Cartesian Therapeutics Receives FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for Descartes-08 for the Treatment of Myasthenia Gravis

May 22, 2024

Topline data from Phase 2b trial of Descartes-08 in myasthenia gravis remains on track for mid-2024

GAITHERSBURG, Md., May 22, 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 U.S. Food and Drug Administration ("FDA") has granted Regenerative Medicine Advanced Therapy ("RMAT") designation for Descartes-08 for the treatment of myasthenia gravis ("MG").

Descartes-08, the Company's lead product candidate, is an autologous mRNA CAR-T directed against the B cell maturation antigen ("BCMA") initially being developed for the treatment of MG, a chronic autoimmune disorder that causes disabling muscle weakness and fatigue.

"Receipt of RMAT designation underscores our belief that Descartes-08, our potential first-in-class mRNA CAR-T cell therapy, could serve as a meaningful addition to the MG treatment landscape," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "We look forward to working closely with the FDA to efficiently advance the development of Descartes-08 for this underserved population. Looking ahead, we remain on track to report topline data from our ongoing Phase 2b study in patients with MG in the middle of this year."

Established under the 21st Century Cures Act, a product candidate is eligible for RMAT designation if it is a regenerative medicine therapy intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or therapy has the potential to address unmet medical needs for such disease or condition. Receiving RMAT designation offers sponsor companies the benefits of the fast track and breakthrough therapy designation programs, allowing for early, close, and frequent interactions with the FDA with the goal of expediting drug development.

Descartes-08 was previously granted Orphan Drug Designation by the FDA for the treatment of MG.

In January 2024, Cartesian announced positive twelve-month follow-up data from its Phase 2a study of Descartes-08 in patients with generalized MG. In this study, Descartes-08 was administered in an outpatient setting without integrating vectors or preconditioning chemotherapy, and durable depletion of autoantibodies and clinically meaningful improvements in MG severity scores during the one-year follow-up period were observed. Descartes-08 was observed to be well-tolerated, with no dose-limiting toxicities, cytokine release syndrome, or neurotoxicity.

The Company remains on track to report topline data from its Phase 2b randomized, double-blind, placebo-controlled trial of Descartes-08 in patients with MG (NCT04146051) in mid-2024.

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.

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 headquarters relocation, the Company's manufacturing capabilities and ability to support necessary quantities of its product candidates for clinical trials and potential commercialization, the Company's ability to maintain control over its product quality and production, the potential of the Company's technology to enable precision control and optimization of engineered cells for diverse cell therapies leveraging multiple modalities, the potential of Descartes-08 and Descartes-15 and the Company's other product candidates to treat myasthenia gravis, systemic lupus erythematosus, or any other disease, the anticipated initiation timing of planned clinical trials, 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 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.

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

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

Source: Cartesian Therapeutics, Inc.