Fate THERAPEUTICS

Better Cells For Better Therapies™

Treatment of Refractory SLE with Off-the-Shelf iPSC-derived Anti-CD19 CAR T-cell Therapy

EULAR European Congress of Rheumatology

June 11, 2025

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Fate Therapeutics, Inc.

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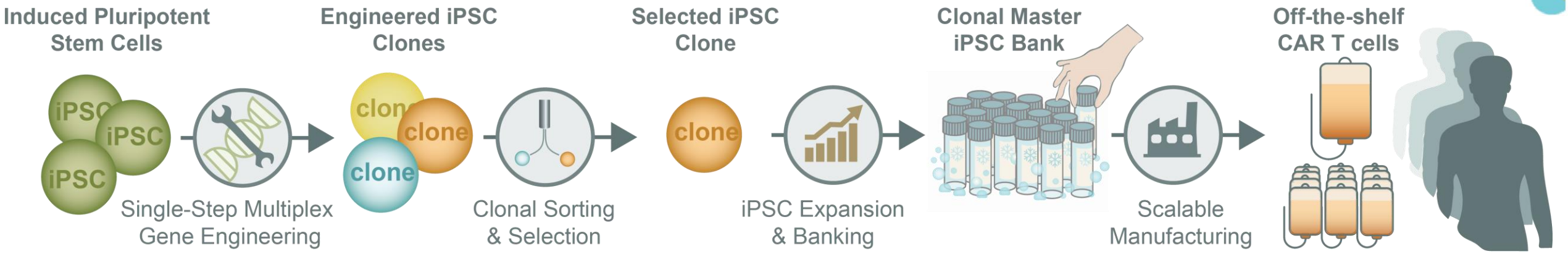
A Unique Platform for the True Delivery of Off-the-Shelf Cellular Therapies

Mass Produced, Multiplexed-engineered Cell Products for On-demand Patient Treatment



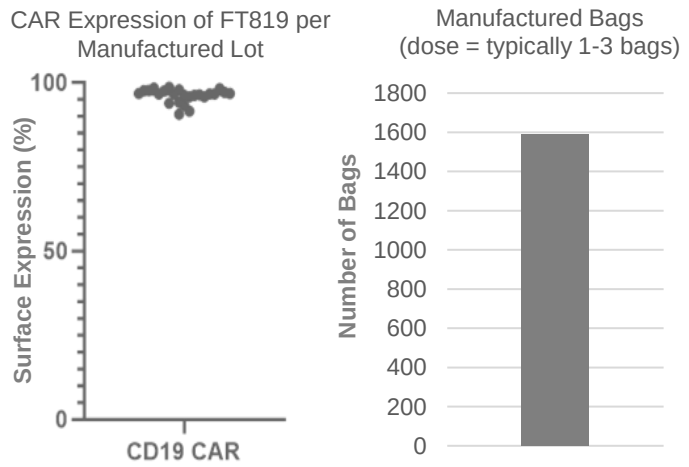
Platform Advantages

- ✓ Defined Clonal MCB: Single-cell derived, complete and uniform for genetic edits, selected for genomic integrity & potency
- ✓ Engineered MCB as the Starting Material: Highly-scalable, uniform final product, one-time genetic engineering, high-quality cellular products, and eliminates the need for repeated donor search
- ✓ Modular Innovation: Rapid, efficient development through multiplexed engineering

iPSC-derived Cell Therapy Products

- ➢ Reliable, Scalable Drug Product: Uniform, consistent and well-characterized with >5-year stability in storage; ~50,000-dose GMP-scale manufacturing capability at current GMP site
- ➢ Cost-Effective & Consistent: Low COGs (~$3,000 per dose), inventory-based cost management, and no donor variability
- ➢ Patient-Centered Therapy: Off-the-shelf, antibody-like treatment with repeat dose capability and combinability ease, reduced toxicity, and administration with reduced hospitalization requirements in community setting

Uniform and Consistent Inventory of Thousands of Doses Generated per Routine Manufacture Starting with a MCB Vial



Select publications: Sci Rep 2013, Stem Cell Reports 2014, Blood 2020, Cell Stem Cell 2021/2024/accepted, Nat Biomed Eng 2022, Nat Comm 2022, Med 2023, Front Immunol 2024, J Cell Mod Med 2025, Lancet 2025, Molec Therapy 2021/accepted, Lancet Hematology accepted, Cell Reports Med accepted

FT819: Off-the-Shelf anti-CD19 CAR T-Cell Product Candidate

Safe and effective targeting of CD19+ B cells with broad patient accessibility in autoimmune

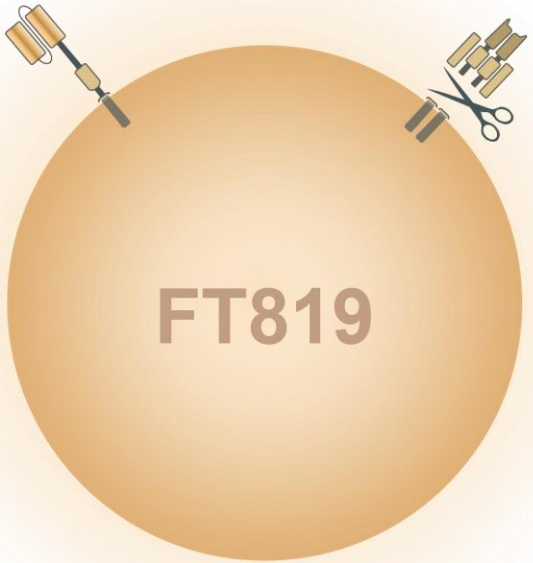
True Off-the-Shelf CAR T cell Drug Product

