Cartesian Therapeutics Announces Positive Long-Term Follow-Up Data from Phase 2a Study of Lead mRNA Cell Therapy Candidate Descartes-08 in Patients with Myasthenia Gravis

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Durable depletion of autoantibodies and clinically meaningful improvements in myasthenia gravis (MG) severity scores observed after one-year follow-up period without need for lymphodepleting chemotherapy

Descartes-08 observed to be well tolerated following administration in outpatient setting

Publication is in peer review and available on the preprint server, medRxiv

Topline data from Phase 2b placebo-controlled study continues to be expected in mid-2024

GAITHERSBURG, Md., Jan. 08, 2024 — Cartesian Therapeutics, Inc. (NASDAQ: RNAC), ("the Company") a clinical-stage biotechnology company pioneering mRNA cell therapies for autoimmune diseases, today announced positive twelve-month follow-up data from its Phase 2a trial of Descartes-08 in patients with generalized myasthenia gravis (MG), a chronic autoimmune disorder that causes disabling muscle weakness and fatigue. The manuscript titled, "Twelve-Month Follow-Up of Patients With Generalized Myasthenia Gravis Receiving BCMA-Directed mRNA Cell Therapy," has been submitted for peer-review and can be accessed on the online preprint server, medRxiv.

Descartes-08, Cartesian's lead mRNA cell therapy candidate and a potential first-in-class mRNA-engineered chimeric antigen receptor T-cell therapy (mRNA CAR-T), is an autologous anti-B-cell maturation antigen (BCMA) mRNA CAR-T. In contrast to conventional DNA-based CAR T-cell therapies, mRNA CAR-T administration is designed to not require preconditioning chemotherapy and has been observed to have predictable and controllable pharmacokinetics that allow outpatient administration and is designed to avoid the risk of genomic integration and cancer transformation.

"The 12-month data build on the positive data reported earlier this year in *The Lancet Neurology,* underscoring the potential of Descartes-08 to drive deep and durable responses in patients with MG," said Milos Miljkovic, M.D., Chief Medical Officer of Cartesian Therapeutics. "Notably, most patients maintained robust, clinically meaningful improvements across all four standard MG severity scores approximately 10 months after the last infusion. In addition, the lasting reductions in autoantibody titers are consistent with the observed clinical responses and the proposed mechanism of action for Descartes-08, supporting the deep and long-lasting effects observed in the study. As the first clinical trial using mRNA CAR-T to treat autoimmunity, the study also highlights the potential of our approach to expand the capabilities of cell therapy to address a variety of autoimmune diseases."

The Company previously announced positive data from a Phase 1b/2a study of 14 patients with MG who received Descartes-08 in the outpatient setting and without lymphodepletion. In that dataset, Descartes-08 was observed to be safe and well-tolerated and was observed to induce deep and durable responses.

Data reported today are headlined by long-term results from all participants who received a once-weekly infusion for six weeks (N=7) during the Phase 2a portion of the study:

- Descartes-08 was infused in an outpatient setting without lymphodepleting chemotherapy. Throughout the study and long-term follow-up interval, Descartes-08 was well-tolerated, with no dose-limiting toxicities, cytokine release syndrome, or neurotoxicity.
- At Month 9 follow-up, all participants continued to experience marked and long-lasting clinical improvements across four validated MG disease scoring systems: MG Composite, MG Activities of Daily Living, Quantitative MG scores, and Quality of Life 15-revised. These assessments occurred approximately 7 months after the last Descartes-08 infusion, and no participants received new or increased MG-directed drugs during the study period.
- At Month 12, five of the seven participants maintained clinically meaningful improvement in the same four scoring systems. These assessments occurred approximately 10 months after the final Descartes-08 infusion.
- Two participants experienced loss of clinical effect at Month 12 and were eligible for retreatment. One participant was retreated, and experienced rapid improvement in clinical scores, which was ongoing at Month 6 of follow-up with minimal symptom expression.
- All three participants with detectable anti-acetylcholine receptor (AChR) antibody levels at baseline experienced marked anti-AChR antibody reductions by Month 6, which deepened further by Month 9, and were maintained at Month 12.

Enrollment is ongoing in a Phase 2b randomized, double-blind, placebo-controlled trial (NCT04146051) in patients with MG. Topline results are expected in mid-2024.

Descartes-08 has been granted Orphan Drug Designation by the U.S. Food and Drug Administration for the treatment of MG, and Investigational New Drug (IND) allowance to begin trials in patients with an additional autoimmune disease, lupus.

About Cartesian Therapeutics

Cartesian Therapeutics is a clinical-stage company pioneering mRNA cell therapies for the treatment of autoimmune diseases. The Company's lead asset, Descartes-08, is a potential first-in-class mRNA CAR-T in Phase 2b clinical development for patients with generalized myasthenia gravis. Additional Phase 2 studies are planned in systemic lupus erythematosus under an allowed IND, as well as basket trials in additional autoimmune indications. The Company's clinical-stage pipeline also includes Descartes-15, a next-generation, autologous anti-BCMA mRNA CAR-T. Cartesian operates a wholly owned, state-of-the-art cGMP manufacturing facility in Gaithersburg, MD.

Forward Looking Statements

Any statements in this press release about the future expectations, plans and prospects of the Company, including without limitation, statements regarding the potential of Descartes-08, Descartes-15, and the Company's product pipeline to treat MG, ocular autoimmune diseases, vasculitic autoimmune diseases, or any other disease, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the anticipated timing or the outcome of the FDA's review of the Company's regulatory filings, the Company's ability to conduct its clinical trials and preclinical studies, the timing or making of any regulatory filings, the anticipated timing or outcome of selection of developmental product candidates, the potential of any therapies developed by the Company to fulfill unmet medical needs, and enrollment in the Company's clinical trials and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "hypothesize," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials, including uncertain outcomes, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a particular clinical trial will be predictive of the final results of that trial and whether results of early clinical trials will be indicative of the results of later clinical trials, the ability to predict results of studies performed on human beings based on results of studies performed on non-human subjects, the unproven approach of the Company's RNA Armory ® technology, potential delays in enrollment of patients, undesirable side effects of the Company's product candidates, its reliance on third parties to conduct its clinical trials, the Company's inability to maintain its existing or future collaborations, licenses or contractual relationships, its inability to protect its proprietary technology and intellectual property, potential delays in regulatory approvals, the availability of funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements, the Company's recurring losses from operations and negative cash flows, substantial fluctuation in the price of the Company's common stock, risks related to geopolitical conflicts and pandemics and other important factors discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and in other filings that the Company makes with the Securities and Exchange Commission. In addition, any forward-looking statements included in this press release represent the Company's views only as of the date of its publication and should not be relied upon as representing its views as of any subsequent date. The Company specifically disclaims any intention to update any forward-looking statements included in this press release, except as required by law.

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