Carisma Therapeutics Announces First Patient Dosed in Phase 1 Clinical Trial of CT-0525, a Novel HER2-Targeting CAR-Monocyte

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CT-0525 is the first CAR-Monocyte to be evaluated in humans in the solid tumor setting

Initial data expected by year-end 2024

PHILADELPHIA, May 16, 2024 /PRNewswire/ -- Carisma Therapeutics Inc. (Nasdaq: CARM) ("Carisma" or the "Company"), a clinical stage biopharmaceutical company focused on discovering and developing innovative immunotherapies, today announced that the first patient was dosed in its Phase 1 clinical trial evaluating CT-0525, an *ex vivo* gene-modified autologous chimeric antigen receptor-monocyte (CAR-Monocyte) cellular therapy, for the treatment of patients with solid tumors that overexpress human epidermal growth factor receptor 2 (HER2).

"Dosing of the first patient in the CT-0525 Phase 1 trial is a significant step in the development of engineered myeloid cells, marking the first time a CAR-Monocyte is tested in humans in the solid tumor setting," said Eugene P. Kennedy, M.D., Chief Medical Officer of Carisma. "Our pre-clinical data leads us to believe that this next-generation approach of our CAR-M platform has the potential to have a greater impact on patients than our initial CAR-Macrophage program, particularly through faster manufacturing, higher dosing, and increased potency, persistence, and tumor infiltration. We look forward to progressing this trial and expect to report initial data by the end of 2024."

"Patients battling HER2-overexpressing solid tumors face an urgent need for new therapeutic options, as disease progression is a common challenge," commented Davendra Sohal, M.D., M.P.H., Professor of Medicine at the University of Cincinnati Cancer Center. "CT-0525 introduces a differentiated approach to potentially address this shortcoming, offering hope for HER2-positive cancer patients. We are proud to be the first site to treat a patient with CT-0525 and look forward to continuing to collaborate with Carisma and other cancer centers to rapidly enroll patients in the Phase 1 trial."

The Phase 1 clinical trial for CT-0525 is an open-label study designed to assess the safety, tolerability, and manufacturing feasibility of CT-0525. This trial will enroll participants with locally advanced (unresectable) or metastatic solid tumors overexpressing HER2 whose disease has progressed on standard approved therapies. The study will consist of two dose escalation cohorts. Further details of the trial can be found at www.clinicaltrials.gov under NCT identifier: NCT06254807.

Carisma will present a Trial in Progress poster outlining the design of the CT-0525 Phase 1 trial at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting, scheduled to take place from May 31 to June 4, 2024, in Chicago, IL.

About CT-0525

CT-0525 is a first-in-class, *ex vivo* gene-modified autologous chimeric antigen receptor-monocyte (CAR-Monocyte) cellular therapy intended to treat solid tumors that overexpress human epidermal growth factor receptor 2 (HER2). It is being studied in a multi-center, open label, Phase 1 clinical trial for patients with advanced/metastatic HER2-overexpressing solid tumors that have progressed on available therapies. The CAR-Monocyte approach has the potential to address some of the challenges of treating solid tumors with cell therapies, including tumor infiltration, immunosuppression within the tumor microenvironment, and antigen heterogeneity. CT-0525 has the potential to enable significant dose escalation, enhance tumor infiltration, increase persistence, and reduce manufacturing time compared to macrophage therapy.

About Carisma Therapeutics

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 and with its current financial and human resources; (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 Annual Report on Form 10-K for the year ended December 31, 2023, its Quarterly Reports on Form 10-Q, 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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