Conference Call Reviewing Data Presented During the 2021 American Society of Nephrology (ASN) Meeting

November 4, 2021

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Agenda

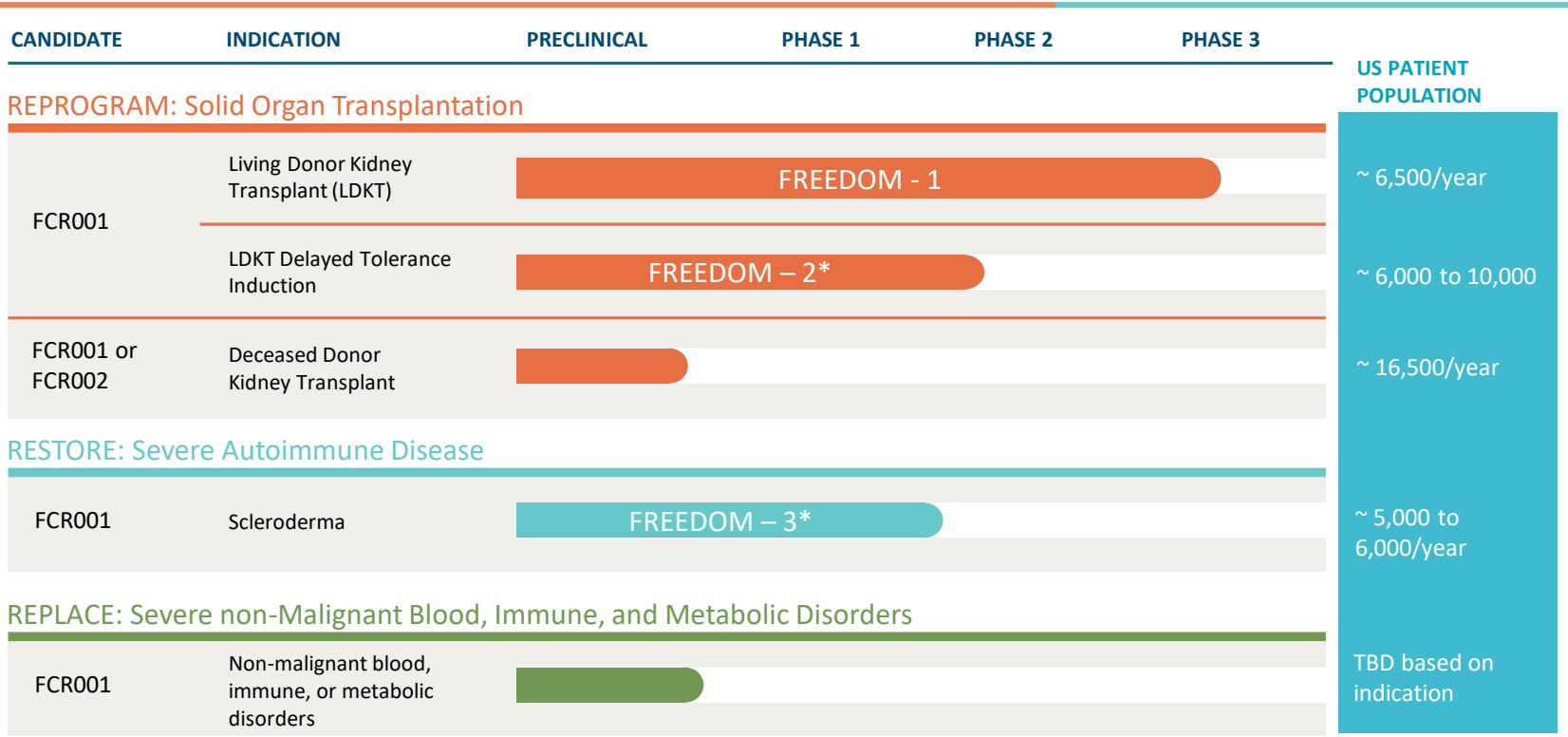
- Welcome and Introduction
- Top Line Results
  - Phase 3 initial data
  - Phase 2 long-term follow-up
  - Potential predictive urinary biomarker
- Q&A
- Conclusion

Talaris at a Glance

Novel, single-dose, investigational cell therapy with potential to transform standard of care in solid organ transplantation and multiple severe immune and non-malignant blood disorders

- **Lead product, FCR001, in Phase 3 to induce durable immune tolerance in living donor kidney transplant (LDKT) recipients**
  - Compelling Phase 2 data
  - Open label Phase 3 design mirrors optimized Phase 2; Orphan drug and RMAT designation from FDA
  - Highly predictive, near-term surrogate marker of long-term success identified in Phase 2
  - First clinical update November 4, 2021
- **FCR001 has pipeline-in-a-product potential across multiple therapeutic applications**
  - Large market opportunity
  - Initiated Phase 2 FREEDOM-2 study in October; additional Phase 2 study in autoimmune disease initiating 4Q 2021
  - Additional indications being investigated
- **Robust, reproducible and fully in-house manufacturing**
- **Strong IP position and high barriers to entry**
- **Well-financed; over $265M cash on hand as of June 30, 2021**

Our Pipeline



* Open IND permits us to move directly into Phase 2 based on existing FCR001 safety data

** Organ transplant population estimates based on UNOS/OPTN data; scleroderma estimates derived from epidemiology and third party market research; LDKT Delayed Tolerance Induction patient numbers based on 1 year to 18 months delayed from incident LDKT; Scleroderma estimated point prevalence of diffuse cutaneous SSc patients with early, rapidly progressing disease and internal organ involvement

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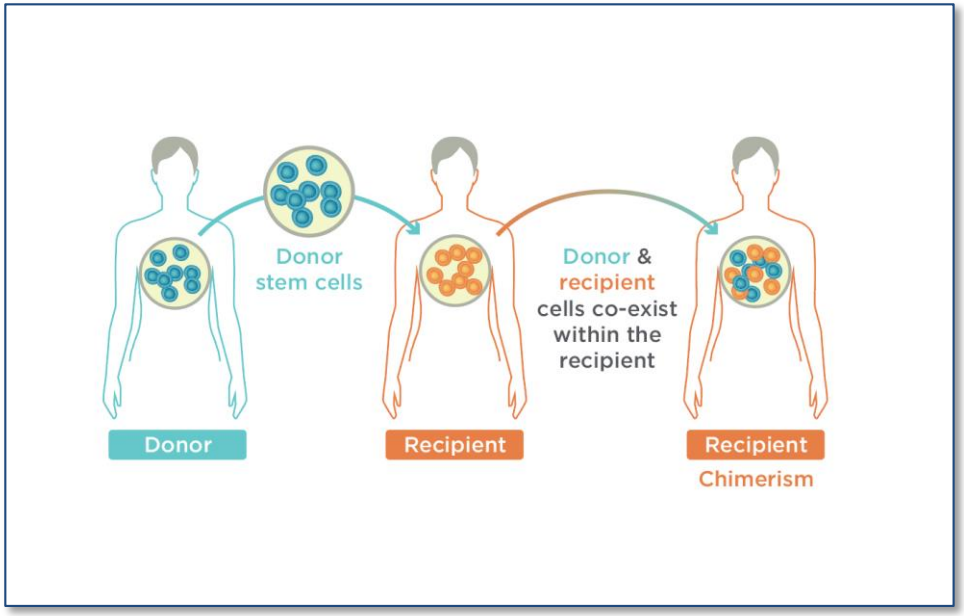
Allogeneic Tolerance and Chimerism

Nobel Prize 1960*

Goal: **facilitate <u>allogeneic</u> tolerance** by establishing **<u>durable</u> chimerism**

Allogenic tolerance: An approach to enable donor HSCs to coexist with recipient HSCs in the recipient's bone marrow ("chimerism"), and mature into mutually-tolerated, functional immune cells and blood cells



Nobel Prize in Physiology or Medicine 1960 was awarded jointly to Sir Frank Macfarlane Burnet and Peter Brian Medawar 'for discovery of acquired immunological tolerance.' The Nobel Prize in Physiology or Medicine 1960. NobelPrize.org. Nobel Media AB 2021. Tue. 16 Mar 2021.

