

RESET-Myositis™: Clinical Trial Evaluating Rese-cel (Resecabtagene Autoleucel), A Fully Human, Autologous 4-1BB CD19-CAR T Cell Therapy in Idiopathic Inflammatory Myopathies

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Disclosures

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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.

Myositis: A Disease of Significant Unmet Need

Affects ~80K U.S. patients; high mortality and limited treatment options^{1–9}

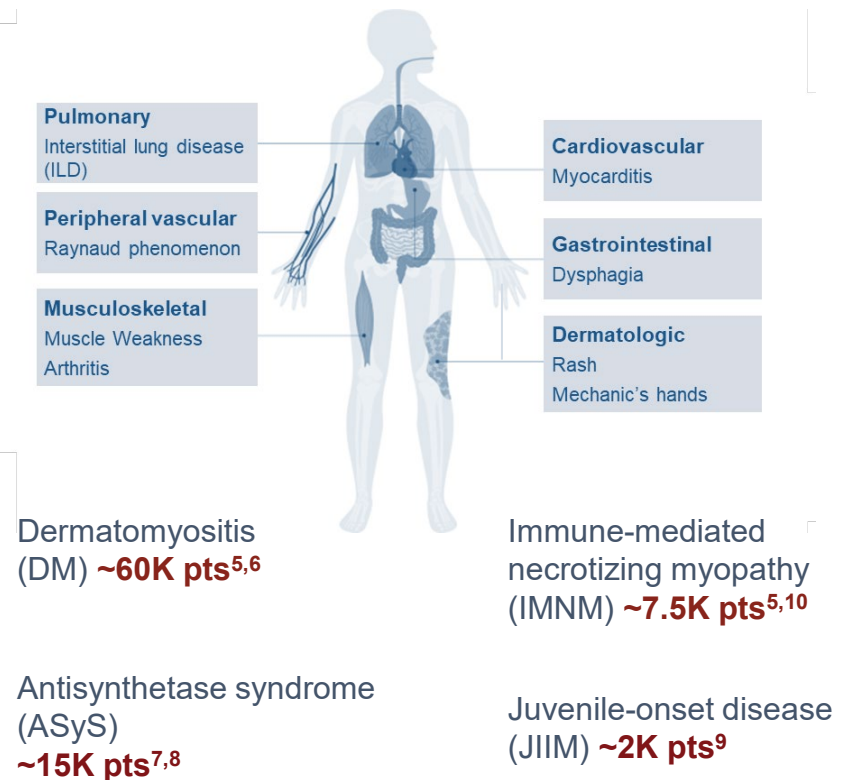
> High disease burden: disability & mortality

- Moderate to severe disability (40% to 65%)²
- Assisted walking devices (18% to 38%)²
- The **risk of mortality is ~3 times higher** than the general population, primarily due to cancer and lung & cardiac complications³
 - ~20% mortality < 5 years with standard immunosuppressive treatment⁴

> High unmet medical need

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

Potential manifestations and subtype prevalence in the US



FDA, U.S. Food and Drug Administration; 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.

B Cells Play a Central Role in the Pathogenesis of Myositis

Current therapeutic options often result in incomplete B cell depletion in tissues and lymphoid organs¹

