Carisma Announces Latest Data from Phase 1 Clinical Trial of CT-0508 at 8th Annual CAR-TCR Summit

September 1, 2023

Group 2 data available to date support primary safety and feasibility endpoints of single-day bolus dosing of CT-0508

New translational analyses combining group 1 & group 2 continue to support CAR-M mechanism of action, demonstrating a correlation between biomarkers and best overall response

PHILADELPHIA, Sept. 1, 2023 /PRNewswire/ -- Carisma Therapeutics Inc. (Nasdaq: CARM) ("Carisma" or the "Company"), a clinical stage biopharmaceutical company focused on discovering and developing innovative immunotherapies, will present findings today at the 8th Annual CAR-TCR Summit from its Phase 1 clinical trial of the Company's lead product candidate, CT-0508, a human epidermal growth factor receptor 2 ("HER2") targeted chimeric antigen receptor macrophage ("CAR-M") for the treatment of advanced/metastatic HER2 overexpressing cancers.

The presentation includes data from group 1 (n=9) and group 2 (n=5). Patients in both groups received the same total dose (up to $5x10^9$ CT-0508) either via a fractionated, multi-day infusion regimen (group 1) or via a single-day bolus infusion (group 2). The data are drawn from the ongoing clinical trial led by Kim A. Reiss, MD, principal investigator of the Phase 1 clinical trial and an associate professor of Hematology-Oncology in the Perelman School of Medicine at the University of Pennsylvania.

In the presentation, Michael Klichinsky, PharmD, PhD, Co-Founder and Chief Scientific Officer at Carisma, will present data demonstrating that, in both groups, CT-0508 was successfully manufactured for patients and that the administration of CT-0508 was well-tolerated after infusion with no dose-limiting toxicities reported to date.

"As the CT-0508 trial progresses, it is promising to see consistent results supporting the safety profile, feasibility, and mechanism of action of this first-in-class CAR-M investigational therapy," commented Dr. Klichinsky. "We look forward to results from the CT-0508 combination sub-study with pembrolizumab and continued development of CAR-M and CAR-Monocyte therapies."

Previously, Carisma presented findings from group 1 showing that CT-0508 remodeled and activated the tumor microenvironment ("TME") and initiated anti-tumor T cell immunity. Translational analyses combining group 1 and group 2 show that various biomarkers including metrics of TME activation, T cell activation, and HER2 status correlate with best overall response ("BOR") of stable disease, providing further evidence of the CT-0508 mechanism of action.

The Phase 1 study translational analyses further demonstrate an increase in exhausted CD8 T cells on treatment, supporting the ongoing combination sub-study with Merck's anti-PD1 therapy KEYTRUDA® (pembrolizumab). This latest data readout follows the dosing of the first patient in the ongoing sub-study of the Phase 1 clinical trial of CT-0508 in combination with pembrolizumab for the treatment of HER2 overexpressing cancers.

The Company is filing a Current Report on Form 8-K today with the U.S. Securities and Exchange Commission disclosing the new data from its Phase 1 clinical trial of CT-0508, including an excerpt of the presentation being made at the 8th Annual CAR-TCR Summit.

Editor's Note: Carisma has licensed certain Penn-owned intellectual property from the University of Pennsylvania, and Penn's Perelman School of Medicine receives sponsored research and clinical trial funding from the company. Penn may be entitled to receive additional financial benefits from technologies licensed and optioned to Carisma. In addition, Penn is a co-founder of the company and holds equity in Carisma.

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 our 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) Penn Medicine's 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 and ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates. 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. 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 August 10, 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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