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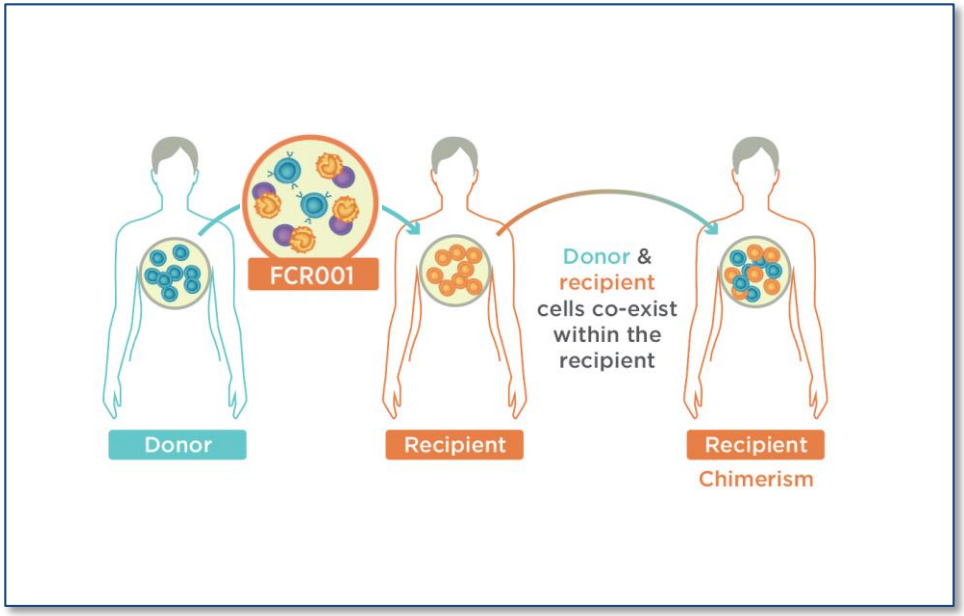

**Nobel Prize in Physiology or Medicine 1960 was awarded jointly to Sir Frank Macfarlane Burnet and Peter Brian Medawar 'for discovery of acquired immunological tolerance.' The Nobel Prize in Physiology or Medicine 1960. NobelPrize.org. Nobel Media AB 2021. Tue. 16 Mar 2021.*

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Facilitating Immune Tolerance

Multiple Potential Applications

Reprogram

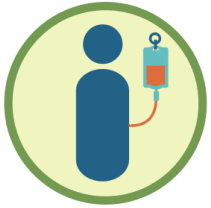
Solid Organ Transplantation

Prevent organ rejection and the need for a lifelong, daily regimen of chronic drugs by reprogramming the transplant recipient's immune system.

Restore

Severe Auto-Immune Disease

Treat autoimmune diseases by restoring the body's immune system to produce cells that are potentially capable of attacking "self".



Replace

Severe Non-Malignant Blood, Immune, and Metabolic Disorders

Treat disorders caused by diseased immune or blood cells by replacing them with healthy cells, without the need for myeloablative conditioning

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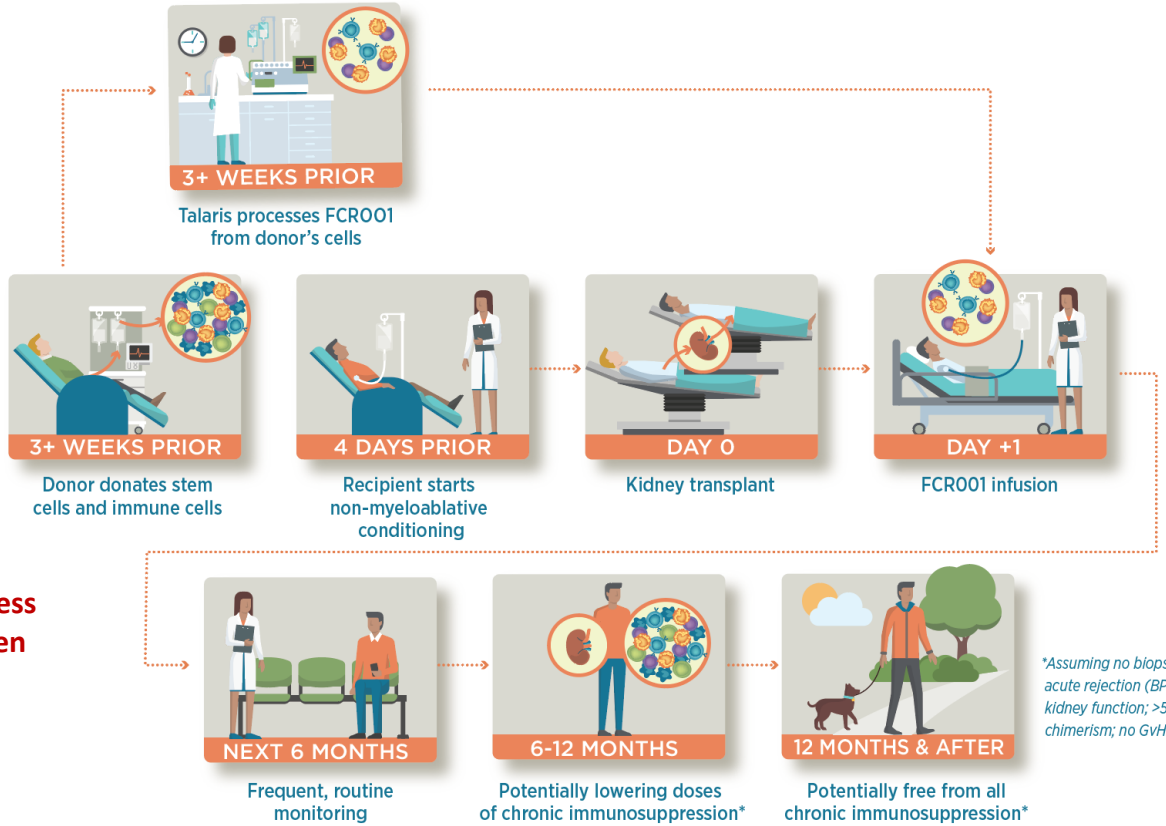
FCR001: The Donor-Recipient Journey



Our "vein to vein" process and protocols have been fully proceduralized

**Assuming no biopsy-proven acute rejection (BPAR); stable kidney function; >50% donor chimerism; no GvHD*

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Highlights from Our Phase 2 Study (+ Long Term Follow Up)*

37 adult living donor kidney transplant (LDKT) patients were dosed with FCR001 at two leading US transplant sites between 2009 - 2016