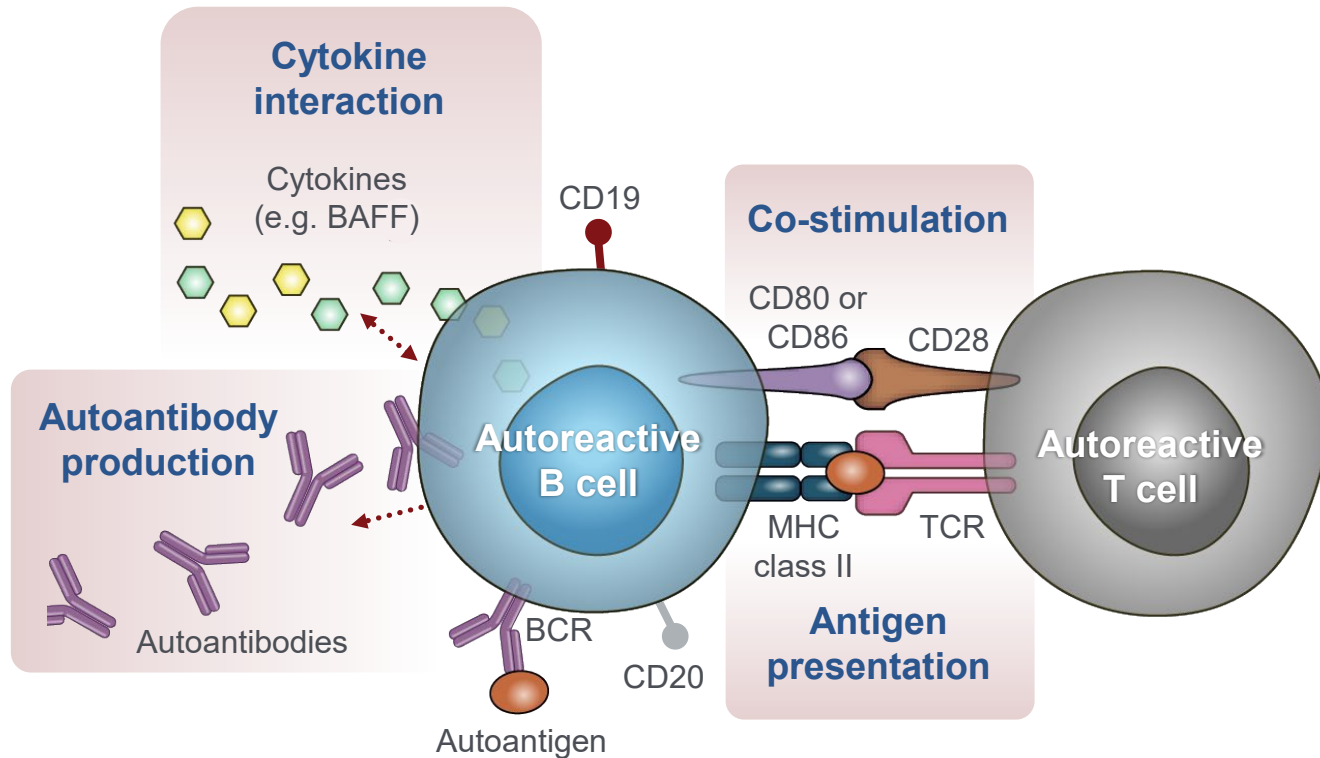


Image adapted from Rubin SJS, et al. 2019²

- Myositis-specific autoantibodies are associated with clinical phenotypes^{3,4}
- BAFF levels are associated with high disease activity^{4,5}
- Presence of B cells in follicular, germinal center-like structures with type 1 interferon signatures are found in the muscle biopsy of some DM patients⁶
- Rituximab, an anti-CD20 monoclonal antibody, has demonstrated some efficacy in some myositis subtypes⁷

BAFF, B cell activating factor; BCR, B cell receptor; CD, cluster of differentiation; DM, dermatomyositis; MHC, major histocompatibility complex; TCR, T cell receptor.

1. Schett G, et al. *Ann Rheum Dis*. 2024;83(11):1409–1420. 2. Rubin SJS, et al. *Nat Rev Rheumatol*. 2019;15(5):303–315. 3. Halilu F, Christopher-Stine L. *Rheumatol Immunol Res*. 2022;3(1):1–10. 4. Aggarwal A, et al. *J Rheumatol*. 2025;52(6):532–542. 5. Baek A, et al. *J Neuroimmunol*. 2012;249(1-2):96–100. 6. Radke J, et al. *Neurol Neuroimmunol Neuroinflamm*. 2018;5(3):e451. 7. Oddis C, et al. *Arthritis Rheum*. 2013;65(2):314–24

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)

