

Safety, efficacy, and correlative analyses of Rese-cel, a Fully Human, Autologous 4-1BB Anti-CD19 CART T Cell Therapy in Patients with Myositis, Lupus, and Scleroderma from the RESET™ Clinical Trials

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Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "would," "should" and "could," and similar expressions or words, identify forward-looking statements.

Various risks, uncertainties and assumptions could cause actual results to differ materially from those anticipated or implied in our forward-looking statements. Such risks and uncertainties include, but are not limited to, risks related to the success, cost, and timing of our product candidate development activities and preclinical studies and clinical trials, risks related to our ability to demonstrate sufficient evidence of safety, efficacy and tolerability in our preclinical studies and clinical trials of rese-cel and MuSK-CAART, the risk that the results observed with the similarly-designed construct, including, but not limited to, due to dosing regimen, are not indicative of the results we seek to achieve with rese-cel, the risk that signs of biologic activity or persistence may not inform long-term results, the risk that persistence observed with effective CD19-CAR T oncology studies in combination with lymphodepletion is not indicative of, or applicable to, clinical responses in patients with mPV, risks related to clinical trial site activation or enrollment rates that are lower than expected, our ability to demonstrate sufficient evidence of safety, efficacy and tolerability in its preclinical studies and clinical trials of rese-cel; risks that modifications to trial design or approach may not have the intended benefits and that the trial design may need to be further modified; our ability to protect and maintain our intellectual property position, risks related to our relationships with third parties, uncertainties related to regulatory agencies' evaluation of regulatory filings and other information related to our product candidates, our ability to retain and recognize the intended incentives conferred by any Orphan Drug Designations and Fast Track Designations, risks related to regulatory filings and potential clearance, the risk that any one or more of our product candidates will not be successfully developed and commercialized, the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies, and risks related to volatile market and economic conditions and public health crises. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause our actual results to differ materially from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent annual report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in our other and subsequent filings with the Securities and Exchange Commission. Certain information contained in this Presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company's own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of this Presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. The Company is the owner of various trademarks, trade names and service marks. Certain other trademarks, trade names and service marks appearing in this Presentation are the property of third parties. Solely for convenience, the trademarks and trade names in this Presentation are referred to without the ® and TM symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

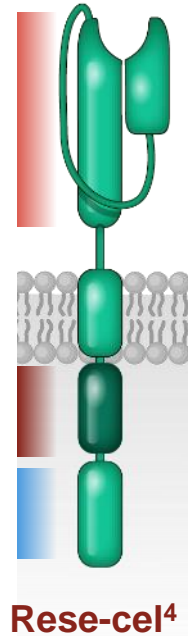
Rese-cel (CABA-201): CD19-CAR T designed for autoimmunity

Cabaletta's CD19 binder with similar in vitro & in vivo activity to FMC63^{1,2} (binder used in academic report³)

Fully human anti-CD19 binder

4-1BB costimulatory domain

CD3- ζ signaling domain



Rese-cel product design & clinical / translational data

- ▶ 4-1BB costimulatory domain with fully human binder
 - Binder with similar affinity & biologic activity to academic FMC63 binder while binding to the same epitopes^{1,2}
- ▶ Same weight-based dose as in academic studies
 - Potential to provide immune reset based on initial clinical and translational data⁵
- ▶ Initial patients treated with rese-cel have shown compelling clinical responses with safety data that supports autoimmune development⁶

1. Peng, Binghao J, et al. "Preclinical specificity and activity of CABA-201, a fully human 4-1BB containing CD19 CAR T therapy for treatment-resistant autoimmune disease." Poster presented at: American Society Gene and Cell Therapy 26th Annual Meeting; 2023 May 19; Los Angeles, CA.

2. Dai, Zhenyu, et al. "Development and functional characterization of novel fully human anti-CD19 chimeric antigen receptors for T-cell therapy." *Journal of Cellular Physiology* 236.8 (2021): 5832-5847.

3. Müller, Fabian, et al. "CD19 CAR T-Cell Therapy in Autoimmune Disease—A Case Series with Follow-up." *New England Journal of Medicine* 390.8 (2024): 687-700.

4. Transmembrane domain in CABA-201 is CD8 α vs. TNFRSF19 (Troy) utilized in the academic construct. The two transmembrane domains have not been shown to have a significant difference in function or IFN- γ production in preclinical studies. The CD8 α transmembrane domain is employed in tisagenlecleucel.

5. Volkov, Jenell, et al. "Case study of CD19 CAR T therapy in a subject with immune-mediate necrotizing myopathy treated in the RESET-Myositis phase I/II trial." *Molecular Therapy* 32.11 (2024): 3821-3828.

6. Abstract 1733: Safety and Efficacy of CABA-201, a Fully Human, Autologous 4-1BB Anti-CD19 CAR T Cell Therapy in Patients with Immune-Mediated Necrotizing Myopathy and Systemic Lupus Erythematosus from the RESET-MyositisTM and RESET-SLETM Clinical Trials. ACR 2024.

RESET™ Clinical Program for Rese-cel, a CD19-directed CAR T

Multiple autoimmune diseases evaluated in disease-specific cohorts enrolling at 44 sites in the US & Europe

Trial	Preclinical	Phase 1/2	Pivotal
RESET-Myositis™	Dermatomyositis		
	Antisynthetase syndrome		
	Immune-mediated necrotizing myopathy		
	Juvenile myositis		
RESET-SLE™	Lupus nephritis		
	Non-renal systemic lupus erythematosus		
RESET-SSc™	Skin + organ cohort		
	Skin cohort		
RESET-MG™	AChR-Ab pos. generalized myasthenia gravis		
	AChR-Ab neg. generalized myasthenia gravis		
RESET-MS™	Relapsing multiple sclerosis		
	Progressive multiple sclerosis		
RESET-PV™	Mucocutaneous & mucosal pemphigus vulgaris		

- Rheumatology
- Neurology
- Dermatology
- Contains cohort(s) without preconditioning
- Pediatric indication

RESET™ Program: Key Inclusion and Exclusion Criteria

Designed to evaluate the safety and tolerability of rese-cel in subjects with active, refractory disease