70%

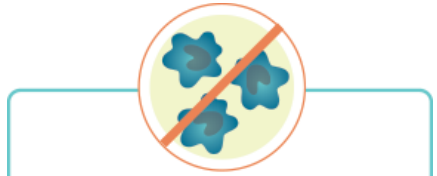
(26 OF 37) OFF ALL IMMUNOSUPPRESSION THERAPIES**

- Across all HLA-mismatches
- 82% success rate (14 of last 17) once key parameters were optimized

100%

TAKEN OFF IMMUNOSUPPRESSION REMAIN IS-FREE

- Median follow up: >6 yrs
- Longest follow up: >12 yrs



7/7

TOLERIZED PATIENTS WITH PRIOR KIDNEY AUTO-IMMUNE CONDITION HAD NO RECURRENCE

- Recurrence ordinarily seen in 20% - 60% of patients***

** Data as October 1, 2021. Includes 33 patients under Phase 2 protocol and 4 compassionate use patients*
*** One year after transplant*
**** Kienzl-Wagner 2018, Lim 2019, Moroni 2019*

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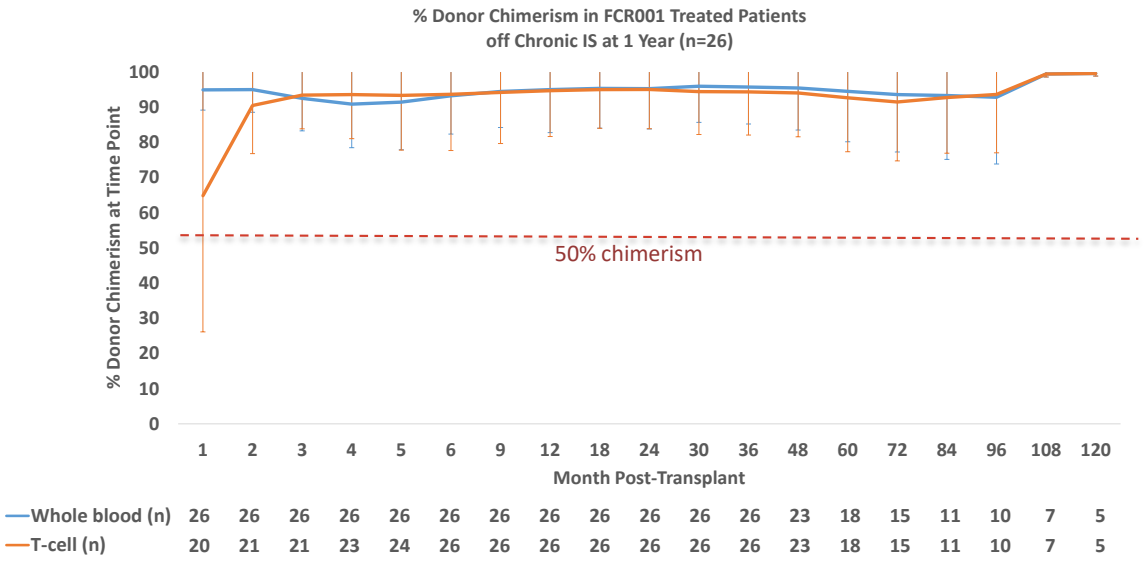
In Phase 2, Three and Six-Month Chimerism Were Highly Predictive of Durable Immune Tolerance



Values are mean +/- standard deviation. N indicates the number of FCR001 treated patients weaned off IS at approximately one year post-transplant for whom % whole blood and T-cell donor chimerism were measured at that time point

- **"Chimerism"**
  - % of recipient's T-cells that are donor-derived
  - Simple blood test, measured at multiple time points
- **26/29 patients** (90%) who achieved chimerism at **month 3** were able to be weaned off chronic immunosuppression (IS)
- **26/27 patients** (96%) who achieved chimerism at **month 6** were able to be weaned off chronic IS
- **Every patient** weaned off chronic IS by **month 12** has remained off chronic IS for full duration of follow up
  - Median follow up >6 years
  - Longest follow up >12 years

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Initial Phase 3 Clinical Data

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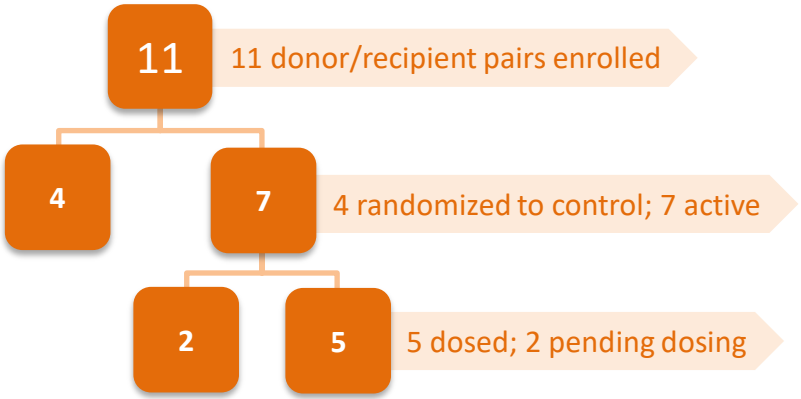
FREEDOM-1 Phase 3 Registration Study

STUDY OVERVIEW	
Study Design	• **Open-label**, randomized, controlled, parallel group study of FCR001 in 120 first time, adult living donor kidney transplant (LDKT) recipients, randomized 2:1 between FCR001 : standard of care (SoC) • Five-year follow up for safety
Protocol; inclusion / exclusion criteria	• Near-identical to optimized Phase 2 protocol
Primary Endpoint	• Proportion of FCR001 recipients who are free from chronic immunosuppression, without biopsy proven acute rejection (BPAR), at Month 24 post-transplant
Key Secondary Endpoint	• In FCR001 recipients only, no meaningful decline in renal function from post-transplant baseline (Month 1) to Month 24
Additional Endpoints	• Chimerism, kidney function, safety
Sites / Territory	• Targeting ~18-20 sites in U.S. (14 active sites as of October 1, 2021)

- **Neither primary nor key secondary endpoint involves statistical comparison to the SoC patients**

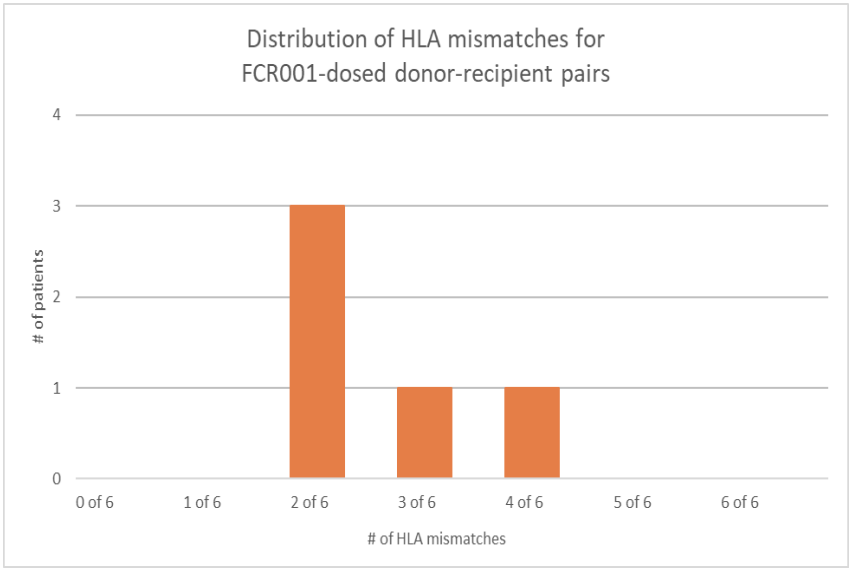
Enrollment, Demographics and HLA-matching