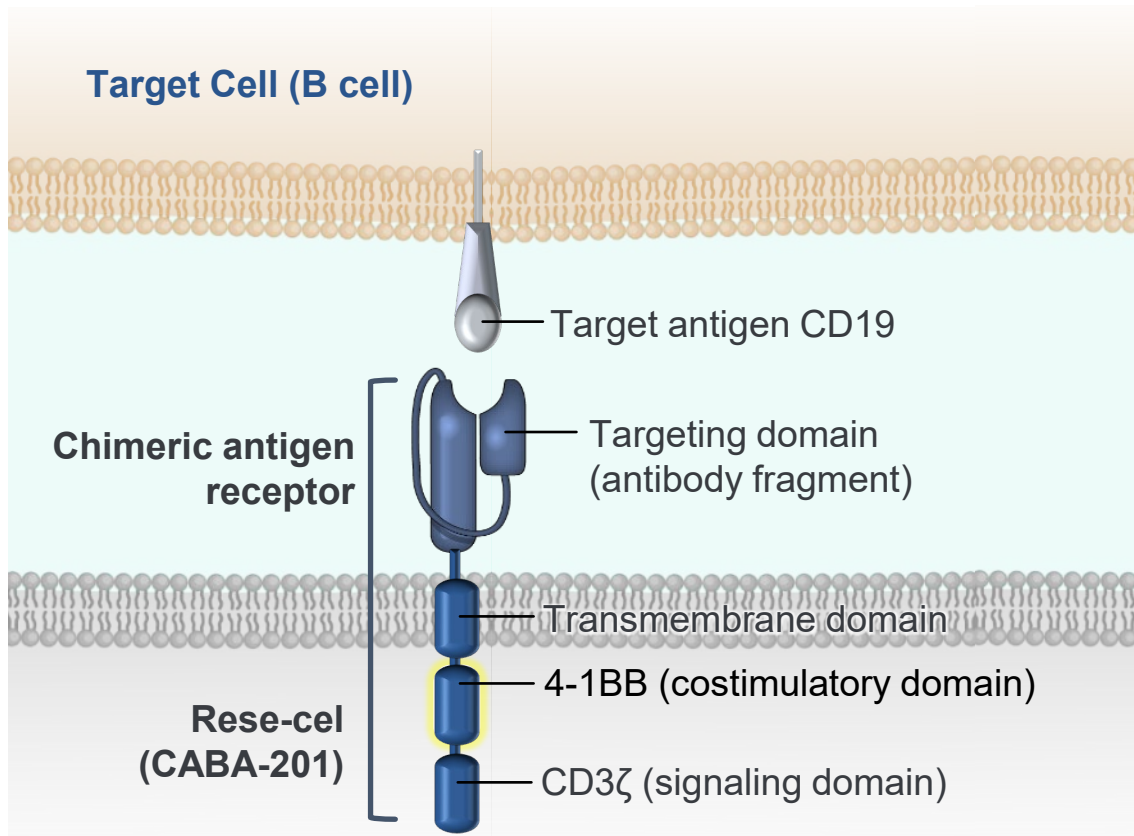


Image adapted from June CH and Sadelain M. 2018.⁴

Rese-cel product design and clinical/translational data

4-1BB costimulatory domain with fully human binder¹

- Binder with similar affinity and biologic activity to academic FMC63 binder while binding to the same epitopes^{1,2}

Same weight-based dose as in academic studies^{3,5}

- Potential to provide immune reset based on initial clinical and translational data⁵

Patients treated with rese-cel have shown compelling clinical responses with safety data that supports autoimmune development⁶

CAR, chimeric antigen receptor; CD, cluster of differentiation; rese-cel, rescabtagene autoleucel.

1. Peng BJ, et al. *Mol Ther Methods Clin Dev*. 2024;32(2):101267. 2. Dai Z, et al. *J Cell Physiol*. 2021;236(8):5832–5847. 3. Müller F, et al. *N Engl J Med*. 2024;390(8):687–700. 4. June CH, Sadelain M. *N Engl J Med*. 2018;379(1):64–73. 5. Volkov J, et al. *Mol Ther*. 2024;32(11):3821–3828. 6. Sheikh S, et al. *Arthritis Rheumatol*. 2024;76 (Suppl 9). Abstr. No. 1733.

Autologous CAR T Cell Therapy: How Rese-cel is Manufactured

Designed to combine antibody-targeting ability with the cell-killing machinery of a patient's own T cells^{1,2}

