Cabaletta Bio®

Recent Advances in CAR T Cell Therapy for Autoimmune Diseases

June 2026

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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 development activities and clinical trials, risks related to our ability to demonstrate sufficient evidence of safety, efficacy and tolerability in our clinical trials, the risk that the results observed with the similarly-designed construct, including, but not limited 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, risks related to clinical trial site activation or enrollment rates that are lower than expected, 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 regulatory 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, risks related to volatile market and economic conditions and our ability to fund operations and continue as a going concern. 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 and quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our other 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.

Individual Speaker Disclosures

Speaker	Disclosures
David J. Chang, MD, MPH, FACR Chief Medical Officer Cabaletta Bio Symposium Chair	**Employee of Cabaletta Bio**
Olalekan O. Oluwole, MBBS, MD, MPH Associate Professor of Medicine Vanderbilt University Medical Center	**Consulting Fees:** AbbVie, ADC, Allogene, Autolus, Bioheng, Cargo, Caribou, Curio Science, Epizyme, Gilead, Janssen, Kite, Nektar, Novartis, TG Therapeutics **Institution Funding:** Cargo, Caribou, Century, Daiichi Sankyo, Kite, Pfizer, Sana **Honoraria:** ADC, Gilead
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Learning Objectives

- Review key learnings from CAR T in hematology that can be extrapolated to autoimmune diseases
- Discuss the latest clinical updates of autologous CAR T cell therapy in rheumatology including the potential for removing preconditioning regimens
- Consider future directions for autologous CAR T cell therapy in autoimmune diseases

Agenda

Time	Talk	Speaker
17:30 to 17:45 BST	**Introduction & Review of an Investigational Autologous CD19 Directed CAR T Cell Therapy Including Trial Cohorts With No Preconditioning Regimens**	David J. Chang
17:45 to 18:05 BST	**Learnings from Hematology and the Early Autoimmune Experience: CAR T Primer and Pearls for Implementing CAR T into Clinical Practice**	Olalekan O. Oluwole
18:05 to 18:25 BST	**Myositis Unmet Needs and CAR T in Myositis: Current Evidence & Future Directions**	Rohit Aggarwal
18:25 to 18:45 BST	**Panel Discussion**	David J. Chang Olalekan O. Oluwole Rohit Aggarwal

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Introduction & Review of an Investigational Autologous CD19-Directed CAR T Cell Therapy

David J. Chang

Rese-cel: Designed for Patients with Autoimmune Disease[1]

Disease-specific cohorts in the RESET clinical program are designed to evolve directly into registrational studies

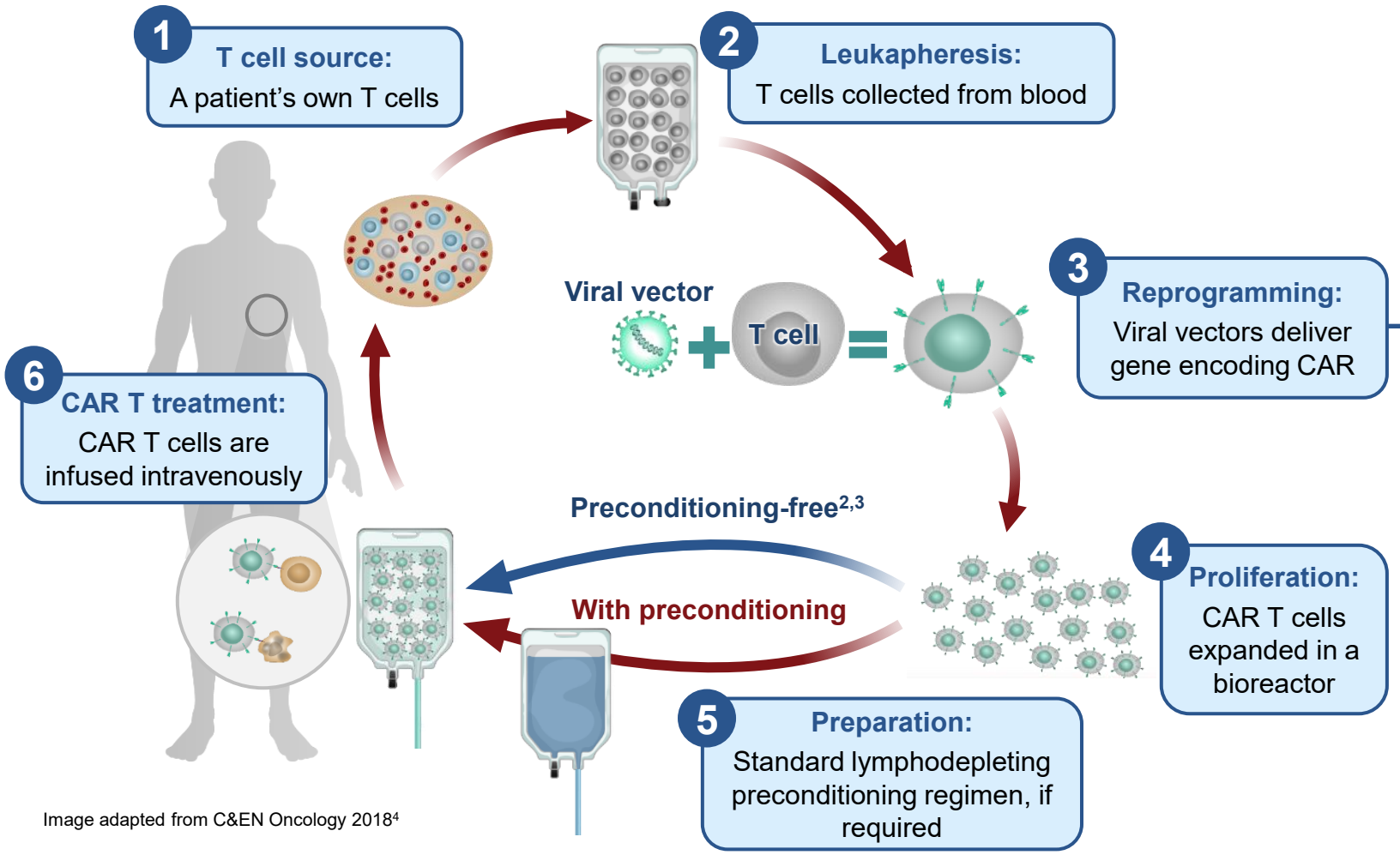
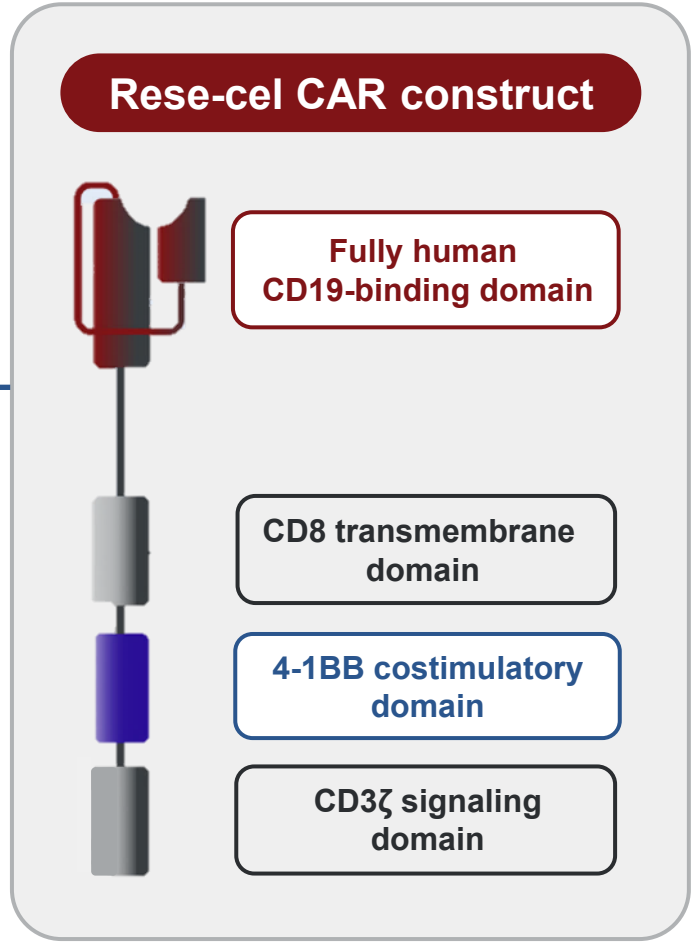


Image adapted from C&EN Oncology 2018[4]

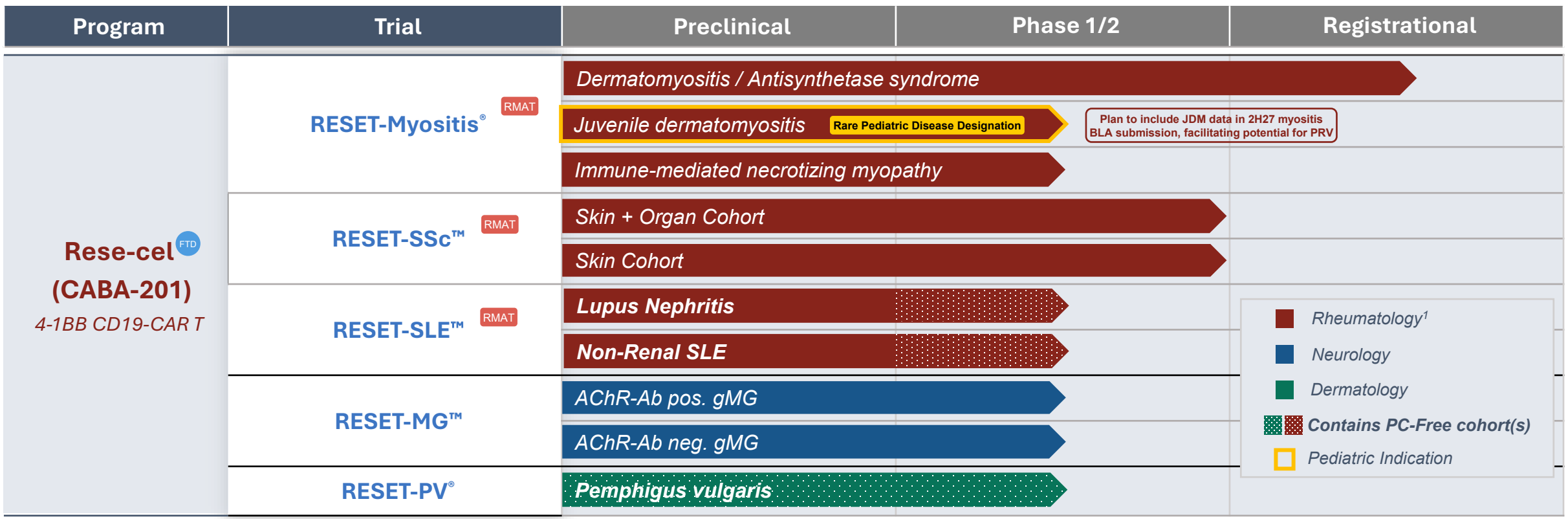


CAR, chimeric antigen receptor; CD, cluster of differentiation; rese-cel, resecabtagene autoleucel; RESET™, REstoring SElf-Tolerance

1. Peng BJ, et al. *Mol Ther Methods Clin Dev*. 2024;32(2):101267. 2. NCT04422912. Available at: https://clinicaltrials.gov/study/NCT04422912 (accessed May 2026). 3. NCT06121297. Available at: https://clinicaltrials.gov/study/NCT06121297 (accessed May 2026) 4. C&EN Oncology. 2018. Available at: https://cen.acs.org/pharmaceuticals/oncology/Controlling-CAR-T-scientists-plan/96/i19 (accessed May 2026).

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

Disease-specific cohorts in the RESET clinical program are designed to evolve directly into registrational studies



RESET™ – **RE**storing **SE**lf-**T**olerance; Ab – Antibody; AChR – Acetylcholine receptor; gMG – Generalized myasthenia gravis; JDM – Juvenile dermatomyositis; PRV – Priority review voucher; PV – Pemphigus vulgaris; SLE – Systemic lupus erythematosus; SSc – Systemic sclerosis

1. Myositis patients can also be treated by neurologists or dermatologists; lupus nephritis patients can also be treated by nephrologists.

● FDA Fast Track Designation received in dermatomyositis, SLE and lupus nephritis, systemic sclerosis, generalized myasthenia gravis and multiple sclerosis.

▬ FDA Regenerative Medicine Advanced Therapy (RMAT) received in myositis, SLE, LN and systemic sclerosis.

Systemic Sclerosis Represents a Profound Unmet Need

Affects ~90K patients in the US and ~60K patients in Europe and is associated with high mortality[1–7]

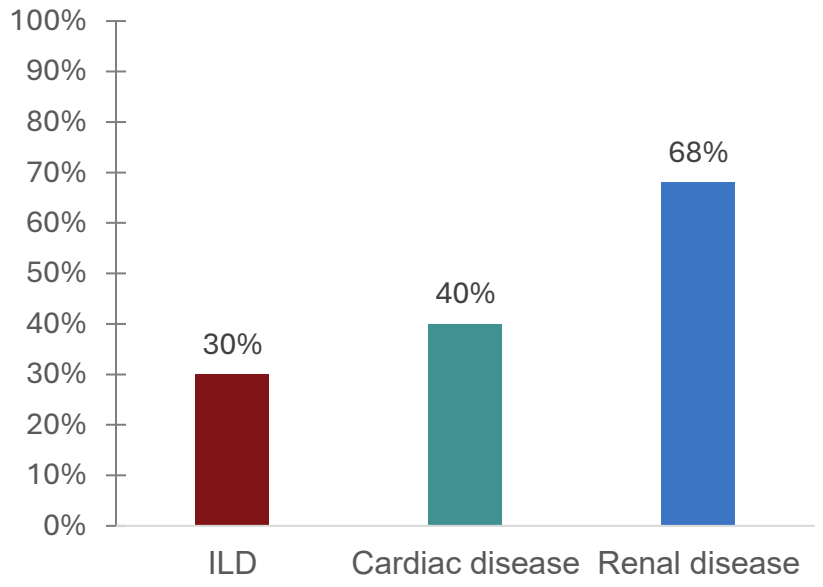
A rare, potentially fatal chronic autoimmune disease[5]

- Characterized by progressive skin and internal organ fibrosis[5]
- Disproportionately impacts women, with less favorable outcomes in people of color[5]
- SSc is associated with the highest mortality of all rheumatological diseases and significant burden from persistent skin and organ manifestations[6,8]

ILD is a major contributor to SSc-associated mortality[2]

- Depending on the diagnostic modality utilized, ILD may be identified in up to 80% of SSc patients[9]
- SSc patients with ILD have ~3 times greater mortality risk than SSc patients without ILD[10]

Cumulative survival rate with severe organ involvement at 9 years[10]