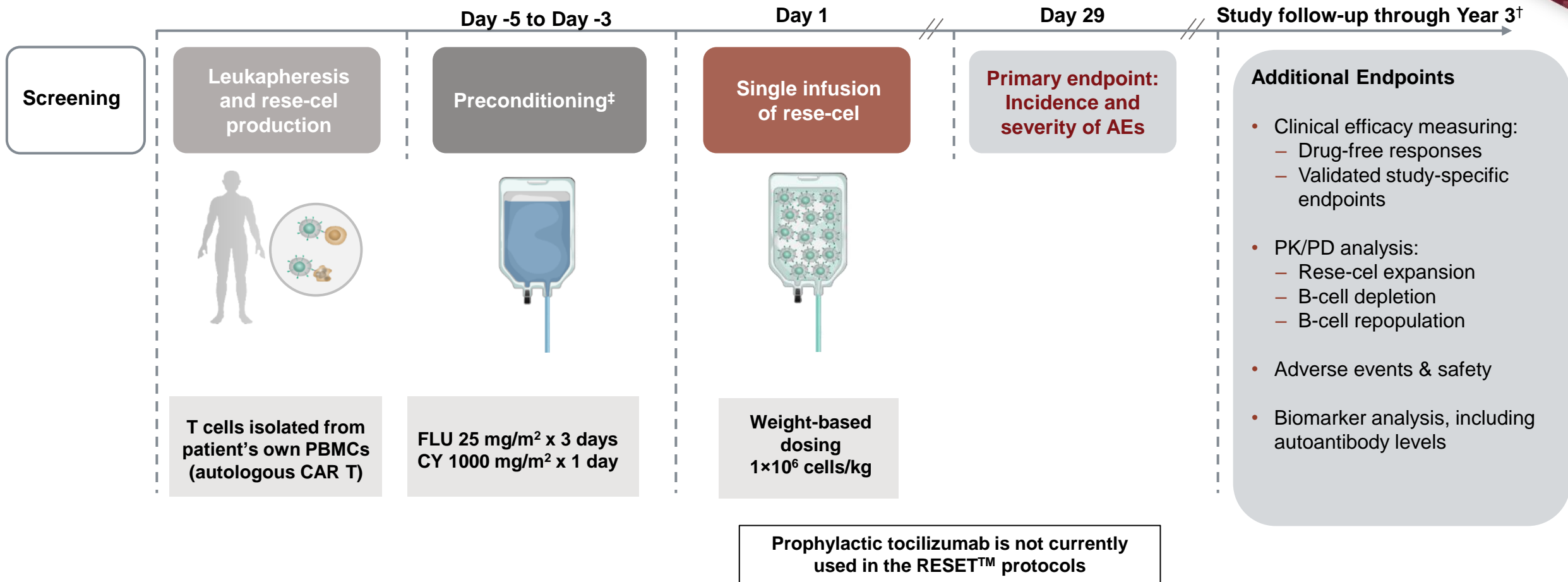
Key inclusion criteria ¹⁻³		
Evidence of active disease despite prior or current treatment with standard of care		
RESET-Myositis™	RESET-SLE™	RESET-SSc™
<ul style="list-style-type: none">• Age ≥18 and ≤75 with a diagnosis of IIM (ASyS, DM, or IMNM)• Presence of at least one MSA• JiIM: Age ≥6 and ≤17 with presence of at least one MSA or MAA	<ul style="list-style-type: none">• Age ≥18 and ≤65 with an SLE diagnosis• Positive ANA or anti-dsDNA at screening• SLE (non-renal): active, moderate to severe SLE, SLEDAI-2K ≥8; pure class V LN patients eligible for this cohort• LN: active, biopsy-proven LN class III or IV (± class V)	<ul style="list-style-type: none">• Age ≥18 and ≤70 with a limited or diffuse SSc diagnosis• Evidence of significant skin, pulmonary, renal, or cardiac involvement
Key exclusion criteria ¹⁻³		
B-cell depleting agent within prior 3-6 months; Previous CAR T therapy and/or HSCT		
<ul style="list-style-type: none">• Cancer-associated myositis• Significant lung or cardiac impairment	<ul style="list-style-type: none">• Presence of kidney disease other than LN• Current symptoms of severe, progressive, or uncontrolled pulmonary or cardiac disease	<ul style="list-style-type: none">• Severe lung or cardiac impairment

ANA, antinuclear antibody; anti-dsDNA, anti-double strand DNA antibodies; ASyS, antisynthetase syndrome; CAR, chimeric antigen receptor; DM, dermatomyositis; HSCT, hematopoietic stem cell transplantation; IIM, idiopathic inflammatory myopathy; IMNM, immune mediated necrotising myopathy; JiIM, juvenile idiopathic inflammatory myopathy; LN, lupus nephritis; MAA, myositis-associated antibody; MSA, myositis-specific antibodies; SLEDAI-2k, SLE disease activity index 2000; SLE, systemic lupus erythematosus; SSc, systemic sclerosis.

1. ClinicalTrials.gov. Available at: www.clinicaltrials.gov/study/NCT06121297 (accessed October 2024). 2. ClinicalTrials.gov. Available at: www.clinicaltrials.gov/study/NCT06328777 (accessed October 2024). 3. ClinicalTrials.gov. Available at: www.clinicaltrials.gov/study/NCT06154252 (accessed October 2024).

RESET™ Clinical Trials Have Consistent Design Principles¹

Individual trials in myositis, SLE, and SSc share common elements of preconditioning, dose, and study design



[†]Follow up period encompasses 15 years in total, aligned to regulatory guidance for CAR T cell therapies. [‡] Preconditioning does not apply to RESET-PV™

AE, adverse event; CABA, Cabaletta Approach to B cell Ablation; FLU, fludarabine; CY, cyclophosphamide; PBMC, peripheral blood mononuclear cell; PD, pharmacodynamics; PK, pharmacokinetics; RESET, REStoring SElf-Tolerance; SLE, systemic lupus erythematosus; SSc, systemic sclerosis.

Cabaletta Bio: Data on file; 1. Peng BJ, et al. *Mol Ther Methods Clin Dev.* 2024;32(2):101267.

Baseline Characteristics: First 10 Patients in the RESET™ Program

All patients had active, refractory disease and most had failed B cell-targeting therapies

	RESET-Myositis™			RESET-SLE™						RESET-SSc™
Patient / Cohort	IMNM-1	IMNM-2	DM-1	SLE-1† Class V LN	SLE-2	SLE-3	SLE-4	LN-1	LN-2	SSc-Skin-1 Severe skin cohort
Age, sex	33 M	60 M	57 M	26 M	36 F	44 F	37 F	24 F	35 F	66 F
Disease duration (y)	~2	~4	~4	~6	~17	~9	~10	~2	~8	~2
Autoantibodies	SRP	HMGCR	SAE	dsDNA	dsDNA	dsDNA	dsDNA	dsDNA	dsDNA	RNA P III
Baseline Disease activity*	MMT-8			SLEDAI-2K						mRSS
	130	126	131	26	10	8	8	22	14	42
	CK (U/L)			UPCR (mg/mg)						
	617	4725	94	1.08†	n/a	n/a	n/a	7.22	4.85	
Therapies at Screening	GC, MTX	GC, IVIG	GC, MMF, HCQ	HCQ, GC, MMF	GC, AZA	HCQ, MMF, BEL	HCQ‡	HCQ, GC, MMF, ANI, VOC	MMF	MMF, BRX
Other prior therapies	RTX, IVIG	RTX, MMF, MTX	IVIG	CYC, BEL, VOC, TAC	HCQ, MTX, ANI, BEL, MSC, RTX, ADA	GC, MTX	MTX, BEL	BEL, LEF	HCQ, GC, AZA, RTX	HCQ
GC dose at Screening (mg/day)#	5	5	20	10	7	n/a	n/a‡	20	N/A	N/A

*Baseline disease activity = activity before preconditioning. #Prednisone/prednisone equivalent dose

†SLE-1 had class V LN; inclusion criteria for LN cohort requires class III/IV LN. ‡SLE-4 initiated 20 mg/day of prednisone after screening and before leukapheresis, tapered to 2.5mg by latest follow-up of week 8 and discontinued as of data cut. ADA, adalimumab; ANI, anifrolumab; AZA, azathioprine; BEL, belimumab; BRX, brentuximab vedotin; CK, creatine kinase; CYC, cyclophosphamide; DM, dermatomyositis; dsDNA, double-stranded DNA; GC, glucocorticoid; HCQ, hydroxychloroquine; HMGCR, 3-hydroxy-3-methylglutaryl-coenzyme A reductase; IMNM, immune-mediated necrotizing myopathy; IVIG, intravenous immunoglobulin; LEF, leflunomide; LN, lupus nephritis; MMF, mycophenolate mofetil; MMT-8, manual muscle testing 8; mRSS, modified Rodnan skin score; MSC, mesenchymal stem cell; MTX, methotrexate; RESET, REStoring SELF-Tolerance; RNA P III, RNA polymerase III; RTX, rituximab; SAE, small ubiquitin-like modifier activating enzyme; SLE, systemic lupus erythematosus; SLEDAI-2K, SLE disease activity index 2000; SRP, signal recognition particle; SSc, systemic sclerosis; TAC, tacrolimus; U/L, units per liter; UPCR, urinary protein-to-creatinine ratio; VOC, voclosporin, y, years.

Cabaletta Bio: Data on file.

