Cartesian Therapeutics Announces First Patient Dosed in Phase 2 Trial of Descartes-08 in Systematic Lupus Erythematosus

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Trial to assess outpatient administration without lymphodepleting chemotherapy in patients with SLE

GAITHERSBURG, Md., July 02, 2024 (GLOBE NEWSWIRE) -- Cartesian Therapeutics, Inc. (NASDAQ: RNAC) (the "Company"), a clinical-stage biotechnology company pioneering mRNA cell therapy for autoimmune diseases, today announced that the first patient has been dosed in its Phase 2 open-label clinical trial evaluating Descartes-08 in patients with systematic lupus erythematosus (SLE).

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 mRNA CAR-T product candidate targeting B-cell maturation antigen (BCMA). In contrast to conventional DNA-based CAR-T cell therapies, mRNA CAR-T administration is designed not to require preconditioning chemotherapy and is not expected to carry the risk of genomic integration associated with cancerous transformation.

Descartes-08 has previously been administered in patients in a Phase 2 clinical trial for the treatment of myasthenia gravis (MG). To date, the safety profile from the MG trial supports outpatient administration with minimal observation.

"Despite recent advances in the SLE treatment landscape, many patients receiving currently available therapies continue to experience severe, incapacitating symptoms and disease progression," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "Descartes-08 is purposefully designed to overcome the limitations associated with the application of conventional, costly DNA-engineered CAR-T cell therapies for autoimmune diseases. We believe that Descartes-08 could serve as a safe and effective outpatient option for the patients with SLE for whom existing therapies fall short. We are committed to unlocking the full potential of Descartes-08 and look forward to advancing this trial in the months ahead."

"Dosing of the first patient with Cartesian's autologous mRNA CAR-T cell therapy is a monumental accomplishment for the lupus patient community," said Susan Manzi, M.D., M.P.H., Chair of the Medicine Institute at Allegheny Health Network and Medical Director for the Lupus Foundation of America. "Treatment options for lupus patients are suboptimal. I am hopeful that Descartes-08 administered as an outpatient therapy will demonstrate early and long-lasting clinical benefit in patients with certain B cell-mediated autoimmune diseases like lupus."

The Phase 2 open-label trial (NCT06038474), which is expected to enroll up to 30 adult patients, is designed to evaluate the safety and tolerability of outpatient administration of Descartes-08 without preconditioning chemotherapy for the treatment of patients with moderate or severe SLE refractory to immunosuppressant therapy. Secondary outcome measures will assess overall disease activity.

About Systemic Lupus Erythematosus

Systemic lupus erythematosus (SLE) is an incurable chronic autoimmune disease marked by systemic inflammation that affects multiple organ systems including the skin, joints, kidneys, brain, and heart. The symptoms of SLE can range from mild to life-threatening and often include fatigue, joint pain, rash, and fever. SLE impacts approximately 1.5 million people in the United States.

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 and Phase 2 development for systematic 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 regarding the ability of Descartes-08 and mRNA CAR-T product candidates generally to be administered in an outpatient setting or without the need for preconditioning lymphodepleting chemotherapy, the ability of Descartes-08 and mRNA CAR-T product candidates generally to avoid the risk of genomic integration associated with cancerous transformation the potential of Descartes-08, Descartes-15, and the Company's other product candidates to treat MG, SLE, 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 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 subsequent 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.

Investor Contact
Ron Moldaver
Senior Director, Investor Relations & Business Development
ron.moldaver@cartesiantx.com

Media Contact
David Rosen
Argot Partners
david.rosen@argotpartners.com

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