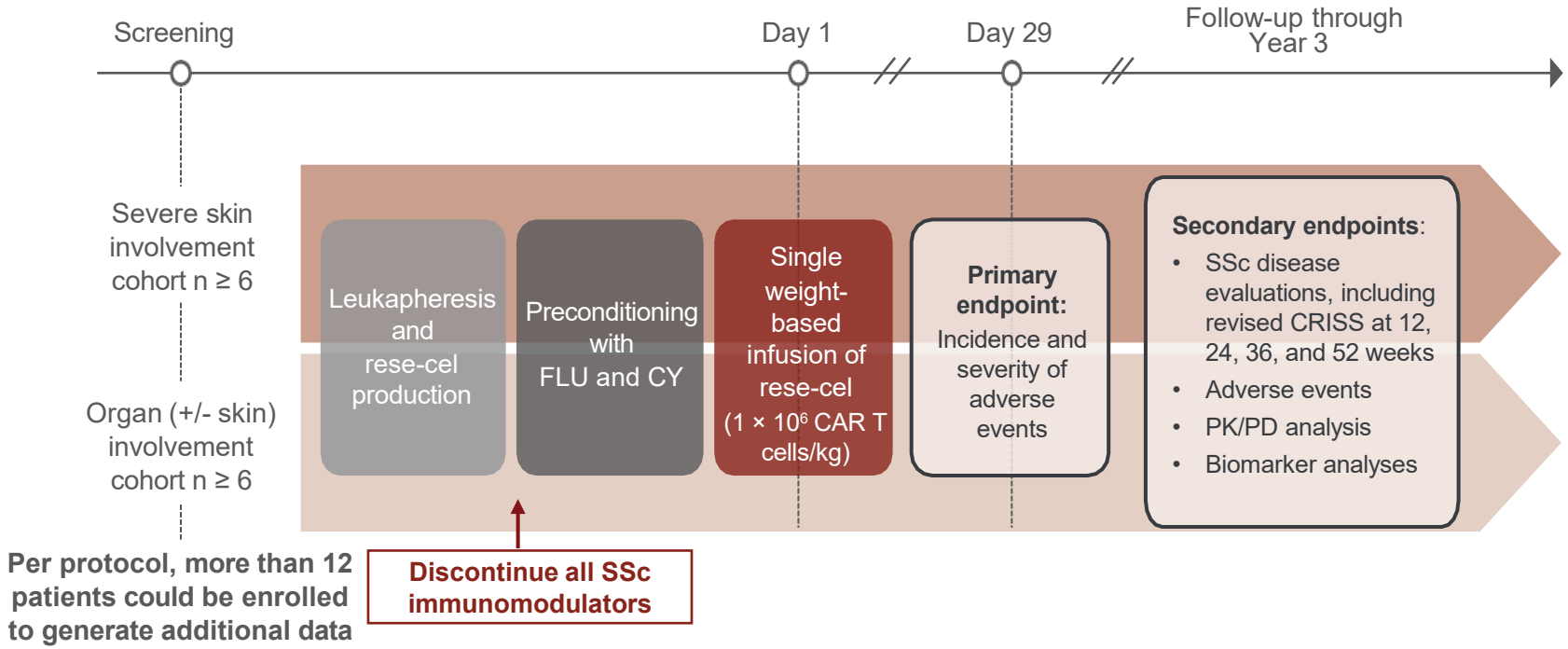


ILD, interstitial lung disease; SSc, systemic sclerosis.

1. Fan Y, et al. *J Manag Care Spec Pharm*. 2020;26(12):1539–1547. 2. Bergamasco A, et al. *Clin Epidemiol*. 2019;11:257–273. 3. Kremer K, et al. *Akt Dermatol*. 2012;38:44–52. 4. ERN ReCONNET Disease: Systemic Sclerosis. Available at: https://reconnet.ern-net.eu/disease-ssc/ (accessed May 2026). 5. Allanore Y, et al. *Nat Rev Dis Primers*. 2015;1:15002. 6. Denton CP, et al. *Lancet*. 2017;390(10103):1685–1699. 7. Truchetet ME, et al. *Clin Rev Allergy Immunol*. 2023;64(3):262–283. 8. Pope JE, et al. *Nat Rev Rheumatol*. 2023;19(4):212–226. 9. Fairley JL, et al Revista Colombiana de Reumatología. 2024;31:15-25. 10. Volkmann ER, Fischer A. *J Scleroderma Relat Disord*. 2021;6(1):11–20.

RESET-SSc™ Phase 1/2 Study Design[1,2]

Enrolling patients with moderate to severe disease that is refractory to standard of care



Key Inclusion Criteria[1,2]

- Age ≥18 and ≤75 with a limited or diffuse SSc diagnosis (2013 EULAR/ACR classification criteria)
- Early, active disease
- Evidence of significant skin, pulmonary, renal, or cardiac involvement

Key Exclusion Criteria[1,2]

- Severe pulmonary or cardiac impairment
- Treatment with B cell-depleting agent within prior ~6 months
- Previous CAR T cell therapy and/or HSCT

ACR, American College of Rheumatology; CAR, chimeric antigen receptor; CRISS, Composite Response Index in Systemic Sclerosis; CY, cyclophosphamide; EULAR, European Alliance of Associations for Rheumatology; FLU, fludarabine; HSCT, hematopoietic stem cell transplant(ation); PK/PD, pharmacokinetic/pharmacodynamic; rese-cel, resecabtagene autoleucel; RESET™, REstoring Self Tolerance; SSc, systemic sclerosis.

1. Cabaletta Bio – Data on File. 2. NCT06328777. Available at: www.clinicaltrials.gov/study/NCT06328777 (accessed May 2026).

Baseline Characteristics: First 15 Patients in RESET-SSc™

All patients had active, refractory disease despite multiple SSc therapies and 12/15 had ILD

Cohort	Severe skin cohort§ (N=6)	Organ cohort§ (N=9)	All (N=15)	ILD (N=12)
Age, years, median (min, max)	57 (42, 66)	43 (19, 70)	54 (19, 70)	54.5 (19, 70)
Female, n (%)	4 (67)	7 (78)	11 (73)	9 (75)
Disease duration,* years, median (min, max)	1.6 (0.5, 2.2)	2.1 (0.4, 5.0)	1.8 (0.4, 5.0)	1.7 (0.4, 5.0)
ILD at screening,† n (%)	4 (67)	8 (89)	**12 (80)**	12 (100)
Cardiac involvement at screening, n (%)	0 (0)	3 (33)	3 (20)	2 (17)
Autoantibodies, %				
Scl-70	17	78	53	58
Anti-RNA pol III	83	11	40	25
Baseline disease activity, median‡				
mRSS	40	19	24	23
HAQ-DI	2.19	1.63	1.88	1.81
FVC (% predicted)	92¶	77	79	78.5
DLCO (% predicted)	75.5¶	66	72	68
PGA	6	5.5**	6**	6**
Therapies at screening, n (%)				
MMF/MPA	5 (83)	7 (78)	12 (80)	11 (92)
Tocilizumab	1 (17)	5 (56)	6 (40)	6 (50)
Prednisone	1 (17)	2 (22)	3 (20)	3 (25)
Methotrexate	1 (17)	1 (11)	2 (13)	2 (17)
HCQ	0 (0)	3 (33)	3 (20)	2 (17)
IVIg	0 (0)	2 (22)	2 (13)	2 (17)
Number of prior SSc therapies, median (min, max)	3 (2, 5)	4 (3, 6)	4 (2, 6)	3 (2, 6)

As of 16 Apr 2026.
*Time of diagnosis to screening. †Per HRCT. ‡Baseline disease activity = activity before preconditioning. §The severe skin cohort includes patients with severe skin involvement and the organ cohort includes patients with significant organ involvement (e.g., pulmonary, renal, or cardiac involvement), irrespective of skin disease severity. ¶Missing data were imputed using last observation carried forward; FVC and DLCO data for 1 patient were imputed using values from screening visit. **Missing baseline data for SSc-Organ-9.
DLCO, % predicted diffusing capacity for carbon monoxide; FVC, forced vital capacity; HAQ-DI, Health Assessment Questionnaire Disability Index; HCQ, hydroxychloroquine; HRCT, high-resolution computed tomography; ILD, interstitial lung disease; IVIg, intravenous immunoglobulin; MMF, mycophenolate mofetil; MPA, mycophenoloic acid; mRSS, modified Rodnan skin score; PGA, Physician Global Assessment; RESET™, REstoring SElf-Tolerance; RNA pol, ribonucleic acid polymerase; Scl-70, anti–topoisomerase I antibody; SSc, systemic sclerosis.
Cabaletta Bio: Data on File.

Incidence of Relevant and Related Serious Adverse Events*

No CRS in 8 of 15 patients and no ICANS in 14 of 15 patients

	All cohorts (N=15)	
	CRS†	ICANS†
None, n (%)	**8 (53)**	**14 (93)**
Any grade, n (%)	**7 (47)**	**1 (7)**
Grade 1	5 (33)	0 (0)
Grade 2	2 (13)	0 (0)
Grade 3	0 (0)	1 (7)‡
Time to onset, median (range), days	9 (3–13)	8 (8–8)
Duration, median (range), days	3 (1–5)	3 (3–3)
Treatments, n (%)		
Tocilizumab	4 (57)	0 (0)
Steroids	0 (0)	1 (100)
Anakinra	0 (0)	0 (0)

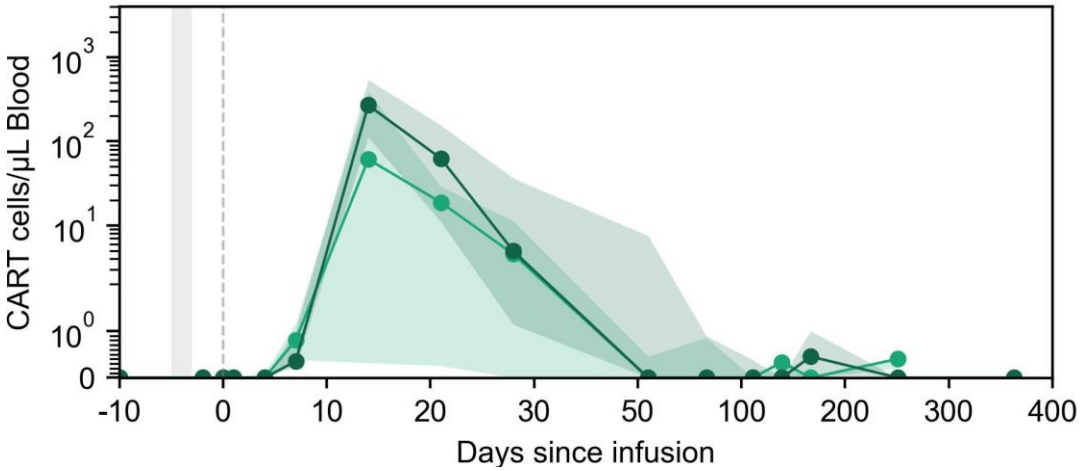
TEAEs of interest	All cohorts (N=15)
Prolonged cytopenias (>28 days)	0 (0)
Hypogammaglobulinemia, n (%)	2 (13)
Serious infections,§ n (%)	0 (0)
Related SAEs,¶ n (%) (excluding CRS/ICANS)	
Encephalopathy, Grade 4 and hypercapnic respiratory failure, Grade 4	1 (7)
Neutropenic fever, Grade 1	1 (7)

As of 16 Apr 2026.
*Primary endpoint is incidence and severity of adverse events through Day 29.
†Graded per ASTCT Consensus Grading Criteria.
‡Grade 3 ICANS was previously presented. Productive cough & fever prior to infusion. Low-grade fever & rigors on Day +8, treated with IV cefepime, vancomycin, and morphine. ICE 3 score on Day +9, progressed to ICE 1 on Day +10: arousable; able to speak and follow commands but answered all questions to the ICE assessment incorrectly; no evidence of seizure, elevated intracranial pressure, or cerebral edema; resolved within 2 days following dexamethasone.
§Coded in System Organ Class of Infections and Infestations and meets seriousness criteria.
¶As assessed per US Food and Drug Administration guidelines.
ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; ICE, immune effector cell-associated encephalopathy; IV, intravenous; SAE, serious adverse event; TEAE, treatment-emergent adverse event.
Cabaletta Bio: Data on File.

Rese-cel Expansion and B Cell Kinetics*

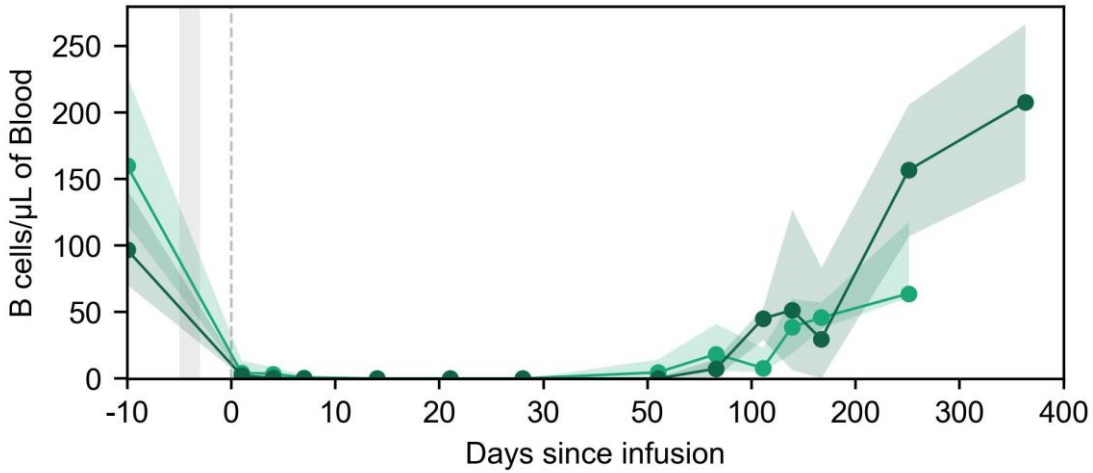
Peak rese-cel expansion and peripheral B cell depletion occurred by 2 weeks post infusion in most patients

Rese-cel Pharmacokinetics



Pharmacodynamics

(B cell counts)



Severe skin cohort (N=6)
Organ cohort (N=9)

Median time to B cell repopulation was approximately 2.5 months†; repopulating B cells were predominantly transitional naïve, indicating deep B cell depletion and B cell reset

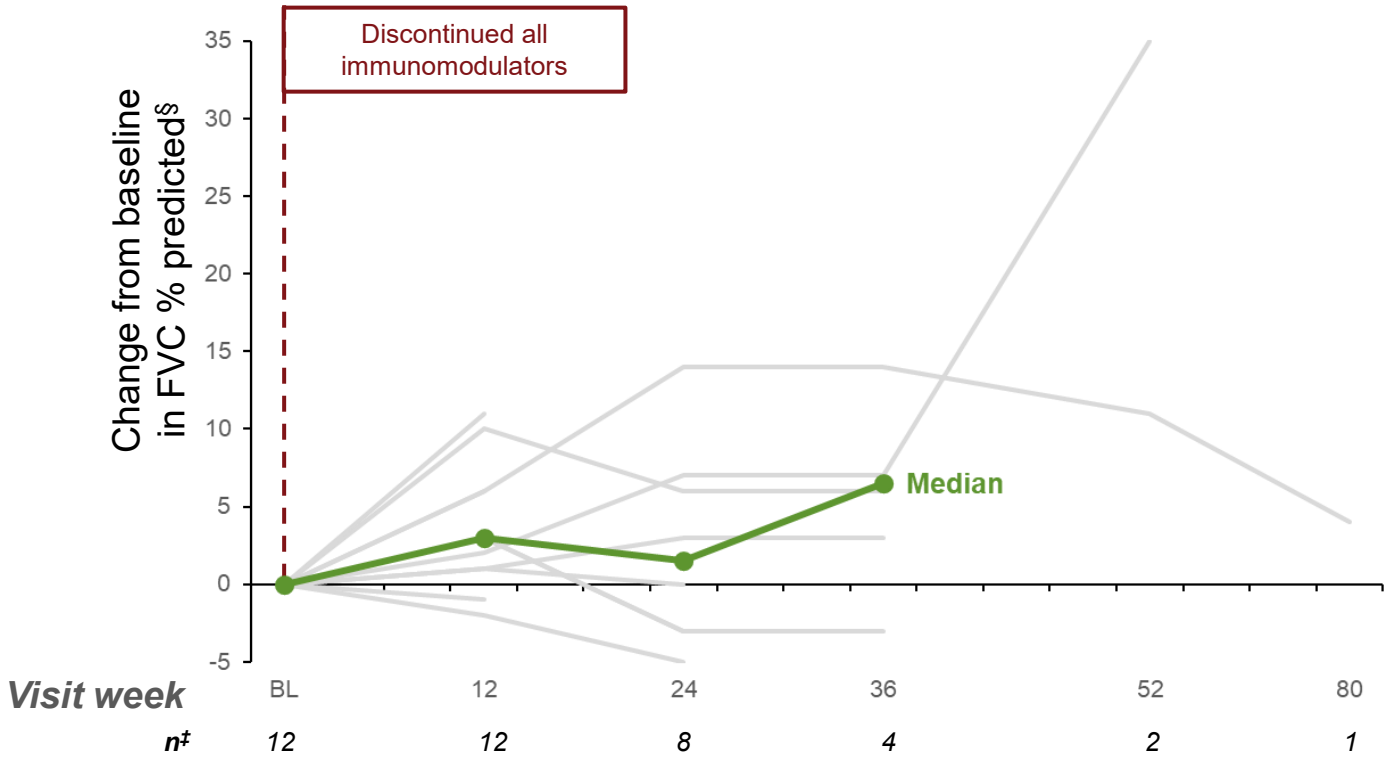
Poster #POS0351;
Sat 06 Jun 2026

All data is as of 16 Apr 2026.
*Data shown as median and IQR.
†Median time includes subjects with depletion and repopulation; one Organ subject did not exhibit peripheral B cell depletion at the time points sampled.
CAR, chimeric antigen receptor; IQR, interquartile range; rese-cel, resecabtagene autoleucel.
Cabaletta Bio: Data on File.