CAR19

State-of-the-art CAR motif and expression control

TCR null

Complete TCR knock-out to prevent GvHD in allogeneic settings



Uniform Product

Clonally engineered iPSC-derived CD8αβ T cell

Derived from a defined clonal MCB incorporating unique functional elements to balance safety and efficacy:

- **1XX CAR19**: Novel CAR with CD28 costimulatory and modified CD3ζ signaling domains for optimal safety and activity
- **TRAC-targeted CAR**: CAR inserted in the T-cell receptor alpha constant (TRAC) locus to reproduce endogenous TCR expression for regulated and optimal function
- **TCR Null**: Complete bi-allelic disruption of TRAC ablates TCR expression and eliminates the possibility of GvHD
- **On-Demand Delivery**: Routinely manufactured at large scale from an engineered MCB that uniquely ensures a uniform, off-the-shelf drug product for broad patient access

Memorial Sloan Kettering Cancer Center

CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

nature biomedical engineering
ARTICLES
https://doi.org/10.1038/s41551-022-00915-0

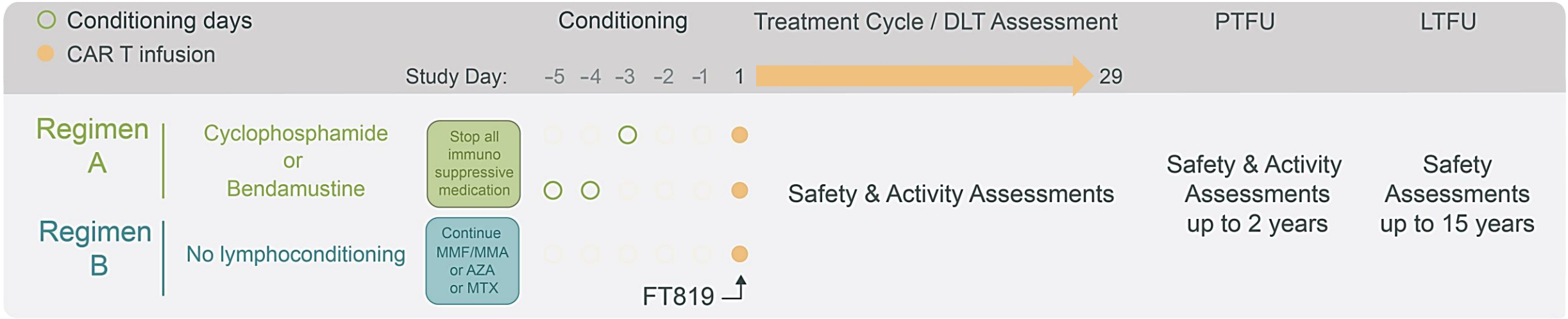
Generation of T-cell-receptor-negative CD8αβ-positive CAR T cells from T-cell-derived induced pluripotent stem cells

Sjoukje J. C. van der Stegen[1,2], Pieter L. Lindenbergh[1,2,3], Roseanna M. Petrovic[1,2], Hongyao Xie[1,2], Mame P. Diop[1,2], Vera Alexeeva[1,2], Yuzhe Shi[1,2], Jorge Mansilla-Soto[1,2], Mohamad Hamieh[1,2], Justin Eyquem[1,2,6], Annalisa Cabriolu[1,2], Xiuyan Wang[4], Ramzey Abujarour[5], Tom Lee[5], Raedun Clarke[5], Bahram Valamehr[5], Maria Themeli[3], Isabelle Riviere[4] and Michel Sadelain[1,2]

FT819-102: A Phase 1 Study of FT819 in B-cell Mediated Autoimmune Diseases

Uniquely administered with either fludarabine-free conditioning or maintenance therapy in the absence of conditioning

NCT06308978



Highly-differentiated therapeutic approach

Available on-demand with:

- No patient apheresis
- Less-intensive or no conditioning chemotherapy regimens
  - No discontinuation of maintenance therapy (Regimen B)
- Shortened hospitalization requirement (3 days)
- Ability to redose in inadequate response or relapse
- Autoimmune diseases in the protocol include: Systemic lupus erythematosus (SLE), ANCA-associated vasculitis (AAV), Idiopathic inflammatory myopathy (IIM), Systemic sclerosis (SSc)

FT819-102: SLE Disease Characteristics

Patient Characteristics

	Regimen A				Regimen B
Patient #	A1-DL1	A2-DL1	A3-DL1	A1-DL2	B1-DL1
Age, Gender	28 F	22 F	29 F	28 F	23 F
BILAG domain for inclusion	Renal	Renal	Renal	MSK, Mucocutaneous	Cardiorespiratory
Disease Duration	~11 years	~4 years	~24 years	~9 years	~5 years
Baseline SLEDAI-2K	20	20	14	18	8
Concomitant SLE Therapies	GC, HCQ	HCQ	GC, HCQ	HCQ	GC, HCQ, MMF
Prior Therapies *B-cell targeted therapy bolded	7 AZA, **BEL**, GC, HCQ, MMF, **RTX**, TAC	8 ANI, **BEL**, CY, GC, HCQ, MMF, MTX, **RTX**	8 AZA, **BEL**, CY, GC, HCQ, MMF, MTX, **RTX**	6 ANI, **BEL**, CY, HCQ, GC, MTX	5 CY, GC, HCQ, MMF, **RTX**
Conditioning	Bendamustine	CY	CY	CY	None