Enrollment and Demographics



- The 11 donor/recipient pairs have been enrolled at 5 different clinical sites
- All donors and recipients were between 18 – 65 years of age and met study eligibility criteria

HLA Mismatching Data



Clinical Update on First Phase 3 Patients

Reprogram

Status of first five patient dosed with FCR001:

	Time Since Kidney Transplant				
# of pts	<3mo	>3mo	>6mo	>12mo	>12/off IS
2	Chimeric* at 3, 6 and 12mo timepoints & removed from IS				
1	Chimeric* at 3 and 6 mo timepoints				
2	NM	*Not measured; patient has not reached 3mo timepoint*			
5					

- **First two FCR001 subjects >12 months since transplant are off all chronic IS**
  - Both have maintained stable kidney function since being discontinued from chronic IS
  - Longest follow up: 15 months

*Chimeric: Achieved and maintained >50% T-cell chimerism at designated study visit timepoint

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Safety Profile Appears Consistent with Phase 2

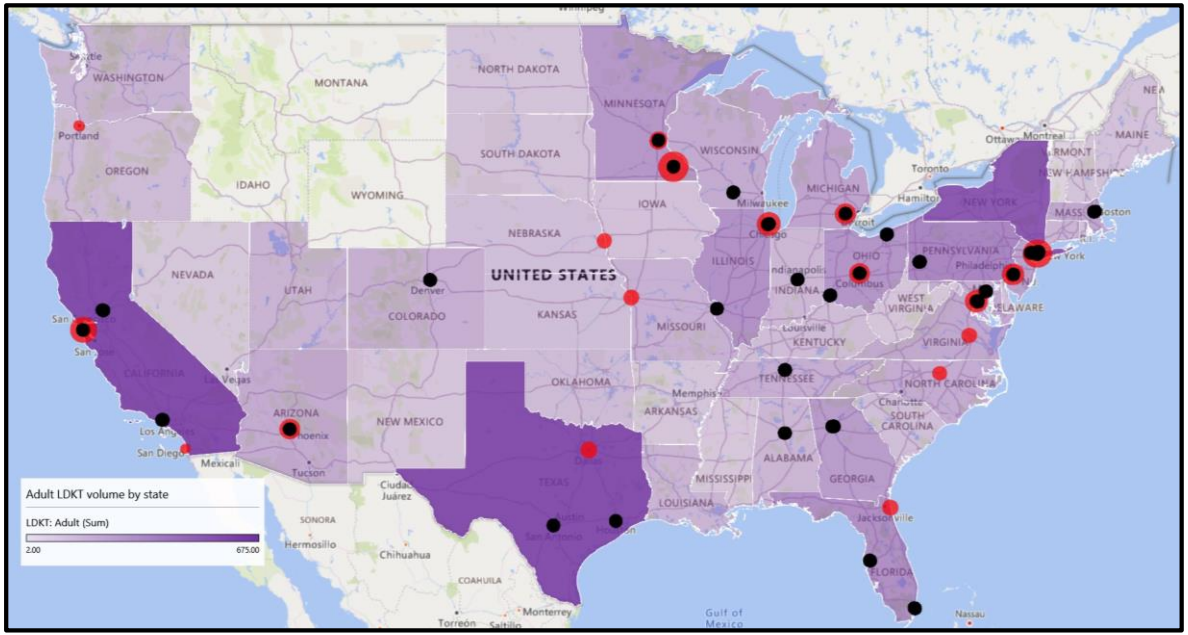
- **Summary of BPAR and DSA data in all FCR-001 patients***
  - No instances of BPAR
  - No patients have developed donor-specific antibodies (DSA)

- **Summary of safety profile in FCR001 patients***
  - AEs and SAEs observed are consistent with those generally expected with kidney and stem cell transplantation involving non-myeloablative conditioning, and with what was observed in the Phase 2 study.
  - No events occurred to cause the Data Safety Monitoring Board (DSMB) to stop the study or modify the study protocol
  - No trial stopping rule was triggered

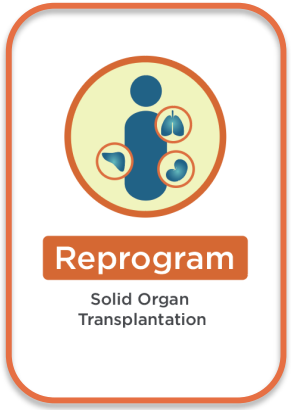
** Through the October 1, 2021, data cutoff date*

Potential to Extend Across Solid Organ Transplant

35 centers (16% of total) perform 50% of all US LDKT procedures



- Highest volume LDKT centers
- Current or proposed FREEDOM-1 sites (circle size proportional to LDKT volume)



Phase 2 Long-Term Follow-Up

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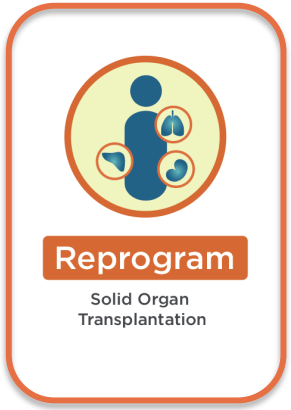
Long-Term Follow-Up of Phase 2 Patients*

- All Phase 2 patients weaned off chronic IS have continued to remain off chronic IS for the duration of their follow-up, without rejecting their donated kidney and without DSA
- Median follow up >6 years; longest follow up >12 years.
- Six Phase 2 LDKT recipients have now exceeded 10 years off all chronic IS
- Since last update, there has been one patient death that the DSMB deemed to be unrelated to FCR001. As previously reported, this patient was not tolerized, remained on IS, and had lost their graft 47 months post-transplant
- Cumulative total of more than 250 patient-years of exposure to FCR001 in the Phase 2 LDKT recipients.
- Most adverse events in the Phase 2 study occurred during the first 12 months post-transplant when the patients were on conventional immunosuppression

** Through the October 1, 2021, data cutoff date*



Urinary mRNA Profiling

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Potential New Signal of Immune Quiescence

- **Summary.** In a subset of FCR001 patients in the Phase 2 study, Talaris identified a potential mRNA signature of immune quiescence in the FCR001-tolerized patients
- **Method.** Using urinary cell mRNA profiling, urine samples from a subset of tolerized Phase 2 FCR001 patients were compared to those from biopsy-matched, non-study LDKT patients on standard of care chronic immunosuppression
- **Results.** The FCR001 patients assessed in the study exhibited a differentiated mRNA signature from the biopsy-matched, non-study LDKT patients. This signature featured increased levels of CTLA4 mRNA and significantly higher ratios of CTLA4 to both granzyme B and perforin. The higher ratios of CTLA4 to granzyme B and perforin in the FCR001-tolerized patients may indicate a greater degree of immune quiescence in the FCR001-tolerized patients than in the biopsy-matched, standard of care kidney transplant recipients
- **Conclusion.** These data support the hypothesis that the FCR001 patients have been tolerized to their donated kidney

