



MAKING CELL THERAPIES ACCESSIBLE TO ALL™

**Emerging Data with FT819: Favorable Tolerability and Clinical Activity in Systemic Sclerosis Using Off-the-Shelf, iPSC-Derived Anti-CD19 CAR T cells without Fludarabine**

Natalie J Shiff, MD, MHSc

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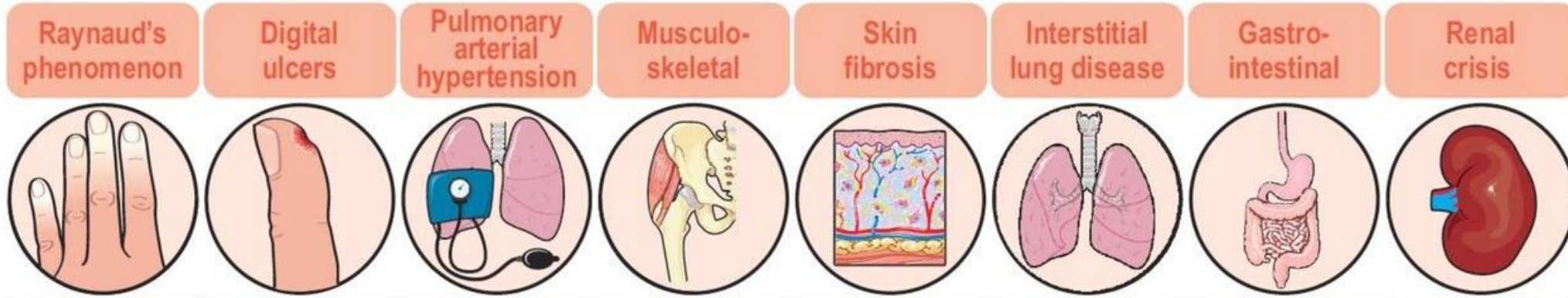
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# Systemic Sclerosis (SSc)