ANI = anifrolumab; AZA = azathioprine; BEL = belimumab; CY = cyclophosphamide; GC = glucocorticoids; HCQ = hydroxychloroquine; MMF = mycophenolate mofetil; MSK = musculoskeletal; MTX = methotrexate; RTX = rituximab; TAC = tacrolimus

FT819-102 Preliminary Clinical Safety Data

Selected Adverse Events, Highest Grade Reported

	Regimen A				Regimen B
Patient (conditioning)	A1-DL1 (Benda)	A2-DL1 (Cy)	A3-DL1 (Cy)	A1-DL2 (Cy)	B1-DL1 (none)
Cytokine Release Syndrome	-	-	-	Grade 2	-
ICANS	-	-	-	-	-
Graft vs. Host Disease	-	-	-	-	-
Anemia	Grade 2	-	-	Grade 2	Grade 2
Thrombocytopenia	Grade 1	-	-	-	-
Neutropenia	-	Grade 4	-	Grade 4	-
Grade ≥ 3 infection	-	-	-	UTI	Influenza

No high-grade CRS, No ICANS, and No DLTs observed

Safety data in line with FT819-101 in B cell lymphoma (NCT04629729)

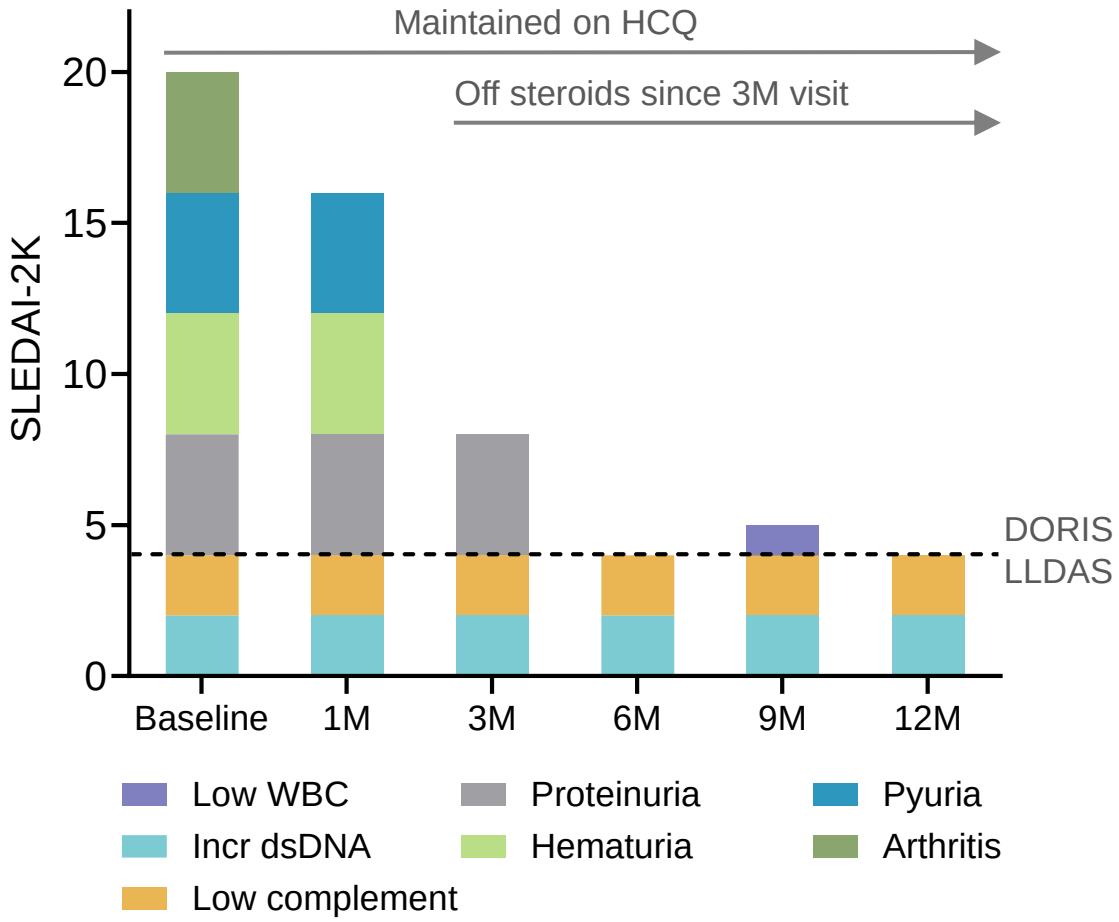
Data cutoff 15 May 2025; Graded per CTCAEv5; Regimen A = Conditioning prior to treatment with either bendamustine (Benda) or cyclophosphamide (Cy); Regimen B = no conditioning chemotherapy; DL = Dose level; DL1 = 360M cells; DL2 = 900M cells; ICANS = Immune effector Cell Associatd Neurotoxicity Syndrome; UTI = urinary tract infection. Grade ≤ 2 Headache reported in 4 participants and Grade ≤ 2 nausea and vomiting reported in 3 participants

