Carisma Therapeutics Reports Third Quarter 2023 Financial Results and Recent Business Highlights

November 9, 2023

Presented updated data from Phase 1 clinical trial of CT-0508 at CAR-TCR Summit, further supporting CAR-M safety, feasibility and mechanism of action

Selected clinical candidate for CT-1119, an anti-mesothelin CAR-Monocyte

Presented pre-clinical proof of concept data of in vivo CAR-M, from the Company's collaboration with Moderna, at SITC

Cash, cash equivalents and marketable securities of $94.1 million expected to fund company into the first quarter of 2025

PHILADELPHIA, Nov. 9, 2023 /PRNewswire/ -- Carisma Therapeutics Inc. (Nasdaq: CARM) ("Carisma" or the "Company"), a clinical-stage biopharmaceutical company focused on discovering and developing innovative immunotherapies, today reported financial results for the quarter ended September 30, 2023, and highlighted recent business updates.

"During the third quarter, Carisma made several key advancements across our clinical and pre-clinical programs and reported data from both our Phase 1 clinical study of CT-0508 and our pre-clinical work with Moderna developing *in vivo* CAR-M," said Steven Kelly, President and Chief Executive Officer of Carisma. "We continue to progress CT-0508 and CT-0525, our assets targeting HER2 overexpressing tumors, as we work to validate our first-in-class engineered macrophage platform. We believe that we have value-driving, next-generation cell therapies in our pipeline that have the potential to improve the treatments available for patients with cancer and other serious disorders."

Third Quarter 2023 and Recent Business Highlights

- **CT-0508**
  - Announced updated data from the Company's Phase 1 clinical trial of CT-0508, a human epidermal growth factor receptor 2 (HER2) targeted chimeric antigen receptor macrophage (CAR-M), which included data from the first five patients from group 2 (single-day bolus dosing). Preliminary results from the nine patients in group 1 (fractionated dosing) were presented in November 2022. The group 2 data, which were presented at the 8th Annual CAR-TCR Summit, support primary safety and manufacturing feasibility endpoints of single-day bolus dosing. The Company believes that translational analyses on early data from the combined groups 1 and 2 show that biomarkers of tumor microenvironment activation, T cell activation, and HER2 status correlate with best overall response of stable disease, providing further evidence of the CT-0508 mechanism of action.

- **CT-1119**
  - Selected a clinical candidate for the CT-1119 program, a CAR-Monocyte for mesothelin overexpressing solid tumors. CT-1119 will incorporate two key enhancements: a next-generation CAR that, as demonstrated in pre-clinical studies, leads to a significant increase in tumor killing and cytokine release, and the incorporation of SIRPα knockdown to overcome the CD47 immune checkpoint. SIRPα knockdown is achieved using Carisma's proprietary intronic shRNA platform, which enables CAR delivery and gene knockdown using a single vector. The Company is targeting an Investigational New Drug Application (IND) for CT-1119 in 2025.

- ***In Vivo* CAR-M (Moderna Collaboration)**
  - Presented pre-clinical proof of concept data demonstrating feasibility, tolerability, and early efficacy of mRNA/LNP *in vivo* CAR-M therapy at the Society for Immunotherapy of Cancer (SITC) 38th Annual Meeting. Accepted as a late-breaking abstract and oral presentation, "*In vivo* CAR-M: Redirecting endogenous myeloid cells with mRNA for cancer immunotherapy," showcased data that demonstrated CAR-M can be directly produced *in vivo,* or within the body, successfully redirecting endogenous myeloid cells against tumor-associated antigens using mRNA/LNP. This novel approach to cancer immunotherapy offers an off-the-shelf solution that has the potential to increase access to CAR-based therapies and be the basis of up to 12 oncology programs developed under the Carisma and Moderna collaboration.

Upcoming Milestones

- The Company recently submitted an IND to the U.S. Food and Drug Administration (FDA) for CT-0525. Subject to regulatory feedback, the Company expects to treat the first patient in the first half of 2024.