ILD-Specific Clinical Efficacy in SSc Following Rese-cel Infusion

After discontinuing immunomodulators, FVC improvement or stabilization was observed in most patients with ILD*

FVC % predicted (Patients with ILD*; N=12)†



While off immunomodulators, patients with ILD achieved highly meaningful improvement in % predicted FVC rarely observed with current standard and approved therapies[1]

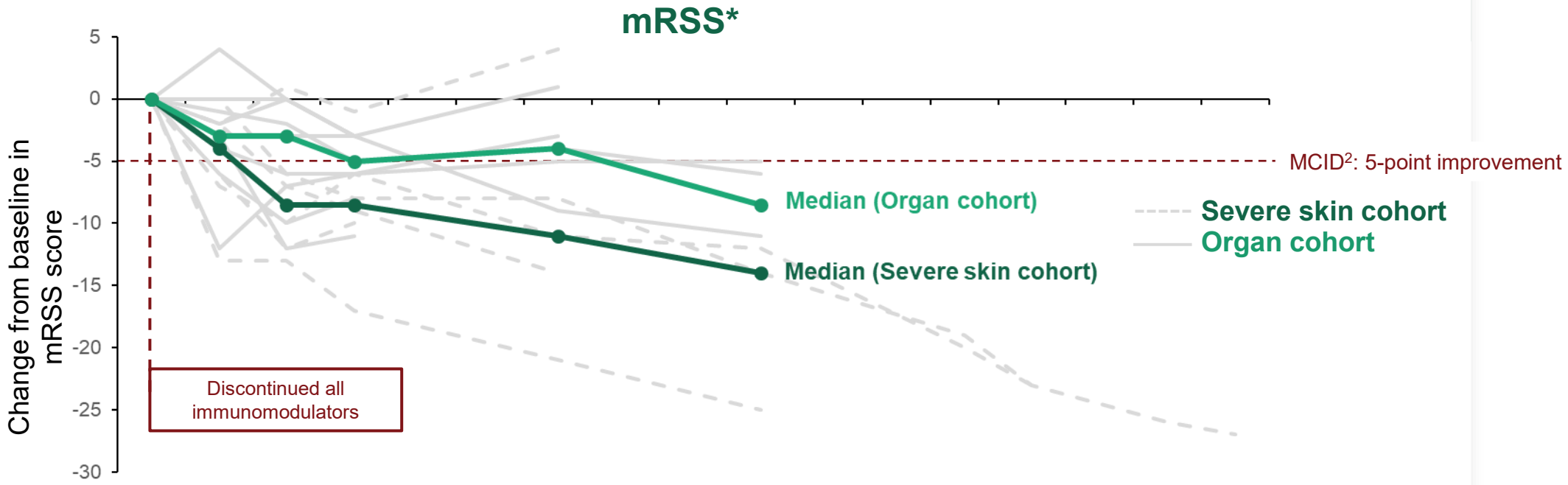
As of 16 Apr 2026.

1. Del Galdo F, et al. Ann Rheum Dis. 2025;84(1):29–40

*Based on HRCT at screening. †Missing data were imputed using last observation carried forward. ‡Median and n numbers are based on SSc patients not receiving rescue immunomodulatory medications. §Absolute change.
BL, baseline; FVC, forced vital capacity; HRCT, high-resolution computed tomography; ILD, interstitial lung disease; rese-cel, resecabtagene autoleucel; SSc, systemic sclerosis.
Cabaletta Bio: Data on File.

Skin-Specific Clinical Efficacy in SSc Following Rese-cel Infusion[1]

After discontinuing immunomodulators, one dose of rese-cel led to improvement from baseline in mRSS score was observed



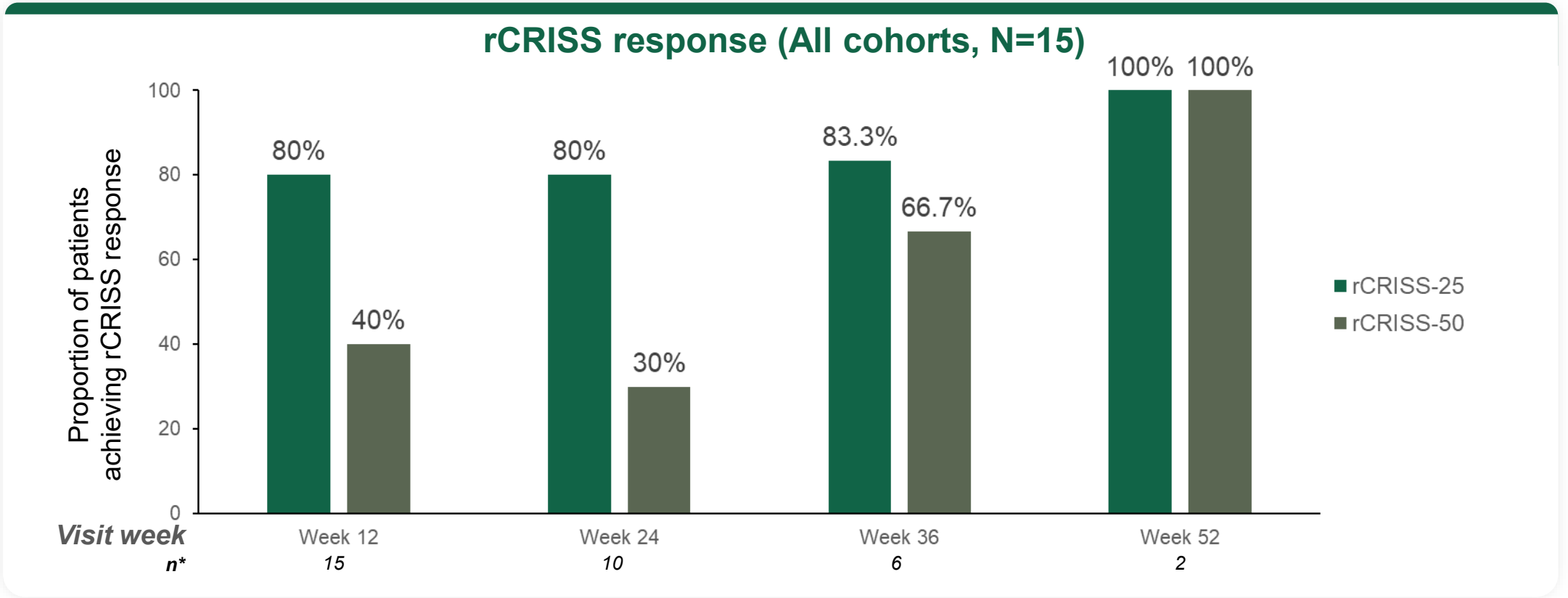
Visit week	BL	4	8	12	24	36	48	52	68	80
Severe skin cohort (N=6), n†	6	6	6	6	5	3	2	2	1	1
Organ cohort (N=9), n†	9	9	9	9	5	2				

While off all immunomodulators, patients achieved mRSS median improvements of 11 and 14 at Weeks 24 and 36 in the severe skin cohort and 4 and 8.5 in the organ cohort, respectively

As of 16 Apr 2026.
*Measure of skin thickness in SSc across 17 body areas, with a maximum score of 51.[2] Missing data were imputed using last observation carried forward. †Median and n numbers are based on SSc patients not receiving rescue immunomodulatory medications.
BL, baseline; MCID, minimal clinically important difference; mRSS, modified Rodnan skin score; rese-cel, resecabtagene autoleucel; SSc, systemic sclerosis.
1. Cabaletta Bio: Data on File. 2. Khanna D, et al. *J Scleroderma Relat Disord*. 2017;2(1):11–18.

rCRISS Outcomes in SSc Following Rese-cel Infusion

≥80% of all SSc patients achieved rCRISS-25 responses as early as Week 12 while off immunomodulators



After one dose of rese-cel, while off immunomodulators, both patients with Week 52 follow up achieved rCRISS-50

As of 16 Apr 2026.
*n numbers are based on evaluable SSc patients.
rCRISS, revised Composite Response Index in Systemic Sclerosis; rese-cel, resecabtagene autoleucel; SSc, systemic sclerosis.
Cabaletta Bio: Data on File.

Key Takeaways: RESET-SSc

- Rese-cel was generally well tolerated in the 15 SSc patients treated to date
  - No CRS in 8 of 15 patients, Grade 1 CRS in 5 patients, and Grade 2 CRS in 2 patients
  - No ICANS in 14 of 15 patients, Grade 3 ICANS in 1 patient (previously reported)
- Rese-cel peak expansion was observed by 2 weeks after infusion
- Deep B cell depletion observed within 2 weeks with a median time to repopulation of ~2.5 months
- After discontinuing all immunomodulators and one dose of rese-cel:
  - Highly meaningful improvement in % predicted FVC rarely observed with current and standard or approved therapies
  - mRSS median improvements of 11 and 14 were observed at Weeks 24 and 36 in the severe skin cohort and 4 and 8.5 in the organ cohort, respectively
  - ≥80% of patients achieved rCRISS-25 responses as early as Week 12 and both patients with Week 52 follow-up achieved rCRISS-50

These complete Phase 1/2 cohort data and multiple FDA discussions provide a strong foundation to advance a single-arm registrational study of ~25 patients with SSc-associated ILD using an FVC-based primary endpoint at 52 weeks with initiation anticipated in 4Q26

As of 16 Apr 2026.
CRS, cytokine release syndrome; FVC, forced vital capacity; FDA, US Food and Drug Administration; ICANS, immune effector cell-associated neurotoxicity syndrome; ILD, interstitial lung disease; mRSS, modified Rodnan skin score; rCRISS, revised Composite Response Index in Systemic Sclerosis; rese-cel, resecabtagene autoleucel; SSc, systemic sclerosis.
Cabaletta Bio: Data on File.

Demographics & CRS/ICANS in first 63 rese-cel patients by indication

Across 4 RESET™ studies, 94% of patients have either no CRS or Grade 1 (fever) and 97% have no ICANS[1]

Baseline characteristics of autoimmune disease patients treated with rese-cel				
	RESET-Myositis	RESET-SLE	RESET-SSc	RESET-MG
Number of patients	17	18	15	13
Age, years, mean (SD)	57.0 (15.1)	29.9 (7.4)	50.4 (14.6)	53.7 (10.0)
Sex, % female	52.9	88.9	73.3	69.2
Duration of disease, years, mean (SD)	4.9 (3.7)	10.2 (5.0)	1.9 (1.2)	7 (6.8)

Incidence, severity and onset of CRS and ICANS in the 1st 28 days in patients treated with rese-cel					
	RESET-Myositis	RESET-SLE	RESET-SSc	RESET-MG	Total
CRS‡, n (%)	5 (29.4)	6 (33.3)	7 (46.7)	2 (15.4)	20 (31.7% CRS)
CRS Grade 1, n (%)	5 (29.4)	5 (27.7)	5 (33.3)	1 (7.7)	16 (25.4% G1 CRS)
CRS Grade 2, n (%)	–	1 (5.6)	2 (13.3)	1 (7.7)	4 (6.3% G2 CRS)
Time to CRS onset, days* (mean)	7.4	6.7	9.0	5.5	7.6 days
CRS duration†, days (mean)	4.6	3.0	2.9	5.0	3.6 days
ICANS‡ n (%) (Grade)	–	1 (5.6) (G4)	1 (6.7) (G3)	-	2 (3.2% ICANS)
Time to ICANS onset, days (mean)	–	9.0	8.0	-	8.5 days
ICANS duration, days (mean)	–	3.0	3.0	-	3.0 days

*Days relative to rese-cel infusion.
†Events occurring within 7 days of each other are considered as 1 episode. IMNM-3 CRS duration includes preceding event of fever which was consistent with CRS definition.
‡Graded per ASTCT Consensus Grading Criteria.
1. Presented at EULAR 2026 with data cut-off as of 16 Apr 2026 (Myositis, SLE and SSc), Presented at AAN 2026 with data cut-off as of 6 Mar 2026 (MG).

Key Takeaways

- Rese-cel was designed for patients with autoimmune diseases with a fully human CD19 binder and 4-1BB costimulatory domain that utilizes a proven and dependable manufacturing process and a weight-based dosing regimen

- The complete Phase 1/2 SSc data demonstrating highly meaningful immunomodulatory-free responses provide a strong foundation to advance a single-arm registrational study of ~25 patients with initiation anticipated in 4Q26

- Safety profile across the 4 RESET autoimmune programs with over 60 patients treated with rese-cel indicates low rates of CRS and ICANS, including no high-grade CRS, which offers the potential for outpatient administration

CD, cluster of differentiation; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; rese-cel, resecabtagene autoleucel; RESETTM, REstoring SElf-Tolerance; SSc, systemic sclerosis

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Learnings from Hematology and the Early Autoimmune Experience: CAR T Primer and Pearls for Implementing CAR T in Clinical Practice

Olalekan O. Oluwole

CD19-CAR T Therapy: From Oncology to Autoimmune Diseases

Efficacy

COMPLETE remission rate:
40%–67%[1–5]

LONG-TERM remission rate:
30%–58%[6–7]

Safety profile in oncology[8–10]

- CRS and ICANS
- Prolonged B cell aplasia
- Infections
- Insertional oncogenesis
- Secondary malignancies

Oncology-derived risk factors may not be generalizable to autoimmune diseases[11–15]

Target-cell burden →	CRS, ICANS
CAR T persistence →	Prolonged B cell aplasia
Prolonged aplasia →	Infection risk
Mutational load →	Malignancy/relapse

Manufacturing failure risk

Poor T cell fitness and/or low T cell counts from prior chemotherapy not a key concern in autoimmune diseases[16]

AE risk may be reduced in autoimmune patients[17]

nature biotechnology

Anti-CD19 CAR T cell therapy in autoimmune diseases appears to have a more favorable safety profile than in oncology

AE, adverse event; CAR, chimeric antigen receptor; CD, cluster of differentiation; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome.