FT819-102 Patient 1 SLE Case (A1-DL1): 12-month Evaluation

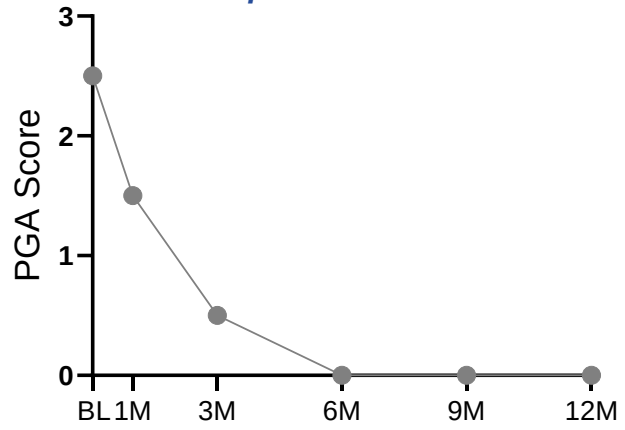
DORIS remission at 1 year is suggestive of durability of response (Regimen A)

✓ *Fludarabine-free lympho-conditioning* ✓ *On-demand CAR T-cell delivery with no apheresis* ✓ *No DLT, CRS, GvHD or ICANS* ✓ *Reduced hospitalization*

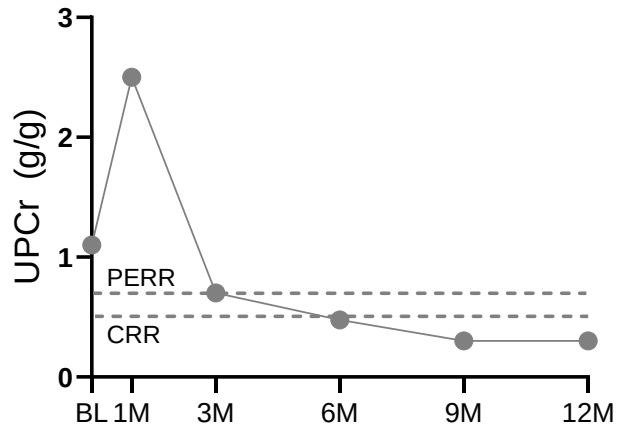
Remission in SLE without use of steroids



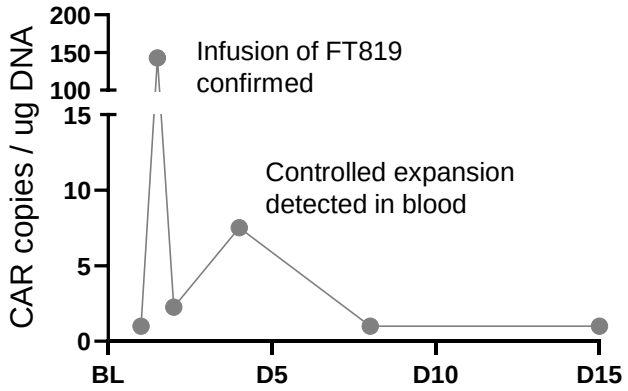
Sustained improvement in overall patient status



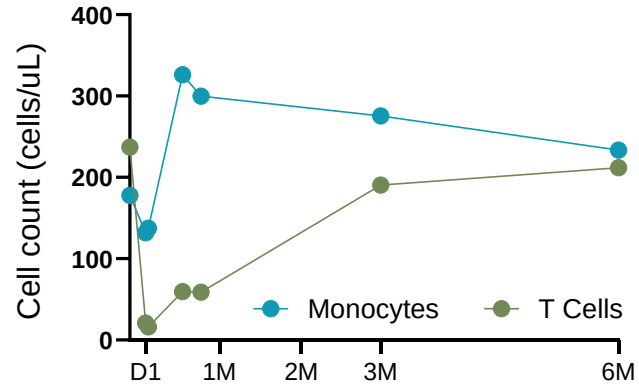
Durable renal response



FT819 designed to show a balance of efficacy and safety



Less intensive conditioning facilitates recovery of patient's immune cells



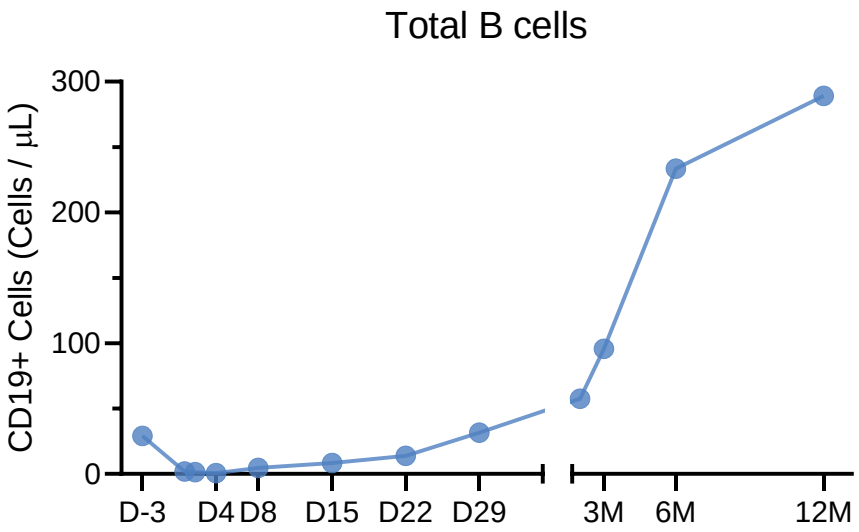
***PERR**: Primary Efficacy Renal Response* ***CRR**: Complete Renal Response* ***DORIS**: Definition Of Remission In SLE* ***LLDAS**: Low Lupus Disease Activity State* ***SLEDAI**: SLE Disease Activity Index* ***PGA**: Physician Global Assessment*

Data cutoff 15 May 2025; Graphs show measurements across study timepoints, BL = baseline, D=day, M=month.