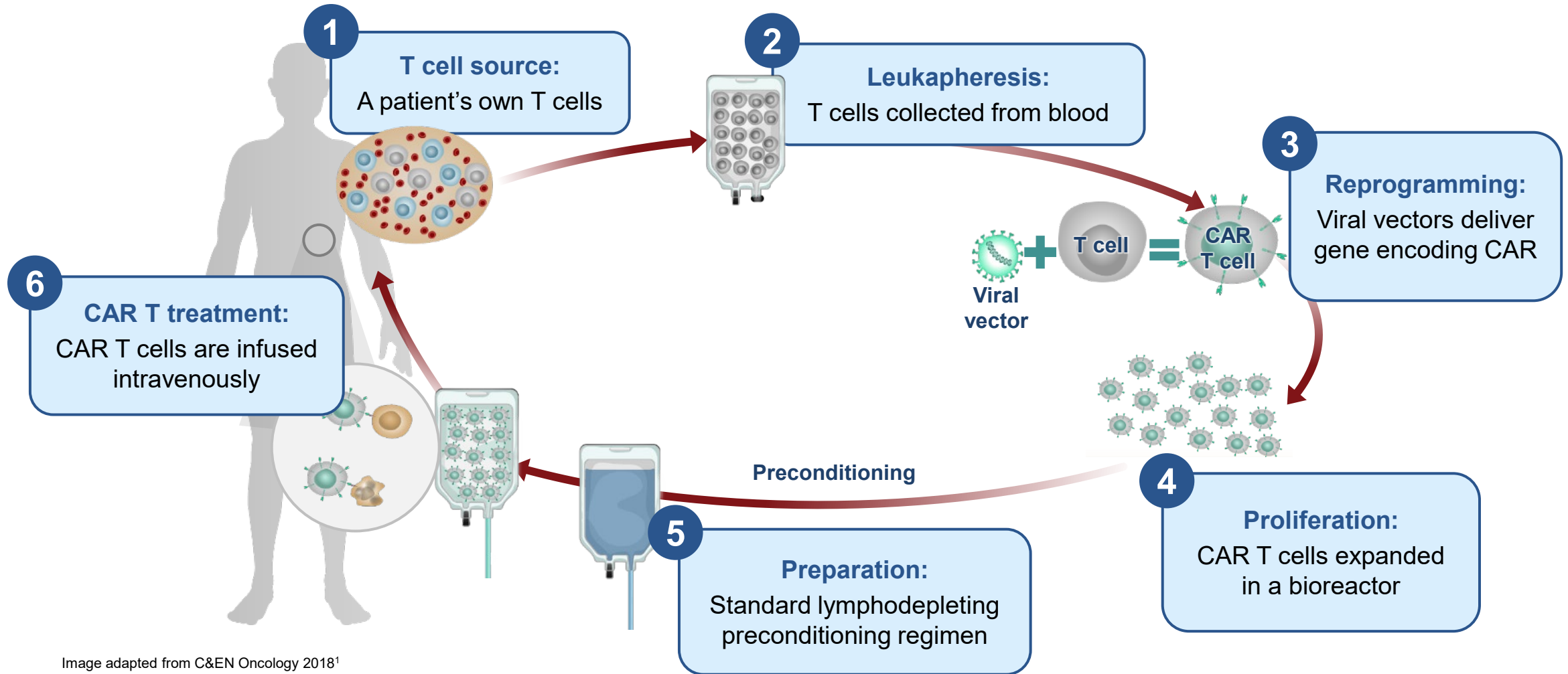


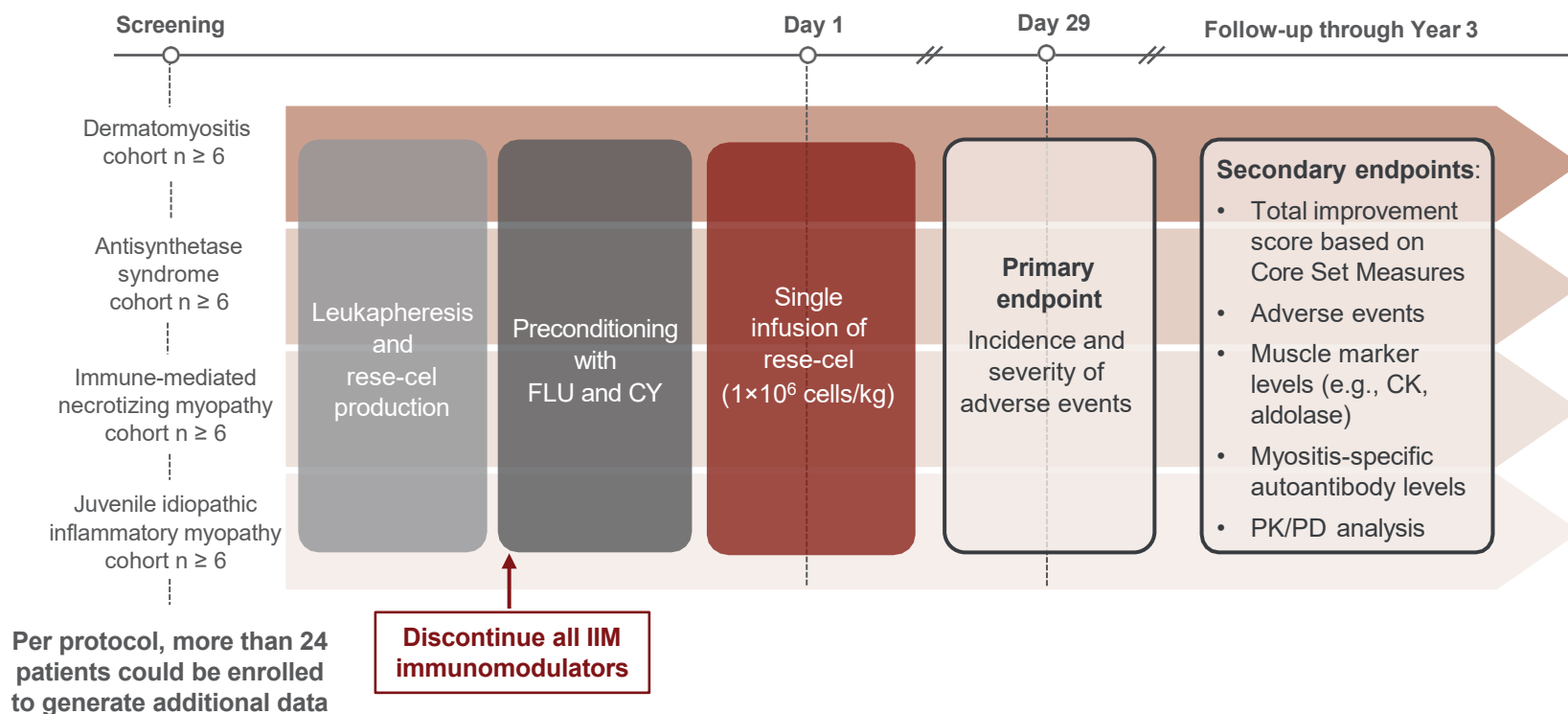
Image adapted from C&EN Oncology 2018¹

CAR, chimeric antigen receptor; rese-cel, rescabtagene autoleucel.