Incidence and Severity of Adverse Events*

	RESET-Myositis™			RESET-SLE™						RESET-SSc™
Cohort	IMNM		DM	Non-renal SLE				LN		Severe Skin
Patient	IMNM-1	IMNM-2	DM-1	SLE-1	SLE-2	SLE-3	SLE-4	LN-1	LN-2	SSc-Skin-1
CRS†	None	None	None	None	Grade 1	None	None	Grade 1	None	Grade 2
ICANS†	None	None	None	None	None	None	None	Grade 4	None	None
Serious infections‡	None	None	None	None	None	None	None	None	None	None
Hypogammaglobulinemia	None	None	None	None	None	None	None	Grade 2	None	None
Related SAEs (Grade)§ (excluding CRS and ICANS)	None	None	None	None	None	None	None	Fever (1) Neutropenic fever (1) Pancytopenia¶ (4)	None	None
Unrelated SAEs (Grade)§	None	Back pain (3) PE# (4)	None	None	None	None	None	None	None	Neutropenia (4) (FLU/CY related)

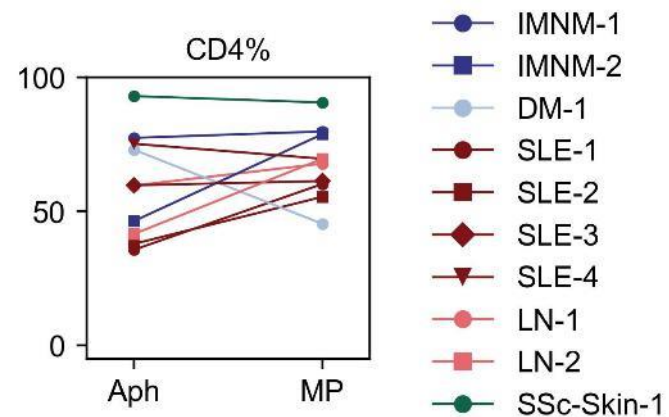
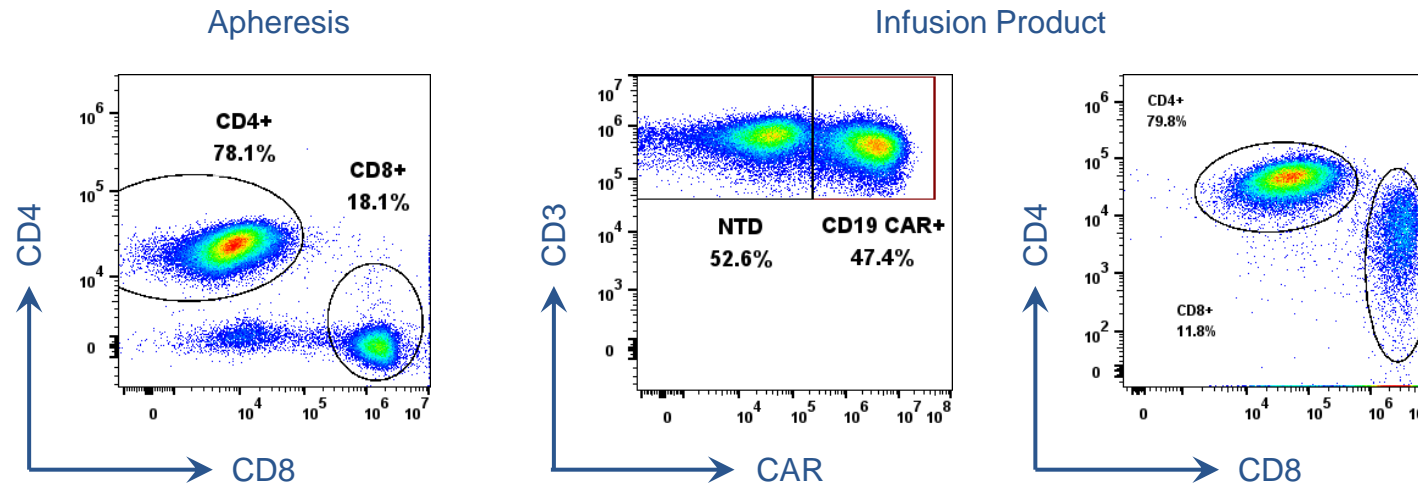
*As of Jan 8, 2025; Primary endpoint is incidence and severity of adverse events through Day 29. †Graded per ASTCT Consensus Grading Criteria. Of these patients, DM-1, SLE-2, SLE-3, SLE-4, LN-2, and SSc-Skin-1 received medication for seizure prophylaxis. Tocilizumab was not administered for any cases of CRS. ‡Coded in System Organ Class of Infections and Infestations and meets seriousness criteria. §As assessed per FDA guidelines.

#Patient with Factor V Leiden heterozygosity (increased risk for thrombosis), recent intravenous immunoglobulin treatment, history of myocardial infarction, recent hospitalization for back pain & fatigue with decreased mobility. Undetectable CABA-201 levels since Day 22. Event occurred at Day 38 and was reported as PE leading to cardiac arrest, followed by successful pulmonary artery thrombectomy.

¶Consistent with “Prolonged Cytopenias,” which is a labeled warning and precaution for approved oncology CAR T products.

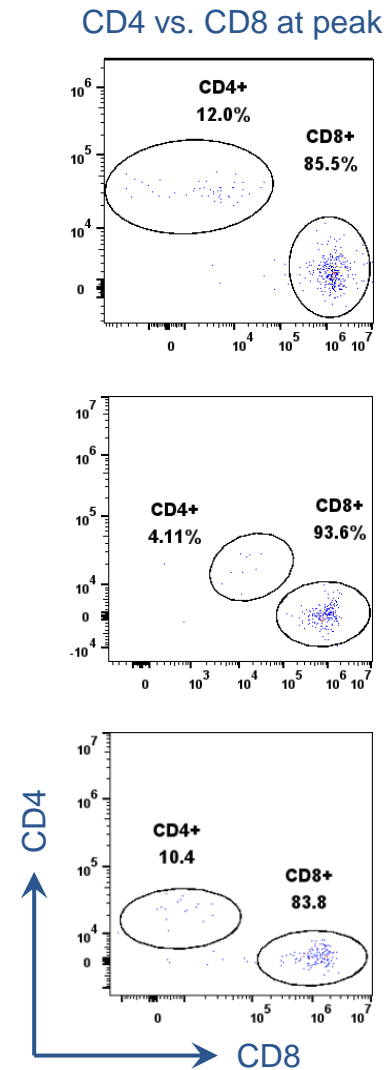
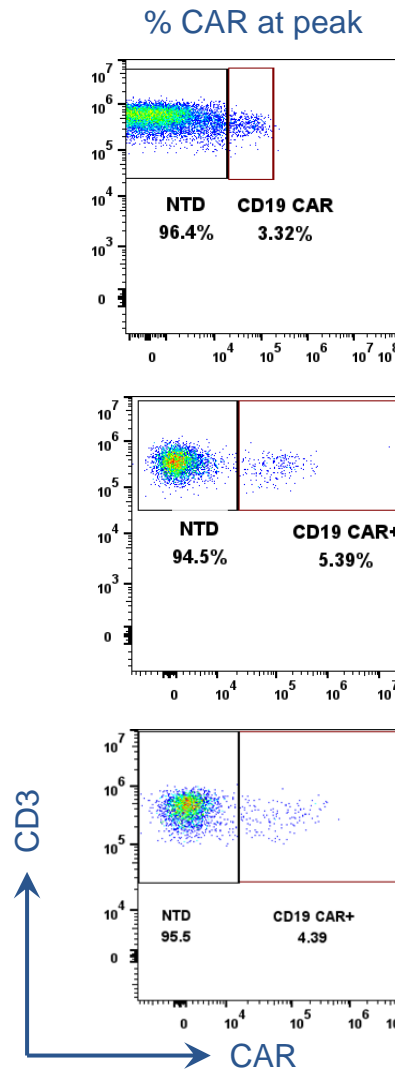
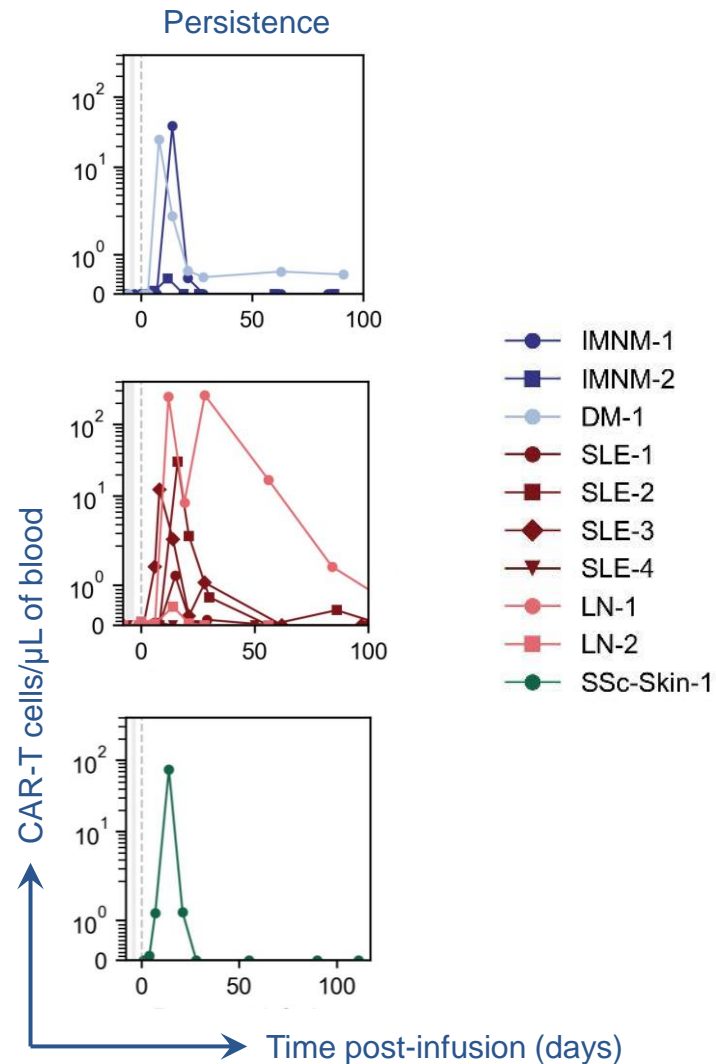
ASTCT, American Society for Transplantation and Cellular Therapy; CAR, chimeric antigen receptor; CRS, cytokine release syndrome; CY, cyclophosphamide; DM, dermatomyositis; FLU, fludarabine; ICANS, immune effector cell-associated neurotoxicity syndrome; IMNM, immune-mediated necrotizing myopathy; LN, lupus nephritis; PE, pulmonary embolism; SAE, serious adverse event; RESET, REStoring SELF-Tolerance; SLE, systemic lupus erythematosus; SSc, systemic sclerosis. Cabaletta Bio: Data on file.