1. Maude SL, et al. *N Engl J Med*. 2018;378(5):439–448. 2. Schuster SJ, et al. *N Engl J Med*. 2019;380(1):45–56. 3. Locke FL, et al. *Lancet Oncol*. 2019;20(1):31–42. 4. Abramson JS, et al. *Lancet*. 2020;396(10254):839–852. 5. Wang M, et al. *N Engl J Med*. 2020;382(14):1331–1342. 6. Schuster SJ, et al. *Lancet Oncol*. 2021;22(10):1403–1415. 7. Neelapu SS, et al. *Blood*. 2023;141(19):2307–2315. 8. Breyanzi. Prescribing information; 2025. Available at: www.fda.gov/media/145711/download (accessed May 2026). 9. Yescarta. Prescribing information; 2024. Available at: www.fda.gov/media/108377/download (accessed May 2026). 10. Kymriah. Prescribing information; 2025. Available at: www.fda.gov/media/107296/download (accessed May 2026). 11. Baker DJ, et al. *Nature*. 2023;619(7971):707–715. 12. Baker DJ, June CH. *Cell*. 2022;185(24):4471–4473. 13. Li YR, et al. *Trends Pharmacol Sci*. 2024;45(9):839–857. 14. Schett G, et al. *Nat Rev Rheumatol*. 2024;20(9):531–544. 8. Blache U, et al. *RMD Open*. 2023;9(4):e002907. 15. Blache U, et al. *RMD Open*. 2023;9(4):e002907. 16. Sharma, et al. Consistency in resecabtagene autoleucel product quality across RESET phase 1/2 clinical trials and manufacturing platforms American Society of Gene & Cell Therapy (ASGCT) 2026 Annual Meeting Oral presentation. 17. Solimani F, et al. *Nature Biotechnology*. 2026;44:547–562.

Limitations of CAR T Cell Therapy in Oncology: My Experience

Challenges in oncology

Time-intensive and complex process

- Lymphodepletion step adds time and cost to process, and carries own adverse event risks[1,2]
- CAR T safety profile risks require close monitoring for several weeks[3]

Barriers to access

- Travel to an academic center and often inpatient stays[3]
- Limited pediatric cancer CAR T data[4,5]

CAR, chimeric antigen receptor.

1. Pavlic J, et al. *Blood*. 2024;144(1):7254. 2. Canelo-Vilaseca M, et al. *Bone Marrow Transplant*. 2025;60(5):559–567. 3. Sureda A, et al. *Future Oncol*. 2024;20(36):2855–2868. 4. Oluwole OO, et al. *Transplant Cell Ther*. 2024;30:131–142. 5. Majzner RG & Mackall CL. *Cancer Discov*. 2018;8(10):1219–1226.

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Limitations of CAR T Cell Therapy in Oncology: My Experience

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Barriers to access

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- Limited pediatric cancer CAR T data[4,5]

Opportunities in autoimmune diseases

1. Is lymphodepletion needed in autoimmune diseases?
2. What CAR T monitoring and management strategies can be applied in autoimmune diseases?
3. Is outpatient CAR T feasible in autoimmune diseases?
4. Should pediatric autoimmune disease patients be included in studies?

CAR, chimeric antigen receptor.

1. Pavlic J, et al. *Blood*. 2024;144(1):7254. 2. Canelo-Vilaseca M, et al. *Bone Marrow Transplant*. 2025;60(5):559–567. 3. Sureda A, et al. *Future Oncol*. 2024;20(36):2855–2868. 4. Oluwole OO, et al. *Transplant Cell Ther*. 2024;30:131–142. 5. Majzner RG & Mackall CL. *Cancer Discov*. 2018;8(10):1219–1226.

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Exploring the Efficacy of Autologous CAR T Without Lymphodepletion

JCI The Journal of Clinical Investigation

Autologous BCMA-CAR T cells with and without lymphodepletion in refractory MM[1]

Similar expansion, clinical responses, and rates of CAR T-associated CRS and neurotoxicity in both groups

Potential in autoimmune disease[2,3]

- Persistence of CAR T cells in autoimmunity appears minimal and may not be required to achieve durable responses
- Hesitancy to expose patients to the toxicity of FLU and CY–especially in younger women who desire future childbearing

BCMA, B cell maturation antigen; CAR, chimeric antigen receptor; CRS, cytokine release syndrome; CY, cyclophosphamide; FLU, fludarabine; MM, multiple myeloma.

1. Cohen AD, et al. *J Clin Invest*. 2019;129(6):2210–2221. 2. Oluwole OO, et al. *Transplant Cell Ther*. 2026 [journal pre-proof] doi: 10.1016/j.jtct.2026.04.045.3. Nunez D, et al. *Blood*. 2026 [online ahead of print PMID 42201777]

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Monitoring Lessons from Oncology

AE grading and scoring systems have been developed, but predictive tools require further validation[1–3]

CRS			Grade	ICANS				
Fever with	Hypotension and/or	Hypoxia		ICE score	Depressed level of consciousness	Seizure	Motor findings	Elevated ICP/ cerebral edema
Temperature ≥38°C	None	None	1	7–9	Awakens spontaneously	N/A	N/A	N/A
Temperature ≥38°C	Not requiring vasopressors	Requiring low-flow nasal cannula or blow-by	2	3–6	Awakens to voice	N/A	N/A	N/A
Temperature ≥38°C	Requiring a vasopressor with or without vasopressin	Requiring high-flow nasal cannula, facemask, non-rebreather mask, or Venturi mask	3	0–2	Awakens only to tactile stimulus	Any clinical seizure focal or generalized that resolves rapidly or nonconvulsive seizures on EEG that resolve with intervention	N/A	Focal/local edema on neuroimaging
Temperature ≥38°C	Requiring multiple vasopressors (excluding vasopressin)	Requiring positive pressure (eg, CPAP, BiPAP, intubation and mechanical ventilation)	4	0 (Patient is unarousable and unable to perform ICE)	Patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse. Stupor or coma	Life-threatening prolonged seizure (>5 min); or Repetitive clinical or electrical seizures without return to baseline in between	Deep focal motor weakness such as hemiparesis or paraparesis	Diffuse cerebral edema on neuroimaging; decerebrate or decorticate posturing; or cranial nerve VI palsy; or papilledema; or Cushing's triad

- CRS and ICANS grading are widely used in autoimmune disease trials; rates appear to be lower than observed in oncology[4]
- Predictive models such as CAR-HEMATOTOX[5] need further evaluation and validation to be used in autoimmune disease

AE, adverse event; BiPAP, bilevel positive airway pressure; CAR, chimeric antigen receptor; CPAP, continuous positive airway pressure; CRS, cytokine release syndrome; EEG, electroencephalogram; ICANS, immune effector cell-associated neurotoxicity syndrome; ICE, immune effector cell-associated encephalopathy; ICP, intracranial pressure.

1. Lee DW, et al. *Biol Blood Marrow Transplant*. 2019;25(4):625-638. 2. Oluwole OO, et al. *Transplant Cell Ther*. 2024;30(2):131-142. 3. Dahunsi D, et al *Clin Hematol Int*. 2025;7(1):47-54. 4. Solimani F, et al. *Nature Biotechnology*. 2026;44:547–562. 5.Rejeski K, et al. *Blood*. 2021;138(24):2499–2513.

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CRS and ICANS Management: Lessons from Axi-cel (CD19-CAR T) ZUMA-1 Study

Refinement of AE management lowered rates of high-grade CRS and ICANS between cohorts in ZUMA-1 in R/R LBCL[1–4]

Reactive management: corticosteroids/tocilizumab at **≥Grade 2** CRS or Neurologic Event

- **Prophylactic** levetiracetam[2]
- **Earlier** corticosteroid and tocilizumab intervention[3]

+ Prophylactic dexamethasone[3,4]

Not used universally across CAR T products in oncology[5,6]

	Cohorts 1+2[1-3]	Cohort 4[2]	Cohort 6[3,4]
Patients treated	101	41	40
Any Grade CRS, n (%)	94 (93%)	38 (93%)	32 (80%)
Median CRS onset	2 days	2 days	5 days
Median CRS duration	8 days	6.5 days	4 days
Grade ≥3 CRS, n (%)	**13 (13%)**	**1 (2%)**	**0 (0%)**
Any grade Neurologic event, n (%)	65 (64%)	25 (61%)	23 (58%)
Grade ≥3 Neurologic event, n (%)	**28 (28%)**	**7 (17%)**	**5 (13%)**

Fewer grade ≥3 CRS/NE in cohorts 4 and 6 vs. 1+2

AE, adverse event; axi-cel, axicabtagene ciloleucel (YESCARTA®); CAR, chimeric antigen receptor; CD, cluster of differentiation; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; NE, neurologic events; R/R LBCL, relapsed/refractory large B cell lymphoma.

1. Neelapu et al. *New Eng J Med*. 2017;377(26):2531-2544. 2. Topp MS, et al. *J Haematol.* 2021;195(3):388-398. 3. Oluwole OO, et al. *Br J Haematol.* 2021;194:690–700. 4. Oluwole OO, et al. *Bone Marrow Transplant*. 2024;59(3): 366–372. 5. Linhares Y, et al. *Blood Adv.* 2024;8(23):6114–6126. Erratum in: *Blood Adv.* 2025;9(19):5009. 6. Darwish C, et al. *Blood* 2025;146 (SUPPL. 1): 4539.

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Outpatient Oncology CAR T Programs Have Removed Barriers To Access

- Comparable safety, efficacy, and quality of life to inpatient administration[1,2]
- Patients may have shorter hospital stay if CAR T is administered on an outpatient basis[1,2]
- More favorable reimbursement model for hospital systems with outpatient administration[1,2]
- Improve accessibility for patients who live far from specialist centers[1–3]

CAR, chimeric antigen receptor.

1. Hansen DK, et al. *Cancers*. 2023;15:5746. 2. Linhares, et al. *Blood Adv* 2024;8(23):6114–6126. 3. Porter DL. *OncLive*. 2024. Available at: www.onclive.com/view/dr-porter-on-community-based-car-t-cell-therapy-administration-for-r-r-cll (accessed May 2026)

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Vanderbilt University Real-World Experience of Outpatient CAR T

Fully outpatient administration of cilta-cel BCMA-CAR T for the treatment of relapsed and refractory multiple myeloma

Requirements for outpatient program:

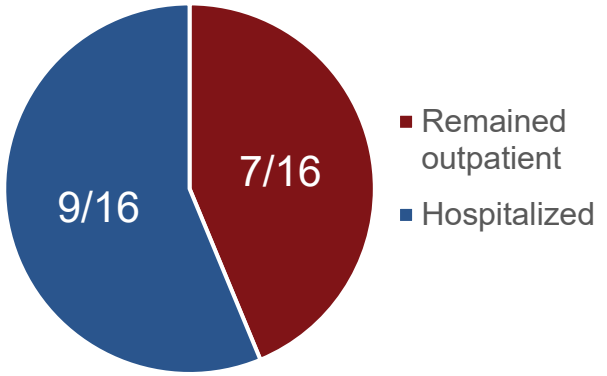
- Reliable caregivers
- Lodging within 30 miles from center

Monitoring during the first 14 days post CAR T infusion:

- Daily in-person clinic visits
- Twice-daily telehealth visits
- Patients and caregivers received education on sign/symptom monitoring and were provided with equipment to conduct telehealth visits and take vital signs

Retrospective analysis of 16 sequential outpatients

- Median time to hospitalization: 4 days from CAR T infusion
- Mean hospital stay duration: 3 days



- CRS incidence: 10/16 (62.5%) treated with anti-pyrectics, tocilizumab, and/or GC. No Grade 3 or higher CRS occurred
- ICANS incidence: 3/16 (18.8%) treated with GC. One Grade 3 or higher ICANS occurred

BCMA, B cell maturation antigen; CAR, chimeric antigen receptor; cilta-cel, ciltacabtagene autoleucel (CARVYKTI®); CRS, cytokine release syndrome; GC, glucocorticoids; ICANS, immune effector cell-associated neurotoxicity syndrome.

1. Wanca M, et al. *Transplant Cell Ther*. 2026;32(2) (SUPPL.):S432–S433.

CAR T Progress in Pediatrics

Pediatric Hematologic Malignancies[1]

- The development of CAR T cell therapies in pediatrics is lacking: one FDA approval for pediatric use compared to seven for adults[2]
- Complex trial designs, administrative issues, and parental views about pediatric experimental treatments may all contribute to this lag

Rationale for Pediatric Autoimmune Diseases[3]

- Childhood autoimmune diseases may have faster onset of organ damage
- Children face a lifelong burden of immunomodulator use

Pediatric Autoimmune Case Series[4]

- Academic case series of 8 children (4 lupus, 3 JDM, 1 SSc) with refractory disease
- Grade 1 CRS was reported in 6 patients and Grade 1 ICANS in 1 patient
- With a median follow-up of 16.5 months, all patients experienced substantial clinical improvements

Cabaletta Bio is pursuing a concurrent JDM indication alongside adult DM in the RESET-Myositis trial[5]

CAR, chimeric antigen receptor; CRS, cytokine release syndrome; DM, dermatomyositis; FDA, U.S. Food and Drug Administration; ICANS, immune effector cell-associated neurotoxicity syndrome; JDM, juvenile dermatomyositis; SSc, systemic sclerosis; RESET™, REstoring SElf-Tolerance.

1. Martínez-Gamboa DA, et al. *Crit Rev Onc*. 2025;209:1-10. 2. National Cancer Institute: CAR T Cells: Engineering Patients' Immune Cells to Treat Their Cancers. Available at www.cancer.gov/about-cancer/treatment/research/car-t-cells (accessed May 2026).
3. Oluwole OO, et al. *Transplant Cell Ther*. 2026 [journal pre-proof] doi: 10.1016/j.jtct.2026.04.045. 4. Becilli M, et al. *Nat Med* 2026;32:1105–1117. 5. NCT06154252. Available at: www.clinicaltrials.gov/study/NCT06154252 (accessed May 2026).

Collaboration within Multidisciplinary Teams is Essential

Sharing knowledge and seeking guidance from peers can help with overcoming logistical and operational challenges in outpatient CAR T administration

CAR, chimeric antigen receptor.

Pantin J. Outpatient CAR-T – Considerations for Practice Implementation. In: TANDEM Meetings; ASTCT and CIBMTR; February 2025; Honolulu, Hawaii.

