



Cartesian Therapeutics Announces Dosing of First Participant in a Phase 2b Randomized Clinical Trial for Generalized Myasthenia Gravis

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• First placebo-controlled study of an engineered cell therapy

Gaithersburg, MD, January 31, 2023 – Cartesian Therapeutics, a fully integrated, clinical-stage biotechnology company pioneering RNA cell therapies for autoimmune diseases and cancer, has dosed the first participant in its Phase 2b randomized controlled trial ([RCT](#)) for generalized myasthenia gravis (MG), an autoimmune disorder that causes muscle weakness and fatigue. The RCT will evaluate the efficacy and safety of the company's lead asset, Descartes-08, a first-in-class, RNA-engineered chimeric antigen receptor T-cell therapy (rCAR-T).

To the company's knowledge, this is the first placebo-controlled study of an engineered cell therapy, and the most advanced investigational cell therapy in clinical development for any autoimmune disease. Descartes-08 is administered over 6 weekly outpatient visits and requires no preconditioning chemotherapy.

"As a physician who treats patients with myasthenia, I have been impressed by the magnitude and duration of responses seen in the Phase 2a trial of Descartes-08 in MG," said Tahseen Mozaffar, MD, Professor of Neurology at University of California, Irvine. "A tantalizing observation is that, after a 6-week course of Descartes-08, clinical responses continue to persist for many months and counting. RCTs are the gold standard for clinical trials, and I commend Cartesian for further studying Descartes-08 with this rigorous design."

"We are excited to begin this RCT in patients with MG," said Miloš Miljković, MD, Chief Medical Officer at Cartesian. "A placebo-controlled design will provide a stringent evaluation of Descartes-08 efficacy while elucidating its mechanisms of action. This will result in important insights on treating MG and other autoantibody-mediated autoimmune diseases with Descartes-08."

The Phase 2b study ([NCT04146051](#)) is a randomized, placebo-controlled, multi-center trial enrolling 30 patients with MG. A crossover design ensures that all participants have an opportunity to receive Descartes-08. The primary endpoint is the proportion of participants who achieve a 6-point or greater improvement in the Myasthenia Gravis Activities of Daily Living (MG-ADL) score at 12 weeks. Secondary endpoints include safety and other validated measures of MG disease severity.

About Descartes-08

Descartes-08 is a first-in-class, rCAR-T in clinical development for MG and other autoimmune diseases. Compared to conventional DNA-based CAR T-cell therapies, rCAR-T has predictable and controllable pharmacokinetics and avoids the risk of genomic integration. These attributes are expected to make Descartes-08 safer than DNA-based cell therapies. Descartes-08 is a personalized (autologous) therapy during which cells are collected, engineered with RNA, and returned to the same individual in the outpatient setting. A course of therapy consists of six weekly infusions.

About Myasthenia Gravis

MG is a chronic autoimmune disorder that causes disabling muscle weakness and fatigue. For most people with MG, the disease is characterized by the presence of antibodies against the acetylcholine receptor, a protein found on the surface of nerve cells that plays a key role in muscle contraction. There is currently no cure for MG, and treatment typically requires chronic immunosuppressive medicines, with their attendant risks and side effects.

About Cartesian Therapeutics

Cartesian is pioneering RNA cell therapies for autoimmune diseases and cancer. The company's lead asset, Descartes-08, is a first-in-class, RNA-engineered chimeric antigen receptor T-cell therapy (rCAR-T) in Phase 2b clinical development for patients with generalized myasthenia gravis. Cartesian operates a wholly owned, state-of-the-art cGMP manufacturing facility in Gaithersburg, MD. For more information visit www.cartesiantherapeutics.com.

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