Rese-cel is a CD4⁺ dominant CAR-T infusion product



Rese-cel peak expansion is observed 7 to 15 days post infusion

Rese-cel at peak expansion becomes CD8⁺ dominant in most patients



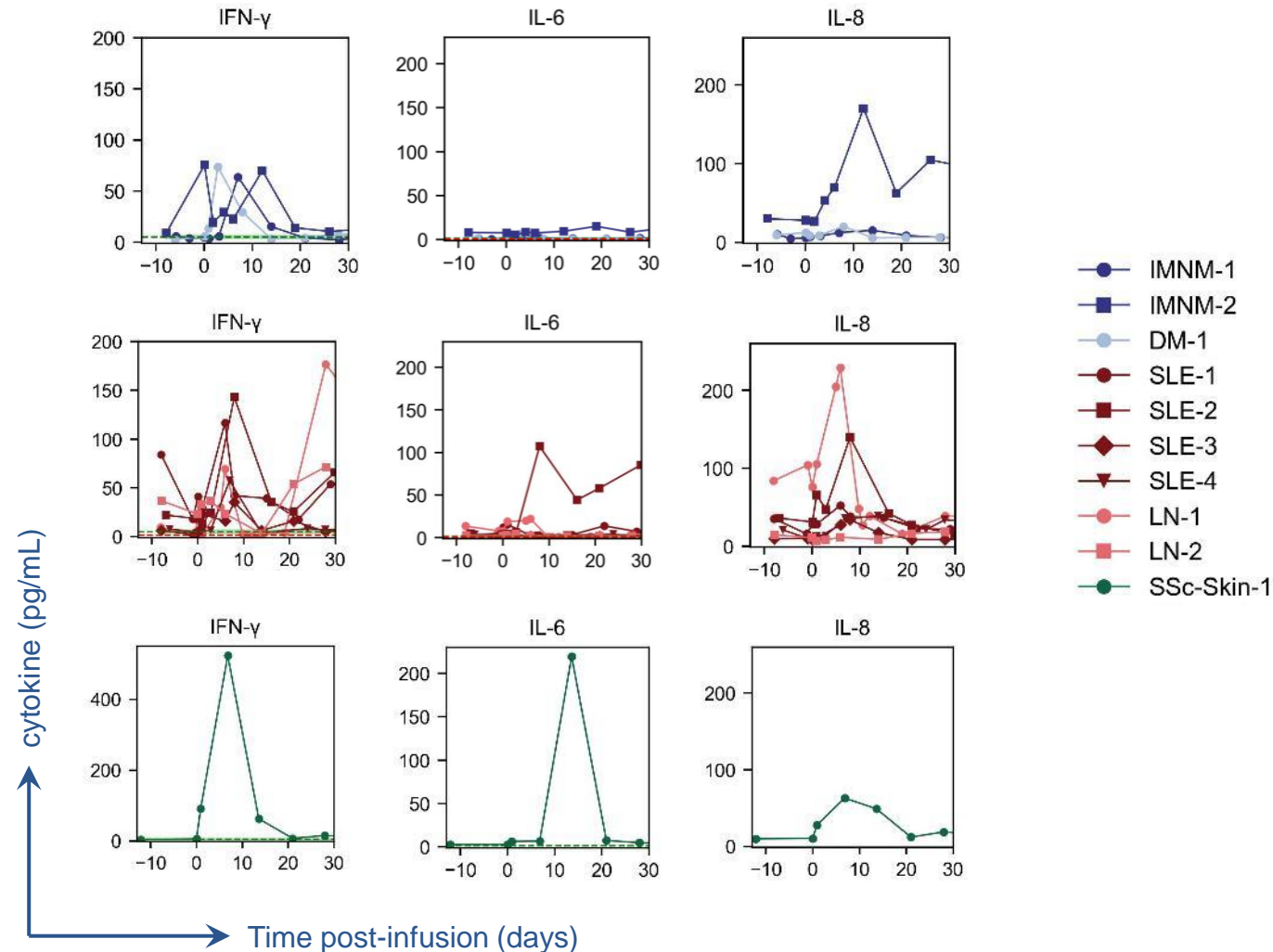
IMNM-1

SLE-3

SSc-Skin1

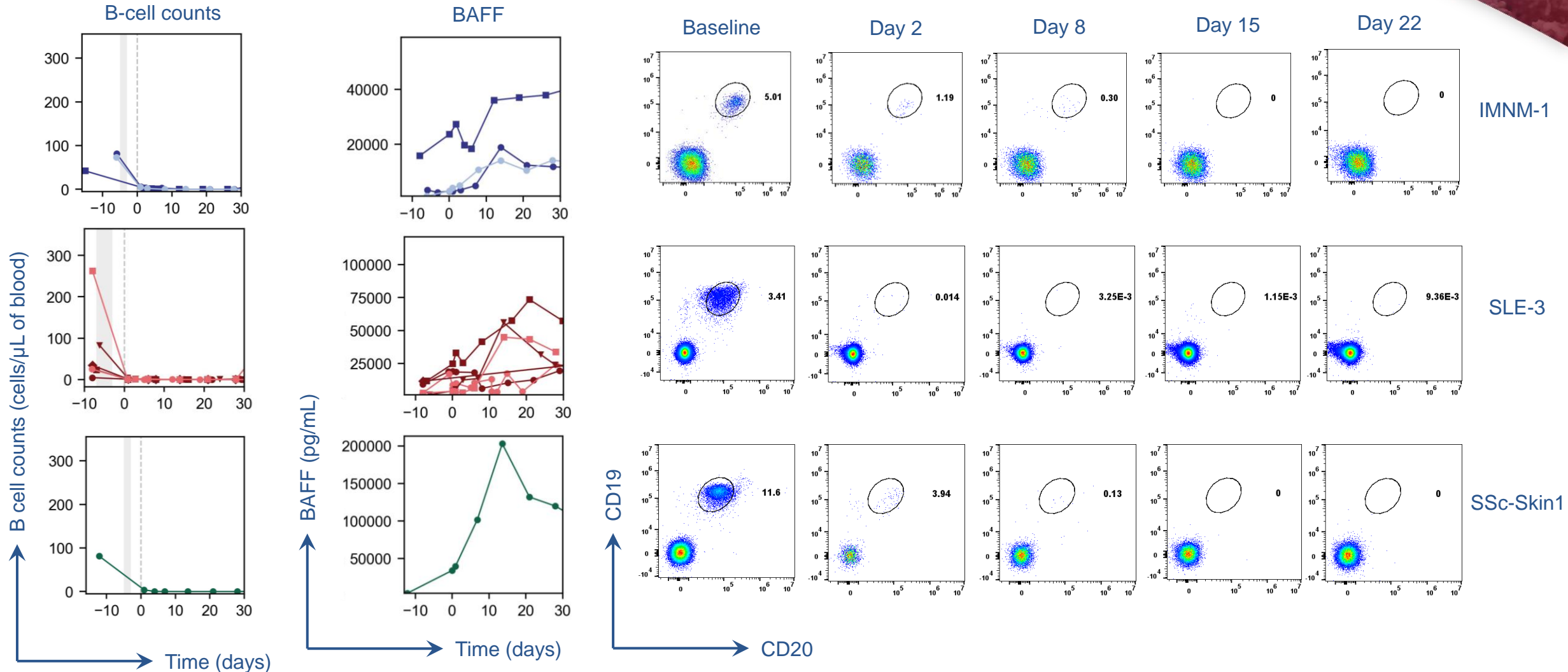
IFN- γ induction observed prior to peak expansion

