Cartesian Therapeutics' Descartes-08 Observed to Provide Deep and Sustained Benefits Through Month 12 After a Single Course of Therapy in Phase 2b Myasthenia Gravis Trial

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After a single course of therapy, Descartes-08-treated participants were observed to sustain deep responses through long-term follow-up, with an average 4.8-point reduction in MG-ADL at Month 12

Deepest and most compelling sustained responses observed in Descartes-08-treated participants who did not have prior exposure to biologic therapies, with an average 7.1-point reduction in MG-ADL and 57% of patients in this subgroup maintaining minimum symptom expression at Month 12

Safety profile consistent with previously reported data and continues to support outpatient administration

Phase 3 AURORA trial on track to dose first patient in 2Q25

FREDERICK, Md., April 08, 2025 (GLOBE NEWSWIRE) -- Cartesian Therapeutics, Inc. (NASDAQ: RNAC) (the "Company"), a clinical-stage biotechnology company pioneering cell therapy for autoimmune diseases, today announced 12-month efficacy and safety data from the Phase 2b trial of Descartes-08 in participants with generalized myasthenia gravis (MG). Participants dosed with a single six-week course of treatment of Descartes-08 were observed to continue to experience a sustained benefit in symptoms of MG at the 12-month assessment. The data will be discussed by management at the 24th Annual Needham Virtual Healthcare Conference today, April 8, 2025, and presented tomorrow, April 9, 2025, by Tuan Vu, M.D., Professor of Neurology at the University of South Florida Morsani College of Medicine, at the 2025 American Academy of Neurology Annual Meeting being held in San Diego.

Descartes-08, Cartesian's lead cell therapy candidate, is an autologous engineered chimeric antigen receptor T-cell therapy (CAR-T) product candidate targeting B-cell maturation antigen (BCMA). Descartes-08 is designed to be administered without preconditioning chemotherapy in an outpatient setting and does not use integrating vectors.

12-Month Phase 2b Trial Results

In the Phase 2b double-blind, placebo-controlled, crossover trial, a total of 36 heavily pretreated, highly symptomatic participants with MG were randomized 1:1 to receive either Descartes-08 or placebo administered as six weekly outpatient infusions without preconditioning chemotherapy. As previously announced, the trial met its primary endpoint and demonstrated a safety profile supporting outpatient administration of Descartes-08. In December 2024, the Company reported updated efficacy and safety data from the trial in which deepening responses were observed over time and some participants were observed to have durable responses through to Month 12.

The primary efficacy dataset for the follow-up portion of the trial consisted of a modified intent-to-treat (mITT) population of all subjects enrolled at academic medical centers who received at least one dose of Descartes-08 and completed at least one post-Month 3 MG Activities of Daily Living (MG-ADL) score follow-up assessment.

As of a March 31, 2025 cutoff date, 12 out of 15 participants who received Descartes-08 in the primary efficacy dataset completed their Month 12 follow-up assessments. Three participants, two of whom were MG Composite (MGC) responders at Month 3, were lost to follow-up after their Month 3 assessments.

12-Month Efficacy Results

- **Deep and sustained responses observed through Month 12 (n=12).**
  - Participants treated with Descartes-08 were observed to have deep responses following initial treatment and sustained symptom improvement, with an average MG-ADL reduction of 5.5 (±1.1) at Month 4 and 4.8 (±1.4) at Month 12.
  - Participants treated with Descartes-08 were observed to have an average Quantitative Myasthenia Gravis Score (QMG) reduction of 4.8 (±1.7) points at Month 4, which deepened through Month 12 (6.0±2.1).
  - 33% (4/12) of participants achieved minimum symptom expression (MSE), defined as an MG-ADL score of 0 or 1, at Month 6, all of whom maintained MSE through Month 12.
  - 83% (10/12) of evaluable participants maintained a clinically meaningful response through Month 12. Clinically meaningful response is defined as a reduction in MG-ADL score of at least 2 points.
- **Deepest and most compelling sustained responses observed in participants without prior biologic therapies (n=7).**
  - The subset of participants who did not have exposure to prior biologic therapies, including complement or neonatal fragment crystallizable receptor (FcRn) inhibitors, were observed to exhibit a deepening of responses throughout

the year, with an average MG-ADL reduction of 6.6 (±1.5) at Month 4 and 7.1 (±1.9) at Month 12.
    - The participants treated with Descartes-08 without exposure to prior biologic therapies were observed to have an average QMG reduction of 5.9 (±2.4) points at Month 4, which deepened through Month 12 (9.4±2.6).
    - 57% (4/7) of these participants were observed to achieve MSE at Month 6 which was maintained through Month 12.
    - 100% (7/7) of these participants were observed to maintain at least a clinically meaningful response through Month 12.