Potential to Extend Across Solid Organ Transplant

Reprogram

Living Donor Kidney Transplant Delayed Tolerance Induction

FREEDOM·2

- Phase 2 study initiated October 2021
- **Goal**: Safely induce durable tolerance and eliminate immunosuppression in **prior recipients of LDKT** (those transplanted 3 – 12 months prior to FCR001 administration)
- Potential to expand market to prevalent LDKT population

Potential US Market Opportunity: ~6,000 – 10,000*/yr

Deceased Donor Kidney Transplant

FREEDOM·4

- Active research program to establish feasibility of extracting same cells directly from deceased donor bone marrow
- Relationships established with KODA and other OPOs
- Product would be administered a few months after organ transplant

Potential US Market Opportunity ~16,500 / yr

Organ transplant population estimates based on UNOS/OPTN data; scleroderma estimates derived from epidemiology and third-party market research
*: Based on 1 year to 18 months delayed from incident LDKT

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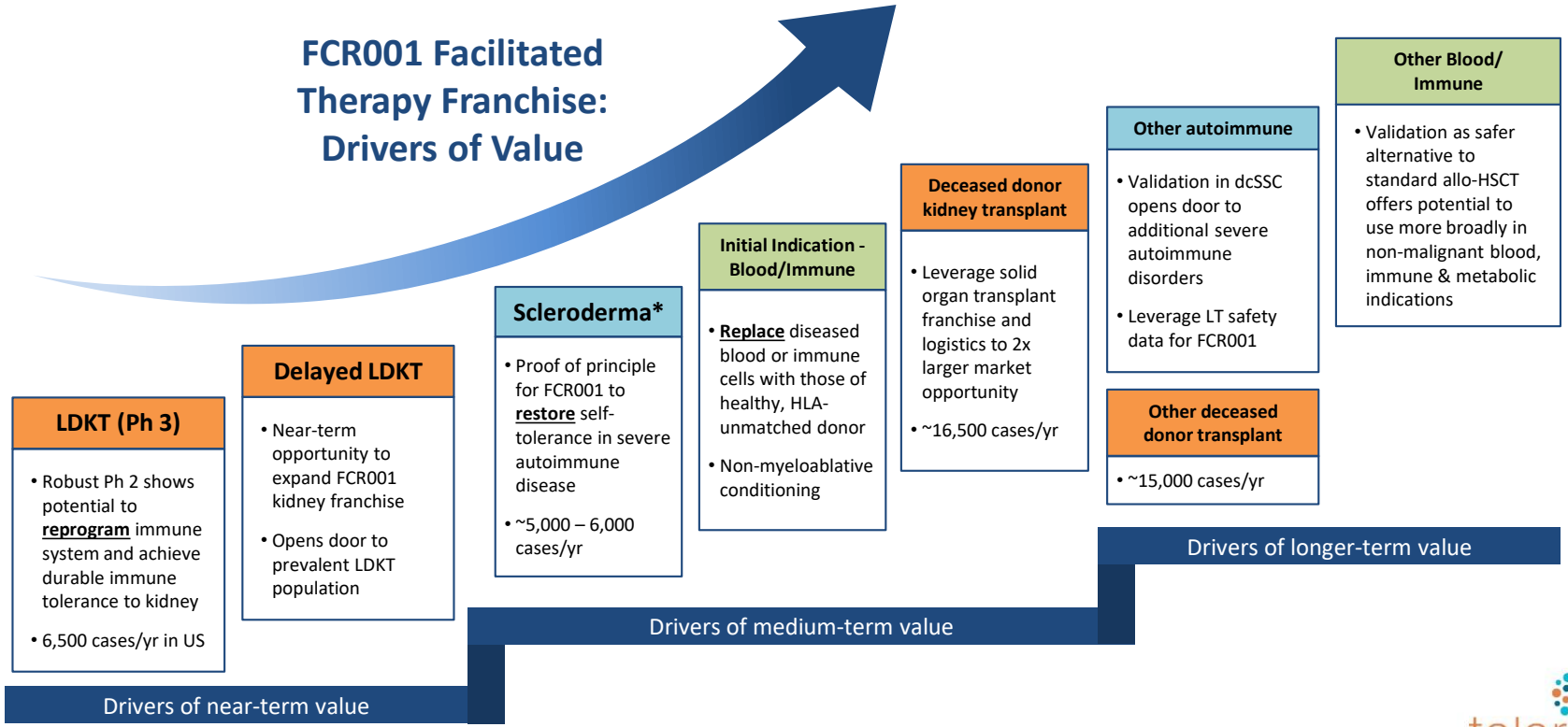
Path to Significant Value Creation



* Diffuse cutaneous systemic sclerosis (dcSSc) patients with early, rapidly progressive disease

Questions?

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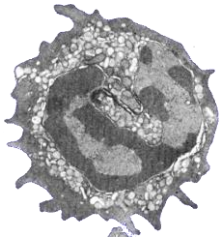
Backup Slides

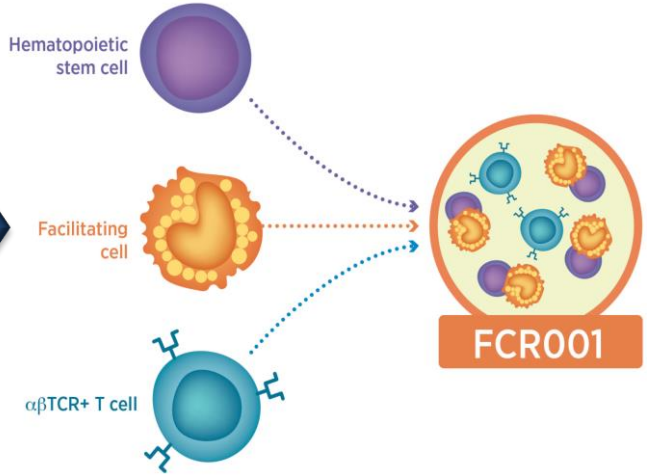
FCR001: A Modified, Allogeneic HSC-based Therapy

Proprietary composition of donor's CD34+ cells, Facilitating cells and αβ T-cells

Facilitating Cell



Unique, tolerogenic "non-stem cells"
(CD8+, TCR-)



Potential to:

- ✓ Promote stem cell engraftment in unmatched recipients
- ✓ Prevent GvHD in mouse models
- ✓ Induce antigen-specific T_{reg}
- ✓ Induce B_{reg}

- FCR001 is administered with **non-myeloablative conditioning**, at doses and using protocols optimized over two decades of study
- Broad, issued composition of matter patents