1. C&EN Oncology. 2024. Available at: <https://cen.acs.org/pharmaceuticals/oncology/Controlling-CAR-T-scientists-plan/96/i19> (accessed October 2025). 2. Peng BJ, et al. *Mol Ther Methods Clin Dev*. 2024;32(2):101267.

RESET- Myositis™: 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 IIM; 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 online at: www.clinicaltrials.gov/study/NCT06154252 (accessed October 2025).

Baseline Characteristics: First 13 Patients in RESET-Myositis™*

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

	DM N=4	ASyS N=2	IMNM N=6	JlIM N=1
Mean age, years (min, max)	~58 (45, 72)	~44 (39, 48)	~55 (33, 64)	14
Female, n (%)	3 (75)	1 (50)	1 (17)	1 (100)
Years since diagnosis, mean (min, max)	3.0 (2.0, 3.6)	9.2 (3.6, 14.8)	4.5 (1.4, 8.8)	8.5
Myositis-specific autoantibody	50% TIF1-γ 25% NXP, 25% SAE	100% Jo-1	67% HMGCR 33% SRP	NXP-2
Baseline disease activity[†]				
Mean MMT-8	109.6	129.5	122.0	134.0
Median CK	40.0	311.5	2214.5	176.0
Mean CDASI-A	26	N/A	N/A	N/A
Prior RTX[‡]	75%	100%	50%	100%
Prior IVIg[‡]	100%	100%	83%	100%
Therapies at Screening				
Systemic GCs	75%	100%	67%	0
≤2 IMs	50%	50%	100%	0
≥3 IMs	50%	50%	0%	100%

*As of 11 Sep, 2025.

[†]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; JlIM, juvenile idiopathic inflammatory myopathy; 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 and Related Serious Adverse Events*

Mild CRS (Grade 1) in 4 of 13 patients and no ICANS in any patients

Cohort	DM				ASyS		IMNM						JIIM
Patient	DM-1	DM-2	DM-3	DM-4	ASyS-1	ASyS-2	IMNM-1	IMNM-2	IMNM-3	IMNM-4	IMNM-5	IMNM-6	JIIM-1
CRS†	None	Grade 1	None	None	Grade 1	Grade 1	None	None	Grade 1	None	None	None	None
ICANS†	None	None	None	None	None	None	None	None	None	None	None	None	None
Serious infections‡	None	None	None	None	None	None	None	None	None	None	None	None	None
Related SAEs (Grade)§ (excluding CRS and ICANS)	None	None	None	None	None	None	None	None	None	None	None	None	Febrile Neutropenia (2)

*As of 11 Sep, 2025; primary endpoint of the Phase 1/2 study is incidence and severity of adverse events through Day 29. Serious infections and related SAEs are reported to latest follow-up.

†Graded per ASTCT Consensus Grading Criteria.

‡Coded in System Organ Class of Infections and Infestations and meets seriousness criteria.

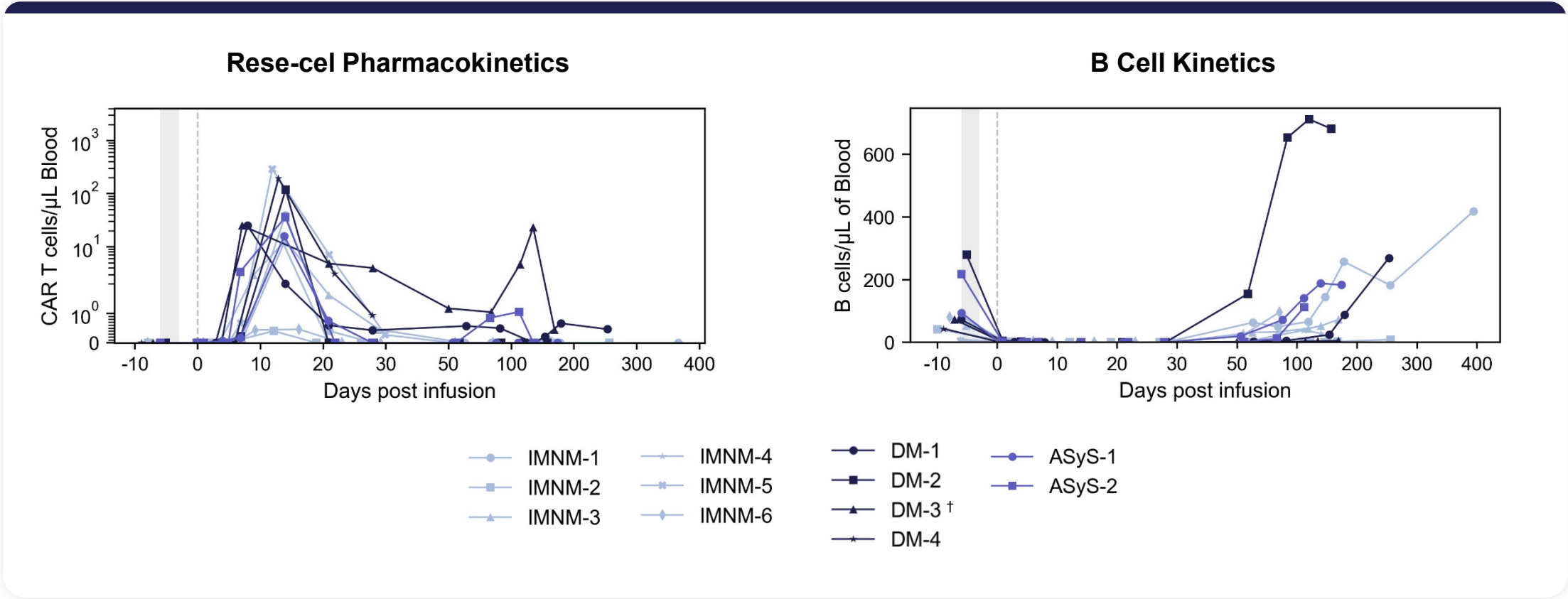
§As assessed per US Food and Drug Administration guidelines.