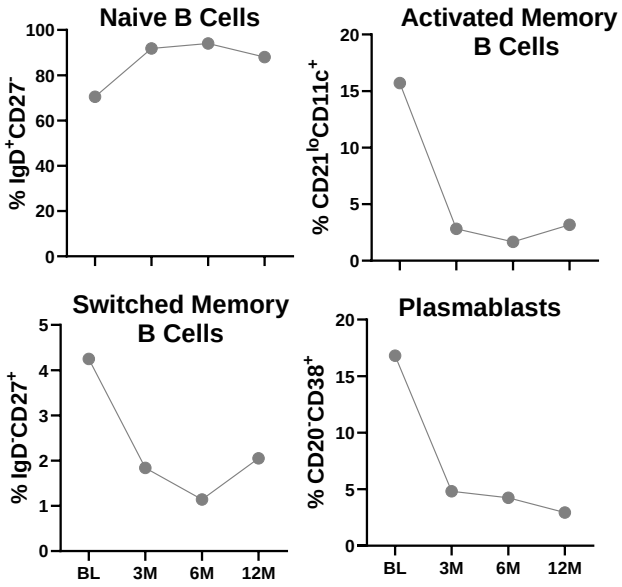
FT819-102 Patient 1 SLE Case (A1-DL1): 12-month Evaluation

Durability of remission is supported by B-cell immunological reset (Regimen A)

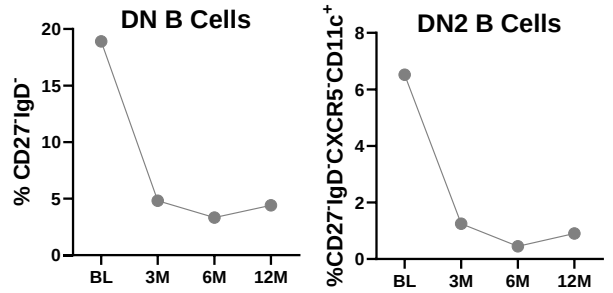
*Effective B cell depletion and repopulation to normal levels**



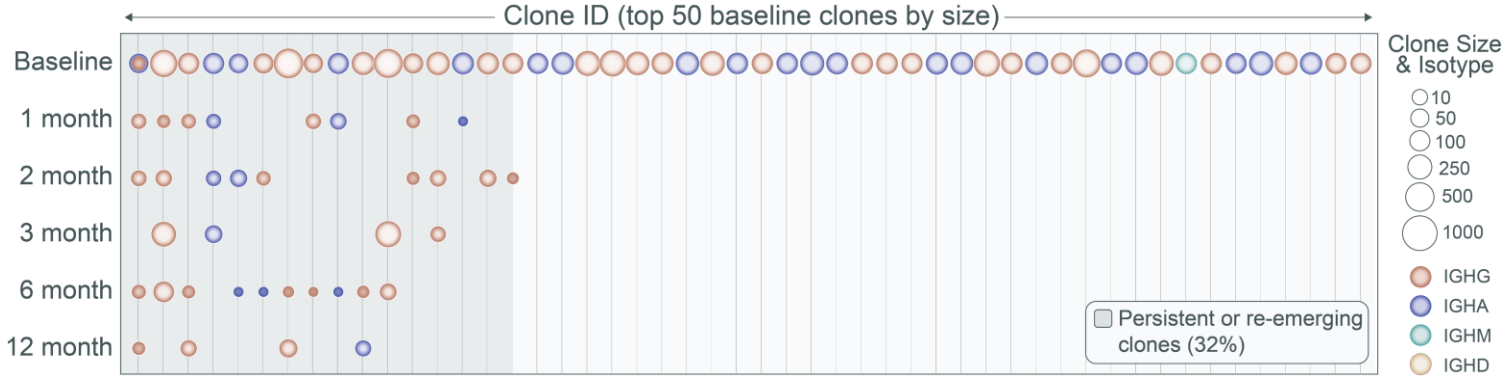
Reconstituting B cells appear to be predominantly naïve with a limited switched memory phenotype

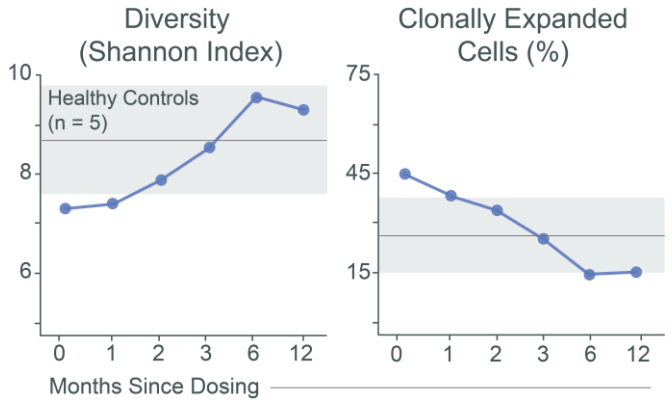


Low pathogenic DN B cell subset in the reconstituting B cells, suggesting immune reset



Persistent depletion of dominant clones and reshaping of the B cell compartment toward a more diverse, less expanded repertoire after treatment with FT819