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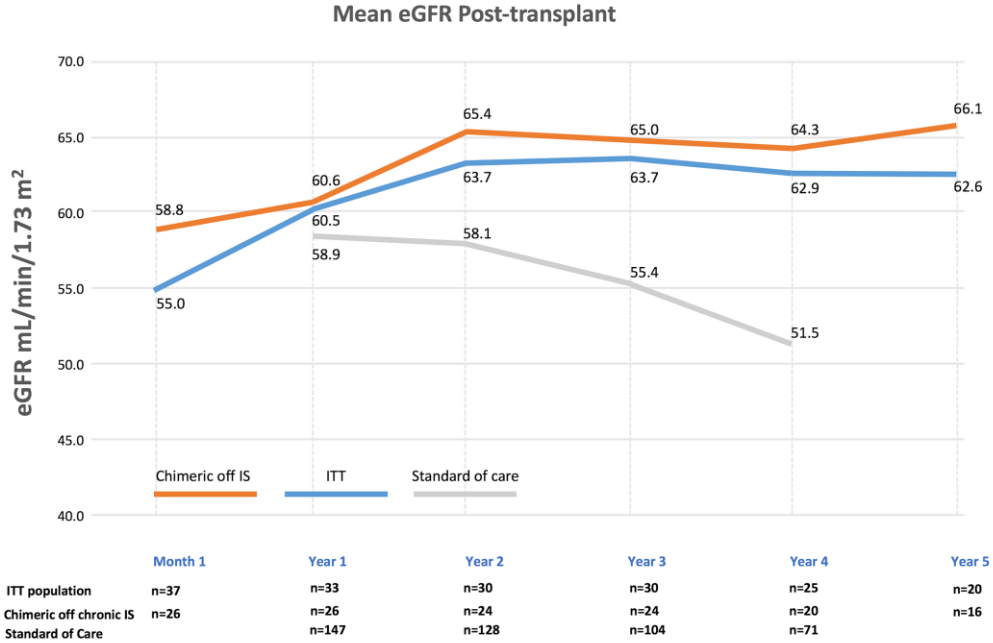
Kidney Function Over Time from Ph 2 Patients

Mean Estimated eGFR* Over Time Post- Transplant



* Standard of care = retrospective analysis by Dr. J Leventhal of transplanted SoC patients at same site between 2009-2012, who met Ph 2 eligibility criteria

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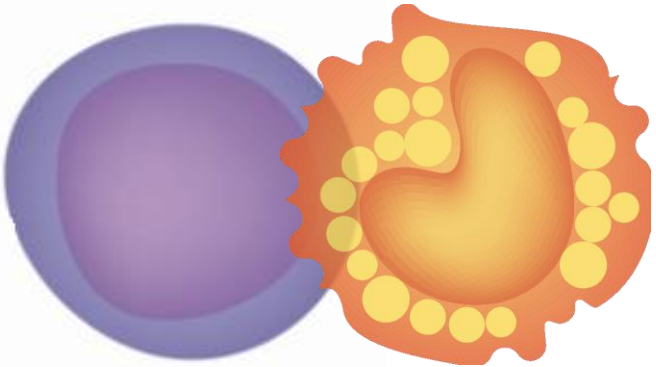
Facilitating Cell Mechanism of Action

Induces IL-10+ B_{reg} *in vitro*
Manuscript in Preparation
Nupur, *Exp Hematol* 2007, 5:1847-1857-1857

Induces antigen-specific T_{reg} *in vivo*
Taylor KN. *J Immunol. 2007;* 179 (4): 2153-62
Huang Y. *Blood*. 2011; 117(8):2494-2505
Colson, *Blood* 2004, 104:3829-3835

Prevents apoptosis of HSC and enhances clonogenicity of HSC
Rezzoug F. *J Immunol.* 2008; 180(1);49-57
Fugier-Vivier I. *J Exp Med.* 2005; 201(3) 373-383

Stem Cell



Facilitating Cell

Gene arrays of mouse and human FC show strong B cell signature
Manuscript in Preparation
Nupur, *Exp Hematol* 2007, 5:1847-1857

Enhances homing and migration
Wen, *Stem Cells.* 2014; 32(1): 2732-43
Kaufman, *Blood* 1994, 84:2436-2446
Gandy, *Immunity* 1999, 11:579-590
Bridenbaugh, *Blood* 2008, 111:1735-1738

Prevents GVHD in Mice
Manuscript in Preparation
Taylor KN. *J Immunol. 2007;* 179 (4): 2153-62
Colson, *Blood* 2004, 104:3829-3835

Black text= Ildstad laboratory publications
Red text = external publications

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Unmet Need in Organ Transplant: Challenges of Chronic Immunosuppression

"Ideally you want to avoid getting sick or being around sick people because your immune system is suppressed. Unfortunately, in the world we live in, you're going to get sick. The first couple of times I got sick, I was terrified."

- Male living donor kidney recipient in 40's

"While others might breeze out the door in the morning, I am already preoccupied with preventing rejection, infection, and cancer."

- FDA Voice of the Patient Panelist

- **Immunosuppression is not disease-modifying; requires lifelong chronic immunosuppression**
- **Kidney toxicity**
  - ~35% of living donor transplants and ~50% of deceased donor transplants fail within 10 years[1]
- **Significantly increased risk of cancer[2]**
- **Hypertension, diabetes, high cholesterol, weight gain[3]**
  - Cardiovascular (CV) issues are leading cause of post-transplant mortality
- **Increased risk of serious infection[4]**
- **High cost, pill burden (>20 pills/day for life) and decreased QoL**
  - Cost ~$25K in first year and $5K-$10K annually for life of organ[1]
  - Poor compliance can lead to rejection or organ loss
  - Sleep disturbance, CNS issues, depression, and other AEs affecting QoL

Sources: patientslikeme; The Voice of the Patient FDA Meeting (Sep 2016): Patients who Have Received an Organ Transplant

1. USRDS 2020 Annual Data Report, Fig 6.16: https://adr.usrds.org/2020/end-stage-renal-disease/6-transplantation
2. Engels et al JAMA 2011; 306(17): 1891-1901
3. Nankivell BJ et al, Lancet 2011, 378:1428-37
4. Karuthu et al, Clin J Am Soc Nephrol. 2012 Dec;7(12):2058-70

QoL: Quality of life; CNS: Central Nervous System

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Durable Immune Tolerance: The "Holy Grail" of Transplant

TRANSPLANTATION

The Quest for Transplantation Tolerance: Have We Finally Sipped from the Cup?

James F. Markmann and Tatsuo Kawai*

New advances in achieving hematopoietic chimerism may facilitate immunological tolerance to kidney transplants.

www.ScienceTranslationalMedicine.org 7 March 2012 Vol 4 Issue 124 124fs5

If the Leventhal *et al.* results are sustained and expanded in number, they may potentially have an enormous, paradigm-shifting impact on solid-organ transplantion.

In 1953, Billingham *et al.* reported the Nobel Prize–winning finding that neonatal inoculation of mice with allogeneic lymphoid cells could induce long-lived donor hematopoietic chimerism and that the resulting intermingling of donor and host immune cells throughout the host yielded immunological tolerance to donor-strain grafts (*1*). This discovery brought with it the promise of organ transplantation without the morbidity of lifelong immunosuppression and set routine attainment of immunological tolerance as the field's seemingly unreachable Holy Grail. Now, Leventhal *et al.* (*2*) add to advances in the last few years that suggest that the 6-decade-long quest for tolerance for kidney transplant patients may finally be nearing its end.