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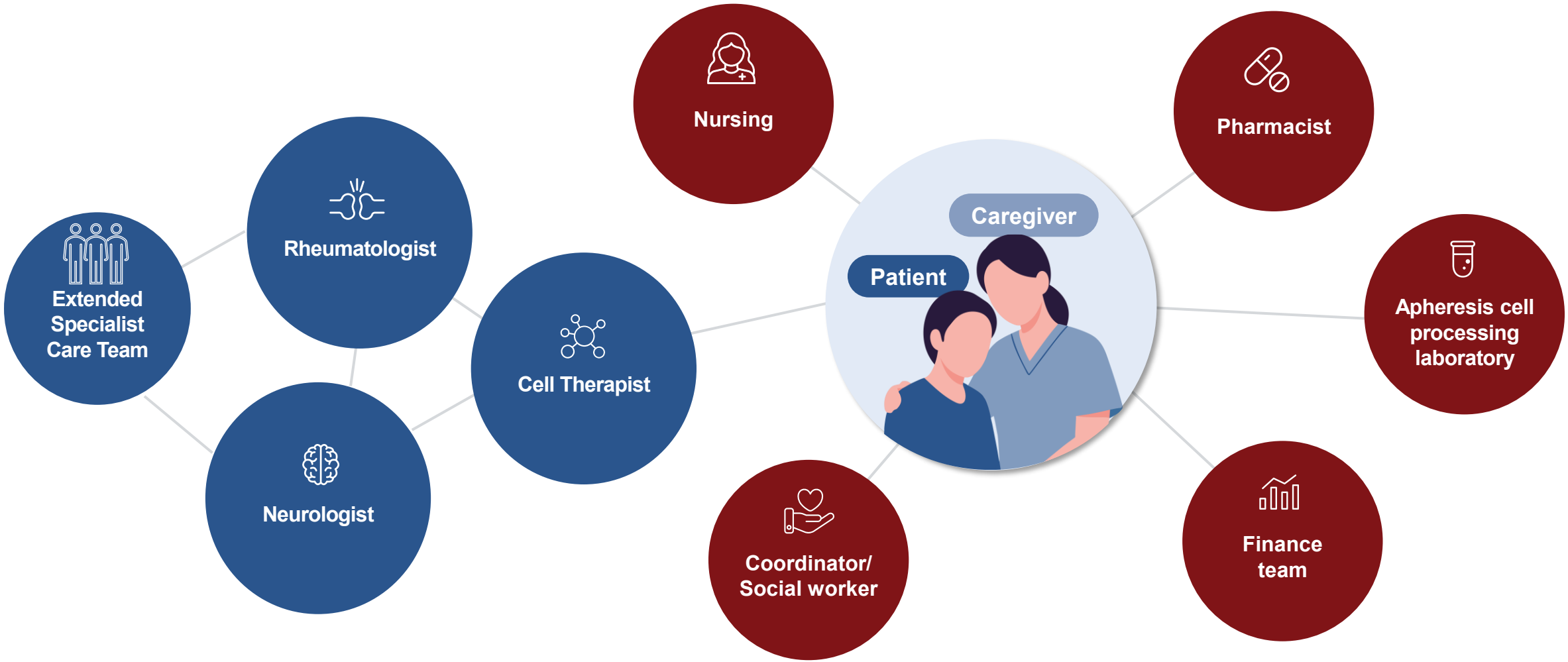

CAR, chimeric antigen receptor.

Pantin J. Outpatient CAR-T – Considerations for Practice Implementation. In: TANDEM Meetings; ASTCT and CIBMTR; February 2025; Honolulu, Hawaii.

Key Takeaways

- Compared to oncology patients, autoimmune disease patients have
  - Reduced adverse events such as:
    - CRS/ICANS due to lower target burden
    - Infections since lower risk for prolonged cytopenias and hypogammaglobulinemia
    - Lower likelihood of secondary malignancies (not seen to date in autoimmunity)
  - Lower rates of manufacturing failures (due to prior chemotherapy in oncology patients)

- Familiarity with managing AEs has decreased frequency of CRS and enabled potential outpatient CAR T administration in oncology
- There is an unmet need to explore CAR T in pediatrics
- Strong partnerships between cell therapists and autoimmune disease specialists are needed to share best practice learnings and education

AE, adverse event; CAR, chimeric antigen receptor; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome.

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Myositis Unmet Needs and CAR T in Myositis: Current Evidence & Future Directions

Rohit Aggarwal

Myositis: A Disease of Significant Unmet Need

Affects ~80K patients in the US and ~85K patients in Europe; high mortality and limited treatment options[1–10]

High disease burden: disability & mortality

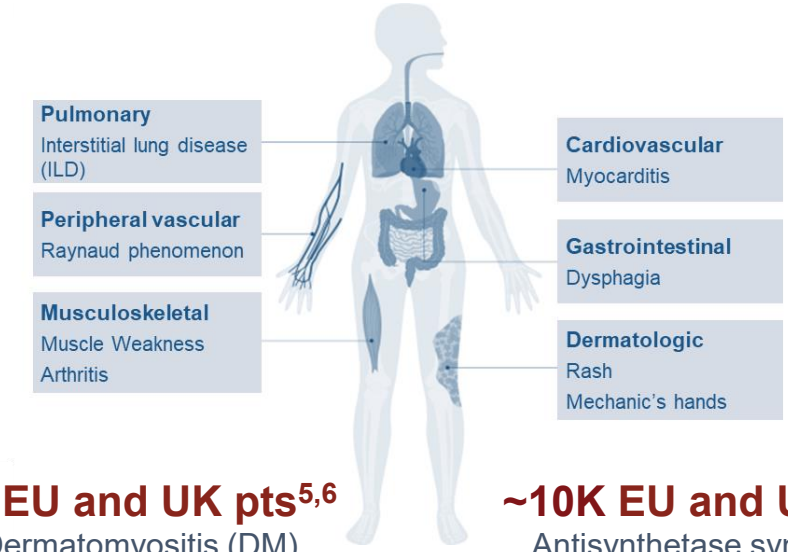
- Moderate to severe disability (40%–65%)[2]
- Assisted walking devices (18%–38%)[2]
- The **risk of mortality is ~3 times higher** than the general population, primarily due to cancer and lung & cardiac complications[3]
  - ~20% mortality <5 years with standard immunosuppressive treatment[4]

High unmet medical need

- Mainstay of therapy is glucocorticoids with immunomodulators[1]
  - Only FDA-approved therapy is IVIg in adult dermatomyositis[1]

Potential manifestations & subtype prevalence in Europe

Key myositis subtypes based on underlying immune mechanisms & clinical characteristics[1]



~59K EU and UK pts[5,6]
Dermatomyositis (DM)

~10K EU and UK pts[5,7,8,11]
Antisynthetase syndrome (ASyS)

~16K EU and UK pts[5]
Immune-mediated necrotizing myopathy (IMNM)

FDA, U.S. Food and Drug Adminisration; IVIg, intravenous immunoglobulin

1. Lundberg IE, et al. *Nat Rev Dis Primers.* 2021;7(1):86. 2. Opinc AH, et al. *Rheumatol Int.* 2019;39(7):1213–1220. 3. Marie I. *Curr Rheumatol Rep.* 2012;14(3):275-285. 4. Schiopu E, et al *Arthritis Res Ther.* 2012;14(1):R22. 5. Khoo T, et al. *Nat Rev Rheumatol.* 2023;19(11):695–712. 6. Kronzer VL, et al. *Arthritis Care Res (Hoboken).* 2023;75(2):348–355. 7. Coffey C, et al. *Arthritis Rheumatol.* 2021;73 (Suppl. 9): Abstr. No. 1022. 8. Dahal K, et al. *Ann Med Surg (Lond).* 2022;82:104571. 9. Papadopoulou C, et al. *Nat Rev Rheumatol.* 2023;19(6):343–362. 10. Shelly S, et al. *Muscle Nerve.* 2022;65(5):541–546. 11. Orphanet: Antisynthetase syndrome. Available at: www.orpha.net/en/disease/detail/81 (accessed May 2026).

Chronic Corticosteroid Use Carries Significant Risk of Adverse Events[1,2]

Novel therapeutic strategies are needed to optimize disease control and reduce GC burden

Long-term steroid use is associated with significantly higher risk of complications and organ damage[1]

Incidence of medical conditions associated with steroid use in myositis*[1]

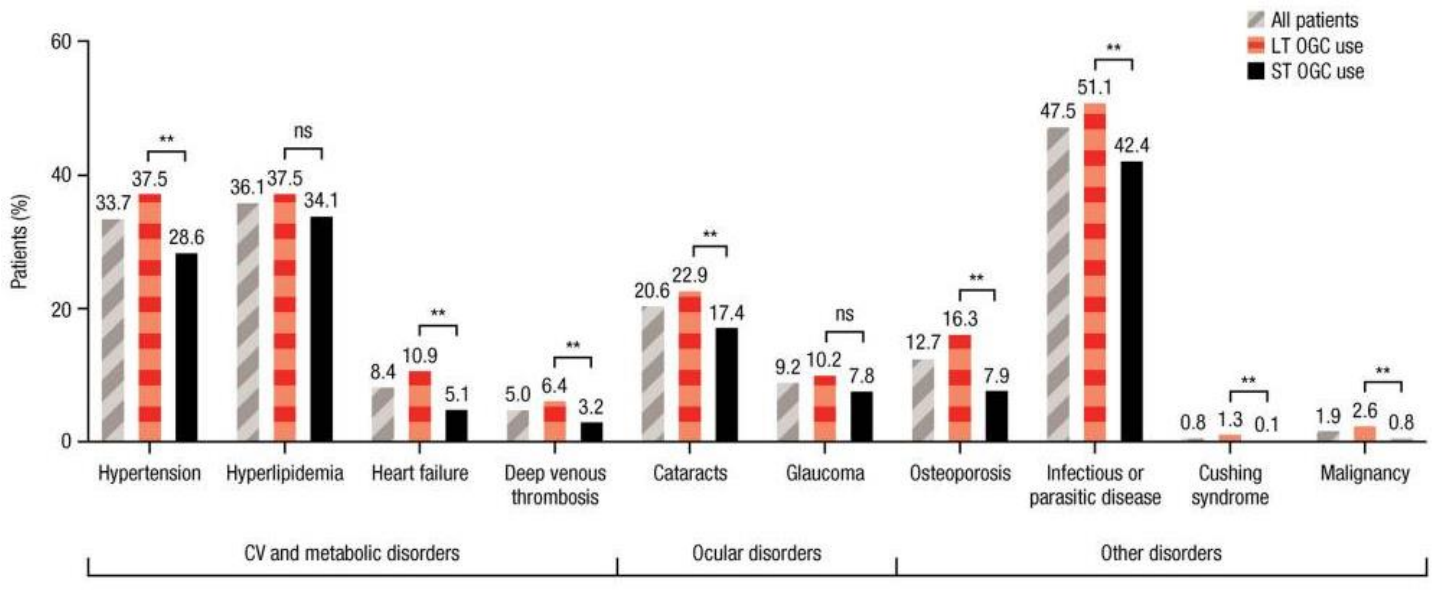


Figure adapted from Aggarwal 2025

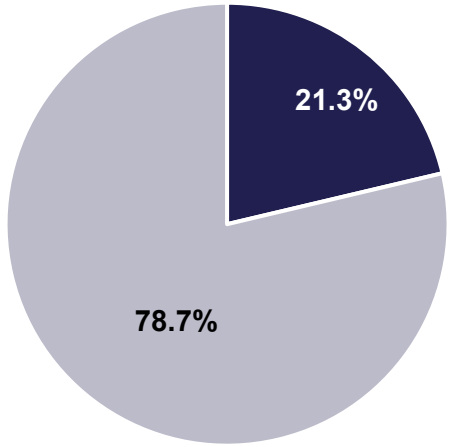
Long-term immunosuppression puts patients at risk of infection. Infections are a leading cause of death in patients with myositis[2]

*Myositis population limited to dermatomyositis and polymyositis.
CV, cardiovascular; LT, long-term; (O)GC, (oral) glucocorticoid; ST, short-term.
1. Aggarwal R, et al. *Clin Rheumatol*. 2025;44(10):4169–4178. 2. Murray SG, et al. *Arthritis Care Res (Hoboken)*. 2015;67(5):673–680.

Significant Unmet Need Remains Despite Progress in Recent Clinical Trials

TIS responses occur when novel therapies are added to chronic background therapies including GCs and/or IM

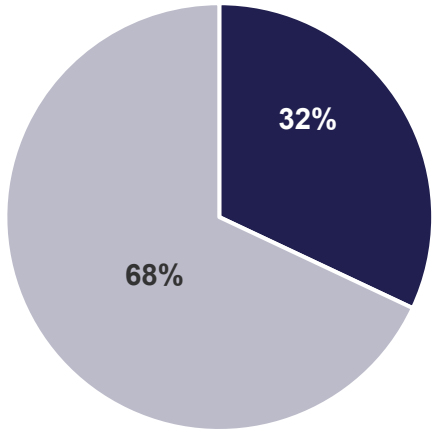
Patients who achieved a TIS response following 24 weeks with efgartigimod ± GC ± IM[1]



- **Minimal or no TIS response**
- **Moderate or major TIS response**

ALKIVIA Phase 2 study,
treatment arm (n=47)

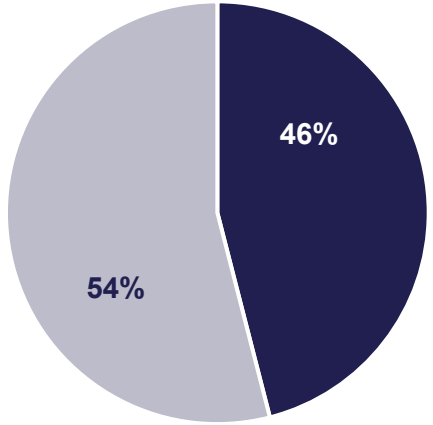
Patients who achieved a TIS response following 1 year with brepocitinib ± GC ± IM[2]



- **Minimal or no TIS response**
- **Moderate or major TIS response**

VALOR Phase 3 study,
brepocitinib 30 mg treatment arm (n=81)

Patients who achieved a TIS response with brepocitinib ± IM and minimal or no systemic GC* at 1 year[2]



- **Minimal or no TIS Response, or GC use**
- **Moderate or major TIS Response, with no/minimal GC**

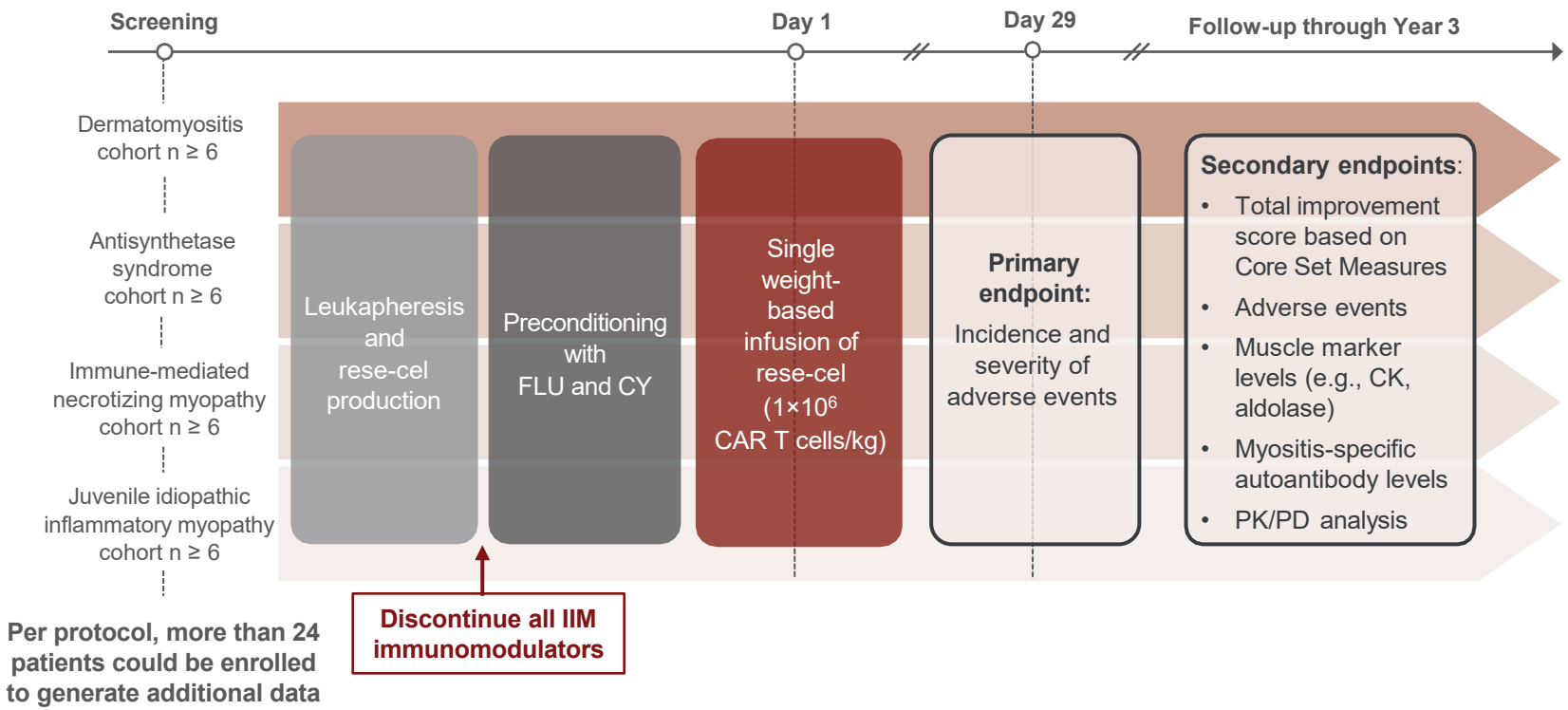
VALOR Phase 3 study,
brepocitinib 30mg treatment arm (n=81)

Clinical trial response rates are summarized for descriptive purposes. No head-to-head trials were conducted, and no comparisons of efficacy are intended or implied

*Defined as a dose of ≤2.5 mg of a prednisone equivalent per day.
GC, glucocorticoid; IM, immunomodulator; TIS, total improvement score.
1. Chinoy H, et al. *Ann Rheum Dis.* 2025;84(suppl. 1): Abstr. No. OP0002. 2. Vleugels RA, et al. *N Engl J Med.* 2026;394(19):1883–1893.

