

Carisma Therapeutics Presents Data from Phase I Clinical Trial of CT-0508, A HER2 Targeted CAR-Macrophage

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First-in-human engineered macrophage cell therapy demonstrates preliminary safety and manufacturing feasibility for patients with solid tumors

PHILADELPHIA, Nov. 12, 2021 /PRNewswire/ -- <u>Carisma Therapeutics Inc.</u>, a clinical stage biopharmaceutical company focused on discovering and developing innovative immunotherapies, presented today for the first time preliminary findings from the landmark <u>Phase 1 multi-center clinical trial of CT-0508</u>, a human epidermal growth factor receptor 2 (HER2) targeted chimeric antigen receptor macrophage (CAR-M).

The early data were presented by Dr. Kim A. Reiss, MD, Principial Investigator for Carisma's clinical trial of CT-0508 at the Abramson Cancer Center of the University of Pennsylvania (Penn), at the Society for Immunotherapy of Cancer (SITC) 36th Anniversary Annual Meeting. The preliminary findings represent the first clinical data with genetically engineered macrophages in humans and demonstrated that CT-0508 was well tolerated after infusion and there were no dose limiting toxicities. CT-0508 was also successfully manufactured using macrophages obtained from heavily pre-treated, advanced solid tumor patients and showed high CAR expression, viability, and purity. The data also demonstrated that CT-0508 remodeled the solid tumor microenvironment (TME) and mediated expansion/activation of T cells within the tumors. The Food and Drug Administration recently granted Fast Track designation to CT-0508 for the treatment of patients with solid tumors.

"This is the first time that genetically engineered macrophages are being studied in humans and we are encouraged by the safety profile and activity observed thus far," said Debora Barton, MD, Chief Medical Officer at Carisma Therapeutics. "We will continue to enroll patients in the landmark clinical trial of CT-0508 and look forward to making additional observations about how CAR-M therapy can potentially address the unmet needs of patients."

Carisma data also accepted for presentation at the SITC 36th Anniversary Annual Meeting:

- "Chimeric Antigen Receptor Macrophages (CAR-M) Elicit a Systemic Anti-Tumor Immune Response and Synergize with PD1 Blockade in Immunocompetent Mouse Models of HER2+ Solid Tumors," Friday, November 12 at 7:00 am ET
- "Development and Characterization of CAR-Mono, a Novel Cell Therapy Platform for Solid Tumor Immunotherapy," Saturday, November 13 at 7:00 am ET
- "SIRPα Deficient CAR-Macrophages Exhibit Enhanced Anti-Tumor Function and Bypass the CD47 Immune Checkpoint," Saturday, November 13 at 7:00 am ET

"We are excited by the early Phase I clinical data demonstrating safety, feasibility, and TME remodeling with CT-0508," shared Michael Klichinsky, PharmD, PhD, co-inventor of the CAR-M technology and scientific co-founder and Senior Vice President of Research at Carisma Therapeutics. "Our research team is committed to innovation in the field of genetically modified myeloid cells, and we are excited to also share novel pre-clinical data with CRISPR editing, combination therapy, and manufacturing advances at the upcoming SITC meeting."

Presentation and posters will be available on the SITC 36th Anniversary Annual Meeting portal for registered attendees.

Editor's Note: Dr. Saar Gill and Penn are both co-founders of Carisma and hold equity in the company. Carisma has licensed certain Penn-owned intellectual property from the University, and Penn's Perelman School of Medicine receives sponsored research funding from the company in support of Dr. Gill's laboratory and clinical trials at Penn, including the trial led by Dr. Reiss. Penn and Dr. Gill may be entitled to receive future financial benefits from development and commercialization of technologies licensed and optioned to Carisma.

About Carisma Therapeutics Inc.

Carisma Therapeutics Inc. is a biopharmaceutical company dedicated to developing a differentiated and proprietary cell therapy platform focused on engineered macrophages, 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 Therapeutics is headquartered in Philadelphia, PA.

For more information, please visit www.carismatx.com

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