CARISMA Therapeutics Announces U.S. Food and Drug Administration Grants Fast Track Designation to CT-0508 for the Treatment of Patients with Solid Tumors

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PHILADELPHIA, Sept. 22, 2021 /PRNewswire/ -- CARISMA Therapeutics Inc., a clinical stage biopharmaceutical company focused on discovering and developing innovative immunotherapies, announced today that that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to CT-0508, a human epidermal growth factor receptor 2 (HER2) targeted chimeric antigen receptor macrophage (CAR-M) for the treatment of patients with solid tumors.

"The FDA's decision to grant Fast Track designation to CT-0508 is another important milestone in gene-based cell therapy development," said Steven Kelly, Chief Executive Officer of CARISMA. "This designation further demonstrates the critical need to expedite the development and review of new therapies that can potentially address the unmet needs of patients, whose cancer may have not responded to existing methods of treatment."

CT-0508 was originally developed by Saar Gill, MD, PhD, Scientific Co-founder of CARISMA Therapeutics, and an Associate Professor of Hematology-Oncology in the Perelman School of Medicine at the University of Pennsylvania, and Michael Klichinsky, PharmD, PhD, Scientific Co-founder, and Senior Vice President of Discovery at CARISMA Therapeutics. It is currently being evaluated in a first-in-human Phase 1 multi-center clinical trial that focuses on patients with recurrent or metastatic HER2-overexpressing solid tumors whose cancers do not have any approved HER2-targeted therapies or who do not respond to treatment. Preclinical findings for CT-0508 indicated that CAR-M therapy may have the potential to overcome challenges that T-cell therapies have encountered in the solid tumor setting.

The FDA's Fast Track program is designed to facilitate the development and expedite the review of investigational treatments that demonstrate a potential to address unmet medical needs in serious conditions. Programs with Fast Track designation can benefit from early and frequent communication with the FDA in addition to a rolling submission of the marketing application.

CARISMA will continue to treat and evaluate patients at three clinical trial sites, including the Abramson Cancer Center of the University of Pennsylvania, the University of North Carolina Lineberger Comprehensive Cancer Center in Chapel Hill, and City of Hope in Duarte, California.

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

Editor's Note: Dr. 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. Penn and Dr. Gill may also be entitled to receive future financial benefits from technologies licensed and optioned to CARISMA.

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