Edematous phase



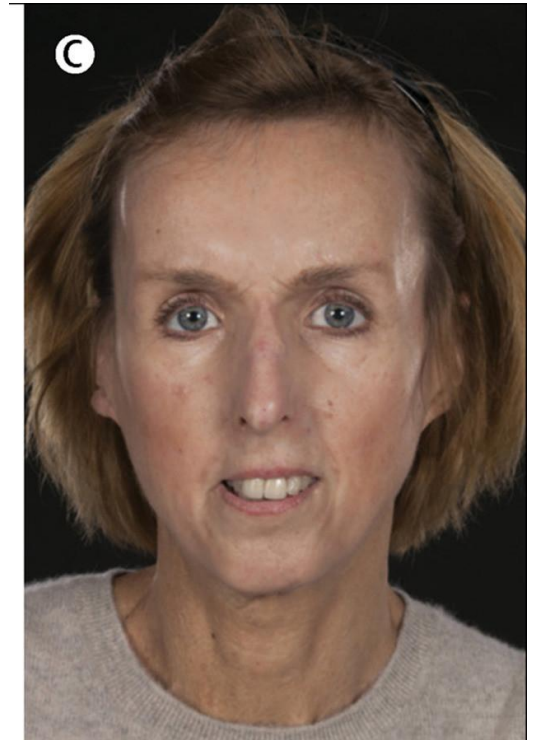
Atrophic phase



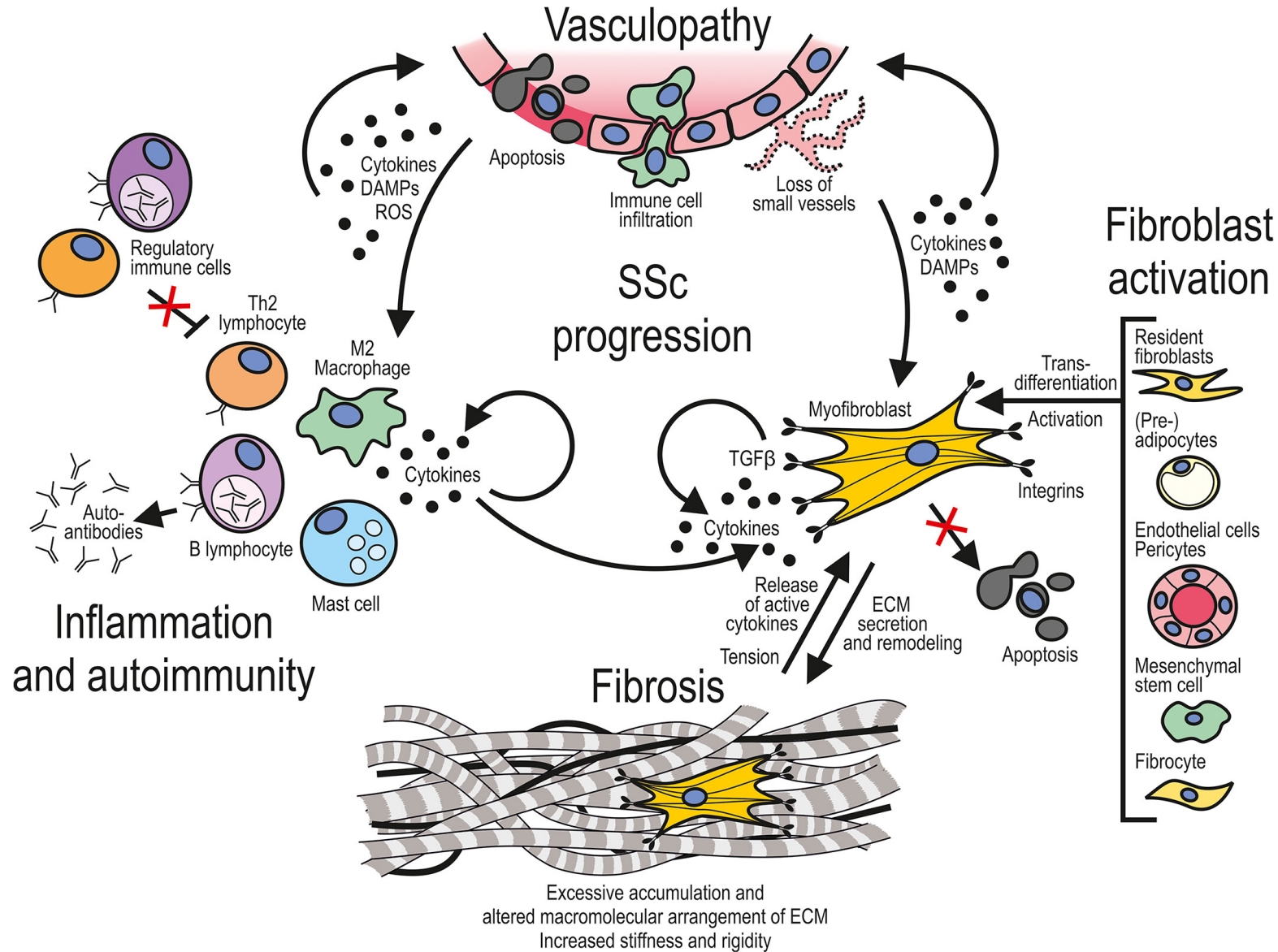
Indurative phase



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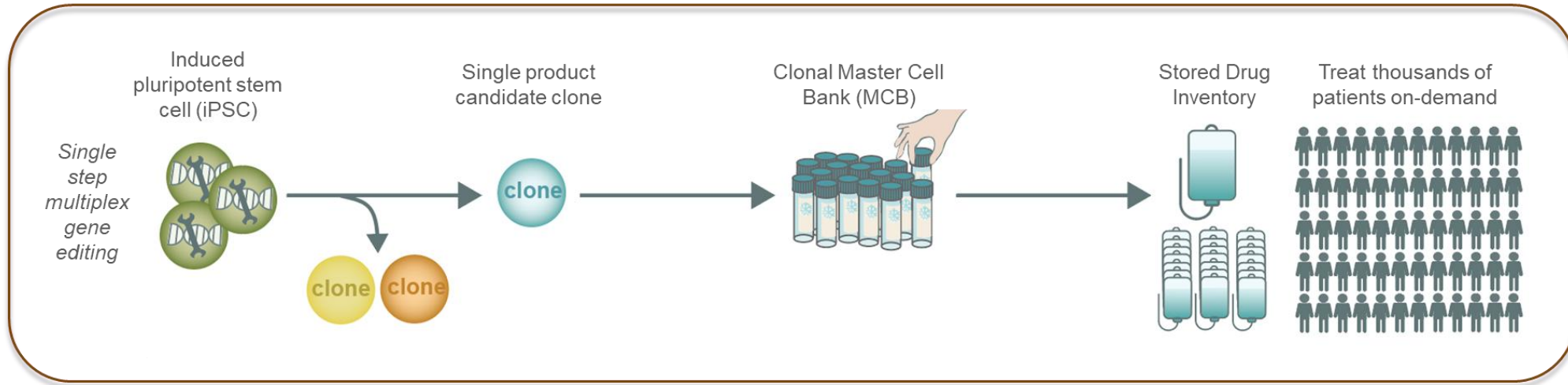


