Cartesian Therapeutics Announces First Participant Enrolled in the Phase 3 AURORA Trial of Descartes-08 in Patients with Myasthenia Gravis

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FREDERICK, Md., May 30, 2025 (GLOBE NEWSWIRE) -- Cartesian Therapeutics, Inc. (NASDAQ: RNAC) ("Cartesian" or the "Company"), a clinical-stage biotechnology company pioneering cell therapy for autoimmune diseases, today announced that the first participant has been enrolled in its Phase 3 AURORA trial of Descartes-08 in patients with myasthenia gravis (MG).

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.

"With the first participant now successfully enrolled, commencement of our Phase 3 AURORA trial represents a significant milestone in our mission to deliver a differentiated, durable treatment option to patients with MG," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "With sustained benefits observed through 12 months in our Phase 2b trial, we believe Descartes-08 has the potential to transform the current MG treatment paradigm with just a single course of therapy."

"Marked by chronic use of steroids and other immunosuppressants while often delivering only limited efficacy, the current standard of care for patients with MG is inadequate," said James (Chip) F. Howard, Jr., M.D., Cartesian Clinical Advisor and Professor of Neurology, Medicine, and Allied Health at the University of North Carolina School of Medicine. "Supported by compelling results from the Phase 2b trial, I firmly believe that Descartes-08 has the potential to serve as a safe, flexible, and durable treatment option for patients with MG. I look forward to helping advance this important study."

The Phase 3 AURORA trial is designed to assess Descartes-08 versus placebo (1:1 randomization) administered as six once-weekly outpatient infusions without preconditioning chemotherapy in approximately 100 participants with acetylcholine receptor autoantibody positive (AChR Ab+) MG. The primary endpoint will assess the proportion of Descartes-08 participants with an improvement in MG Activities of Daily Living (MG-ADL) score of three points or more at Month 4 compared to placebo.

In April 2025, the Company announced updated efficacy and safety data from the Phase 2b trial of Descartes-08 in participants with MG. 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 the MG-ADL score at Month 12. The deepest and most compelling sustained responses were 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. The safety profile of Descartes-08 was consistent with previously reported data and continues to support outpatient administration.

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 in 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. 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, 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, multiple myeloma, 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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