Talaris Therapeutics Presents Additional Phase 2 Data and Analyses at American Transplant Congress 2022

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- *Real-world, retrospective analysis of Phase 2 patients versus matched controls finds FCR001-treated patients have improved kidney function and fewer cardiometabolic complications than patients on immunosuppression after 5 years*
- *In long-term follow up of Phase 2 patients, all patients originally weaned off IS have continued to remain off IS without rejecting their donated kidney*
- *Update on FREEDOM-1 study originally planned for June 8 now rescheduled to June 30*

BOSTON and LOUISVILLE, Ky., June 07, 2022 (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 and severe immune and blood disorders, presented additional data and analyses from its Phase 2 trial of FCR001 and other studies of its Facilitated Allo-HSCT Therapy platform at the 2022 American Transplant Congress (ATC).

"We are pleased to be sharing a number of new clinical and preclinical analyses at ATC, including a real-world, retrospective analysis reflecting key health outcomes of our Phase 2 patients treated with FCR001 compared to a matched group of patients treated with standard of care," said Scott Requadt, Chief Executive Officer of Talaris. "This study underscores the potential benefits to kidney function and cardiometabolic health experienced by patients who are able to avoid long-term immunosuppression."

A conference call to provide an interim update on the FREEDOM-1 study, originally planned for June 8, 2022, has been rescheduled pending receipt of data from all participating sites and will now be held on June 30, 2022.

ATC Data Presentation Highlights

- **Real-world data comparison of matched controls to Phase 2 treated patients.** In a poster presented at the 2022 ATC meeting, Talaris reported findings of a retrospective, real-world assessment of the safety and efficacy of FCR001 as compared with standard of care (SOC) immunosuppression. Medical records were used to identify 144 patients who received transplants contemporaneously and at the same institution as 36 of the 37 Phase 2 clinical trial participants, and who met the study's inclusion and exclusion criteria, including age, HLA mismatch and BMI.

  The analysis indicated that patients treated with FCR001 had no higher incidence of death, graft loss or biopsy-proven acute rejection than did patients on IS in the five years post-transplant. Kidney function, defined as estimated glomerular filtration rate (eGFR), was significantly higher in patients treated with FCR001 at five years (p=0.02), and key immunosuppression-related cardiometabolic complications were observed less frequently in patients treated with FCR001 compared to those on IS.

- **Phase 2 long-term follow-up shows consistent durability off IS.** In an oral presentation at the 2022 ATC meeting, Talaris provided an update on the continued long-term follow-up of patients in its Phase 2 LDKT study. Talaris previously reported that 26 of 37 (70%) patients in its Phase 2 study achieved stable T-cell chimerism and were weaned off all chronic IS by approximately 12 months after their transplant. To date, all surviving patients weaned off IS remain IS- and rejection-free. Talaris has followed these patients from five to 12.8 years post-transplant. Six subjects have remained off IS > 10 years.
  - In the Phase 2 study, Talaris did not observe any correlation between the degree of HLA mismatch and the safety or efficacy measures in the study. Patients at all levels of HLA matching were able to discontinue chronic immunosuppression, with 19 out of 26 recipients (73%) who durably discontinued their chronic IS having an HLA match of three or less to their donor.
  - As of May 31, 2022, Talaris has accumulated over 250 patient-years of exposure to FCR001 in LDKT, and the safety profile observed in the Phase 2 patients remains generally consistent with that expected with kidney and allogeneic stem cell transplantation involving non-myeloablative conditioning.

- **COVID-19 outcomes among Phase 2 patients.** In a poster presented at the 2022 ATC meeting, investigators at Northwestern University shared updated data on COVID-19 rates, effects of COVID-19 infection and antibody response to vaccination among evaluable patients in the Company's Phase 2 study. Of the 23 durably chimeric patients off chronic IS, 18 were vaccinated, of whom 5 (28%) tested positive for COVID-19. None of these 18 patients lost chimerism as a result of their COVID-19 vaccination. Among the remaining 5 patients who were off all chronic IS but were unvaccinated, 3 (60%) tested positive for COVID-19. Among the 5 patients who remained on chronic IS, 4 of whom were vaccinated, 3 (60%) tested positive for COVID-19. COVID-19 infection did not lead to reduction in renal function for patients, and none of the COVID-19-infected patients were hospitalized or experienced acute kidney injury as a result of their infection.

  As previously reported, post-vaccination antibody testing had been performed on 4 patients (3 durably chimeric, 1 not). These data showed that all 4 patients produced strong antibody responses to COVID-19 vaccination.

- **Identification of immune cells involved in sensitization.** In a poster presented at the 2022 ATC meeting, Talaris reported findings from a study in animal models to discern the mechanisms of immune sensitization, which increases the risk of graft rejection for bone marrow and solid organ transplants. An examination of immune response to foreign cells in mice engineered to lack either T cell receptors or Fcγ receptors found that Fcγ-bearing macrophages and NK cells, and not T cells, mediate this type of immune rejection.

- **Potential urinary biomarker of immune quiescence.** In an oral presentation at the 2022 ATC meeting, Talaris reported findings of urinary mRNA profiling that it performed in a subgroup of Phase 2 LDKT patients who were tolerized to their donated kidney, as well as in a biopsy-matched cohort of standard of care LDKT recipients on chronic IS. The analysis identified potential signals of greater immune quiescence in the kidneys of tolerized patients as compared to the standard of care cohort. These findings may provide further support that these patients have been tolerized to their donated kidney.

Conference Call & Webcast Information
Talaris will host an investor webcast and conference call on Thursday, June 30, 2022 at 8:00 a.m. ET to discuss its presentations at the American Transplant Congress (ATC) and provide a data update from its ongoing Phase 3 FREEDOM-1 study in living donor kidney transplant (LDKT) recipients, pending receipt of data from all participating sites. To access the conference call, the dial-in numbers are 1-855-605-1739 for domestic callers and 1-914-987-7955 for international callers. The conference ID number for the live call will be 6249115. A live webcast and replay of the conference call will also be available under "News & Events" in the Investors section of the Company's website at www.talaristx.com.

About Talaris Therapeutics
Talaris Therapeutics, Inc. is a late-clinical stage cell therapy company developing therapies with the potential to transform the standard of care in solid organ transplantation and severe immune and blood disorders. Talaris maintains corporate offices in Boston, MA, its cell processing facility in Louisville, KY, and additional research operations in Houston, TX.

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 impact of COVID-19 on countries or regions in which the Company has operations or does business, as well as on the timing and anticipated timing and results of its clinical trials, strategy and future operations, including the expected timing and results from FREEDOM-1, the risk that the results of Talaris' clinical trials may not be predictive of or consistent with future and/or final results in connection with the Company's ongoing or future clinical trials; the therapeutic benefits expected from the Company's product candidates, including FCR001 and 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 March 31, 2022, 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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