In a subset of patients, IL-6 and IL-8 observed after IFN- γ induction



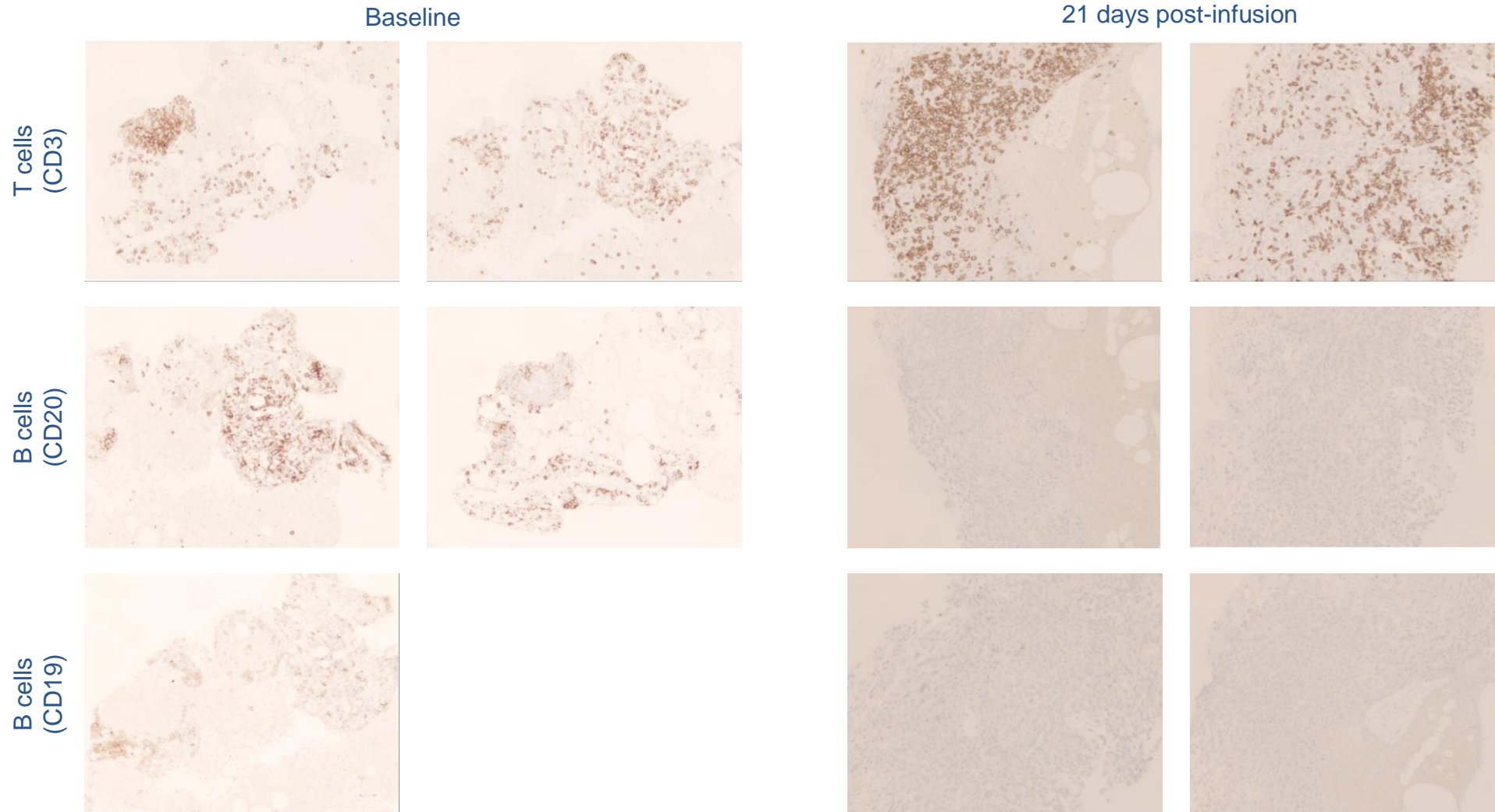
B cell depletion occurs rapidly after infusion

Increases in BAFF observed with B cell depletion



B cell depletion in lymphoid tissue 21 days post-infusion in SSc-Skin-1

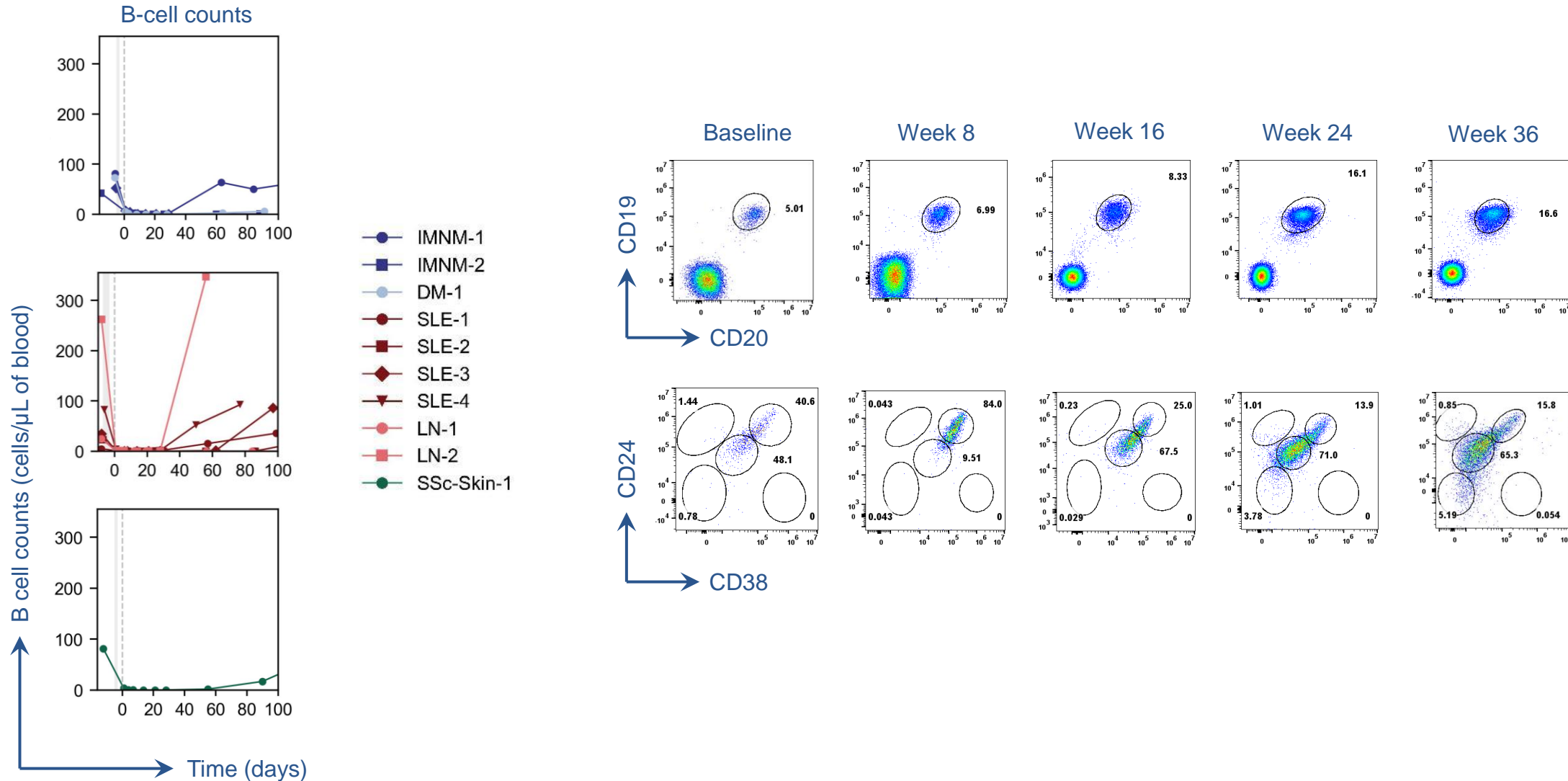
Lymph node B cell depletion is contemporaneous with peripheral B cell depletion



