Carisma Unveils Promising Pre-Clinical Data on Anti-GPC3 In Vivo CAR-M Therapy for Hepatocellular Carcinoma

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New findings showcase the potential of in vivo CAR-M technology as an effective, off-the-shelf treatment for hepatocellular carcinoma (HCC)

PHILADELPHIA, Nov. 8, 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 positive pre-clinical data on its anti-GPC3 *in vivo* chimeric antigen receptor macrophage and monocyte (together, "CAR-M") therapy for hepatocellular carcinoma ("HCC"), developed in collaboration with Moderna, Inc. (Nasdaq: MRNA). The data demonstrated that the development candidate can successfully create CAR-M directly *in vivo*, reprogramming endogenous myeloid cells to target and destroy Glypican-3 ("GPC3"), expressing cancer cells.

Pre-clinical results showed that the novel *in vivo* anti-GPC3 CAR-M therapy exhibits specificity for the GPC3 tumor antigen, driving potent dose-dependent cytotoxicity against GPC3+ tumor cells. Additionally, the CAR-M produced pro-inflammatory cytokines and adopted an inflammatory, activated macrophage phenotype upon antigen engagement. In both syngeneic and humanized tumor models, systemic administration of anti-GPC3 CAR mRNA/LNP significantly reduced tumor burden and suppressed metastasis to the liver. The therapy was well tolerated in mouse models, highlighting its potential as an off-the-shelf treatment for GPC3+ solid tumors, including HCC.

"The data demonstrate our ability to generate anti-GPC3 CAR-M cells directly *in vivo* using mRNA/LNP technology, leading to significant tumor reduction in translationally relevant pre-clinical models," said Michael Klichinsky, PharmD, PhD, Co-Founder and Chief Scientific Officer at Carisma. "This novel off-the-shelf approach offers a promising new strategy for treating hepatocellular carcinoma, and we are eager to advance it toward clinical development."

"These preclinical data highlights the successful application of our mRNA/LNP platform in enabling *in vivo* cell therapy," said Lin Guey, PhD, CSO of Therapeutic Research Ventures, Moderna. "We look forward to further advancing the anti-GPC3 *in vivo* CAR-M therapy for HCC patients and continuing our collaboration with Carisma to bring innovative treatments to those patients with solid tumors."

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

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, anticipated discovery, preclinical and clinical development activities for Carisma's product candidates, the potential safety, efficacy, benefits and addressable market for Carisma's product candidates, and clinical trial results for Carisma's product candidates. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," "schedule," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are predictions based on the Company's current expectations and projections about future events and various assumptions. Although Carisma believes that the expectations reflected in such forward-looking statements are reasonable, Carisma cannot guarantee future events, results, actions, levels of activity, performance or achievements, and the timing and results of biotechnology development and potential regulatory approval is inherently uncertain. Forward-looking statements are subject to risks and uncertainties that may cause Carisma's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to Carisma's ability to advance its product candidates, the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, clinical trial sites and our ability to enroll eligible patients, supply chain and manufacturing facilities, Carisma's ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of preclinical and clinical trials, Carisma's ability to fund development activities and achieve development goals, Carisma's ability to protect intellectual property, and other risks and uncertainties described under the heading "Risk Factors" in Carisma's Annual Report on Form 10-K for the year ended December 31, 2023, its Quarterly Reports on Form 10-Q and other documents that Carisma files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and Carisma undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof, except as may be required by law.

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