Safety

- **Well-tolerated safety profile supports outpatient administration without the need for lymphodepleting chemotherapy.**
    - Consistent with previously reported data, Descartes-08 was observed to be well-tolerated across the safety dataset through Month 12 (n=12), and adverse events were transient and mostly mild, with no new adverse events reported in the 12-month follow-up data. Notably, there were no cases of cytokine release syndrome (CRS), and no cases of immune effector cell-associated neurotoxicity syndrome (ICANS). In addition, treatment with Descartes-08 was not observed to lead to a decrease in vaccine titers for common viruses and was not associated with increased rates of infection or hypogammaglobulinemia.
    - There were no Descartes-08-related adverse events reported in Month 4 through Month 12 follow-up. As previously reported, common side effects through the Month 3 primary endpoint observed in participants who received any dose of Descartes-08 were infusion-related reactions manifesting as fever (60% of participants receiving Descartes-08), chills (60% of participants receiving Descartes-08), headache (55% of participants receiving Descartes-08) and nausea (45% of participants receiving Descartes-08), all of which typically resolved within 24 hours of infusion.

"This impressive data highlights the potential of Descartes-08 to serve as an important therapeutic option to deliver deep and sustained reductions in MG-ADL for patients with myasthenia gravis," said Tuan Vu, M.D., Professor of Neurology at the University of South Florida Morsani College of Medicine, Division Director for Neuromuscular Medicine and EMG and investigator in the Phase 2b trial. "The data in participants who had not received prior biologic therapy is particularly striking as this population is most comparable to the patient populations in trials of standard-of-care biologics. Participants in this subgroup who were randomized to Descartes-08 were observed to experience a profound average 7.1-point reduction in MG-ADL and 57% these patients were observed to maintain MSE out to Month 12. I look forward to following the continued development of Descartes-08 in MG as it moves into the Phase 3 AURORA trial."

"The remarkable results presented today underscore the potential of utilizing our cell therapy to deliver deep and durable responses in MG patients one year after receiving a single course of therapy in a convenient outpatient setting with no preconditioning chemotherapy," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "The impressive strength and duration of response shown in the data reinforce our confidence in the potential of Descartes-08 to transform the current treatment landscape in MG, offering patients a safe, flexible, and durable treatment option. We look forward to dosing the first patient in our Phase 3 AURORA trial in the second quarter of this year."

Descartes-08 was previously granted Regenerative Medicine Advanced Therapy (RMAT) Designation and Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of MG. Cartesian received written agreement from the FDA under the Special Protocol Assessment (SPA) process indicating the overall design of the planned Phase 3 AURORA trial of Descartes-08 is acceptable to support a future Biologics License Application in MG, subject to the ultimate outcome of the trial. Cartesian remains on track to commence the Phase 3 AURORA trial of Descartes-08 in MG in the second quarter of 2025.

About Myasthenia Gravis

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 Descartes-08

Descartes-08, Cartesian's lead cell therapy candidate, is an autologous chimeric antigen receptor T-cell therapy (CAR-T) product targeting B-cell maturation antigen (BCMA) in clinical development for generalized myasthenia gravis (MG) and systemic lupus erythematosus. In contrast to conventional DNA-based CAR T-cell therapies, Cartesian's CAR-T administration is designed to not require preconditioning chemotherapy, can be administered in the outpatient setting, and does not carry the risk of genomic integration associated with cancerous transformation. Descartes-08 has been granted Orphan Drug Designation and Regenerative Medicine Advanced Therapy Designation by the U.S. Food and Drug Administration for the treatment of MG, and Rare Pediatric Disease Designation for the treatment of juvenile dermatomyositis.

About Cartesian Therapeutics

Cartesian Therapeutics is a clinical-stage company pioneering cell therapy for the treatment of autoimmune diseases. The Company's lead asset, Descartes-08, is a CAR-T entering Phase 3 clinical development for patients with generalized myasthenia

gravis and Phase 2 development for systemic lupus erythematosus, with a Phase 2 basket trial planned in additional autoimmune indications. A Phase 3 trial of Descartes-08 in patients with generalized myasthenia gravis has received written agreement from the FDA under the Special Protocol Assessment process. The Company's clinical-stage pipeline also includes Descartes-15, a next-generation, autologous anti-BCMA CAR-T currently being evaluated in a Phase 1 trial in patients with multiple myeloma. For more information, please visit www.cartesiantherapeutics.com or follow the Company on LinkedIn or X, formerly known as Twitter.

Forward Looking Statements

Any statements in this press release about the future expectations, plans and prospects of the Company, including without limitation, statements regarding observations and data from the Company's clinical trials of Descartes-08 in myasthenia gravis, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the ability of the Company's product candidates to be administered in an outpatient setting or without the need for preconditioning lymphodepleting chemotherapy, the potential of Descartes-08, Descartes-15, or any of the Company's other product candidates to treat myasthenia gravis, systemic lupus erythematosus, juvenile dermatomyositis, or any other disease, 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 novelty of treatment paradigms that the Company is able to develop, 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 proof of concept 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, whether results of early clinical trials will be indicative of the results of later clinical trials, and whether results observed in certain patient subgroups will be indicative of the results in such subgroups in later clinical trials or are reflective of a product candidate's overall characteristics, 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 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 subsequently filed 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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