Talaris Therapeutics Announces Initiation of Phase 2 Clinical Trial of FCR001 in Individuals with a Severe Form of Scleroderma

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FREEDOM-3 trial will evaluate the safety and efficacy of the company's investigational allogeneic cell therapy, FCR001, to treat severe cases of diffuse cutaneous systemic sclerosis (dcSSc)

BOSTON and LOUISVILLE, Ky., Nov. 30, 2021 (GLOBE NEWSWIRE) -- Talaris Therapeutics, Inc., (Nasdaq: TALS), a late-clinical stage cell therapy company developing therapies with the potential to transform the standard of care in solid organ transplantation, certain severe autoimmune diseases, and certain severe non-malignant blood, immune and metabolic disorders, today announced the initiation of the company's Phase 2 FREEDOM-3 trial in diffuse cutaneous systemic sclerosis (dcSSc), a severe form of the rare autoimmune disease scleroderma. This trial will explore the safety of the company's investigational allogeneic cell therapy, FCR001, delivered with non-myeloablative conditioning, in these patients, as well as its potential to halt the progression of organ damage or induce clinical remission in individuals with dcSSc. The University of Michigan is the first FREEDOM-3 clinical site to be activated and has now begun screening for eligible patients. Additional sites are expected to be activated in 2022.

"Currently there are no approved, disease-modifying therapies for dcSSc. While there is encouraging data that suggests that patients with dcSSc could benefit from autologous hematopoietic stem cell transplant (HSCT), the myeloablative conditioning generally associated with those treatment protocols poses considerable safety risks, and disease recurrence has been observed. Unlike autologous HSCT, which infuses the patient's own cells and requires full myeloablative conditioning to optimize efficacy, our investigational therapy, FCR001, is administered with non-myeloablative conditioning and involves the use of cells from a healthy donor with no genetic predisposition for scleroderma," said Nancy Krieger, M.D., Chief Medical Officer at Talaris. "Positive proof-of-concept data in this trial could support the potential applicability of FCR001 to other severe, systemic autoimmune diseases."

FREEDOM-3 (NCT# NCT05098145) is a multicenter, open-label study evaluating the efficacy, safety and tolerability of FCR001, the company's investigational allogeneic cell therapy, in adults with rapidly progressive dcSSc at risk for organ failure. It consists of a one-time treatment administered with non-myeloablative conditioning, after which patients are followed for five years, with a primary analysis on a variety of safety and exploratory efficacy endpoints performed at 24 months.

"Having observed firsthand the promise of autologous stem cell therapy in dcSSc patients, I look forward to exploring the potential of FCR001 to benefit these patients without the need for full myeloablative conditioning," said Dinesh Khanna, M.D., M.Sc., Director of the Scleroderma Program and Professor of Medicine at the University of Michigan Medical School and one of the study's principal investigators. "I am delighted that the University of Michigan is the first activated site to participate in this important study."

"Scientists and healthcare professionals have long been looking for a way to restore self-tolerance in patients suffering from severe autoimmune diseases," said Keith Sullivan, M.D., James B. Wyngaarden Professor of Medicine at Duke University Medical School. "I am excited that FCR001 will be explored as a potential disease-modifying and perhaps corrective therapeutic option for patients with severe scleroderma."

About FCR001
FCR001 is an investigational, allogeneic cell therapy developed by Talaris Therapeutics to induce or restore patients' immune tolerance. FCR001 builds on over 30 years of research by the company's founder, Dr. Suzanne Ildstad, into the means by which durable immune tolerance can be induced in a patient who receives a transplanted organ or can be restored in patients with certain immune-mediated or blood disorders. FCR001 has received both Orphan Drug Designation and Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration. A Phase 3 trial of FCR001 in living donor kidney transplant recipients, FREEDOM-1, is now enrolling patients; more information can be found at: http://freedom1study.com/

About Scleroderma and Diffuse Cutaneous Systemic Sclerosis
Scleroderma is a rare, chronic autoimmune disease that is potentially fatal. The condition involves progressive scarring, or fibrosis, of the body's connective tissues, which affects the skin and vital internal organs, especially the lungs, kidneys, gut and heart, resulting in organ dysfunction. Scleroderma can be classified as either localized or systemic with systemic scleroderma (SSc) being further identified as either limited cutaneous or diffuse cutaneous based on the degree of skin impacted. Patients with the diffuse cutaneous subtype of SSc generally have more rapid skin and internal organ decline and worse outcomes than the limited cutaneous subtype.

About Talaris Therapeutics
Talaris Therapeutics, Inc. is a late-clinical stage biopharmaceutical company developing investigational, one-time, allogeneic cell therapies with the potential to transform the standard of care in solid organ transplantation, certain severe autoimmune diseases, and certain severe non-malignant blood, immune and metabolic disorders. Talaris maintains corporate offices in Boston, MA, and its cell processing facility in Louisville, KY.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended,

including, without limitation, implied and express statements regarding Talaris Therapeutics, Inc.'s ("Talaris," the "Company," "we," or "our") strategy, business plans and focus; the progress and timing of the preclinical and clinical development of Talaris' programs, including FCR001. The words "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" or the negative of these terms and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: the timing and anticipated timing and results of its clinical trials; the risk that the results of Talaris' clinical trials may not be predictive of future results in connection with future clinical trials; the Company's ability to successfully demonstrate the safety and efficacy of its drug candidates. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Talaris' views only as of today and should not be relied upon as representing our views as of any subsequent date. Talaris explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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