# Systemic Sclerosis: Pathophysiology



- Autoimmunity
- Fibrosis
- Vasculopathy

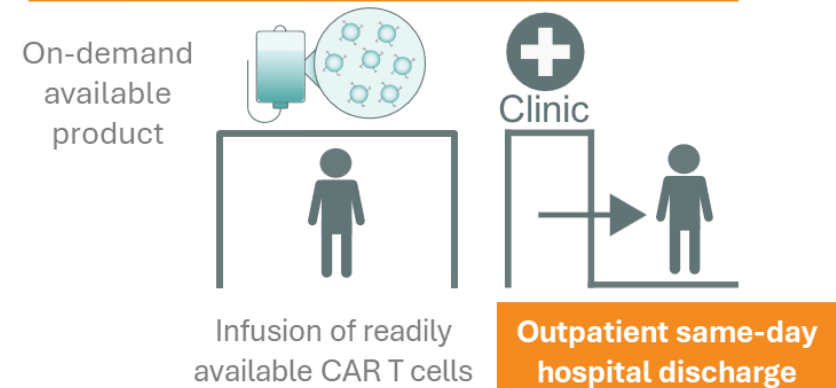
# Induced Pluripotent Stem Cells: Accessible Cell Therapy



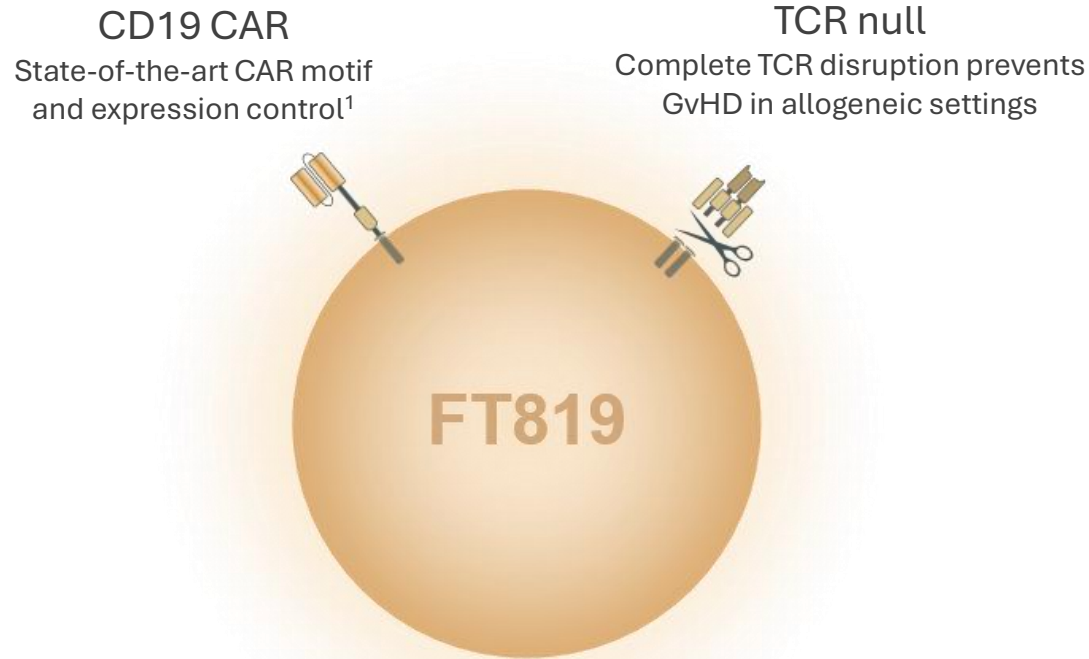
## ENGINEERED FOR SAFETY & ACCESSIBILITY

- Clonally derived
- Uniform product candidates
- Reproducible & scalable manufacturing
- On demand, off-the-shelf
- Patient friendly workflow
- Less intense/no conditioning
- Outpatient administration/same day discharge