RESET *Myositis*® : Phase 1/2 Study Design[1,2]

Enrolling patients with moderate to severe disease that is refractory to standard of care



Key Inclusion Criteria[1,2]

- A definite or probable clinical diagnosis of IIM (2017 EULAR/ACR classification criteria)
- **For adult IIM cohorts**: Age ≥18 and ≤75 with a diagnosis of **dermatomyositis, antisynthetase syndrome, or immune-mediated necrotizing myopathy** based on presence of serum myositis-specific antibodies (MSA)
- **For JIIM cohort:** Age ≥6 and ≤17 with presence of at least one MSA or myositis-associated antibody (MAA)

Key Exclusion Criteria[1,2]

- Cancer-associated myositis or malignancy within the last 5 years
- Significant lung or cardiac impairment
- Previous CAR T cell therapy and/or HSCT
- Treatment with B cell-depleting agent within prior ~6 months

ACR, American College of Rheumatology; CAR, chimeric antigen receptor; CK, creatine kinase; CY, cyclophosphamide; EULAR, European Alliance of Associations for Rheumatology; FLU, fludarabine; HSCT, hematopoietic stem cell transplant; IIM, idiopathic inflammatory myopathy; JIIM, juvenile idiopathic inflammatory myopathy; MAA, myositis-associated antibody; MSA, myositis-specific antibodies; PK/PD, pharmacokinetic/pharmacodynamic; rese-cel, resecabtagene autoleucel; RESET™, REstoring SElf-Tolerance.

1. Cabaletta Bio – Data on File. 2. NCT06154252. Available at: www.clinicaltrials.gov/study/NCT06154252 (accessed May 2026).

Baseline Characteristics: First 17 Patients in RESET-Myositis

All patients had active, refractory disease despite multiple IM agents, including IVIg and B cell-targeting therapies

	DM N=6	ASyS N=4	IMNM N=6	JIIM N=1
Age, years, median (min, max)	57 (45, 72)	44 (26, 57)	59 (33, 64)	14
Female, n (%)	5 (83)	2 (50)	1 (17)	1 (100)
Disease duration, years, median (min, max)	3.5 (2.0, 10.3)	2.7 (0.9, 14.8)	4.7 (1.4, 8.8)	8.5
Myositis-specific autoantibody	50% TIF1-γ 17%: NXP, SAE, MDA-5	100% Jo-1	67% HMGCR 33% SRP	NXP-2
Baseline disease activity, median*				
MMT-8	123.0	129.5	127.5	134.0
CK	40.0	257.5	2214.5	176.0
CDASI-A	23.5	N/A	N/A	5
Prior RTX† (%)	50%	100%	83%	100%
Prior IVIg† (%)	67%	75%	83%	100%
Therapies at Screening				
Systemic GCs	67%	75%	67%	0
≤2 IMs	67%	75%	100%	0
≥3 IMs	33%	25%	0	100%

As of 16 Apr 2026.
*Baseline disease activity = activity before preconditioning. †Reflects any exposure to RTX and IVIg prior or at time of study entry. RTX is not allowed within approximately 6 months of screening.
ASyS, antisynthetase syndrome; CDASI-A, Cutaneous Dermatomyositis Disease Area and Severity Index – Activity; CK, creatine kinase; DM, dermatomyositis; GC, glucocorticoid; HMGCR, 3-hydroxy-3-methylglutaryl-coenzyme A reductase; IM, immunomodulatory medication; IMNM, immune-mediated necrotizing myopathy; IVIg, intravenous immunoglobulin; JIIM, juvenile idiopathic inflammatory myopathy; MDA-5, melanoma differentiation-associated gene 5; MMT-8, manual muscle testing 8; NXP, nuclear matrix protein; N/A, not applicable; RESET, REstoring SElf-Tolerance; RTX, rituximab; SAE, small ubiquitin-like modifier activating enzyme; SRP, signal recognition particle; TIF1, transcription intermediary factor 1; U/L, units per liter.
Cabaletta Bio – Data on File.

Incidence of Relevant Treatment-Emergent Adverse Events*

17 of 17 of patients experienced only Grade 1 or no CRS and no ICANS

All cohorts (N=17)		
	CRS†	ICANS†
None, n (%)	**12 (71)**	**17 (100)**
Any grade, n (%)	**5 (29)**	**0 (0)**
Grade 1 (fever only)	5 (29)	0 (0)
Grade 2 or above	0 (0)	0 (0)
Time to onset, median (range), days	7 (4–12)	0
Duration, median (range), days	5.0 (3–7)	0
Treatments, n (%)		
Tocilizumab	5 (29)	0 (0)
Steroids	1 (6)	0 (0)
Anakinra	0 (0)	0 (0)

TEAEs of interest	All cohorts (N=17)
Prolonged cytopenias (>28 days)‡, n (%)	0 (0)
Hypogammaglobulinemia§, n (%)	0 (0)
Related serious infections¶, n (%)	0 (0)
Related SAEs**, n (%) Febrile neutropenia, Grade 2	1 (6)

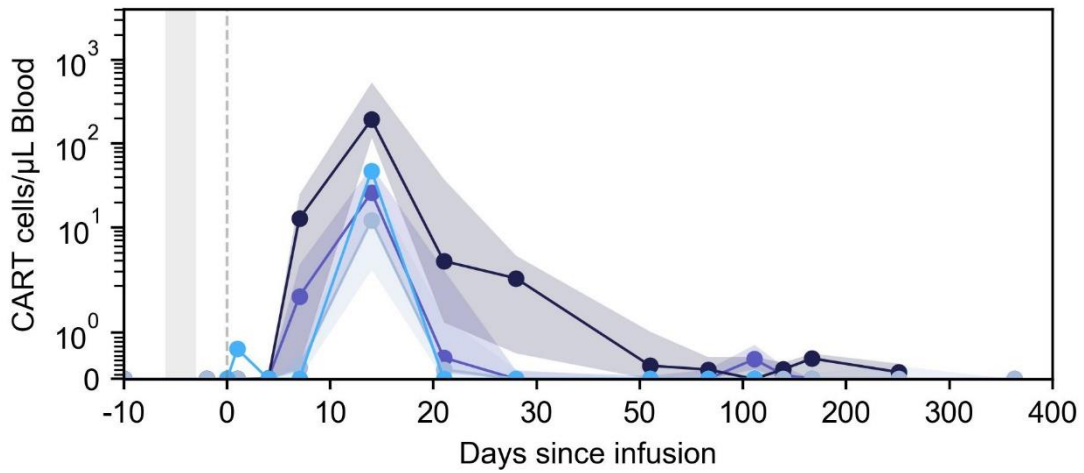
As of 16 Apr 2026.
*TEAEs of interest are reported to latest follow-up.
†Graded per ASTCT Consensus Grading Criteria.
‡Grade 3 or higher neutropenia, anemia, thrombocytopenia or pancytopenia lasting for more than 28 days.
§Grade 3 or higher (IgG level ≤400 mg/dL) and requiring treatment with external immunoglobulin.
¶Coded in System Organ Class of Infections and Infestations and meets seriousness criteria.
**As assessed per US Food and Drug Administration guidelines; excludes CRS and ICANS
ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; IgG, immunoglobulin G; SAE, serious adverse event; TEAE, treatment emergent adverse event.
Cabaletta Bio: Data on File.

Poster #POS0351
to be presented
06 Jun 2026

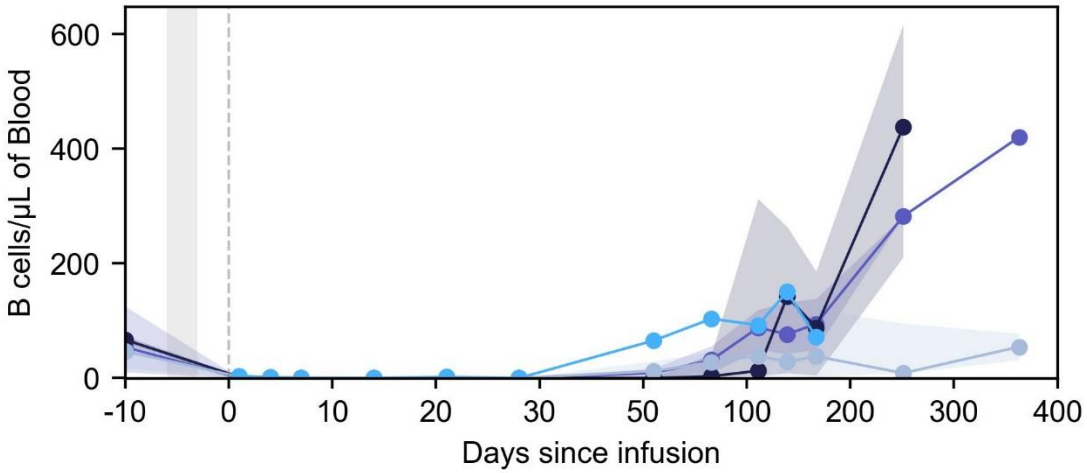
Rese-cel Expansion and B Cell Kinetics[1,*]

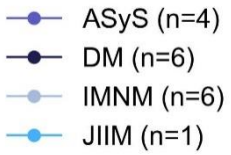
Peak rese-cel expansion and peripheral B cell depletion occurred by 2 weeks post infusion

Rese-cel Pharmacokinetics



Pharmacodynamics
(B Cell Counts)†





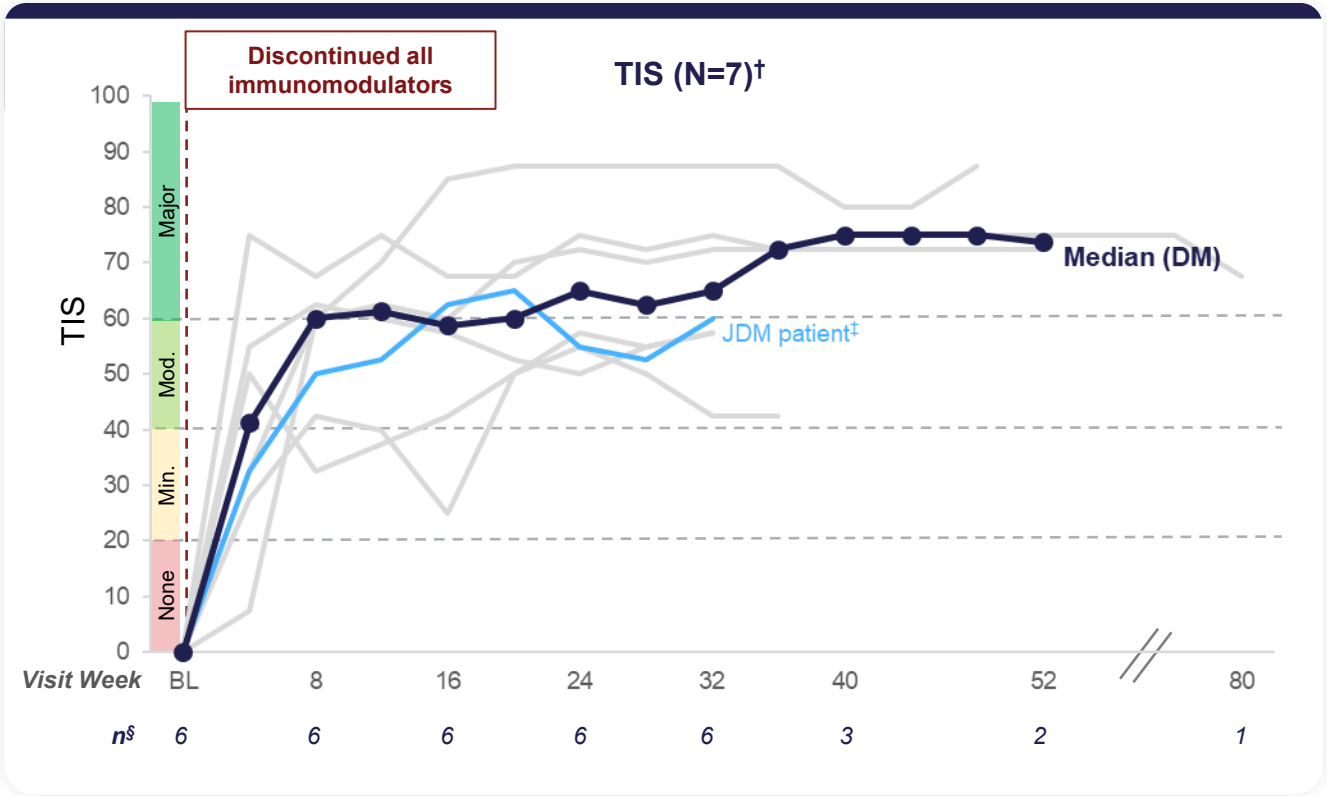
Median time to B cell repopulation was approximately 2.3 months;
Repopulating B cells were predominantly transitional naïve, indicating deep B cell depletion and B cell reset[2]

As of 16 Apr 2026.
*Data shown as median and IQR. Note baseline (pre-preconditioning) B cell count for the JDM patient was not available. †B cell count data excluded from any patient after receiving B cell-depleting rescue therapy.
ASyS, antisynthetase syndrome; DM, dermatomyositis; IMNM, immune-mediated necrotizing myopathy; IQR, interquartile range; JDM, juvenile dermatomyositis; JIIM, juvenile idiopathic inflammatory myopathy; rese-cel, resecabtagene autoleucel.
1. Cabaletta Bio: Data on File. 2. Furmanak T, et al. EULAR 2026 Poster #POS0351 *to be presented 06 Jun 2026*.

