Cartesian Therapeutics Highlights Progress and 2024 Strategic Priorities Across Innovative Pipeline of mRNA Cell Therapies for Autoimmunity

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Topline data from Phase 2b study of Descartes-08, the Company's potential first-in-class mRNA CAR-T cell therapy in myasthenia gravis (MG) remains on track for mid-2024

Positive 12-month follow-up data from Phase 2a study in MG reported today; durable depletion of autoantibodies and clinically meaningful improvements in MG severity scores observed approximately 10 months after last infusion

Phase 2 study of Descartes-08 in systemic lupus erythematosus expected to initiate in 1H24

Clinical pipeline expanded following recent IND clearance for Descartes-15, a next-generation mRNA CAR-T product candidate

Approximately $118M pro forma cash and cash equivalents as of December 31, 2023, expected to support planned operations into second half of 2026

GAITHERSBURG, Md., Jan. 08, 2024 (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 2024 strategic priorities across its pipeline of mRNA cell therapy product candidates.

"Following a transformative 2023 for Cartesian, we believe we are well-positioned to execute on several potential value-driving milestones anticipated in the year ahead across our growing pipeline of internally manufactured, innovative mRNA cell therapy product candidates," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "Notably, we continue to expect topline data from the ongoing Phase 2b study of our lead asset, Descartes-08, in patients with myasthenia gravis (MG) in the middle of 2024, which, supported by positive data from the Phase 2a portion of the study, we firmly believe could serve as a meaningful treatment option for patients with MG. We continue to expect the initiation of our Phase 2 study of Descartes-08 in patients with systemic lupus erythematosus (SLE) in the first half of 2024."

Dr. Brunn added, "Beyond Descartes-08, we are also excited to announce that the U.S. Food and Drug Administration (FDA) recently cleared our investigational new drug (IND) application for Descartes-15, a next-generation mRNA-engineered chimeric antigen receptor T-cell therapy (mRNA CAR-T). We are steadfast in our commitment to delivering meaningful new therapies to patients with autoimmune diseases in areas of high unmet need and look forward to continuing to advance this mission in the coming year."

Program Updates and Anticipated 2024 Milestones

Cartesian's internally manufactured portfolio of mRNA cell therapies are purposefully designed to be administered conveniently in an outpatient setting. The Company's RNA-engineering approach is designed to expand the reach of cell therapy to autoimmunity with potent therapies that can be dosed more reliably and safely in an outpatient setting without lymphodepletion. Cartesian's proprietary technology platform, RNA Armory®, is designed to enable precision control and optimization of engineered cells for diverse cell therapies leveraging multiple modalities, including autologous, allogeneic, and *in situ* transfection.

Descartes-08

Descartes-08 is an autologous anti-B cell maturation antigen (BCMA) mRNA CAR-T. Compared to conventional DNA-based CAR T-cell therapies, mRNA CAR-T is designed not to require preconditioning chemotherapy, has been observed to have predictable and controllable pharmacokinetics, and is designed to avoid the risk of genomic integration. Descartes-08 has been granted Orphan Drug Designation by the U.S. FDA for the treatment of MG, a chronic autoimmune disorder that causes disabling muscle weakness and fatigue.

- Enrollment remains ongoing in the Company's Phase 2b randomized, double-blind, placebo-controlled trial of Descartes-08 in patients with MG (NCT04146051), with topline results expected in mid-2024. In the open label Phase 2a portion of the study, Descartes-08 was administered in an outpatient setting without preconditioning chemotherapy. The drug was observed to be safe, well tolerated, and appeared to lead to deep, durable clinical responses. These results were published earlier this year in *The Lancet Neurology*.

- In a separate press release issued today, the Company announced positive twelve-month follow-up data from the Phase 2a portion of the Descartes-08 trial in patients with MG. In the study, five out of seven patients maintained clinically meaningful improvements across all four standard MG severity scores approximately 10 months after the last infusion. In addition, all three participants with detectable anti-acetylcholine receptor antibody levels at baseline experienced durable depletion of autoantibodies through the one-year follow-up period. Descartes-08 was observed to be well-tolerated, with no dose-limiting toxicities, cytokine release syndrome, or neurotoxicity.

- The Company remains on track to initiate a Phase 2 study of Descartes-08 in patients with SLE (NCT06038474) in the first half of 2024. SLE is an incurable autoimmune disease marked by systemic inflammation that affects multiple organ systems. It impacts approximately 1.5 million people in the United States. The Phase 2 study, for which the Company has received IND clearance, is designed to assess the safety and tolerability of outpatient Descartes-08 administration without preconditioning chemotherapy.

- Cartesian continues to anticipate the initiation of Phase 2 basket studies in additional autoimmune indications in the second half of 2024. The studies are designed to assess the safety and tolerability of outpatient Descartes-08 administration without preconditioning chemotherapy.

Descartes-15

Descartes-15 is a next-generation, autologous anti-BCMA mRNA CAR-T. In preclinical studies, Descartes-15 was observed to be significantly more potent than Descartes-08. As with Descartes-08, Descartes-15 is designed not to require preconditioning chemotherapy, has been observed to have predictable and controllable pharmacokinetics and is designed to avoid the risk of genomic integration.

- The Company today announced that the U.S. FDA has cleared its IND application for Descartes-15. Planning for a first-in-human Phase 1 dose escalation study is underway. The study will be designed to assess the safety and tolerability of outpatient Descartes-15 administration in patients with multiple myeloma. The Company expects to subsequently assess Descartes-15 in autoimmune indications.

Financial Update

Cartesian ended 2023 with a pro forma cash position of approximately $118 million, which reflects the anticipated receipt of $40 million through two delayed settlement payments previously announced as part of the November 2023 financing, which are expected later this month and in February 2024. The Company's current pro forma cash balance is expected to support planned operations and the development of Cartesian's pipeline into the second half of 2026, through the Phase 3 study of lead candidate Descartes-08. As of December 31, 2023, the Company had 161.9 million shares of common stock outstanding and 534,261 shares of Series A Non-Voting Convertible Preferred Stock outstanding, which are convertible into approximately 534.3 million shares of common stock.

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 Company's expected cash resources and cash runway, the Company's estimated cash on hand, the expected receipt of proceeds from the Company's November 2023 private placement, conversion of the Company's Series A Non-Voting Convertible Preferred Stock, the potential of RNA Armory® to enable precision control and optimization of engineered cells for diverse cell therapies leveraging multiple modalities, the potential of Descartes-08, Descartes-15, Descartes-33 and the Company's other product candidates to treat myasthenia gravis, systemic lupus erythematosus, 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 ability of the Company to consummate any expected agreements and licenses and to realize the anticipated benefits thereof, 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, the Company's ability to enter into and maintain its strategic partnerships, 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 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.

Contact Information:
Investor Relations:
Melissa Forst
Argot Partners
cartesian@argotpartners.com

Media:
David Rosen
Argot Partners
cartesian@argotpartners.com

Cartesian Therapeutics, Inc.