## Off-the-Shelf CAR T-cell Therapy



# FT819: Anti-CD19 CAR T-Cell Product Candidate



*CD19 CAR T-cell designed to eliminate pathological auto-reactive B-cells with balanced efficacy and safety to establish immune reset and clinical remission<sup>2</sup>*

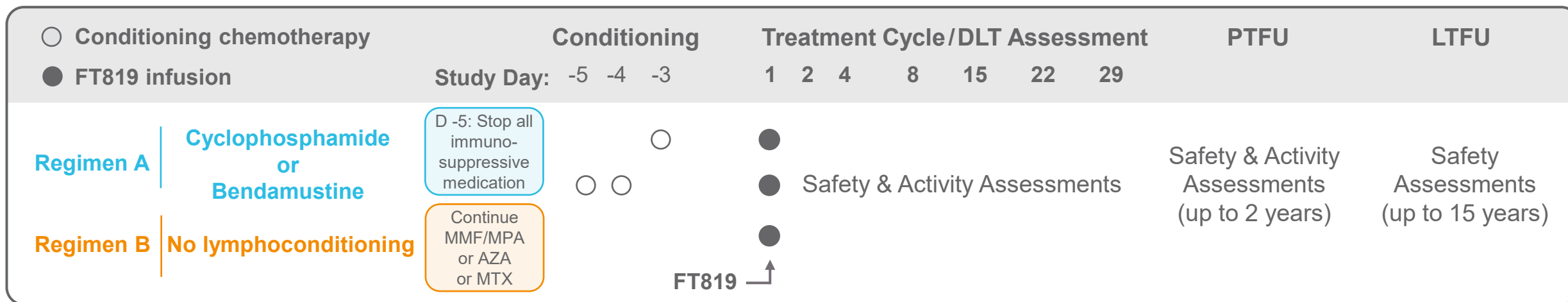
Derived from a defined clonal MCB incorporating unique functional elements to balance safety & efficacy

- **1XX CAR19:** Novel CAR with CD28 costimulatory and modified CD3z signaling domains for optimal safety and activity<sup>1</sup>
- **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

1. van der Stegen, S.J.C., et al. *Nat. Biomed. Eng* 6, 1284–1297 (2022).

2. V. Sandhu, et al. *Annals of the Rheumatic Diseases*, Volume 84, Supplement 1, 2025.

# FT819-102 Phase 1 Single Arm Basket Study Design



## Baskets

ANCA associated vasculitis, systemic lupus erythematosus, systemic sclerosis, idiopathic inflammatory myopathies

Viable cells: Dose Level (DL) 1:  $3.6 \times 10^8$ ; DL2:  $9 \times 10^8$

## Key SSc inclusion criteria

- Met ACR/EULAR 2013 SSc criteria
- Tried and failed or intolerant to  $\geq 2$  immunosuppressive therapies for  $\geq 3$  months

## Enrollment activities

- 21 sites (16 US, 5 ex-US)
- 30 patients dosed\*
- 5 Systemic Sclerosis patients dosed\*
  - 3/5 as outpatients or discharged in  $\leq 24$ -hour

NCT06308978

\* Data as of June 12, 2026; 1 SSc patient was treated with FT819 after data cut date.

# FT819-102: Baseline Characteristics of Patients with Systemic Sclerosis

	A1	A2	A3	A4	B1
CCT/background	Benda	Benda	Cy	Benda	MMF
Dose level	2	2	2	2	1
Age, yr	31	51	32	28	32
Sex	F	F	F	F	F
Disease duration, yr	6.1	3.0	9.6	8.7	1.5
Last follow up, months	6M	3M	3M	0M	3M
Prior therapies	8	3	3	4	5
ILD	Y	N	Y	Y	N

CCT=conditioning chemotherapy, Benda=bendamustine, Cy=cyclophosphamide, MMF=mycophenolate mofetil, yr=year, ILD=interstitial lung disease; SSc=systemic sclerosis