ASTCT, American Society for Transplantation and Cellular Therapy; ASyS, antisynthetase syndrome; CRS, cytokine release syndrome; DM, dermatomyositis; ICANS, immune effector cell-associated neurotoxicity syndrome; IMNM, immune-mediated necrotizing myopathy; JIIM, juvenile idiopathic inflammatory myopathy; SAE, serious adverse event.

Cabaletta Bio: Data on File.

Rese-cel Expansion and B Cell Kinetics*

Peak rese-cel expansion and complete and transient peripheral B cell depletion occurred within 1 to 2 weeks post-infusion in all patients



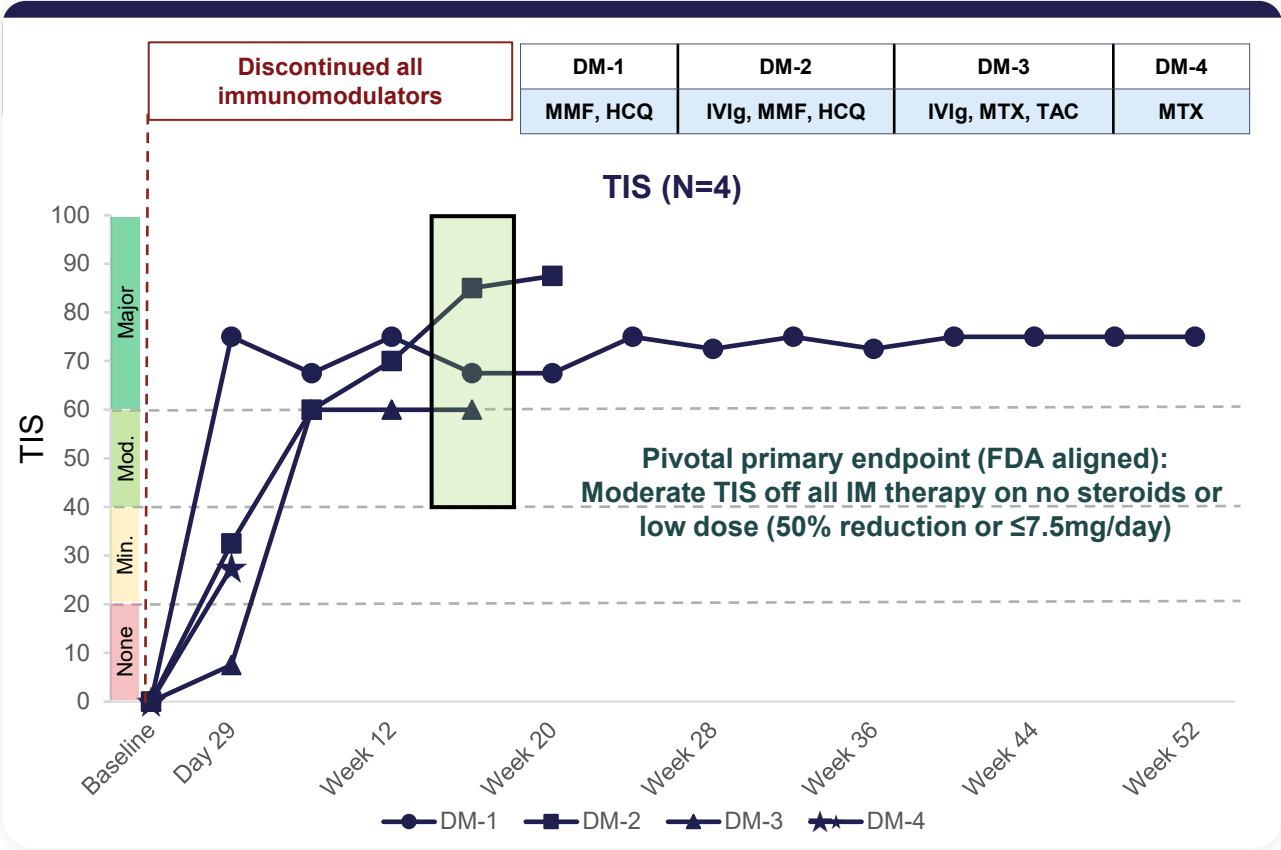
Peripheral B cells began repopulating 2–3 months after rese-cel infusion with transitional naïve cells, indicating B cell reset, in patients with sufficient follow-up data