Efficacy Data in DM and JDM Patients Following Rese-cel Infusion

6 of 7 patients achieved moderate or major IM-free TIS response at Week 16 which was maintained through latest follow-up

Assessment at Week 16	DM and JDM patients (N=7)
Complete B cell depletion (%)	**100%**
IM-free & low-dose* or no GC (%)	**100%**
Moderate or major TIS response (%)	**86%**
Meets moderate or major TIS off IM therapy & on low-dose or no GCs* (*Pivotal primary endpoint*)	**86%**

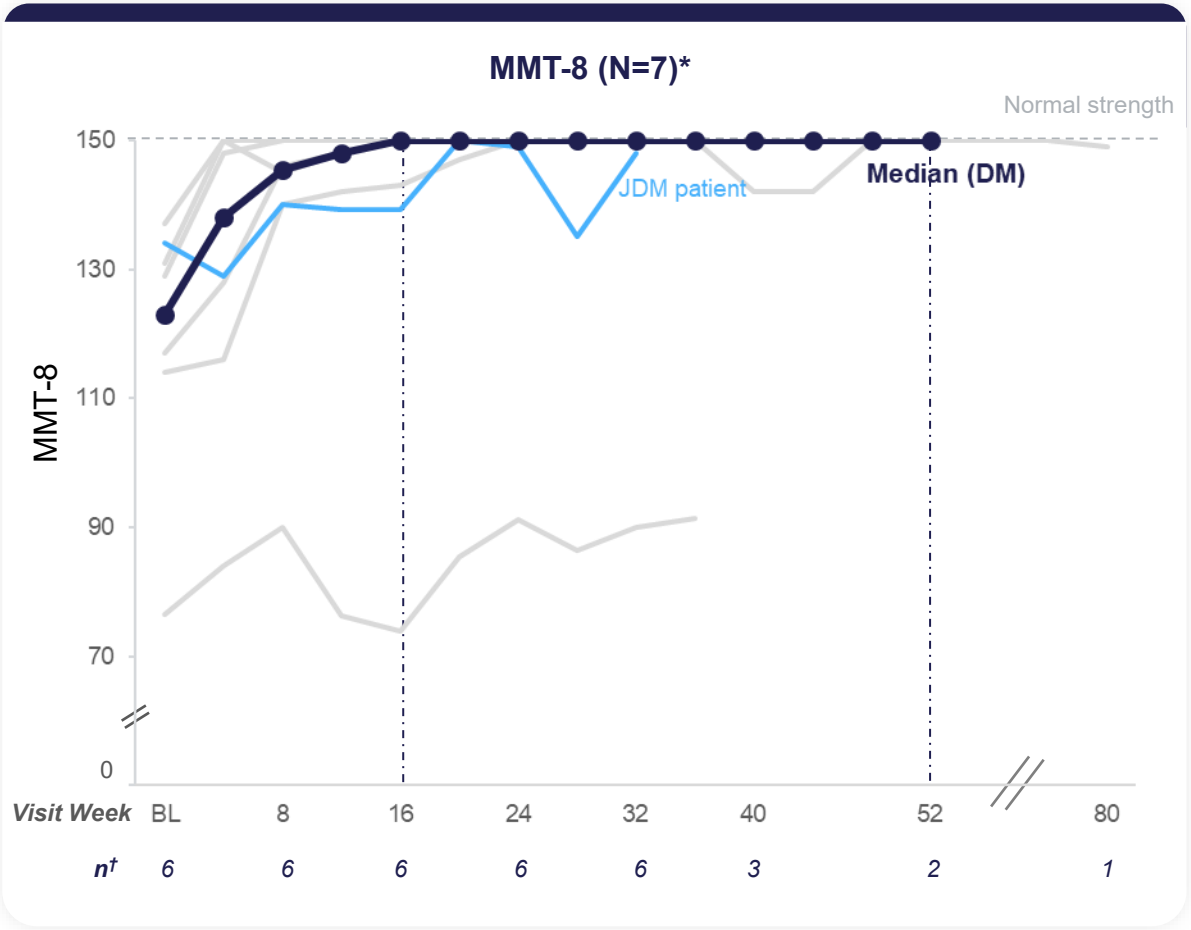


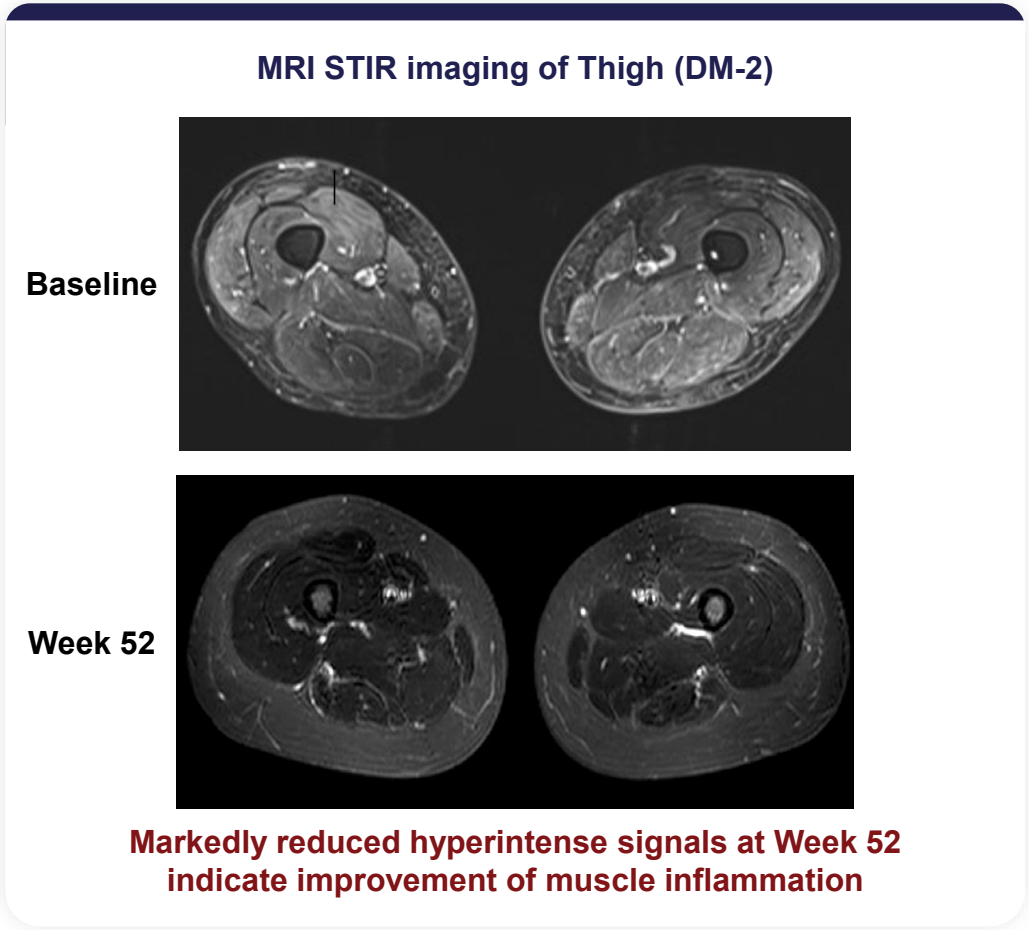
5 of 6 DM patients and the JDM patient achieved the 16-week primary endpoint for the ongoing pivotal study and all of these patients maintained IM-free TIS response through latest follow-up, as long as 1.5 years

As of 16 Apr 2026.
*Low-dose steroids is defined as 50% reduction from baseline or ≤7.5 mg/day. †Missing data were imputed using last observation carried forward. ‡TIS threshold for a moderate response is ≥45 in patients with JIIM; TIS scale on the Y-axis reflects adult thresholds.
§Median and n numbers are based on DM patients (excluding JDM patient) not receiving rescue immunomodulatory medications.
BL, baseline; DM, dermatomyositis; GC, glucocorticoids; IM, immunomodulatory medication; JDM, juvenile dermatomyositis; JIIM, juvenile idiopathic inflammatory myopathy; mg, milligrams; rese-cel, resecabtagene autoleucel; TIS, total improvement score.
Cabaletta Bio: Data on File.

Efficacy Data in DM and JDM Patients Following Rese-cel Infusion

Durable clinical improvement in muscle strength and improvement of inflammation on muscle MRI has been observed





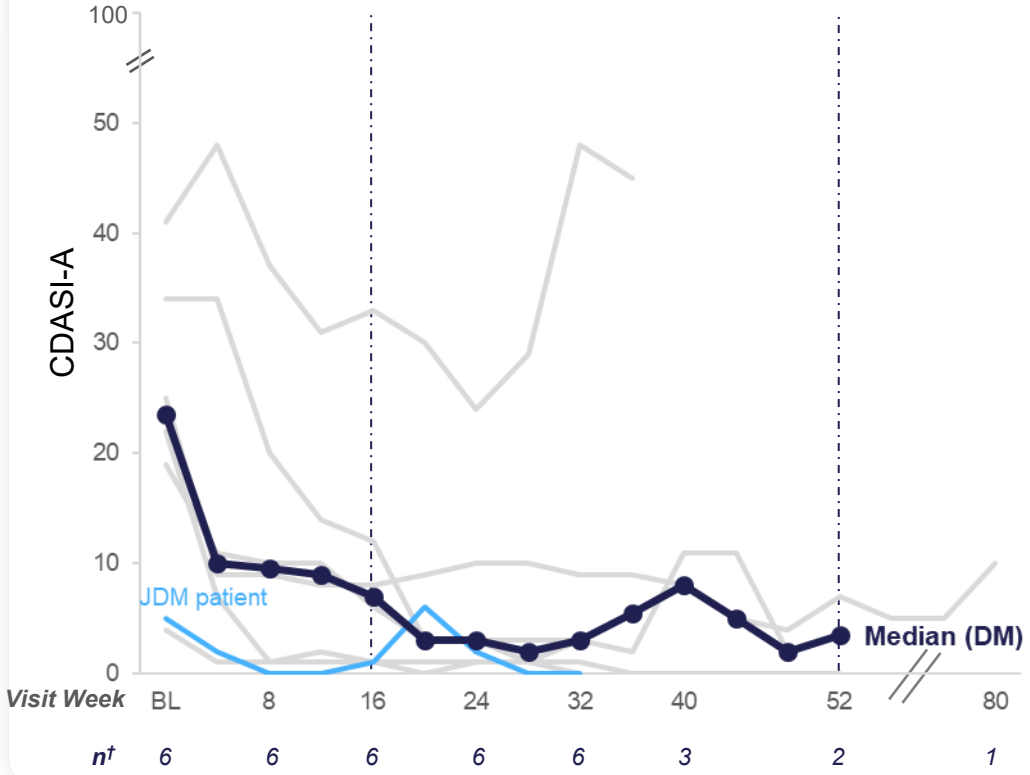
Markedly reduced hyperintense signals at Week 52 indicate improvement of muscle inflammation

As of 16 Apr 2026.
*Missing data were imputed using last observation carried forward. †Median and n numbers are based on DM patients (excluding JDM patient) not receiving rescue immunomodulatory medications.
BL, baseline; DM, dermatomyositis; JDM, juvenile dermatomyositis; MMT-8, manual muscle testing 8; MRI, magnetic resonance imaging; rese-cel, resecabtagene autoleucel; STIR, short tau inversion recovery.
Cabaletta Bio: Data on File.

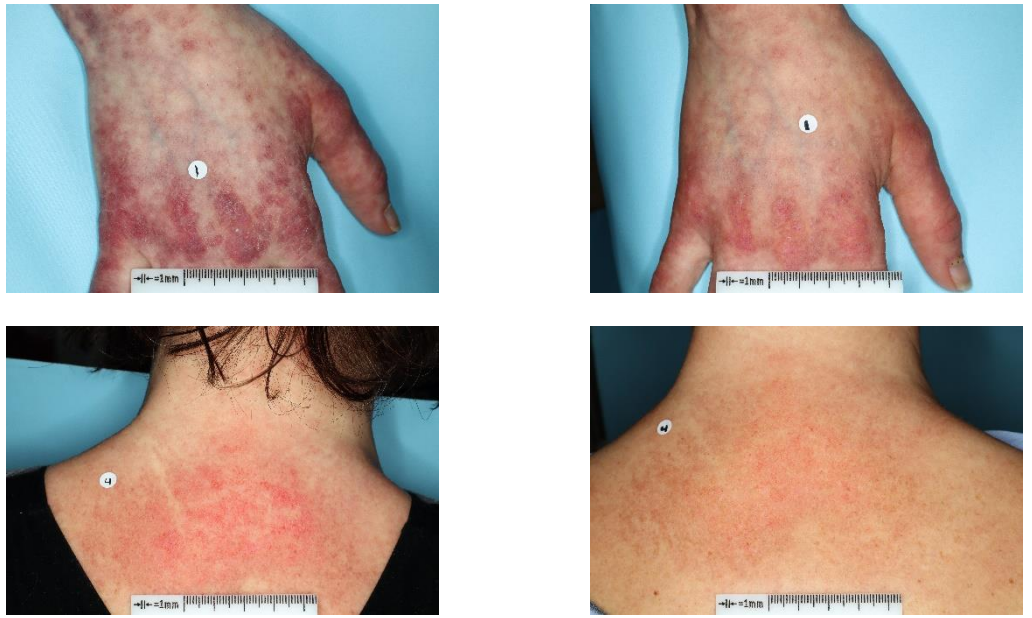
Efficacy Data in DM and JDM Patients Following Rese-cel Infusion

Skin manifestations improved in 86% of patients with DM or JDM while off immunomodulators

CDASI-A (N=7)*



Skin images (DM-2)‡



Baseline

Week 12

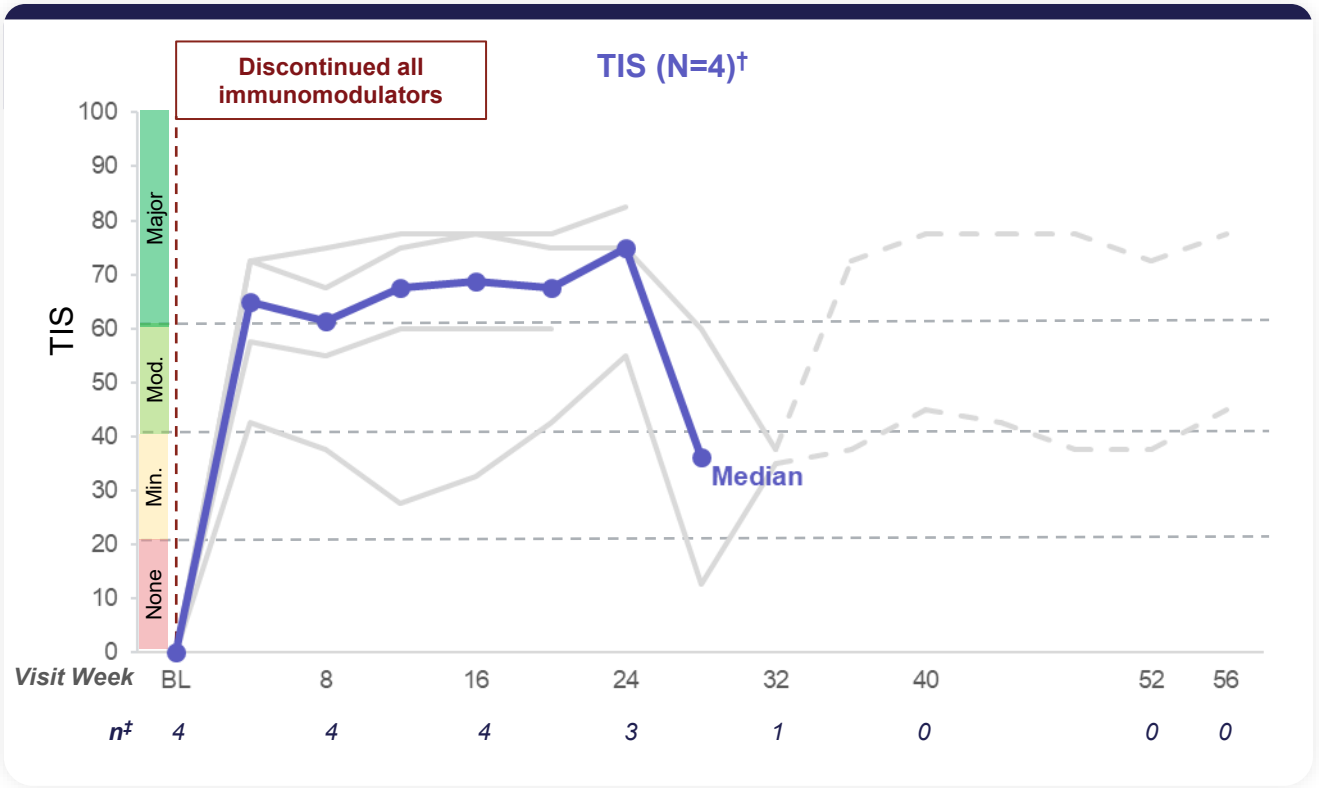
Median 16.5-point improvement in CDASI-A at Week 16 among adults with DM with associated clinically visible improvement in skin manifestations off immunomodulators

As of 16 Apr 2026.
*Missing data were imputed using last observation carried forward. †Median and n numbers are based on DM patients (excluding JDM patient) not receiving rescue immunomodulatory medications. ‡Participant provided consent to optional clinical photography.
BL, baseline; CDASI-A, Cutaneous Dermatomyositis Disease Area and Severity Index – Activity; DM, dermatomyositis; JDM, juvenile dermatomyositis; rese-cel, resecabtagene autoleucel.
Cabaletta Bio: Data on file.