**Many clinical trials exclude SSc patients with > 5 years disease duration**

# FT819-102: Preliminary Safety Data in Patients with SSc

Safety Parameter	Incidence n(%) (n=4)
CRS	0
ICANS	0
GvHD	0
Hypogammaglobulinemia	0
DLT	0
Grade $\geq$ 3 adverse event (any)	2 (50%)
Migraine	1 (25%)
ITP*	1 (25%)

**All patients tolerated FT819 without DLT**  
**No CRS, ICANS, GvHD, or deaths were reported on study**

\*ITP includes preferred terms immune thrombocytopenia and thrombocytopenic purpura, which occurred in the same patient. CRS=Cytokine Release syndrome; ICANS=Immune Effector Cell-Associated Neurotoxicity Syndrome; GvHD=Graft versus Host Disease, DLT=dose limiting toxicity

# FT819-102: Early Responses in Treatment Resistant SSc

## rCRISS Responses at 3 Months

	25	50	75	100
✓	✓	✓	✓	✓
✓				
✓				
✓	✓			

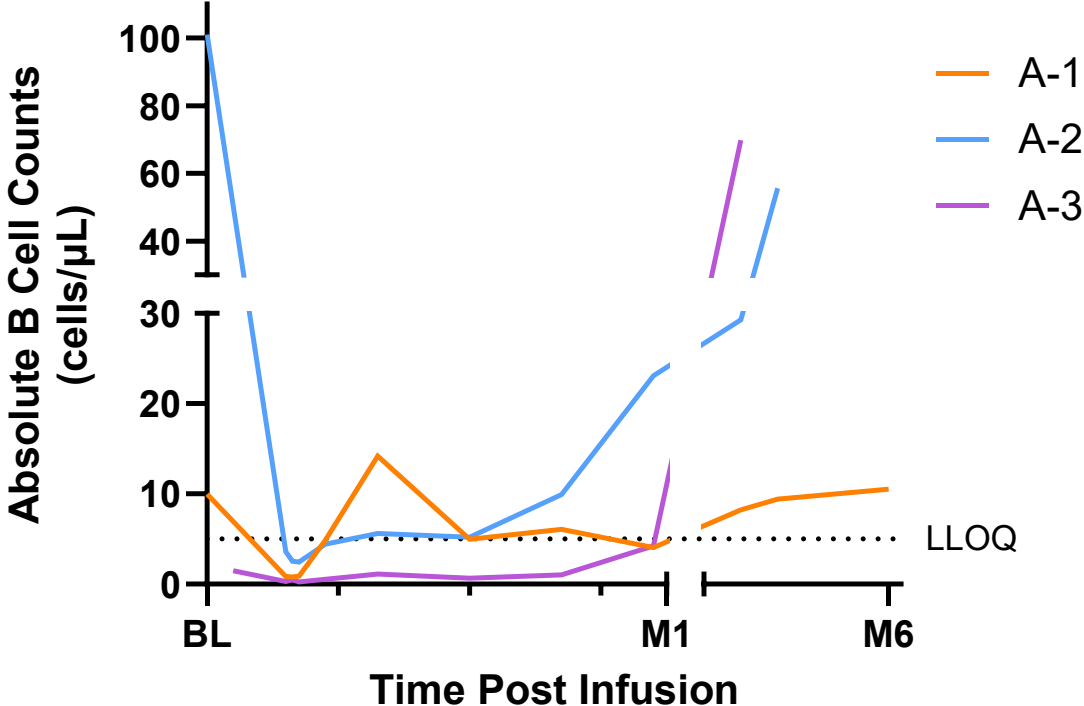
## All participants demonstrated an rCRISS25 or higher at 3M

Assessment	Results
mRSS	↓ = Improvement
CGA	↓ = Improvement
PtGA	↓ = Improvement
FVC%, predicted	↑ = Improvement
HAQ-DI	↓ = Improvement
rCRISS	≥25%/50%/75%/100%

