Carisma Therapeutics Granted FDA Fast Track Designation for CT-0525 for the Treatment of HER2-overexpressing Solid Tumors

June 25, 2024

Fast Track designation highlights potential for CT-0525 to address unmet need for patients with solid tumors

Initial Phase 1 data expected by year-end 2024

PHILADELPHIA, June 25, 2024 /PRNewswire/ -- Carisma Therapeutics Inc. (Nasdaq: CARM) ("Carisma" or the "Company"), a clinical stage biopharmaceutical company focused on discovering and developing innovative immunotherapies, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation 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).

The FDA's Fast Track program is aimed to facilitate the development, and expedite the review, of novel potential therapies that are designed to treat serious conditions and have the potential to address significant unmet medical need.

"Receiving Fast Track designation for CT-0525 from the FDA marks a significant milestone for Carisma, highlighting the FDA's recognition of the serious and life-threatening nature of these malignancies and the potential of CT-0525 to meet this critical medical need," said Eugene P. Kennedy, M.D., Chief Medical Officer of Carisma. "We are committed to working closely with the FDA to accelerate the development of CT-0525. Currently, we are enrolling patients in the Phase 1 clinical trial and remain on track to report initial clinical data by the end of 2024."

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 initial study design will consist of two dose escalation cohorts. Further details of the trial can be found at www.clinicaltrials.gov under NCT identifier: NCT06254807.

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 realize the anticipated benefits of its pipeline reprioritization and corporate restructuring, (ii) Carisma's ability to obtain, maintain and protect its intellectual property rights related to its product candidates; (iii) 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; (iv) Carisma's ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates; (v) 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; (vi) 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; (vii) changes to clinical trial designs and regulatory pathways; (viii) risks associated with Carisma's ability to manage expenses; (ix) changes in capital resource requirements; (x) risks related to the inability of Carisma to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; and (xi) 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, the Company's Quarterly Report on Form 10-Q for the Quarter ended March 31, 2024, 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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