*All data is as of 11 Sep. 2025, except DM-3 which includes Week 24 data as of 08 Oct 2025.
ASyS, antisynthetase syndrome; CAR, chimeric antigen receptor; DM, dermatomyositis; IIM, idiopathic inflammatory myopathy; IMNM, immune-mediated necrotizing myopathy; rese-cel, resecabtagene autoleucel.
Cabaletta Bio: Data on File.
[†]DM-3 rese-cel PK at Week 20 was artifactually elevated due to low circulating lymphocyte counts.

Efficacy Data in DM Patients Following Rese-cel Infusion*

3 of 3 patients with DM and sufficient follow-up achieved at least moderate TIS response at Week 16 following rese-cel infusion

Assessment at Week 16	DM Patients (baseline autoantibody)			
	DM-1 (SAE)	DM-2 (None detected†)	DM-3 (TIF1-γ)	DM-4 (TIF1-γ)
IM-free	✓	✓	✓	✓‡
Low dose or no GC	✓	✓	✓	✓‡
TIS Response	Major	Major	Major	N/A§
Complete and transient B cell depletion	✓	✓	✓	✓‡
Antibody trend¶	↓	N/A	↓	N/A§
Meets pivotal primary endpoint	✓	✓	✓	N/A§

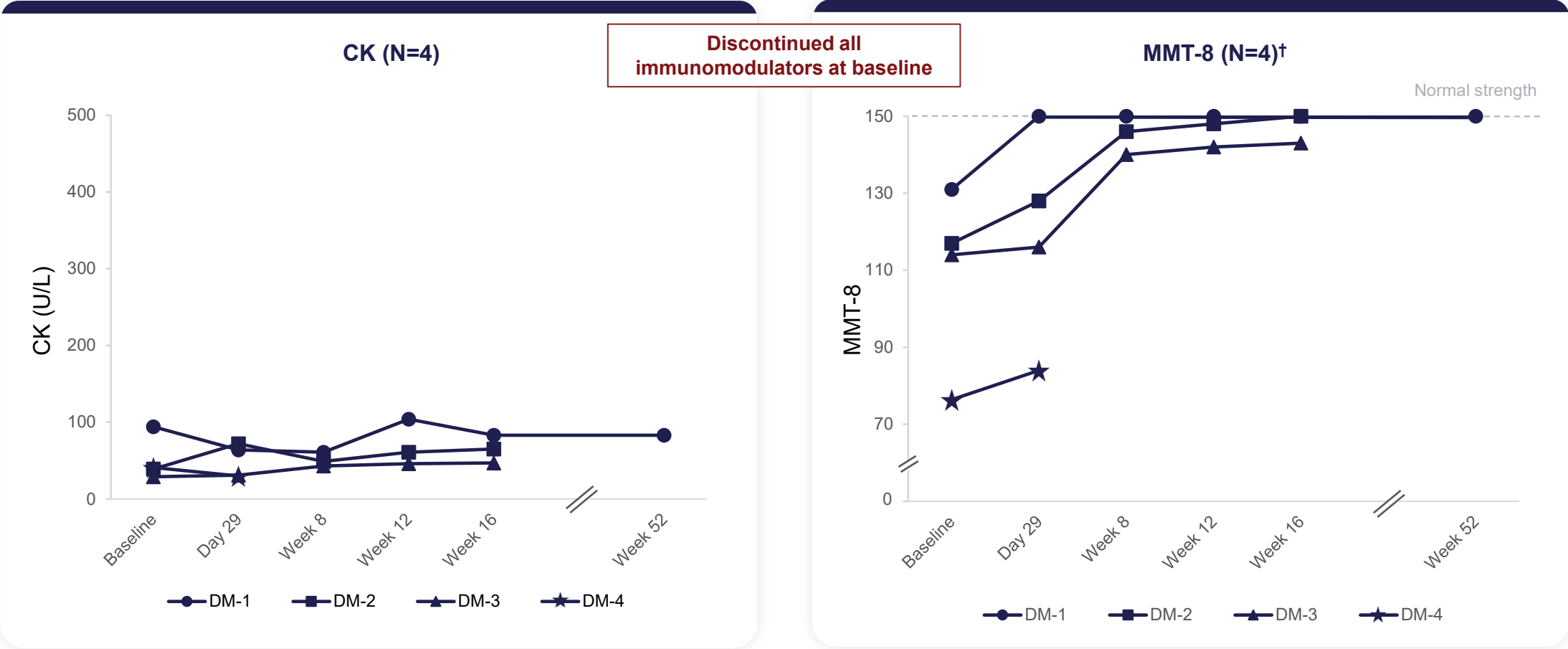


After discontinuation of all IM medications, 3 of 3 DM patients achieved the FDA-aligned 16-week primary endpoint for the upcoming pivotal study of at least moderate TIS response