Efficacy Data in ASyS Patients Following Rese-cel Infusion

3 of 4 patients achieved moderate or major IM-free TIS response at Week 16 with durability being evaluated[1]

Assessment at Week 16	ASyS patients (N=4)
Complete B cell depletion (%)	**100%**
IM-free & low-dose* or no GC (%)	**100%**
Moderate or major TIS response (%)	**75%**
Meets moderate or major TIS off IM therapy & on low-dose or no GCs* (*Pivotal primary endpoint*)	**75%**



Consistent with other CD19 CAR T data in ASyS patients[2], after a robust initial response, durability may be variable despite complete B cell depletion potentially due to persistent CD19-negative long-lived plasma cells

As of 16 Apr 2026.
*Low-dose steroids is defined as 50% reduction from baseline or ≤7.5 mg/day. †Dashed single patient trend lines represent patients receiving rescue immunomodulatory medications. ‡Median and n numbers are based on ASyS patients not receiving rescue immunomodulatory medications.
ASyS, antisynthetase syndrome; BL, baseline; CAR, chimeric antigen receptor; GC, glucocorticoids; IM, immunomodulatory medication; mg, milligrams; rese-cel, resecabtagene autoleucel; TIS, total improvement score.
1. Cabaletta Bio: Data on File. 2. Müller, F, et al. *Nat Med.* 2025:31(6):1793–1797

Key Takeaways

- Despite progress in recent clinical trials for myositis, a significant unmet need remains for drug-free responses without the need for chronic GCs and IM
- Rese-cel was well tolerated across 17 IIM patients treated to date
  - Only Grade 1 (fever) or no CRS in all 17 subjects
  - No ICANS
- B cell depletion observed by 2 weeks with a median repopulation time of ~2.3 months[1]
- DM: 5 of 6 patients achieved IM-free moderate to major TIS response at Week 16 (pivotal primary endpoint)
  - 100% of these patients had durable IM-free TIS responses at latest follow-up of 32 to 80 weeks
- JDM: The first patient achieved IM-free moderate TIS response that was maintained through 32 weeks
  - Additional patients are being evaluated
- ASyS: 3 of 4 patients achieved IM-free moderate to major TIS response at Week 16 with variable durability

**Based on these data, patient enrollment is ongoing in a pivotal study of 17 DM/ASyS patients with a 16-week primary endpoint of moderate to major TIS off IMs and on no or low dose steroids*.
A concurrent JDM indication is also being pursued alongside adult DM**

As of 16 Apr 2026
*Low-dose steroids is defined as 50% reduction from baseline or ≤7.5 mg/day. [1]Furmanak et al. EULAR 2026 Poster #POS0351 to be presented 06 Jun 2026.
ASyS, antisynthetase syndrome; CRS, cytokine release syndrome; DM, dermatomyositis; GC, glucocorticoid, ICANS, immune effector cell-associated neurotoxicity syndrome; IIM, idiopathic inflammatory myopathy; IM, immunomodulatory medication; IMNM, immune-mediated necrotizing myopathy; JDM, juvenile dermatomyositis; mg, milligrams; rese-cel, resecabtagene autoleucel; RESET™, REstoring SElf-Tolerance; TIS, total improvement score.
Cabaletta Bio: Data on File.

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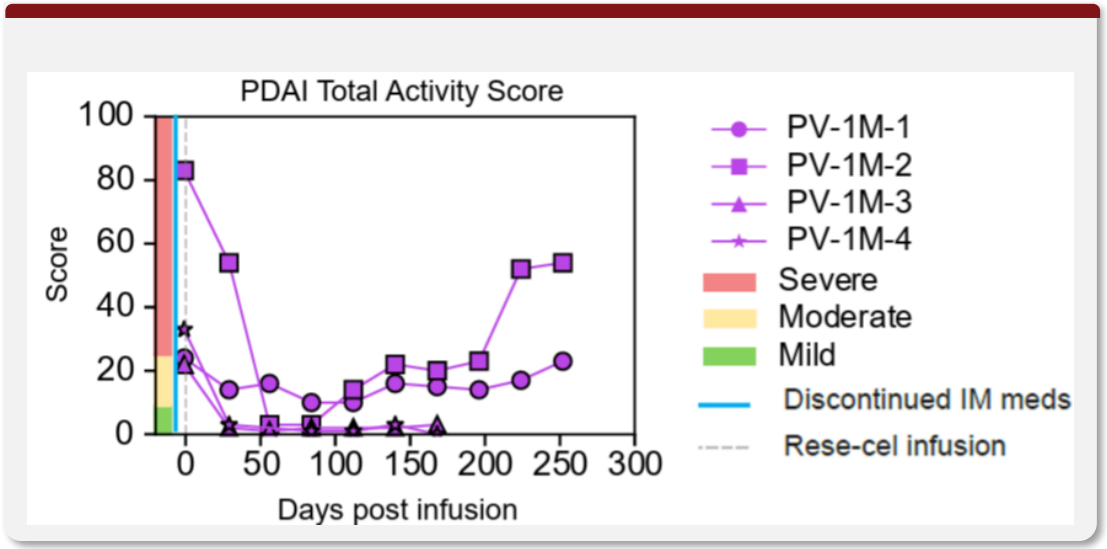
Autoimmune CAR T Advances Including Preconditioning-Free Trial Cohorts

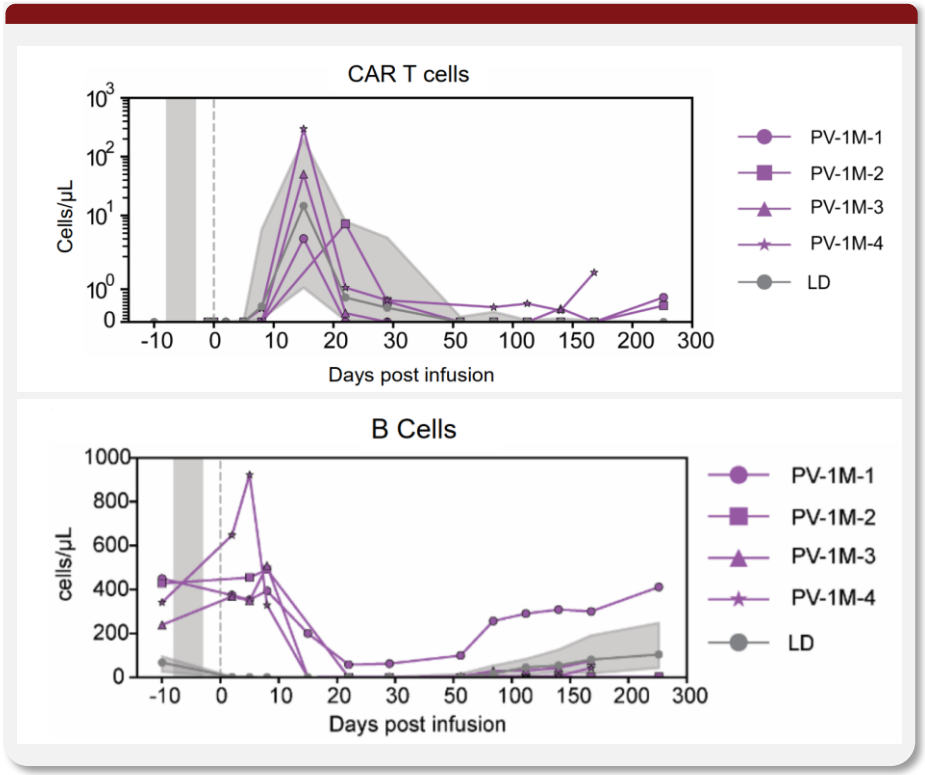
David J. Chang

Preconditioning-Free Data for Rese-cel in Pemphigus Vulgaris: RESET-PV[1]

In the initial low dose cohort (1x10^6 CAR T cells/kg), similar CAR T expansion vs. PC-treated patients was observed with complete B cell depletion in some patients

	RESET-PV			
Patient	**PV-1M-1**	**PV-1M-2**	**PV-1M-3**	**PV-1M-4**
CRS*	Grade 1	None	None	None
ICANS*	None	None	None	None





The vertical gray dotted line indicates the day of rese-cel infusion. For comparison, autoimmune patients who received rese-cel with PC, the vertical gray shading prior to infusion indicates the window for PC administration, and the gray line and shading show the median and 50th percentile intervals of values

RESET-PV: PC-free rese-cel longer-term data from multiple dose cohorts expected 2H2026

*Graded per ASTCT Consensus Grading Criteria.
CAR, chimeric antigen receptor; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; IM, immunomodulatory; LD, lymphodepletion; PC, preconditioning; PDAI, Pemphigus Disease Area Index; PV, pemphigus vulgaris; rese-cel, resecabtagene autoleucel; RESET™, REstoring SElf-Tolerance.

1. Nunez D, et al. *Blood*. 2026 [online ahead of print PMID 42201777]

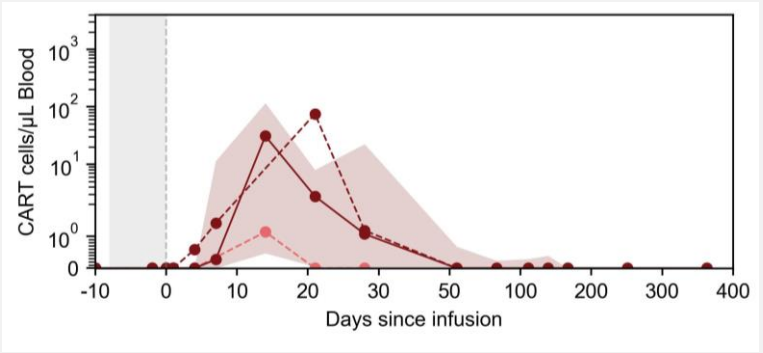
Preconditioning-Free Data for Rese-cel: RESET-SLE[1]

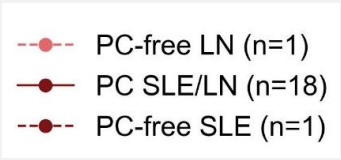
Encouraging primary data from the low dose PC-free cohort of 1x10^6 CAR T cells/kg; clinical follow up is ongoing while the next higher dose cohort is progressing

Incidence of CRS & ICANS†

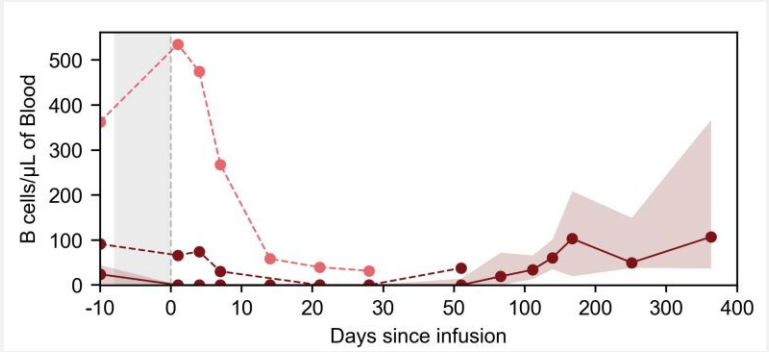
Cohort	PC-free* (n=2)	
	CRS‡	ICANS‡
Any Grade, n	**1**	**0**
Grade 1	1	0
Grade 2	0	0
Grade 3	0	0
Grade 4	0	0
Time to onset, days	12	–
Duration, days	3	–
Treatments, n		
Tocilizumab	1	–
Steroids	0	
Anakinra	0	

CAR T Cells (rese-cel PK)*





B cells*



Rese-cel PK represented as CAR T cells per µL blood as measured by digital PCR (dPCR) and B cell counts ($CD19^+CD20^+$) in peripheral blood at baseline and over time following rese-cel infusion measured by flow cytometry. The vertical gray dotted line indicates the day of rese-cel infusion and the vertical gray shading prior to infusion indicates the window in time for preconditioning in applicable patients. The two PC-free patients are represented as individual dotted lines. PC-free SLE patient did not have PK/PD samples collected at Day 15.

In the first two PC-free lupus patients, initial PK/PD findings suggest the lowest PC-free rese-cel dose may represent a threshold dose

*PC cohorts: as of 16 Apr 2026; PC-free cohort: as of 16 May 2026.
†Primary endpoint of the Phase 1/2 study is incidence and severity of adverse events through Day 29. No patient experienced clinical sequelae from CRS, ICANS, or related SAEs.
‡Graded per ASTCT Consensus Grading Criteria.
ASTCT, American Society for Transplantation and Cellular Therapy; CAR, chimeric antigen receptor; CD, cluster of differentiation; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; LN, lupus nephritis; PC, preconditioning; PD, pharmacodynamic; PK, pharmacokinetic; rese-cel, resecabtagene autoleucel; RESET™, REstoring SElf-Tolerance; SAE, serious adverse event; SLE, systemic lupus erythematosus.
1. Palma CM, et al. *Ann Rheum Dis*. 2026;85(1):s849. EULAR 2026 Poster #POS0698 presented 04 June 2026.

Opportunity To Broaden Access to Rese-cel in Autoimmune Diseases

PC-Free Administration

- Unanticipated activity of the lowest PC-free rese-cel dose, likely representing a “threshold dose”, was observed in lupus and pemphigus vulgaris patients

➡ Treat more patients PC-free & generate dose-ranging data across multiple autoimmune indications

Pediatrics

- Rese-cel has been granted Rare Pediatric Disease Designation for JDM

➡ Advance enrollment in juvenile myositis cohort to support incorporation in 2H27 BLA submission

  - First patient treated with additional patients enrolling and expected to be treated

Outpatient Administration

- An adult DM patient in RESET-Myositis phase 1/2 expansion cohort was recently treated and managed as an outpatient successfully

➡ Pursue additional rese-cel treatment in the outpatient setting

BLA, Biologics License Application; DM, dermatomyositis; JDM, juvenile dermatomyositis; PC, preconditioning; rese-cel, resecabtagene autoleucel; RESET™, REstoring SElf-Tolerance

Panel Discussion

David J. Chang

Olalekan O. Oluwole

Rohit Aggarwal

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Thank you for your participation!

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Attend our Translational Medicine Poster Tour on Saturday, June 6th at 10:39 AM BST
POS0351
Position G115
Basic Poster Tours:
Another one BITes the CAR-T