CARISMA Therapeutics Announces FDA Clearance of IND Application for First-Ever Engineered Macrophage Immunotherapy

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- Plans to Initiate Phase 1 Clinical Trial This Year

- Expands Corporate Advisors with Board of Directors and Scientific Advisory Board Appointments

PHILADELPHIA, July 27, 2020 /PRNewswire/ -- CARISMA Therapeutics Inc., a biopharmaceutical company focused on discovering and developing innovative immunotherapies, today announced that the U.S. Food and Drug Administration (FDA) has cleared an investigational new drug (IND) application for the Company's lead product candidate, CT-0508, an anti-human epidermal growth factor receptor 2 (HER2) targeted chimeric antigen receptor macrophage (CAR-M). Under this IND, CARISMA intends to initiate its Phase 1, first-in-human, multi-center study in patients with recurrent or metastatic HER2 overexpressing solid tumors after failure of approved HER2 targeted agents.

"This will be the first time that an engineered macrophage has progressed successfully to the in-patient study phase and represents a new chapter for CARISMA: advancing from a preclinical discovery-stage company to a clinical development stage company," said Steven Kelly, President and Chief Executive Officer. "The clearance of our IND application for CT-0508 is a ground-breaking milestone in the field of cell-based cancer immunotherapy."

Historically, cell therapies have encountered key challenges treating solid tumors, including limited trafficking to the tumor site, an immunosuppressive tumor microenvironment, and the heterogeneous expression of tumor-associated antigens, but CARISMA's preclinical findings suggest that CAR-M therapy could overcome these challenges.

"Our preclinical findings indicate that CAR-M have the ability to mount a broad immune response against cancers, and the acceptance of the CT-0508 IND brings this technology to patients with incurable solid tumors," said Michael Klichinsky, PharmD, PhD, co-inventor of the CAR-M technology, Scientific Co-founder, and Vice President of Discovery at CARISMA Therapeutics.

CARISMA Scientific Co-founder and Assistant Professor of Hematology-Oncology in Penn's Abramson Cancer Center, Saar Gill, MD, PhD, added, "I'm incredibly pleased and excited to see the technology that was originally developed in my lab progress to the clinic. Getting a chance to translate your preclinical research and evaluate its potential impact for patients is the reason why I do this type of work."

The planned clinical trial will be conducted at two trial sites—University of Pennsylvania in Philadelphia, Pennsylvania, and University of North Carolina in Chapel Hill, North Carolina—and will enroll patients with different types of recurrent or metastatic cancers with HER2 overexpressing solid tumors.

"HER2 is overexpressed not only in breast and gastroesophageal cancers, but in a wide variety of epithelial origin solid tumors, such as non-small cell lung, colorectal, bladder, and pancreatic cancers," said Debora Barton, MD, Chief Medical Officer at CARISMA Therapeutics. "There is an important unmet medical need that remains to be addressed and we aim to achieve that during this clinical trial."

Corporate Developments

CARISMA also announced today the expansion of its Board of Directors to include Briggs W. Morrison, MD, as well as additions to the Scientific Advisory Board, Nina Bhardwaj, MD, PhD, and Prasad S. Adusumilli, MD.

"CARISMA is at an exciting juncture," said Mike Heffernan, Chairman of the Board of Directors. "Evolving from a preclinical stage company, having demonstrated reduced tumor burden and significantly improved overall survival with our CAR-M technology in humanized mouse models, to quickly approaching the in-clinic study of this first-of-its-kind therapy. We are eager to have Drs. Morrison, Bhardwaj and Adusumilli's counsel as CARISMA embarks on this new chapter."

The CARISMA Board of Directors welcomes Dr. Briggs Morrison, who brings with him over 25 years of pharmaceutical, global regulatory and business development leadership experience. Joining the Scientific Advisory Board are Drs. Nina Bhardwaj and Prasad S. Adusumilli. Dr. Bhardwaj brings extensive immunology experience: she is currently the Director of Immunotherapy, Medical Director of the Vaccine and Cell Therapy Laboratory, and Co-Director of the Cancer Immunology Program at The Tisch Cancer Institute and holds the Ward Coleman Chair in Cancer Research. She has made influential contributions to human dendritic cell biology, specifically regarding isolation, biology, antigen presenting function and use as vaccine adjuvants in humans. Dr. Adusumilli, Deputy Chief of Thoracic Service at Memorial Sloan Kettering Cancer Center, brings his extensive experience with the investigation of the tumor immune microenvironment and the development of CAR T-cell-mediated immunotherapies.

About CARISMA Therapeutics Inc.
CARISMA Therapeutics Inc. is a biopharmaceutical company 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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