Cartesian Therapeutics Highlights Progress and 2025 Strategic Priorities Across Pipeline of mRNA Cell Therapies for Autoimmune Diseases

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Phase 3 AURORA trial of Descartes-08 in myasthenia gravis on track to commence in 1H25

Deepening responses observed over time in Descartes-08-treated participants in Phase 2b trial in myasthenia gravis; Safety profile continues to support outpatient administration based on updated data shared in December 2024

Phase 2 systemic lupus erythematosus (SLE) trial of Descartes-08 ongoing with expected data readout in 2H25

Cash resources expected to support planned operations, including completion of planned Phase 3 trial for Descartes-08 for myasthenia gravis, into mid-2027

FREDERICK, Md., Jan. 13, 2025 (GLOBE NEWSWIRE) -- Cartesian Therapeutics, Inc. (NASDAQ: RNAC) (the "Company"), a clinical-stage biotechnology company pioneering mRNA cell therapy for autoimmune diseases, today highlighted its recent progress and outlined its 2025 strategic priorities across its pipeline of mRNA cell therapy product candidates.

"On the heels of what was a highly productive 2024, we are entering the new year with strong momentum and believe we are well positioned to continue to make meaningful progress advancing our pipeline in 2025," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "With respect to Descartes-08 for the treatment of myasthenia gravis (MG), we recently shared updated Phase 2b results which continue to support the potential for Descartes-08 to provide deep and durable improvements for patients with MG in the convenient outpatient setting without the need for preconditioning chemotherapy. We believe these results provide strong support for the design of our planned Phase 3 program in this patient population, and we remain on track to commence our Phase 3 AURORA trial in the first half of this year."

Dr. Brunn continued, "In addition, we remain focused on exploring the potential of Descartes-08 beyond MG, with enrollment ongoing in our Phase 2 open-label trial in patients with systemic lupus erythematosus (SLE), and our planned Phase 2 basket trial in pediatric patients with select autoimmune conditions expected to commence later this year. We also continue to develop our work of Descartes-15, our next-gen, autologous anti-BCMA mRNA CAR-T cell therapy, as we move through our Phase 1 dose escalation trial."

Program Updates and Anticipated 2025 Milestones

Descartes-08

- In December 2024, the Company announced positive updated results from the Phase 2b trial of Descartes-08 in participants with MG. Deepening responses were observed over time, with Descartes-08-treated participants included in the primary efficacy dataset (n=12) experiencing an average MG Activities of Daily Living (MG-ADL) reduction of 5.5 (±1.1) at Month 4. Consistent with previously reported data, Descartes-08 was observed to be well-tolerated, supporting outpatient administration without the need for lymphodepleting chemotherapy.

- The Company expects to commence its Phase 3 AURORA trial of Descartes-08 in patients with MG in the first half of 2025. The randomized, double-blind, placebo-controlled Phase 3 trial is designed to assess Descartes-08 versus placebo (1:1 randomization) administered as six once weekly 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-ADL score of three points or more at Month 4 compared to placebo.

- Enrollment remains ongoing in the Company's Phase 2 open-label trial evaluating Descates-08 in SLE. The trial is designed to assess the safety, tolerability and clinical activity of outpatient Descartes-08 administration without preconditioning chemotherapy in patients with SLE. A data readout for this trial is expected in the second half of 2025. SLE is an incurable autoimmune disease marked by systemic inflammation that affects multiple organ systems and impacts approximately 1.5 million people in the United States.

- The Company expects to commence a Phase 2 basket trial of Descartes-08 in pediatric patients with select autoimmune diseases, including juvenile dermatomyositis (JDM), in 2025. The U.S. Food and Drug Administration (FDA) previously granted Rare Pediatric Disease Designation to Descartes-08 for the treatment of JDM, a rare pediatric autoimmune disorder.

Descartes-15

- Dosing is underway in the Company's first-in-human Phase 1 clinical trial of Descartes-15, its next-generation, autologous anti-BCMA mRNA CAR-T cell therapy. The Phase 1 dose escalation trial is designed to assess the safety and tolerability of outpatient Descartes-15 administration in patients with multiple myeloma. Following the Phase 1 dose escalation trial, the Company expects to subsequently assess Descartes-15 in autoimmune indications.

About Descartes-08

Descartes-08, Cartesian's lead mRNA cell therapy candidate, is an autologous mRNA-engineered chimeric antigen receptor T-cell therapy (mRNA 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, mRNA 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 Descartes-15

Descartes-15 is a next-generation, autologous anti-BCMA mRNA CAR-T cell therapy. In preclinical studies, Descartes-15 has been observed to achieve an approximately ten-fold increase in CAR expression and selective target-specific killing, relative to Descartes-08. Similar to Descartes-08, Descartes-15 is designed to be administered without preconditioning chemotherapy and does not use integrating vectors.

About Cartesian Therapeutics

Cartesian Therapeutics is a clinical-stage company pioneering mRNA cell therapy for the treatment of autoimmune diseases. The Company's lead asset, Descartes-08, is an mRNA CAR-T in Phase 2b 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 mRNA CAR-T. 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 about the Company's expected cash resources and cash runway, statements regarding observations and data from the myasthenia gravis Phase 2a/2b trial, 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 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 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 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 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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