1. LN biopsies were from the left inguinal area using USG at U. Michigan by Dr. Khanna
2. All Images are 20X magnification

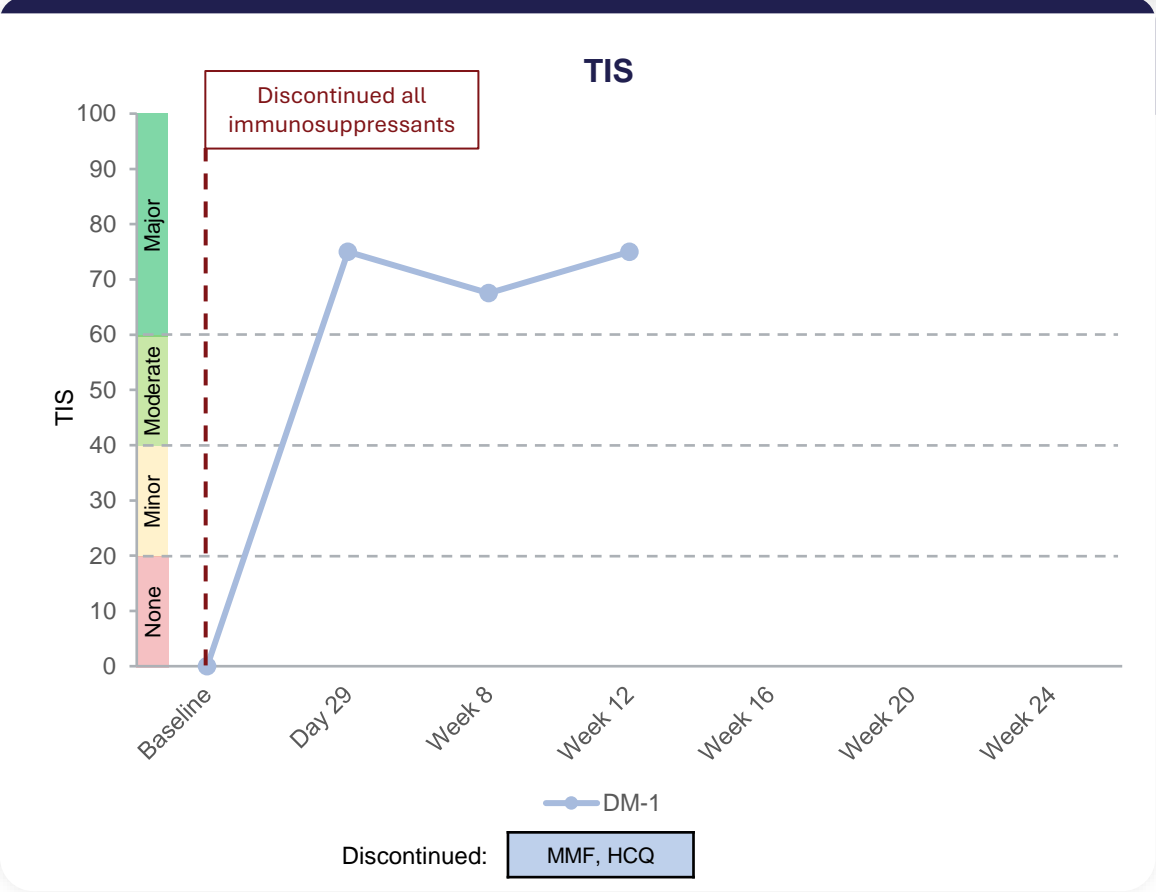
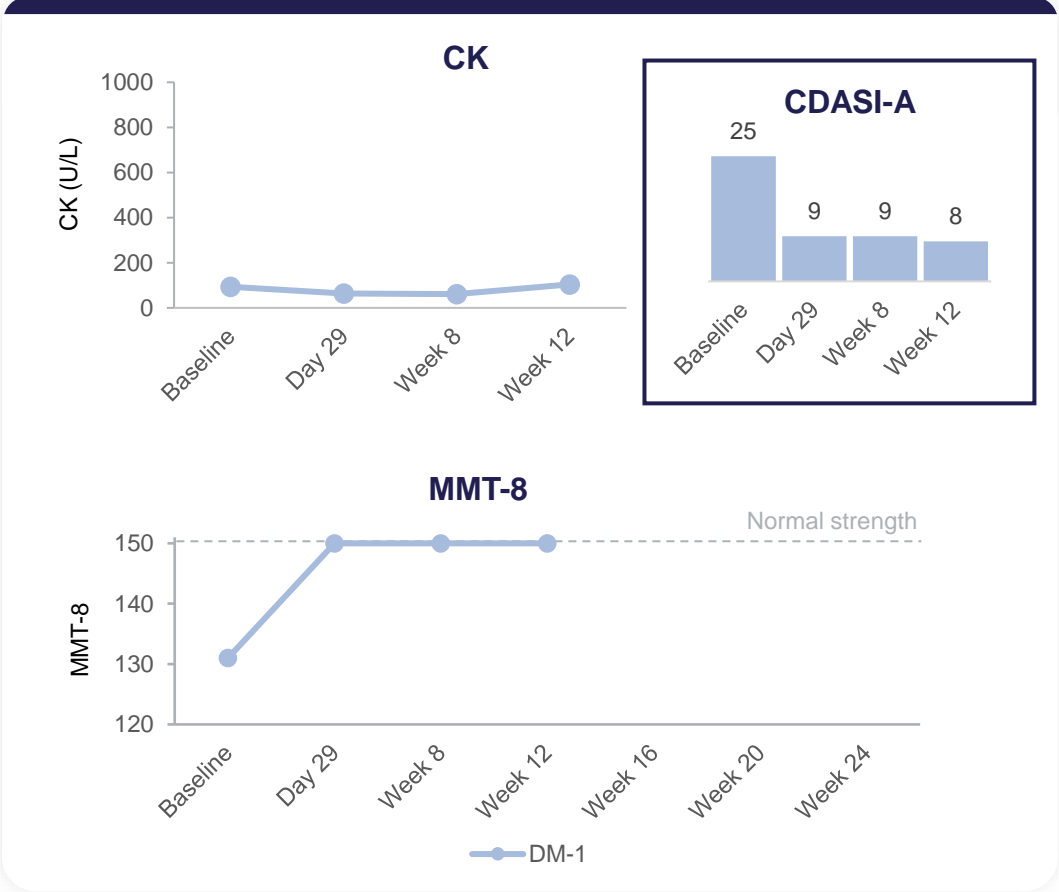
B cell repopulation starts at 2 months post-infusion

Re-emergent cells are transitional naïve B cells ($CD24^{hi}CD38^{hi}$), implying recent bone marrow emigration



RESET- Myositis™: Early Efficacy Data Following Rese-cel Infusion

First known adult DM patient dosed with CAR T demonstrated compelling early clinical response off immunosuppressants*