Data cutoff 15 May 2025; Graphs show measurements across study timepoints, BL = baseline, D=day, M=month. *Normal B cell levels defined as 100-700 cells/µL

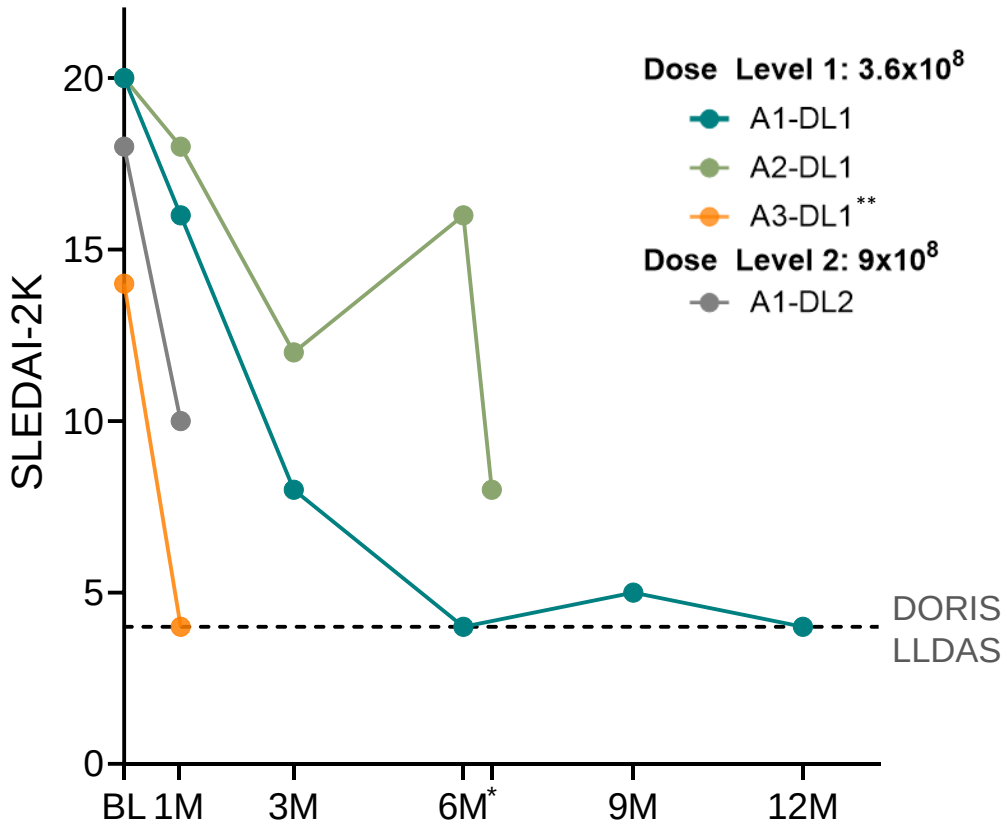
FT819-102 Preliminary Clinical Responses with Fludarabine-free Conditioning

Collective reduction in disease burden (Regimen A)

✓ *Fludarabine-free lympho-conditioning* ✓ *On-demand CAR T cell delivery with no apheresis* ✓ *Reduced hospitalization* ✓ *Low COGs ($3000/dose)*

Improved disease activity in all patients

(n=4)

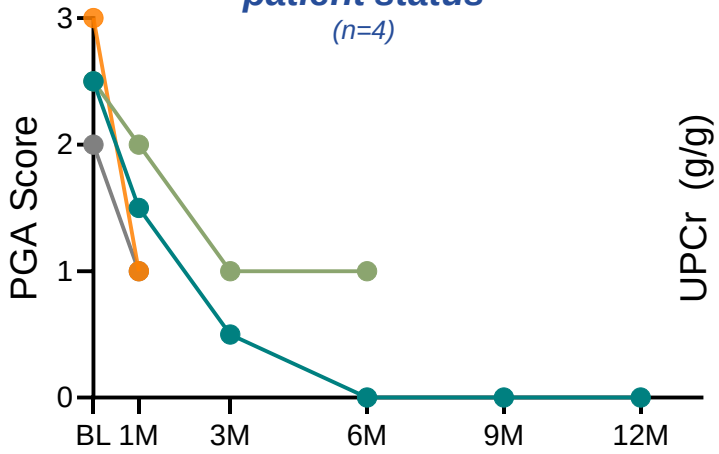


*A2-DL1: fluctuating UPCr around 0.5 g/g at 6M

**A3-DL1: Patient discontinued due to nonadherence to protocol procedures after 1M visit

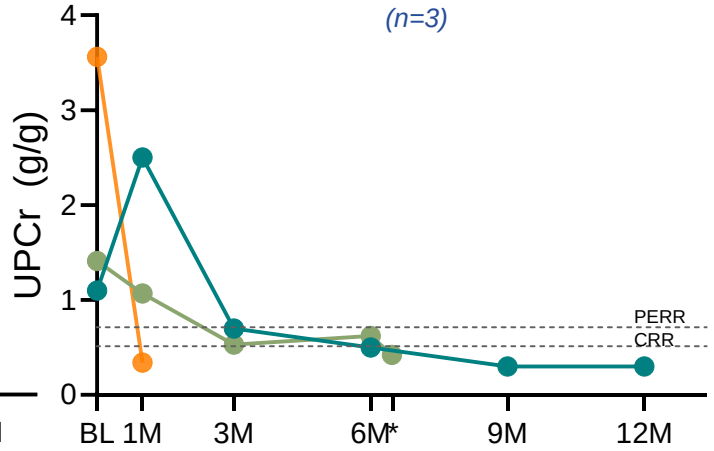
Sustained improvement in overall patient status