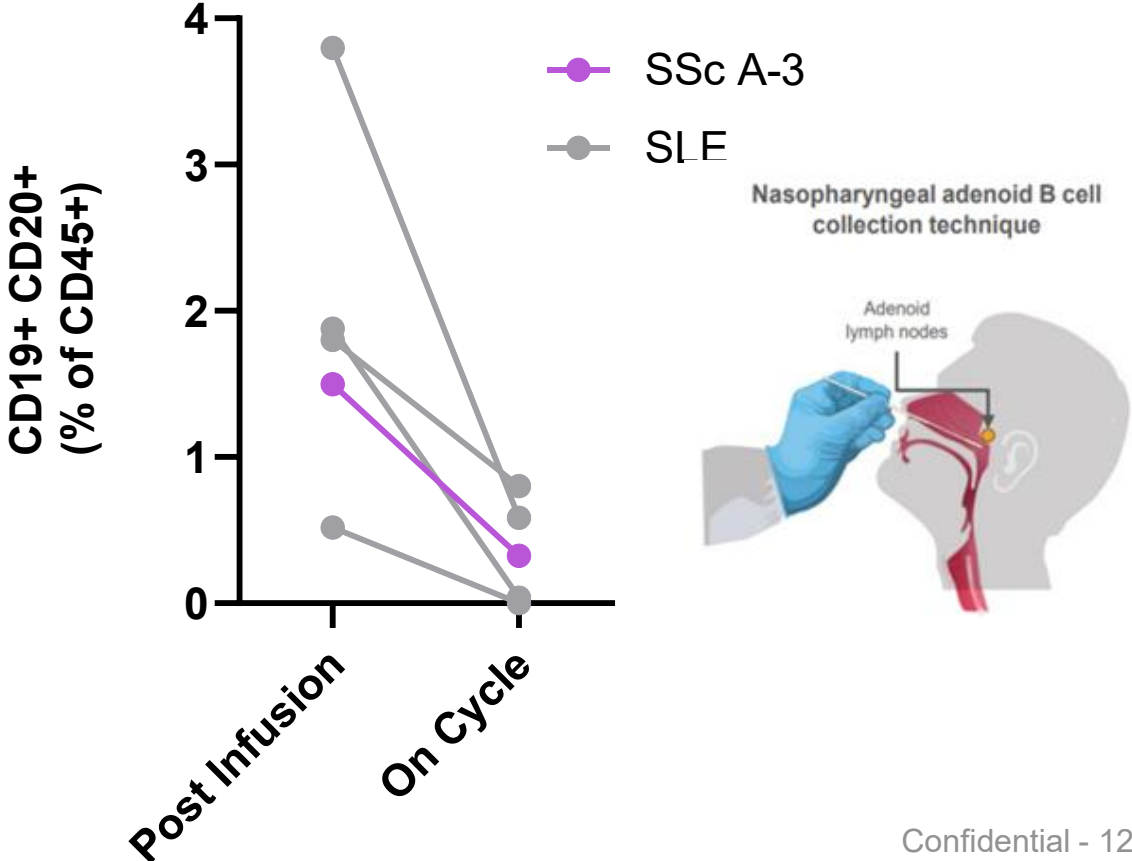
	A1			A2		A3		B1	
	BL	M3	M6*	BL	M3	BL	M3	BL	M3
mRSS	22	15 ↓	15 ↓	32	23 ↓	18	10 ↓	34	30 ↓
CGA	6	2 ↓	4 ↓	6	3 ↓	3	1 ↓	5	2 ↓
PtGA	5	0 ↓	6 ↓	5	3 ↓	5	3 ↓	8	7 ↓
FVC%, predicted	99	95	105 ↑	67	64	93	93	86	92 ↑
HAQ-DI	1.125	0 ↓	0.125 ↓	2.125	1.375 ↓	1.750	1.625 ↓	1.75	1.75

# FT819 Drives B Cell Depletion in Peripheral Blood and Lymphoid Tissue

FT819 Drives Deep B cell Depletion in SSc



FT819 Depletes B Cells in Lymphoid Tissue



- Preliminary data from 4 patients with moderate-to-severe treatment resistant SSc showed:
  - Acceptable safety and tolerability profile
  - Successful dosing in outpatient setting or with same day discharge
  - Clinically meaningful improvement as measured by rCRISS 25/50/75/100 as early as 3 months post-FT819
  
- These findings support further development of FT819 in SSc and other autoimmune diseases using a drug product that is available on-demand and outpatient-ready

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