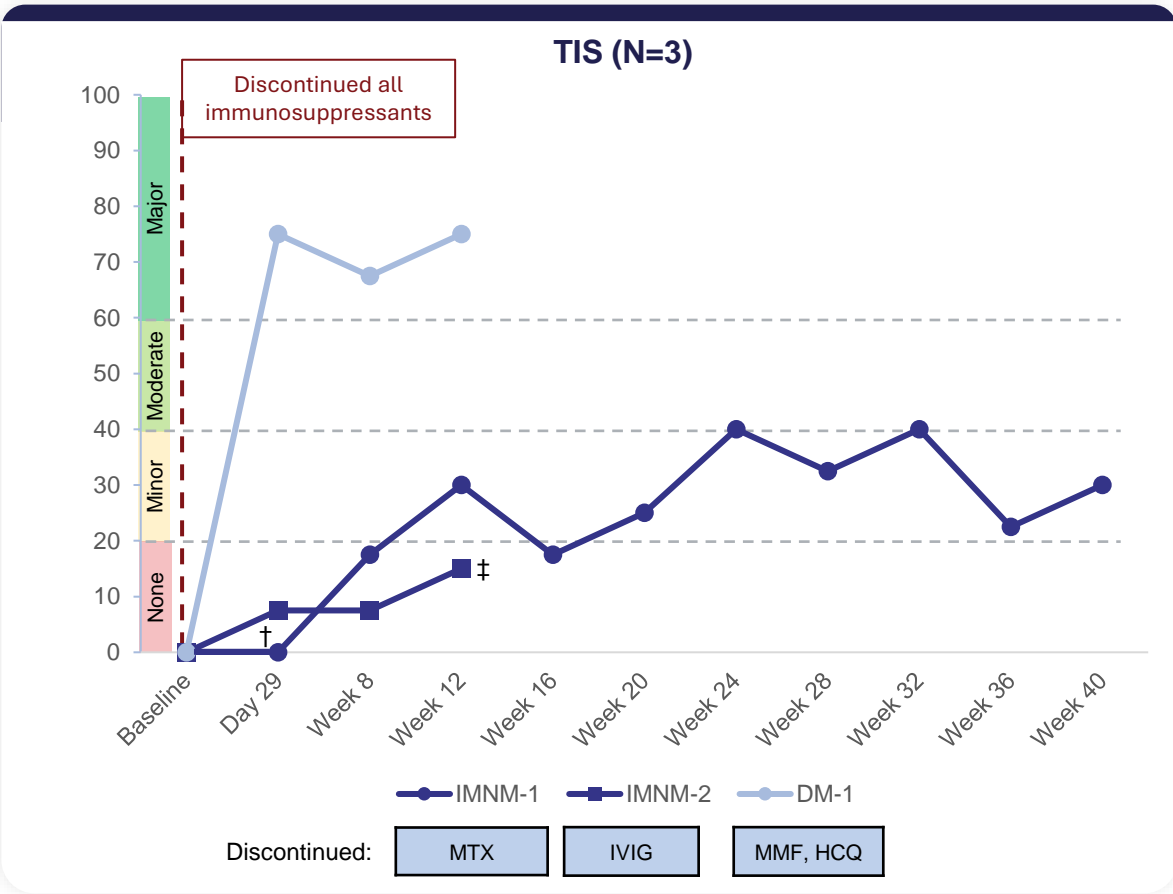
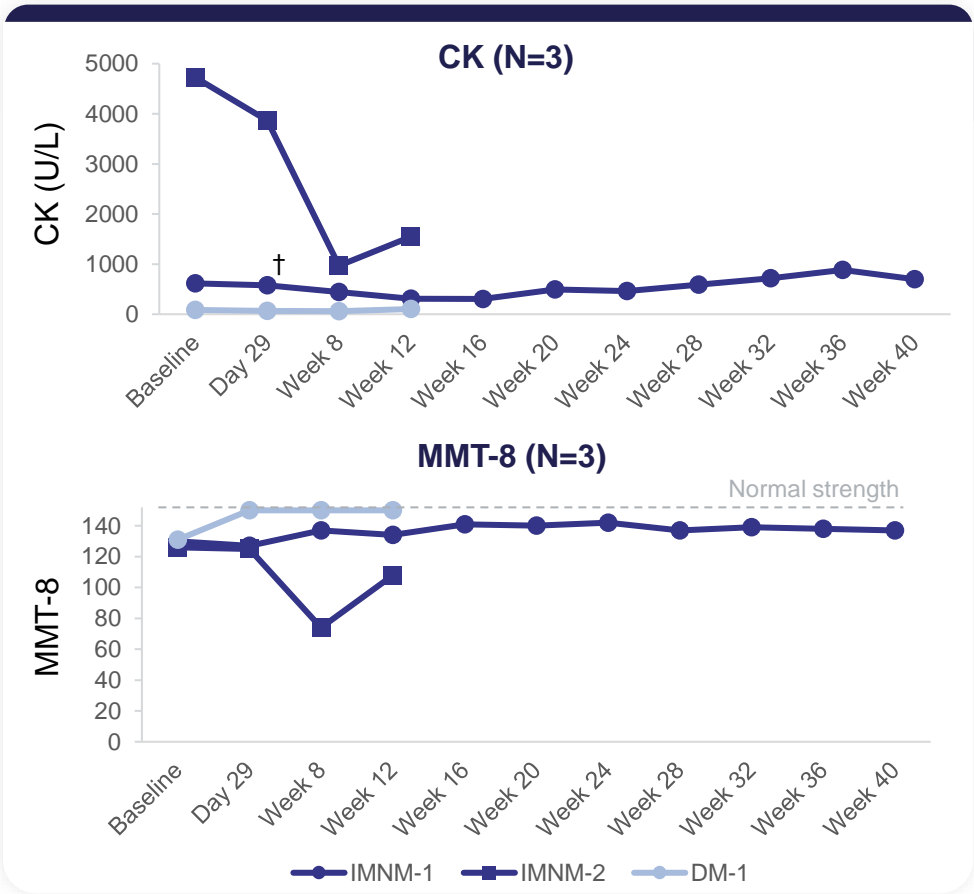


Maintenance of major response to treatment (TIS) in DM-1 shows promise for achieving drug-free remission in patients with refractory myositis

*As of Jan 8, 2025.
CAR, chimeric antigen receptor; CDASI-A, Cutaneous Dermatomyositis Disease Area and Severity Index – Activity; CK, creatinine kinase; DM, dermatomyositis HCQ, hydroxychloroquine; MMF, mycophenolate mofetil; MMT-8, manual muscle testing 8; rese-cel, resecabtagene autoleucel; RESET, REstoring SElf-Tolerance; TIS, total improvement score; U/L, units per liter.
Cabaletta Bio: Data on file.

RESET- Myositis™: Early Efficacy Data Following Rese-cel Infusion¹

First IMNM patient with longer follow up demonstrated continuing clinical response off immunosuppressants without flares*



Initial clinical responses in IMNM are consistent with published data;² response kinetics may differ among myositis subtypes

*As of Jan 8, 2025. †IMNM-1 Day 29 CK measurement was unavailable; Day 22 used. ‡IMNM-2 developed a PE at Day 38 with a prolonged hospitalization and recovery and received IVIG just after Week 12 visit and increased prednisone from 5 mg to 20 mg 2 weeks later. CK, creatinine kinase; DM, dermatomyositis; HCQ, hydroxychloroquine; IMNM, immune-mediated necrotizing myopathy; IVIG, intravenous immunoglobulin; MTX, methotrexate; MMF, mycophenolate mofetil; MMT-8, manual muscle testing 8; rese-cel, resecabtagene autoleucel; RESET, REStoring SElf-Tolerance; TIS, total improvement score; U/L, units per liter.
1. Cabaletta Bio: Data on file. 2. Schett, G. 'CAR-T Cell Therapy: "The Future is Now."' 5th Global Conference on Myositis. iMyoS. Pittsburgh, PA.