(n=4)



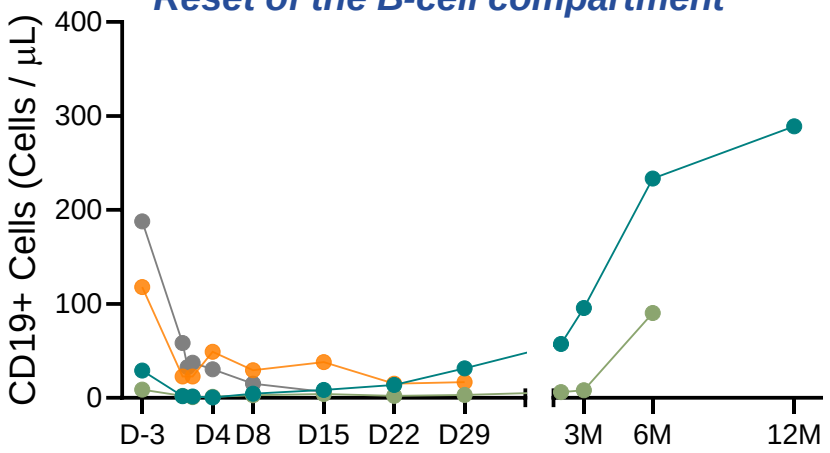
Renal responses achieved in all LN patients

(n=3)



*A2-DL1: fluctuating UPCr around 0.5 g/g at 6M

Reset of the B-cell compartment



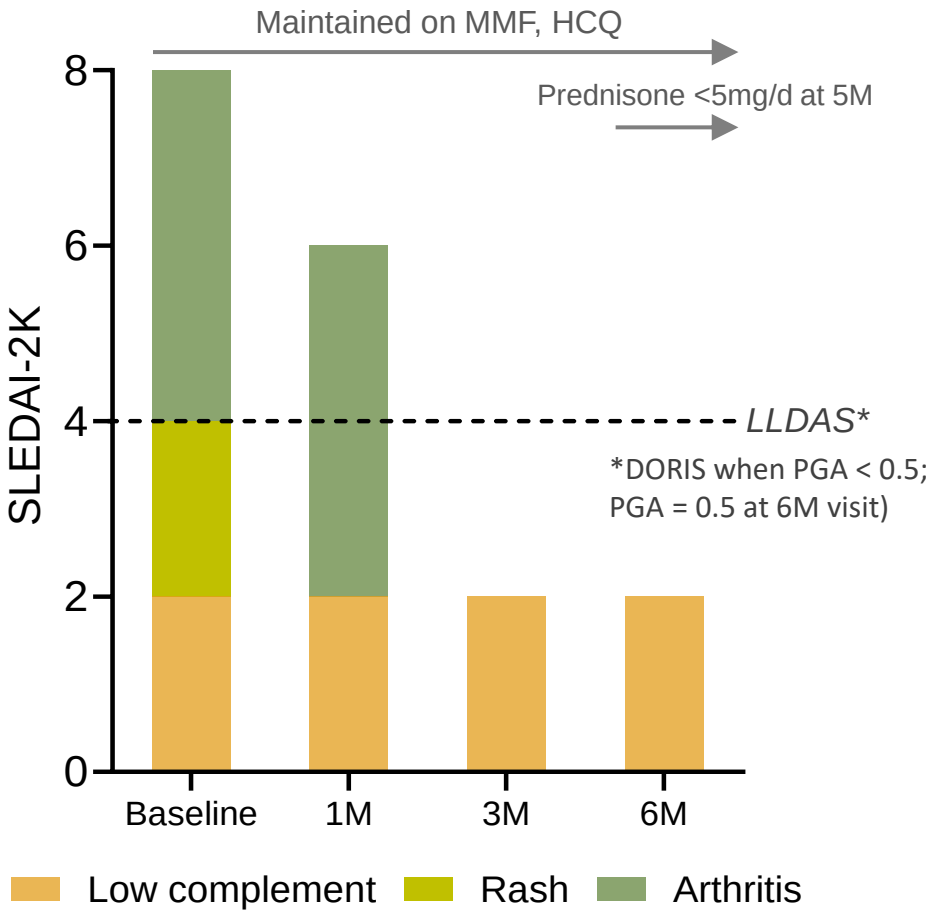
Data cutoff 15 May 2025; Graphs show measurements across study timepoints, BL = baseline, D=day, M=month.