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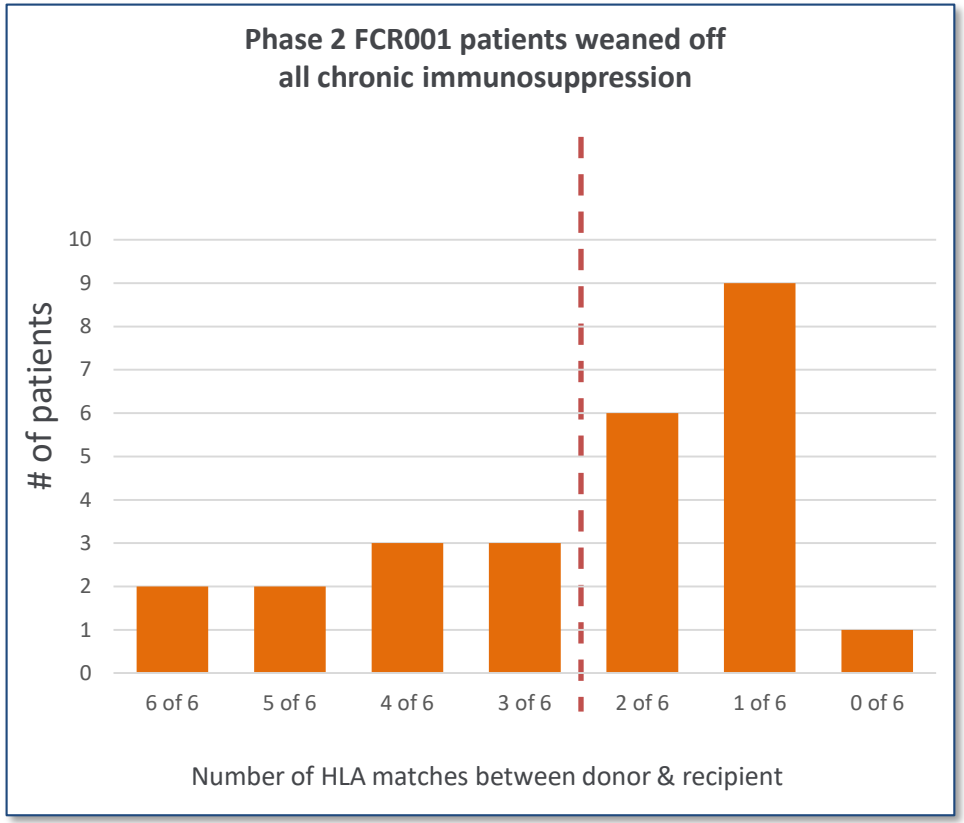
Robust Results Across All Degrees of HLA-Mismatch



- 19/26 (73%) durably off all chronic immunosuppression had HLA match of 3 or less between LDKT donor & recipient
- Comparable kidney and patient survival for all FCR001 vs standard of care (SoC) LDKT patients
- FCR001 safety & tolerability generally consistent with separate SoC kidney transplant + allogeneic HSCT with non-myeloablative conditioning
- Only 2 instances of GvHD despite very high degrees of HLA-mismatch
  - Phase 3 protocol modified to mitigate this risk
- No acute rejection or donor-specific antibodies in FCR001 patients off immunosuppression

Data as of January 31, 2021

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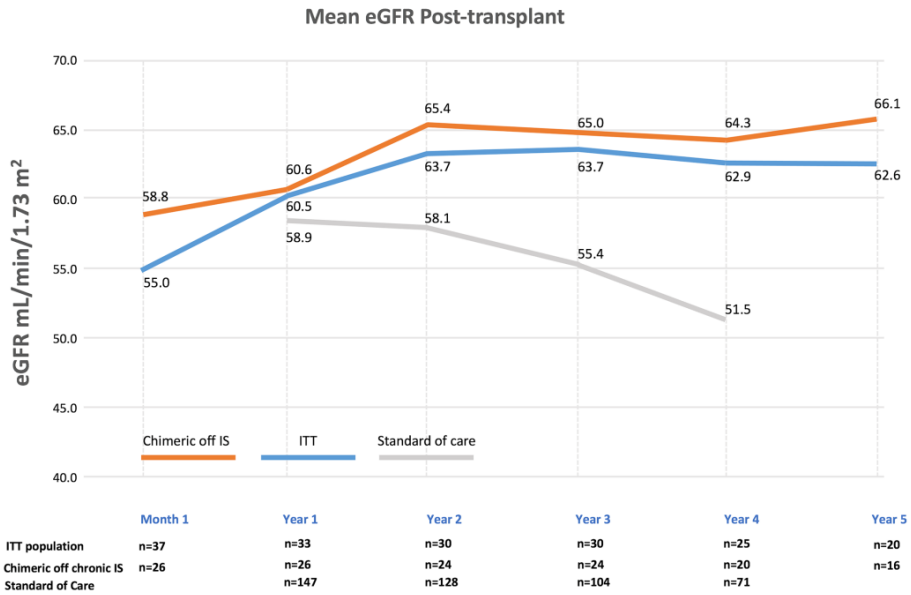
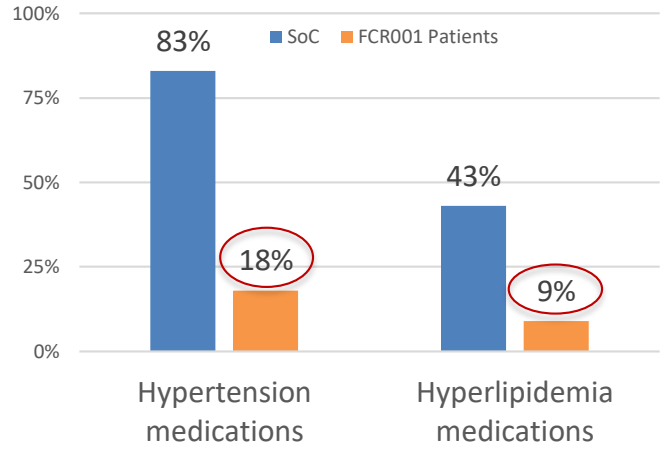
Evidence of Potential Longer-Term Clinical Benefit

FCR001 improved Quality of Life[1], preserved kidney function and enabled lower reliance on cardiovascular medications[2][3]

Mean Estimated eGFR* Over Time Post- Transplant



Cardiovascular Medication Usage SoC vs Durably Chimeric FCR001 Patients



1. Results presented at ATC 2019 by Dr. D. Tollerud, based on cardiac and renal dysfunction measures under ESRD-SCL-TM and general health as measured by SF-36
2. Retrospective analysis by Dr. J Leventhal of transplanted SoC patients at same site between 2009-2012, who met Ph 2 eligibility criteria (n=132)
3. FCR001 patients off all chronic immunosuppression (n=26)

