Carisma Therapeutics Announces First Patient Dosed in Phase 1 Study of CT-0508 in Combination with KEYTRUDA® (pembrolizumab) in Patients with HER2 Overexpressing Solid Tumors

June 28, 2023

Study is designed to evaluate the potential for a synergistic effect of CAR-M therapy in combination with KEYTRUDA®

PHILADELPHIA, June 28, 2023 /PRNewswire/ -- Carisma Therapeutics Inc. (Nasdaq: CARM) ("Carisma" or the "Company"), a clinical stage biopharmaceutical company focused on discovering and developing innovative immunotherapies, announced that the first patient has been dosed in its Phase I clinical trial that will test the safety and tolerability of the Company's lead product candidate, CT-0508, a human epidermal growth factor receptor 2 (HER2) targeted chimeric antigen receptor macrophage (CAR-M) in combination with Merck's anti-PD1 therapy KEYTRUDA® (pembrolizumab) for the treatment of HER2 overexpressing cancers.

Pre-clinical data presented at SITC in 2022 demonstrated that the mice that received both therapies had improved tumor control, overall survival, and tumor microenvironment (TME) activation as compared to either treatment alone, indicating synergy and the capacity for CAR-M to sensitize solid tumors to checkpoint blockade.

This first patient's cells were manufactured at the Novartis Cell Therapy Site in Morris Plains, New Jersey, following the successful completion of the tech transfer of CT-0508 to Novartis earlier this year. This is Carisma's first clinical product to be manufactured and administered from this collaboration.

"We are excited by the progress being made on our CT-0508 clinical program with the dosing of the first patient in the combination study with KEYTRUDA®," said Michael Klichinsky, PharmD, PhD, Co-Founder and Chief Scientific Officer at Carisma Therapeutics. "The CT-0508 monotherapy trial has demonstrated early clinical validation of the CAR-M mechanism of action, and we are eager to explore this sub-study to assess the potential synergistic effect of CAR-M therapy in combination with KEYTRUDA®. The initiation of clinical manufacturing at Novartis' GMP cell therapy site is also a meaningful step forward in progressing our overarching manufacturing strategy, and demonstrates our desire to work alongside best-in-class companies."

In January 2023, Carisma appointed nationally regarded cancer immunologist and oncologist, Dr. Padmanee Sharma, MD, PhD, to the company's Scientific Advisory Board. The Company expects that Dr. Sharma's scientific knowledge in immunotherapy will provide valuable guidance in the studies of CT-0508 and KEYTRUDA®.

The clinical trial sub-study of CT-0508 in combination with KEYTRUDA® has been initiated at multiple site locations in the U.S. and will enroll patients with different types of recurrent or metastatic cancers with HER2 overexpressing solid tumors. To learn more about this, please visit ClinicalTrials.gov (NCT04660929) or Carisma's clinical trial website.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp, a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

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 are not eligible for treatment with currently available HER2-targeted therapies or who do not respond to treatment. The trial is enrolling 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 is first-of-its-kind, marking the first time that genetically engineered macrophages are being studied in humans. The trial continues to enroll patients at seven clinical sites in the U.S., including (i) the University of Pennsylvania 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 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. The first applications of the platform, developed in collaboration with the University of Pennsylvania, are autologous chimeric antigen receptor (CAR)-macrophages for the treatment of solid tumors. 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 Therapeutics' business, strategy, future operations, cash runway, the advancement of Carisma Therapeutics' product candidates and product pipeline, and clinical development of Carisma Therapeutics' product candidates, including expectations regarding timing of initiation and results of clinical trials, and participation by Carisma Therapeutics in future healthcare industry and investor conferences. 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 May 11, 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.

Media Contact:
Julia Stern
(763) 350-5223
jstern@realchemistry.com

Investor Contact:
investors@carismatx.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/carisma-therapeutics-announces-first-patient-dosed-in-phase-1-study-of-ct-0508-in-combination-with-keytruda-pembrolizumab-in-patients-with-her2-overexpressing-solid-tumors-301865175.html

SOURCE Carisma Therapeutics Inc.