Descartes-08 Generalized Myasthenia Gravis Clinical Trial

University of California, Irvine | UCLA-UCI Alpha Stem Cell Clinic | Department of Neurology

**Study Title:** Autologous T-Cells Expressing a Chimeric Antigen Receptor Directed to B-Cell Maturation Antigen (BCMA) in Patients with Generalized Myasthenia Gravis (GMG)

**Lead Investigator:** Tahseen Mozaffar, MD

**Study Sponsor:** Cartesian Therapeutics, Inc.

What is the study?

The purpose of this study is to test a possible new cell therapy treatment called Descartes-08 in patients with Generalized Myasthenia Gravis (GMG). This study will test the safety, tolerability, and feasibility of Descartes-08.

How long will my participation last?

Study participation will last approximately 8 months, with up to 13 study visits.

How can I take part in this trial?

Up to 18 patients will participate in the study. Please note this may not be a complete list of eligibility criteria.

**Main Inclusion Criteria**

* Adults ≥ 18 years of age
* Confirmed diagnosis of GMG
* Failed treatment for more than 1 year with 2 or more immunosuppressive therapies (ISTs), or failed at least 1 IST and chronic plasma exchange (PE) or intravenous immunoglobulin (IVIg)

**Main Exclusion Criteria**

* Treatment with IVIg or PE within 2 weeks prior to dosing
* Treatment with Rituximab within the past 6 months or Eculizumab within the past 8 weeks
* Current treatment with any immunosuppressive drug, other than prednisone, azathioprine, mycophenolate mofetil, methotrexate
* History of primary immunodeficiency, organ or allogeneic bone marrow transplant
* Have any significant cardiac or pulmonary disease
* History of malignancy that required treatment in the past 3 years
* Have active Hepatitis B, Hepatitis C, HIV, or tuberculosis

How does it work?

Patients will be screened for safety and eligibility through a review of their medical history, physical and mental assessments, and blood tests. In Part I, eligible patients will receive a single infusion of Descartes-08. Part I is a dose escalation phase with three dose levels. A minimum of three patients will be dosed at each level. In Part II, eligible patients will receive 4 weekly infusions at the maximum dose determined in Part I.

**Description of the Study Product:** The study product, Descartes-08, is an autologous T-cell product expressing a chimeric antigen receptor directed against BCMA. Descartes-08 will bind to BCMA protein, eventually reducing or eliminating all types of autoantibodies that play a role in GMG.

Where is the study conducted?

At the UC Irvine Medical Center in Orange, CA.

Will I be compensated?

*TBD*

For more information, please contact:

**UC Irvine Alpha Stem Cell Clinic**

949-824-3990 or stemcell@uci.edu