Carisma Therapeutics Announces FDA Clearance of IND Application for 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

First patient expected to be treated in the first half of 2024

PHILADELPHIA, Nov. 28, 2023 /PRNewswire/ -- Carisma Therapeutics Inc. (Nasdaq: CARM) ("Carisma" or the "Company"), a clinical stage biopharmaceutical company focused on discovering and developing innovative immunotherapies, today announced the clearance of its Investigational New Drug application (IND) by the U.S. Food and Drug Administration (FDA) for CT-0525, an 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). Having received a Study May Proceed notification from the FDA, Carisma expects to initiate a Phase 1 study in the coming months and to treat the first patient in the first half of 2024.

"Clearance of the IND for CT-0525 is a significant milestone in Carisma's mission to develop innovative myeloid cell therapies for metastatic solid tumors," said Steven Kelly, President and Chief Executive Officer of Carisma. "Through this Phase 1 study, we aim to advance our understanding of safety, tolerability, manufacturing feasibility and mechanism of action of CT-0525."

Monocytes are the precursor cells to macrophages, and there are numerous potential benefits to a CAR-Monocyte approach to help overcome certain challenges of treating solid tumors. The CAR-Monocyte manufacturing platform enables the ability to manufacture up to 10 billion cells from a single apheresis and utilizes a rapid, single-day manufacturing process. This manufacturing process holds the potential to significantly reduce the future cost of goods and manufacturing turnaround time associated with this autologous cell therapy. Pre-clinical data presented at The Society for Immunotherapy of Cancer's Annual Meeting in November 2022 demonstrate that CT-0525 therapy reduced tumor growth in multiple pre-clinical solid tumor models.

"CT-0525 is the first CAR-Monocyte to be evaluated in the solid tumor setting. With a CAR-Monocyte's in vivo persistence, ability to differentiate into pro-inflammatory CAR macrophages, and multi-modal anti-tumor mechanism of action, along with its high cell yield, CT-0525 has the potential to improve the treatment paradigm for patients with HER2 overexpressing metastatic solid tumors," said Michael Klichinsky, PharmD, PhD, Co-Founder and Chief Scientific Officer at Carisma. "We look forward to the clinical development of CT-0525."

The Phase 1 study for CT-0525 is designed to assess the safety, tolerability, and the manufacturing feasibility of CT-0525. This study 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 cohorts: Cohort 1 will receive IV administration of up to 3 billion CAR-positive cells, while Cohort 2 will receive IV administration of CT-0525 of up to 10 billion CAR-positive cells.

About CT-0525

CT-0525 is an 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). The CAR-Monocyte approach has the potential to address the challenges of treating solid tumors with cell therapies, including tumor infiltration, immunosuppression within the tumor microenvironment, and antigen heterogeneity.

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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