Cartesian Therapeutics Initiates Phase 2 Clinical Trial of First RNA-Engineered Cell Therapy for Frontline Cancer

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- *Descartes-11 specifically designed to integrate into standard treatment regimen for newly diagnosed multiple myeloma without requiring lymphodepleting chemotherapy*
- *Cartesian plans to enroll up to 30 patients in a single arm, open-label, multicenter study*

Gaithersburg, MD, Feb. 22, 2021 – Cartesian Therapeutics, a fully integrated, clinical-stage biopharmaceutical company pioneering mRNA-engineered cell therapy in and beyond oncology, today announced that it has initiated a Phase 2a clinical trial of its mRNA chimeric antigen receptor (CAR) T-cell therapy, Descartes-11, in patients with newly diagnosed, high-risk multiple myeloma. Based upon the company's research and analysis, this program is understood to be the first RNA-engineered cell therapy to enter clinical development for a frontline cancer. Descartes-11 is the third product candidate to be evaluated in clinical trials resulting from Cartesian's RNA Armory ℠ engineering platform.

"Patients newly diagnosed with high-risk multiple myeloma seldom achieve deep, durable responses after frontline therapy," said Kenneth Anderson, MD, Kraft Family Professor of Medicine at Harvard Medical School and Program Director of the Jerome Lipper Multiple Myeloma Center and LeBow Institute for Myeloma Therapeutics. "Integrating a CAR T-cell therapy into our standard of care, without using lymphodepleting chemotherapy, would be a welcome addition to our toolkit for treating this currently incurable disease."

Descartes-11 is engineered with Cartesian's RNA Armory ℠ platform to express its CAR molecules transiently instead of permanently, thereby reducing both short-term and long-term risks inherent with conventional CAR T-cell therapies. Descartes-11 is manufactured in-house at Cartesian's wholly owned, state-of-the-art cGMP manufacturing facility in Gaithersburg, MD.

A Phase 1 study of Descartes-11 in patients with advanced myeloma showed no evidence of typical CAR T-cell toxicities such as cytokine release syndrome (CRS) of neurotoxicity. Tens of billions of cells are mRNA-engineered with the CAR molecule so that the full therapeutic dose can be administered with each infusion. This eliminates the need for preconditioning chemotherapy required by conventional CAR T-cell therapies.

Murat Kalayoglu, MD, PhD, President and Chief Executive Officer at Cartesian Therapeutics added, "We are hopeful that this study will validate the preliminary safety and efficacy of Descartes-11 in newly diagnosed myeloma, bringing us one step closer to offering a new frontline cell therapy treatment for multiple myeloma patients. Descartes-11 is one of six wholly-owned cell therapy programs being developed using our proprietary RNA-based cell engineering platform, the RNA Armory℠. Our vision is to cure disease by mRNA-engineering any cell, to target to any tissue, any combination of therapies. Our approach enables us to potentially impact a broad range of indications beyond oncology, including respiratory and autoimmune conditions."

About the Phase 1/2a Clinical Trial

The Phase 2a study (NCT04436029) is enrolling patients with newly diagnosed, high-risk multiple myeloma at multiple centers in the United States. This study aims to determine the safety and preliminary efficacy of Descartes-11 in patients with newly diagnosed multiple myeloma who complete a pre-transplant anti-myeloma drug combination treatment but have residual disease after therapy. The study aims to enroll approximately 30 patients. For more information visit cartesiantherapeutics.com/Descartes-11-NDMM.

About Multiple Myeloma

Multiple myeloma, a cancer of plasma cells, is the second most common blood cancer in the world with over 150,000 new cases diagnosed yearly worldwide. The malignant myeloma cells accumulate in the bone marrow, crowding out healthy cells and increasing risk of bone fractures. The disease can also affect the kidneys and immune system. For more information visit https://themmrf.org/.

About the RNA Armory℠

The RNA Armory℠ is Cartesian's proprietary cell therapy platform that enables mRNA-engineering any cell, to target to any tissue, any combination of therapies. Unmodified donor cells enter the RNA Armory℠ in the millions; a battle-ready cell army leaves the RNA Armory℠ in the tens of billions. Each cell is equipped with a combination of therapeutics rationally chosen to have a synergistic effect on the disease. In the body, the cells deliver a precision-targeted treatment regimen directly to the site of disease. The cells express therapeutics with a defined half-life, enhancing their safety profile and making repeat dosing and outpatient administration possible. The platform is agnostic to cell type; we choose the best cell for the job, whether autologous or off-the-shelf. For more information visit cartesiantherapeutics.com/rna-armory.

About Cartesian Therapeutics

Founded in 2016 and with three assets currently in clinical trials, Cartesian is the leader in mRNA-engineered cell therapy. Cartesian's vision is to cure disease by mRNA engineering any cell, to deliver to any tissue, any combination of therapies. The company is pioneering mRNA cell therapies in and beyond oncology, with products in development for respiratory, autoimmune, and oncologic disorders. All investigational therapies are manufactured at Cartesian's wholly owned, state-of-the-art cGMP manufacturing facility in Gaithersburg, MD. For more information visit www.cartesiantherapeutics.com.

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