy naïve patients with recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC). **Vaccinex plans to complete the interim analysis in May and to publicize results in June, 2023 after meeting with Merck** to discuss the next steps.
- **ASCO 2023 Annual Meeting:** Two abstracts will be presented at the Annual Meeting of the American College of Clinical Oncology (ASCO), being held in Chicago from June 3-6. The first will describe the Vaccinex-sponsored **Phase 1b/2 PDAC Study** to evaluate pepinemab in combination with BAVENCIO®/avelumab as second line combination immunotherapy for patients with metastatic pancreatic ductal adenocarcinoma (PDAC, NCT05102721). This Vaccinex-sponsored study will be conducted with the University of Rochester Cancer Center and Wilmot Cancer Institute, with grant support from a Gateway Discovery Award. Prior studies suggest that treatment with pepinemab may promote the infiltration and activation of dendritic cells and CD8+ cells into the tumor microenvironment, rendering "cold" tumors such as PDAC immunologically "hot" and leading to enhanced efficacy of immune checkpoint inhibitors (ICIs) such as avelumab. The second abstract presents rationale and update of an ongoing Phase 1/2 trial evaluating pepinemab in combination with adoptive cell therapy for breast cancer patients and will be presented by our collaborators, Dr. Hyo S. Han and Dr. Brian Czerniecki of the Moffitt Cancer Center (NCT05378464). In preclinical studies, it was shown that SEMA4D antibody blockade in combination with a dendritic cell vaccine improved trafficking of dendritic cells to tumors and stimulated adaptive tumor immunity, resulting in improved regression of both primary and distant tumors. ASCO is the largest clinical oncology meeting in US and affords an opportunity to discuss progress and strategy with partners and collaborators.

ActivMAb® Platform Technology:

- **Nature Communications Paper**: Vaccinex and its collaborators published a report in Nature Communications, March 30, 2023, "*A Vaccinia-based system for directed evolution of GPCRs in mammalian cells*", describing a novel way that the ActivMAb® platform can be used for functional studies and drug discovery of the "hard to drug" class of membrane-associated G protein-coupled receptors (GPCRs) and ion channels. The publication highlights the potential for the ActivMAb® system to generate improved variants of any GPCR in a mammalian signaling system, enabling a better understanding of the functional properties of these complex receptors and the potential development of new and valuable drugs against these important targets.
- **First ActivMab®-based clinical program**: Vaccinex's partner, Surface Oncology, announced the initiation of a Phase 1/2 study of SRF114, a fully human monoclonal antibody targeting CCD8, for the potential treatment of solid tumors. SRF114 is the first clinical candidate to emerge from the ActivMAb® platform.

Financial Results for the Three Months Ended March 31, 2023:
Cash and Cash Equivalents and Marketable Securities. Cash and cash equivalents and marketable securities on March 31, 2023 were $3.3 million, as compared to $6.4 million as of December 31, 2022.

Cash and Cash Equivalents and Marketable Securities: Subsequent Events.

- On May 15, 2023, the Company closed the private placement of approximately 7.9 million shares of its common stock for aggregate gross proceeds of $3.0 million, following the private placement that raised $2.0 million in aggregate gross proceeds on March 31, 2023. FCMI Parent Co. ("FCMI"), which is controlled by Albert D. Friedberg, the chairman of the Company's board of directors, purchased shares in both the March and May 2023 transactions and Vaccinex (Rochester) L.L.C., which is majority owned and controlled by Dr. Maurice Zauderer, the Company's President, Chief Executive Officer, and a member of its board of directors, purchased shares in the March transaction. The Company intends to use the net proceeds from these private placements to fund the ongoing development and clinical trials of its lead drug candidate, pepinemab, in Alzheimer's disease and in cancer and for working capital and general corporate purposes.

Research and Development Expenses. Research and development expenses for the quarter ended March 31, 2023 were $3.8 million as compared to $3.0 million for the comparable period in 2022.

The increase in research and development expenses is primarily attributable to increased patient enrollment in the SIGNAL-AD study and the Phase 1b/2 KEYNOTE B84 study in R/M HNSCC.

General and Administrative Expenses. General and administrative expenses for the quarter ended March 31, 2023 were $1.7 million as compared to $1.6 million for the comparable period in 2022.

Essentially flat level of general and administrative expenses reflects careful cost control measures.

Revenue. Vaccinex recorded revenue for the quarter ended March 31, 2023 of $0.6 million in recognition of a milestone payment from Surface Oncology, following dosing of the first patient in a Phase 1/2 study for SRF114.