- The Company expects to present data from the sub-study of its Phase 1 clinical trial of CT-0508 in combination with pembrolizumab in the first half of 2024.

- The Company expects pre-clinical proof of concept data for its initial program outside of oncology, in liver fibrosis, in the first half of 2024.

- The Company is targeting an IND for CT-1119 in 2025.

Third Quarter 2023 Financial Results

- Cash, cash equivalents and marketable securities as of September 30, 2023, were $94.1 million, compared to $117.1 million as of June 30, 2023.

- Research & development expenses were $19.6 million for the third quarter of 2023, compared to $15.6 million for the same period in 2022. The increase of $4.0 million was primarily due to a $2.9 million increase in direct costs associated with the pre-clinical development of CT-0525, a $1.2 million increase in personnel costs due to growth in research and development employee headcount, and a $0.3 million increase in direct costs associated with the pre-clinical development related to CT-1119, partially offset by a $0.2 million decrease in direct costs associated with CT-0508 and a $0.1 million decrease of other clinical and pre-clinical development expenses associated with tracking CT-0525 and CT-1119 separately.

- General & administrative expenses were $6.6 million for the third quarter of 2023, compared to $3.8 million for the same period in 2022. The increase of $2.8 million was primarily due to a $1.4 million increase of higher personnel costs as a result of an increase in headcount, a $0.4 million increase in facilities and supplies due to an increase in office expenditures, a $0.6 million increase in legal and professional fees in support of our patent portfolio and expanding infrastructure, as well as a $0.4 million increase in other expenses due to an increase in travel expenses and subscriptions.

- Net loss was $21.4 million for the third quarter of 2023, compared to net loss of $18.3 million for the same period in 2022, primarily due to increased research and development expenses to support CT-0525 as well as an increase in expanding headcount and infrastructure, which was partially offset by Moderna collaboration revenue.

Outlook

Carisma believes that its cash, cash equivalents and marketable securities of $94.1 million as of September 30, 2023, are sufficient to sustain Carisma's planned operations into the first quarter of 2025.

About CT-0508

CT-0508 is a human epidermal growth factor receptor 2 (HER2) targeted chimeric antigen receptor macrophage (CAR-M). It is being evaluated in a landmark Phase 1 multi-center clinical trial that focuses on patients with recurrent or metastatic HER2-overexpressing solid tumors whose cancers do not have approved HER2-targeted therapies or who do not respond to treatment. Carisma is selecting participants who have tumors of any anatomical origin, but with the commonality of overexpressing the HER2 receptor on the cell surface, which is the target for its CAR-M. The Phase 1 clinical trial marks the first time that engineered macrophages are being studied in humans. The trial continues to enroll patients at seven clinical sites in the U.S., including (i) the University of Pennsylvania Abramson Cancer Center, (ii) the University of North Carolina Lineberger Comprehensive Cancer Center, (iii) the City of Hope National Medical Center, (iv) the MD Anderson Cancer Center, (v) the Sarah Cannon Cancer Research Institute, (vi) Oregon Health & Science University and (vii) Fred Hutchinson Cancer Center.

About Carisma

Carisma Therapeutics Inc. is a clinical stage biopharmaceutical company focused on utilizing our proprietary macrophage and monocyte cell engineering platform to develop transformative immunotherapies to treat cancer and other serious diseases. We have created a comprehensive, differentiated proprietary cell therapy platform focused on engineered macrophages and monocytes, cells that play a crucial role in both the innate and adaptive immune response. Carisma is headquartered in Philadelphia, PA. For more information, please visit www.carismatx.com.