FT819-102: Preliminary Observation without the use of Conditioning

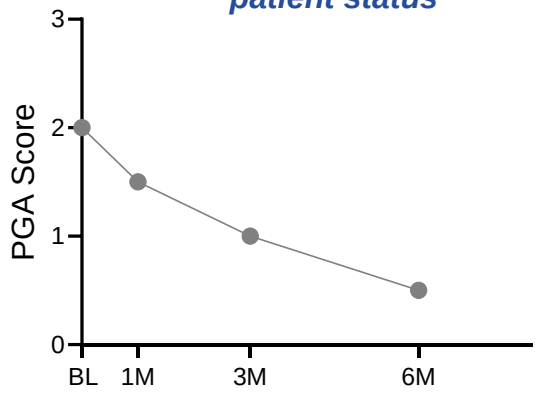
First patient data suggestive of FT819 treatment response without conditioning chemotherapy (Regimen B)

✓ *No lympho-conditioning (Regimen B)* ✓ *On-demand CAR T cell delivery with no apheresis* ✓ *No DLT, CRS, GvHD or ICANS* ✓ *Reduced hospitalization*

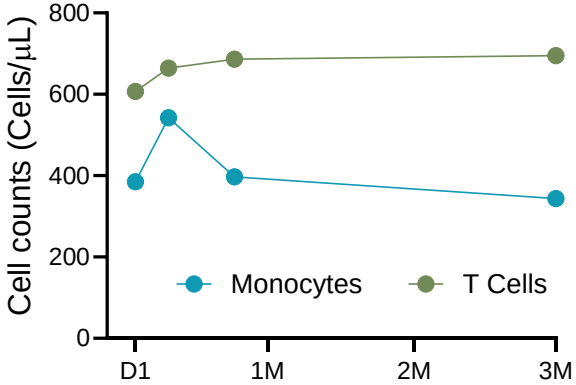
Disease Response in SLE without conditioning



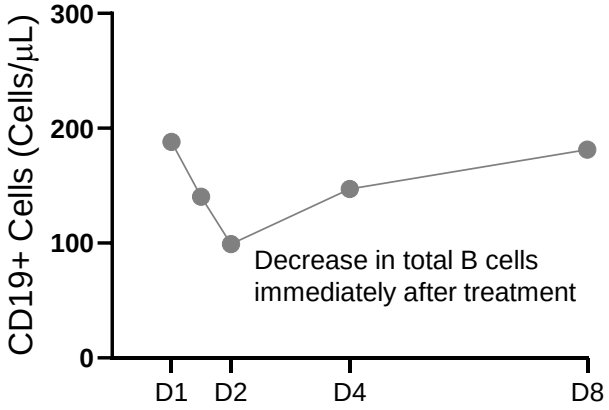
Sustained improvement in overall patient status



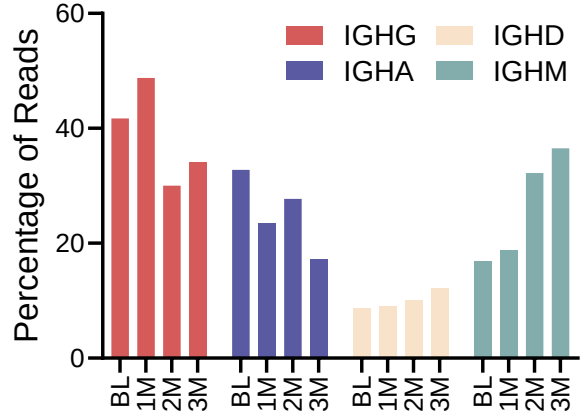
Maintained normal levels of patient's immune cells



Initial drop in B cells and recovery is seen within the first week



Remodeling of the B-cell Compartment towards a non-switched naïve repertoire



***DORIS**: Definition Of Remission In SLE* ***LLDAS:** Low Lupus Disease Activity State* ***SLEDAI**: SLE Disease Activity Index* ***PGA**: Physician Global Assessment*

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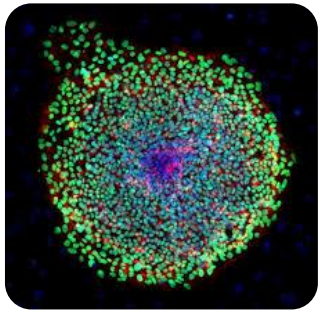
FT819-102 Summary and Next Steps

- FT819 provides a true off-the-shelf CAR T-cell therapeutic option that overcomes many of the challenges seen in autologous and allogenic cellular therapies
- Preliminary clinical data suggests FT819 can support durable clinical activity with less intensive conditioning or in combination with maintenance therapy without conditioning
- Complemented by the initial clinical trial in lymphoma (> 50 patients), FT819 exhibits a differentiated safety profile with no reported ICANS, GvHD or CRS > Grade 2
- Trial open to treat ANCA vasculitis, Myositis (DM/PM/IMNM), SLE, and Systemic Sclerosis aged 12-70 years; treatment option includes redosing after relapse or inadequate response
- Current data generated from 2 clinical sites (University of Nebraska and University of Minnesota)
  - 8-10 sites projected to be active by summer 2025, in addition to ongoing efforts to expand to multiple outside of US sites in 2025
- Upcoming regulatory discussions:
  - RMAT designation granted with goal to have pivotal trial design reviewed with the FDA by YE2025
  - Removal of hospitalization requirement

Acknowledgements

Patients, Families and Treatment Sites

The Fantastic People of Fate Therapeutics



Key Collaborators & Collaboration Sites

University of Minnesota
Driven to Discover℠

Memorial Sloan Kettering Cancer Center

University of Nebraska Medical Center

CIRM
California Institute for Regenerative Medicine

Parastoo Fazeli, Jennifer Medlin, Debra Zack, Rebecca Elstrom, Andrew Bitmansour

Bertha Villa, Lilly Wong, John Goulding, Nicholas Brookhouser, Trever Greene

Kyla Omilusik, Jonathan Tuncel, Cara Bickers, Carol Wong, Beatrice Ferguson

Julie Stewart, Jode Goodridge, Tom Lee, Marie Hu, Veronika Bachanova

Jeffery S. Miller, Matthew Lunning, Bahram Valamehr