RESET-SLE™: Efficacy Data Following Rese-cel Infusion*

3 out of 4 SLE patients have achieved DORIS remission and 1st LN patient achieved CRR

	SLE				LN	
Patient	SLE-1 [†]	SLE-2	SLE-3	SLE-4	LN-1	LN-2
Latest follow-up (weeks)	36	16	8	8	24	4
DORIS remission (at latest follow-up)	–	✓	✓	✓	–	–
LLDAS (at latest follow-up)	–	✓	✓	✓	✓	–
SLEDAI-2K score[‡] (baseline to latest follow-up)	26→8	10→0	8→2	8→2	22→2	14→11
UPCR (baseline to latest follow-up)	1.08→0.55	N/A	N/A	N/A	7.22→0.45	4.85→2.56
CRR (at latest follow-up)	–	N/A	N/A	N/A	✓	–
GC-free[#]	✓	✓	✓	✓	✓	✓
IS-free	✓	✓	✓	✓	✓	✓

*As of Jan 8, 2025

[†] Enrollment in the LN cohort requires class III/IV +/- V LN. SLE-1 had isolated class V LN and extra-renal SLE disease activity that met inclusion criteria for the non-renal cohort. Proteinuria contributed 4 SLEDAI-2K points at all assessments.

[‡] SLEDAI-2K components at latest follow up: SLE-1: proteinuria-4, complement-2, dsDNA-2; SLE-3: dsDNA-2; SLE-4: dsDNA-2; LN-1: rash-2; LN-2: proteinuria-4, leukopenia-1, alopecia-2, complement-2, dsDNA-2

[#] SLE-4 and LN-1 had discontinued GC as of the data cut; as of the latest follow up SLE-4 was on 2.5mg/d of prednisone (week 8) and LN-1 was on 7mg/d of prednisone (week 24)

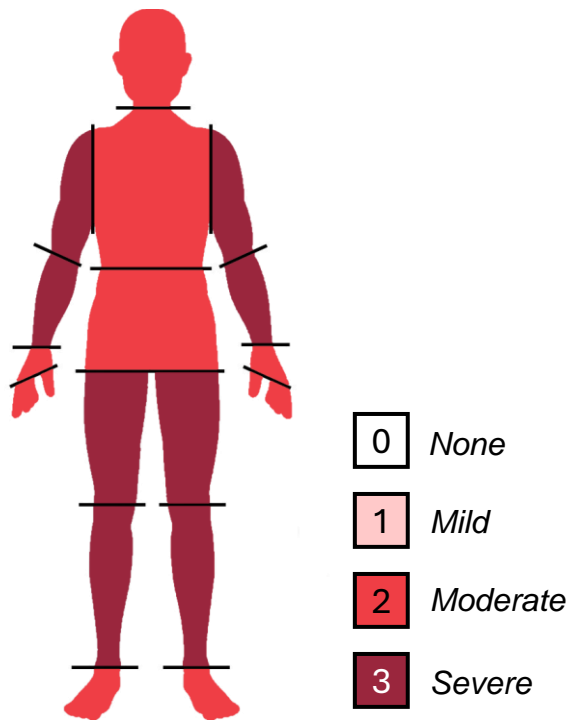
CRR, complete renal response; DORIS, definition of remission in SLE; GC, glucocorticoid; IS, immunosuppressant; LLDAS, lupus low disease activity state; LN, lupus nephritis; N/A, not applicable; rese-cel, resecabtagene autoleucel; RESET, REStoring SElf-Tolerance; SLE, systemic lupus erythematosus; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000; UPCR, urine protein-creatinine ratio.

Cabaletta Bio: Data on file

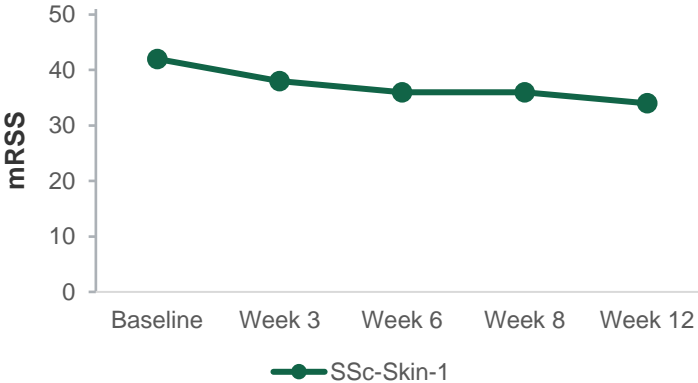
RESET-SSc™: SSc-Skin-1 Efficacy Data Following Rese-cel Infusion¹

Skin improvements across multiple body areas, and improvement in lung function, after discontinuing immunosuppressants*

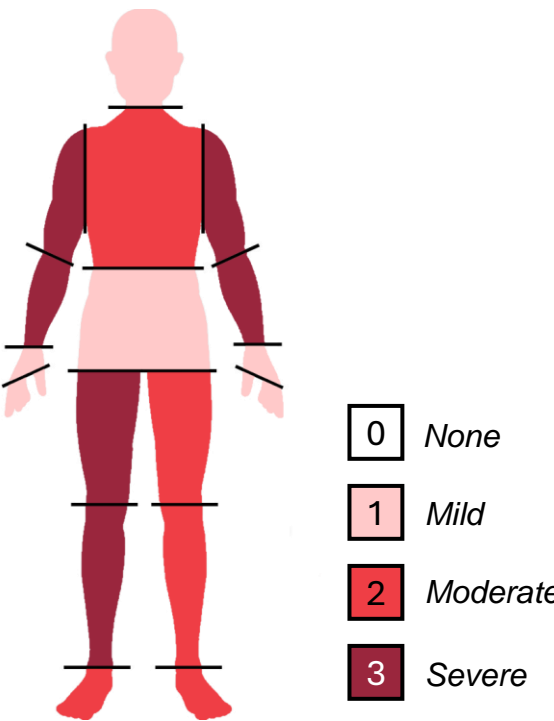
Baseline mRSS score by body area



Overall mRSS score



Week 12 mRSS score by body area



Pulmonary function tests

	Baseline	Week 12
DLCO	70%	85%
FVC	91%	97%

Early clinical data indicate emergence of a drug-free clinical response*

*As of Jan 8, 2025 patient is not taking immunosuppressants or steroids.
DLCO, % predicted diffusing capacity for carbon monoxide; FVC, % predicted forced vital capacity; mRSS, modified Rodnan Skin Score (measure of skin thickness in SSc across 17 body areas, with a maximum score of 51. Used as an outcome measure in SSc clinical trials as a surrogate for disease activity, severity, and mortality)²; rese-cel, rescabtagene autoleucel; RESET, REstoring SELF-Tolerance; SSc, systemic sclerosis.
1. Cabaletta Bio: Data on file. 2. Khanna D, et al. *J Scleroderma Relat Disord*. 2017;2(1):11–18.

Summary from Clinical and Translational Data on the First 10 Patients

- Rese-cel is well tolerated across subjects treated to date
 - No CRS in 7/10 subjects
 - Grade 1 CRS observed in 2/10 subjects and Grade 2 CRS observed in 1/10 subjects
 - No ICANs in 9/10 subjects
- Rese-cel provided compelling efficacy in highly active and refractory autoimmune patients
 - 3 of 4 SLE patients met DORIS remission
 - 1st LN patient met CRR
 - 1st DM patient major improvement in TIS
 - 1st SSc patient clinically meaningful skin improvement

} Immunosuppressant free
- Rese-cel peak expansion observed at approximately 13 days post-infusion
 - CD4⁺ dominant infusion product becomes a CD8⁺ dominant in the peripheral blood at peak expansion
 - In most patients, rapid contraction observed, and cells are undetectable after 30 days post-infusion
 - IFN- γ induction observed before or simultaneously with peak expansion
- B cells rapidly depleted in blood & lymph nodes (SSc-Skin-1) following rese-cel infusion
 - B cells come back by week 8 post-infusion in most patients
 - B cells exhibit a transitional B cell phenotype upon re-emergence, implying elimination of auto-reactive B cells

Acknowledgements

Patients and caregivers involved in the RESET™ clinical program

Site investigators and staff involved with these patients from the RESET™ clinical program

- Mayo Clinic, Rochester
- University of California, Davis
- University of California, Irvine
- University of Michigan
- University of North Carolina
- MGH, Massachusetts

Cabaletta Bio team

- Biostatistics
- Clinical Development
- Clinical Operations
- Computational Biology
- Manufacturing
- Medical Affairs
- Translational Medicine
- Quality and Compliance