Cautionary Note on Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to Carisma's business, strategy, future operations, cash runway, the advancement of Carisma's product candidates and product pipeline, and clinical development of Carisma's product candidates, including expectations regarding timing of initiation and results of clinical trials. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "goals," "intend," "may," "might," "outlook," "plan," "project," "potential," "predict," "target," "possible," "will," "would," "could," "should," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, (i) Carisma's ability to obtain, maintain and protect its intellectual property rights related to its product candidates; (ii) Carisma's ability to advance the development of its product candidates under the timelines it anticipates in planned and future clinical trials; (iii) Carisma's ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates; (iv) Carisma's ability to realize the anticipated benefits of its research and development programs, strategic partnerships, research

and licensing programs and academic and other collaborations; (v) regulatory requirements or developments and Carisma's ability to obtain and maintain necessary approvals from the U.S. Food and Drug Administration and other regulatory authorities related to its product candidates; (vi) changes to clinical trial designs and regulatory pathways; (vii) risks associated with Carisma's ability to manage expenses; (viii) changes in capital resource requirements; (ix) risks related to the inability of Carisma to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; and (x) legislative, regulatory, political and economic developments.

For a discussion of these risks and uncertainties, and other important factors, any of which could cause Carisma's actual results to differ from those contained in the forward-looking statements, see the "Risk Factors" set forth in the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2023, as well as discussions of potential risks, uncertainties, and other important factors in Carisma's other recent filings with the Securities and Exchange Commission. Any forward-looking statements that are made in this press release speak as of the date of this press release. Carisma undertakes no obligation to revise the forward-looking statements or to update them to reflect events or circumstances occurring after the date of this press release, whether as a result of new information, future developments or otherwise, except as required by the federal securities laws.

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CARISMA THERAPEUTICS INC.
Unaudited Consolidated Balance Sheets
(in thousands, except share and per share data)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 83,132	$ 24,194
Marketable securities	11,005	27,802
Prepaid expenses and other assets	3,428	2,596
Total current assets	97,565	54,592
Property and equipment, net	7,379	8,628
Right of use assets – operating leases	1,664	4,822
Restricted cash	30	—
Deferred financing costs	146	4,111
Total assets	$ 106,784	$ 72,153
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,409	$ 1,728
Accrued expenses	7,026	10,361
Deferred revenue	1,185	2,459
Operating lease liabilities	856	3,437
Finance lease liabilities	532	1,162
Other current liabilities	943	523
Total current liabilities	12,951	19,670
Deferred revenue	45,000	45,000
Convertible promissory note	—	33,717
Derivative liability	—	5,739
Operating lease liabilities	891	976
Finance lease liabilities	468	872
Other long-term liabilities	1,176	1,041
Total liabilities	60,486	107,015
Convertible preferred stock	—	107,808
Stockholders' equity (deficit):		
Common stock $0.001 par value, 350,000,000 shares authorized, 40,304,436 and 2,217,737 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	40	2
Additional paid-in capital	270,029	1,197
Accumulated other comprehensive income (loss)	373	(41)
Accumulated deficit	(224,144)	(158,223)

Total Carisma Therapeutics Inc. stockholders' equity (deficit)	46,298	(157,065)
Noncontrolling interests	—	14,395
Total stockholders' equity (deficit)	46,298	(142,670)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 106,784	$ 72,153

CARISMA THERAPEUTICS INC.
Unaudited Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Three Months Ended September 30,	
	2023	**2022**
Collaboration revenues	$ 3,827	$ 2,578
Operating expenses:		
Research and development	19,551	15,557
General and administrative	6,620	3,772
Total operating expenses	26,171	19,329
Operating loss	(22,344)	(16,751)
Change in fair value of derivative liability	—	(668)
Interest income (expense), net	941	(908)
Pre-tax loss	(21,403)	(18,327)
Income tax expense	—	—
Net loss	$ (21,403)	$ (18,327)
Share information:		
Net loss per share of common stock, basic and diluted	$ (0.53)	$ (8.37)
Weighted-average shares of common stock outstanding, basic and diluted	40,285,858	2,189,265
Comprehensive loss		
Net loss	$ (21,403)	$ (18,327)
Unrealized gain (loss) on marketable securities	108	37
Comprehensive loss	$ (21,295)	$ (18,290)

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