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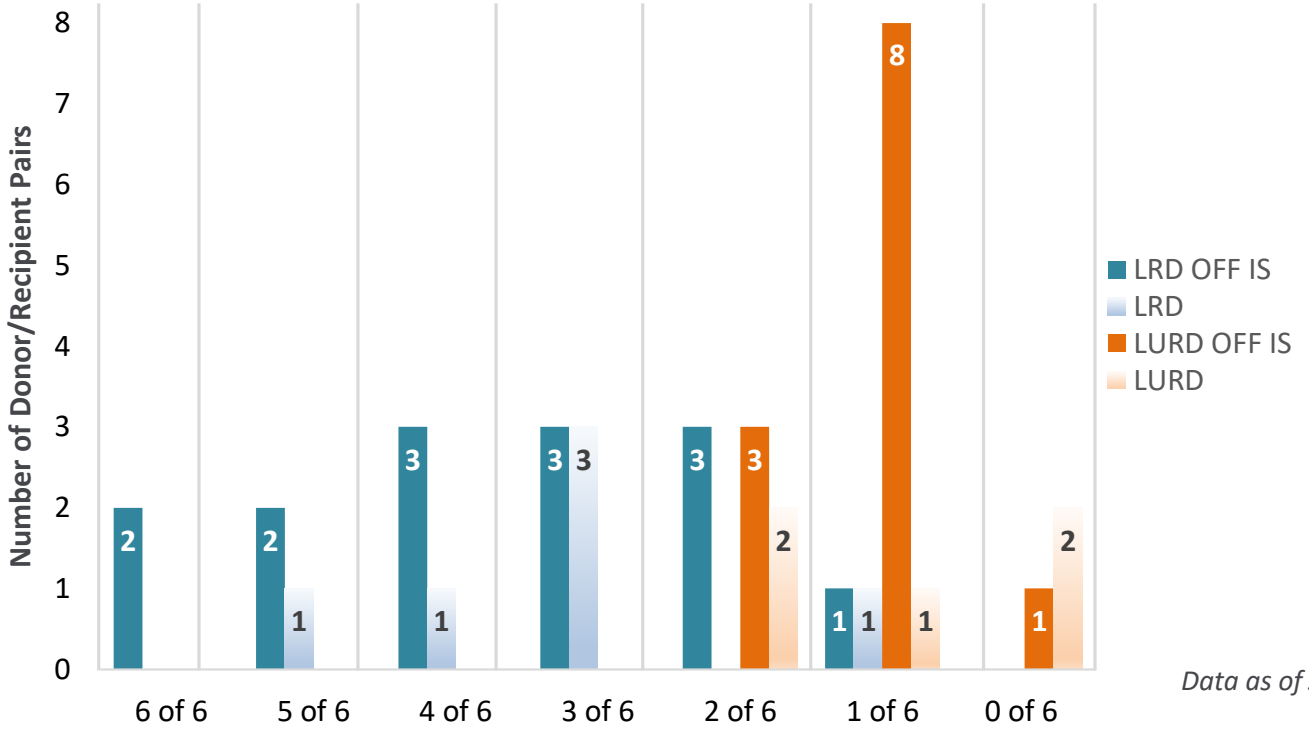
HLA Matching and Relatedness – Patient Status



LRD = Living Related Donor (n=20)
LURD = Living Unrelated Donor (n=17)
IS = Chronic Immunosuppression

Data as of January 31, 2021

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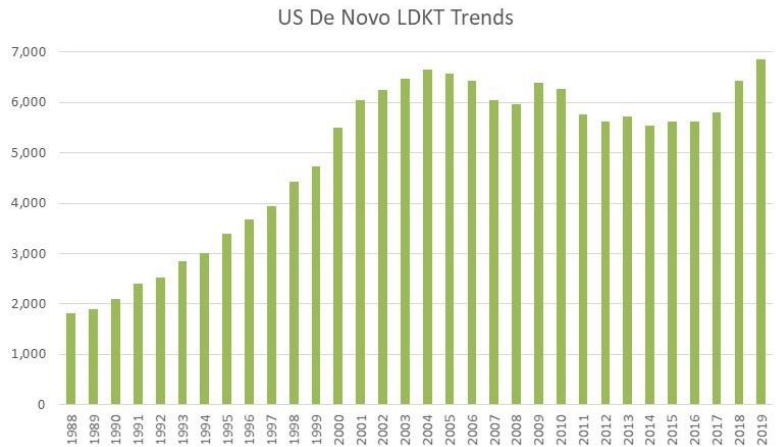
Overview of Living Donor Kidney Transplant (U.S.)

Incidence



- Since 2000, average 6,080 cases/year
- 2019 highest volume on record: 6,867
- ~30% of total kidney transplants annually

Prognosis and Prevalence

Yr. Post LDKT	Graft Survival	Patient Survival
1 year	97%	99%
5 year	85%	94%
10 year	65%	79%

- Excellent short-term outcomes with LDKT
- Unmet need for improved long-term outcomes
- ~50K prevalent LDKT patients with functioning graft transplanted in past decade

Sources: UNOS/OPTN 2019; USRDS 2020 Annual Data Report

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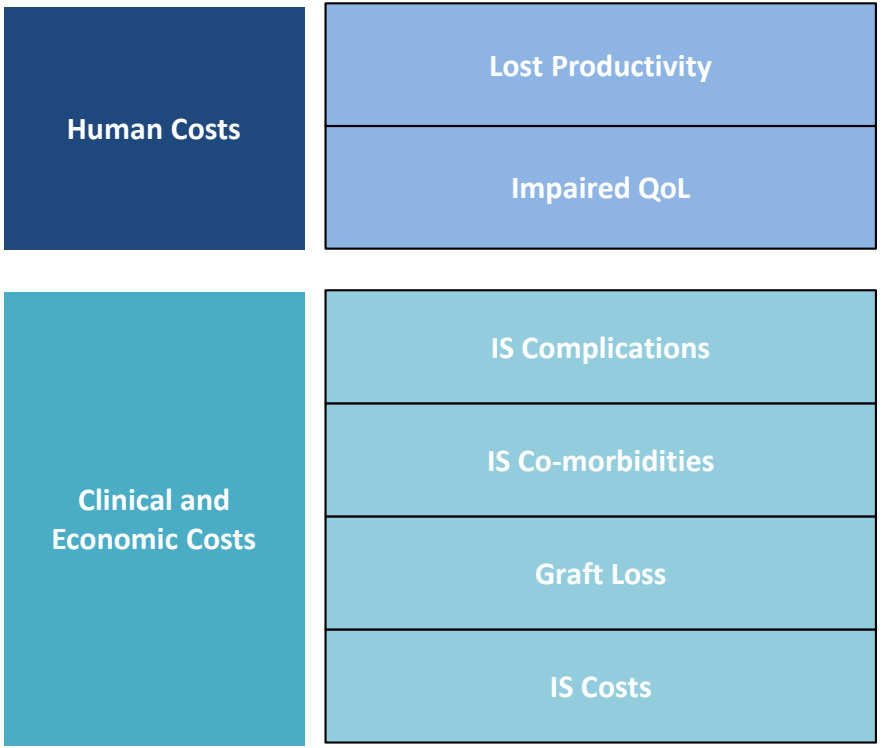
Value Proposition for “One Transplant for Life”

Dimensions of Current Potential Burden of Chronic IS



Value From Eliminating Chronic IS

- Improve outcomes
  - Fewer rejections, graft losses
  - No IS co-morbidities or complications
  - Enhance patient’s QoL and freedom
- Reduce systematic costs
  - IS and meds to manage co-morbidities
  - Avoid return to dialysis or 2nd transplant
  - Bolster recipients’ productivity

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Well Controlled, In-House Manufacturing Process

- Robust, reproducible process (< 24 hours)
  - No viral vectors, no genetic engineering, no cell expansion
- All manufacturing & key analytical work in-house
  - cGMP cleanroom facility
  - Capacity to supply all currently anticipated clinical needs
- No critical manufacturing processes or controls were changed between Phase 2 and Phase 3
- **Same process used for FCR001 across all indications (except deceased donor)**

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Multiple Barriers to Entry

IP & reference product exclusivity potential

- Issued composition of matter patents through 2029
- Pending applications directed at certain release assays would run to 2038
- Potential for 12 years biologics data exclusivity in US
- Potential for Orphan drug exclusivity
- Substantial know-how & trade secrets associated with manufacturing process

Substantial first mover advantage

- Since durability off immunosuppression is the key goal, we have first mover advantage compared to third parties seeking to demonstrate comparable results
- Talaris' FCR001 could define a new standard of care for tolerance induction
- Safety database can be leveraged across multiple indications

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