Comprehensive loss/Net loss per share. The Comprehensive Loss and Net loss per share for the quarter ended March 31, 2023 was $5.0 million and $(0.10) per share compared to $4.6 million and $(0.12) per share for the comparable period in 2022.

Full financial tables are included below. For further details on Vaccinex's financials, please refer to its Form 10Q filed May 15, 2023 with the SEC.

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 link.

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

BAVENCIO®/avelumab is co-developed and co-commercialized by Merck KGaA, Darmstadt, Germany and Pfizer Inc.

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 inflammatory reactions in the brain as well as in tumor immune evasion. Data show that by preventing deleterious inflammatory gliosis during disease progression, pepinemab preserves normal function of astrocytes and microglia, two types of glial cells that play a crucial role in the function and health of neurons in the brain. Additional clinical data show that pepinemab promotes infiltration and activation of dendritic cells and CD8+ T cells and reverses immunosuppression within the tumor microenvironment. Pepinemab is being evaluated in several studies in neurodegenerative disease and oncology. Pepinemab has been administered to more than 400 patients and appears to have a favorable safety and tolerability profile.

About ActivMAb®
Vaccinex has developed a proprietary mammalian cell-based antibody discovery platform with unique capabilities for multi-pass membrane targets such as G-protein-coupled receptors (GPCRs) and ion channels. The ActivMAb® technology has five main applications: complex membrane antigen presentation, antibody or antigen discovery, directed evolution, and protein optimization. The first clinical candidate selected through use of this technology (SRF114, a fully human monoclonal antibody targeting CCR8 for the potential treatment of solid tumors), recently entered development in a Phase 1/2 study sponsored by our licensee, Surface Oncology. Vaccinex has entered into multiple antibody discovery collaborations with leading biopharmaceutical companies.

About Vaccinex Inc.

Vaccinex, Inc. is pioneering a differentiated approach to treating slowly progressive neurodegenerative diseases (NDD) 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 NDD, 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 (R/M 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. The Company has also developed a proprietary drug discovery platform, ActivMAb®, that it is leveraging through strategic collaborations, particularly by applying its unique capability to select high value antibodies against important multi-pass membrane receptors.

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 the KEYNOTE-B84 clinical trial, planned interim analysis, the use and potential benefits of pepinemab in R/M HNSCC, metastatic pancreatic adenocarcinoma (PDAC) and other indications, the potential for benefits as compared to single agent KEYTRUDA® or BAVENCIO®, the expected timeline for publication and disclosure of trial results, the expected timeline of a response from the FDA on the proposed Phase 3 HD trial, the use of proceeds from our private placements, and other statements identified by words such as "may," "will," "appears," "expect," "planned," "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 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 impact of the COVID-19 pandemic, 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 ("SEC") 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 Consolidated Balance Sheets (Unaudited)
(in thousands, except share and per share data)

	As of March 31, 2023	As of December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,323	$ 6,391
Accounts receivable	-	175
Prepaid expenses and other current assets	1,095	912
Total current assets	4,418	7,478
Property and equipment, net	207	189
Operating lease right-of-use asset	270	310
TOTAL ASSETS	$ 4,895	$ 7,977
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,093	$ 1,518
Accrued expenses	975	781
Current portion of long-term debt	75	74
Operating lease liability	167	164
Total current liabilities	2,310	2,537
Long-term debt	82	101
Operating lease liability, net of current portion	103	146
TOTAL LIABILITIES	2,495	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 March 31, 2023, and December 31, 2022; 54,857,221 and 49,881,613 shares issued as of March 31, 2023 and December 31, 2022, respectively; 54,856,369 and 49,880,761 shares outstanding as of March 31, 2023 and December 31, 2022, respectively	5	5
Additional paid-in capital	327,044	324,875
Treasury stock, at cost; 852 shares of common stock as of March 31, 2023 and December 31, 2022, respectively	(11)	(11)
Accumulated deficit	(324,638)	(319,676)
TOTAL STOCKHOLDERS' EQUITY	2,400	5,193
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 4,895	$ 7,977

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

VACCINEX, INC.

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

	Three Months Ended March 31,	
	2023	**2022**
Revenue	$ 550	$ -
Costs and expenses:		
Research and development	3,812	2,966
General and administrative	1,724	1,628
Total costs and expenses	5,536	4,594
Loss from operations	(4,986)	(4,594)
Interest expense	(0)	(1)
Other income (expense), net	24	-
Loss before provision for income taxes	(4,962)	(4,595)
Provision for income taxes	-	-
Comprehensive loss	$ (4,962)	$ (4,595)
Net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (0.10)	$ (0.12)
Weighted-average shares used in computing net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	49,880,761	38,758,283

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Source: Vaccinex, Inc.