FCR001 is a cryopreserved facilitated allogeneic stem cell therapy derived from mobilized peripheral blood of the kidney donor that is delivered as a single dose with a nonmyeloablative conditioning regimen. FCR001 contains the donor’s CD34+ hematopoietic stem cells (HSCs), facilitating cells, and αβTCR+ T-cells.

The goal of FCR001 treatment is to induce immune tolerance by creating a “dual immune system” (part donor and part recipient) in the transplant recipient. These two immune systems coexist, recognizing both the recipient’s own body as well as the donated organ as “self.” This is also referred to as achieving chimerism in the recipient’s immune system.

**Achieving durable chimerism in a recipient’s immune system potentially enables long-term immune tolerance in the absence of chronic immunosuppression.**

### Unmet Need with Current Standard of Care

While solid organ transplantation can be a life-saving procedure, continued risk for graft rejection remains a primary obstacle. Dependence on immunosuppression (IS) drugs has been important to prevent rejection. Current immunosuppressive regimens are not always sufficient to prevent organ rejection over time and may cause toxicity (e.g., kidney toxicity with calcineurin inhibitors) that may compromise the health of the transplanted organ.

Chronic IS therapies are also the treatment for autoimmune diseases, where they control the autoimmune reaction that develops as a result of loss of self-tolerance; however, IS only minimizes the impact on affected organs and is not curative.

An unmet need remains for alternative therapies that minimize or eliminate the requirement for indefinite IS through the induction of immune tolerance.
### Overview of Ongoing Clinical Trials

#### FREEDOM 1

**NCT03995901**: Phase 3, randomized, controlled, multicenter, safety and efficacy study of FCR001 cell-based therapy relative to a tacrolimus- and mycophenolate-based regimen in LDKT recipients and safety in FCR001 donors

**Recipients**: Adults (≥18 years old) undergoing a first or second LDKT

**Donors**: Age 18–60 years and willing to undergo mobilization, apheresis, and 12-month safety follow-up

Currently enrolling patients. For more information, visit [https://freedom1study.com/](https://freedom1study.com/)

#### FREEDOM 2

**NCT01649388**: Phase 2, randomized, controlled, multicenter, safety and efficacy study of FCR001 cell-based therapy relative to a tacrolimus- and mycophenolate-based regimen in de novo LDKT recipients and safety in FCR001 donors

**Recipients**: Adults (≥18 years old) who received a first kidney transplant from a living donor 3–12 months prior to study enrollment

**Donors**: Age 18–60 years and willing to undergo mobilization, apheresis, and 12-month safety follow-up

Currently enrolling patients. For more information, visit [https://freedom-2study.com/](https://freedom-2study.com/)

#### FREEDOM 3

**NCT05098145**: Phase 2, single-arm, open-label, multicenter, proof-of-concept exploring the safety and clinical activity of FCR001 in patients with a rapidly progressive form of scleroderma

**Recipients**: Adults (≥18 and <70 years old) with rapidly progressive diffuse cutaneous systemic sclerosis at risk of organ failure with modified Rodnan Skin score >15 and <40; <5 years from first non-Raynaud’s phenomenon symptom; past or current IS

**Donors**: Age 18–60 years and willing to undergo mobilization, apheresis, and 12-month safety follow-up

Currently enrolling patients. For more information, visit [https://talaristx.com/our-programs/severe-autoimmune-disease/](https://talaristx.com/our-programs/severe-autoimmune-disease/)

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### References