*As of 11 Sep, 2025.
† Historical NXP-2 autoantibody, but none detected at Pre-preconditioning (Baseline) visit). ‡ At latest follow-up (Day 29). § Insufficient follow-up. ¶ Reflects trend from baseline to latest timepoint.
DM, dermatomyositis; FDA, Food and Drugs Administration; GC, glucocorticoids; HCQ, hydroxychloroquine; IM, immunomodulatory medication; IVIg, intravenous immunoglobulin; mg, milligrams; MMF, mycophenolate mofetil; MTX, methotrexate; N/A, not available; NXP, nuclear matrix protein; rese-cel, rescabtagene autoleucel; SAE, small ubiquitin-like modifier activating enzyme; TAC, tacrolimus; TIF1-γ, transcription intermediary factor 1 gamma; TIS, total improvement score.
Cabaletta Bio: Data on File.

Efficacy Data in DM Patients Following Rese-cel Infusion*

All patients with DM show improvement in muscle strength on MMT-8 following rese-cel and normal CK levels

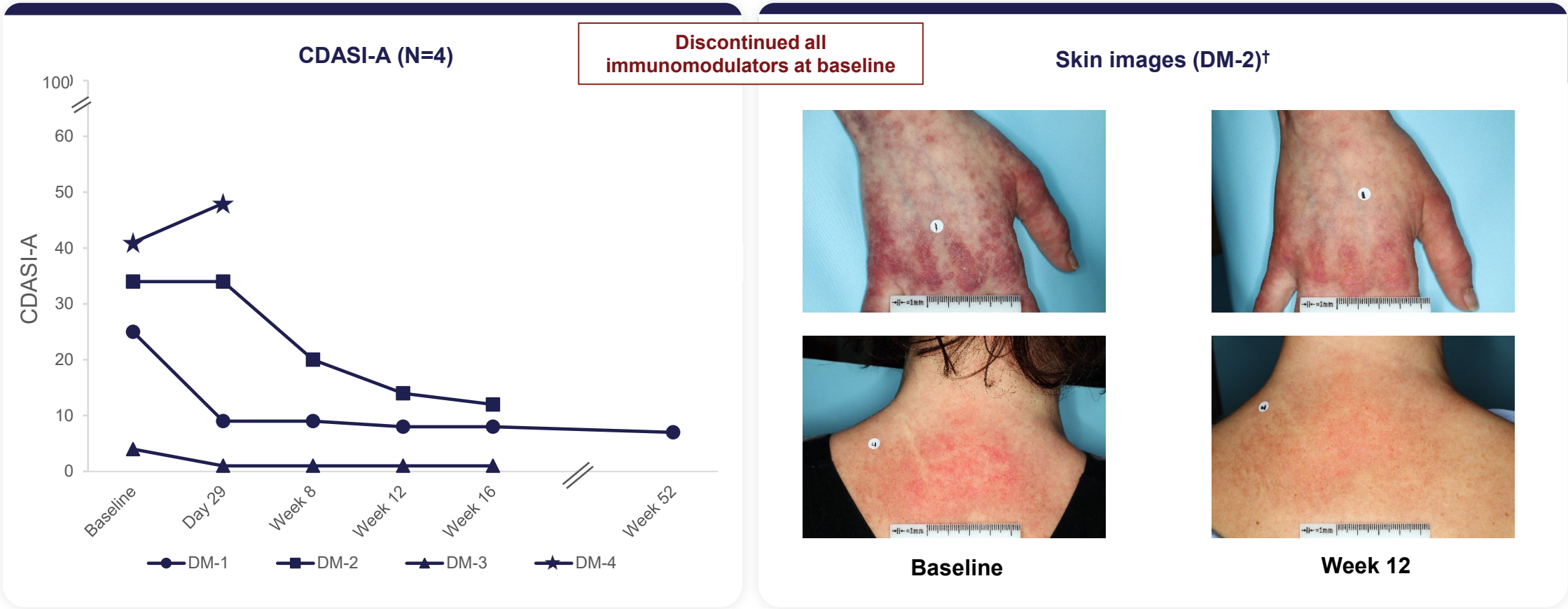


Clinical responses to rese-cel among DM patients
show potential for achieving drug-free remission in patients with refractory myositis

*As of 11 Sep, 2025.
[†]DM-4 MMT-8 measurements were normalized to a total score of 150; not all muscle groups could be evaluated.
CK, creatine kinase; DM, dermatomyositis; FDA, Food and Drugs Administration;; MMT-8, manual muscle testing 8; rese-cel, reseccabtagene autoleucel; TIS, total improvement score; U/L, units per liter.
Cabaletta Bio: Data on File.

Efficacy in DM Patients Following Rese-cel Infusion*

Early clinical responses in DM skin manifestations have been observed off immunomodulators



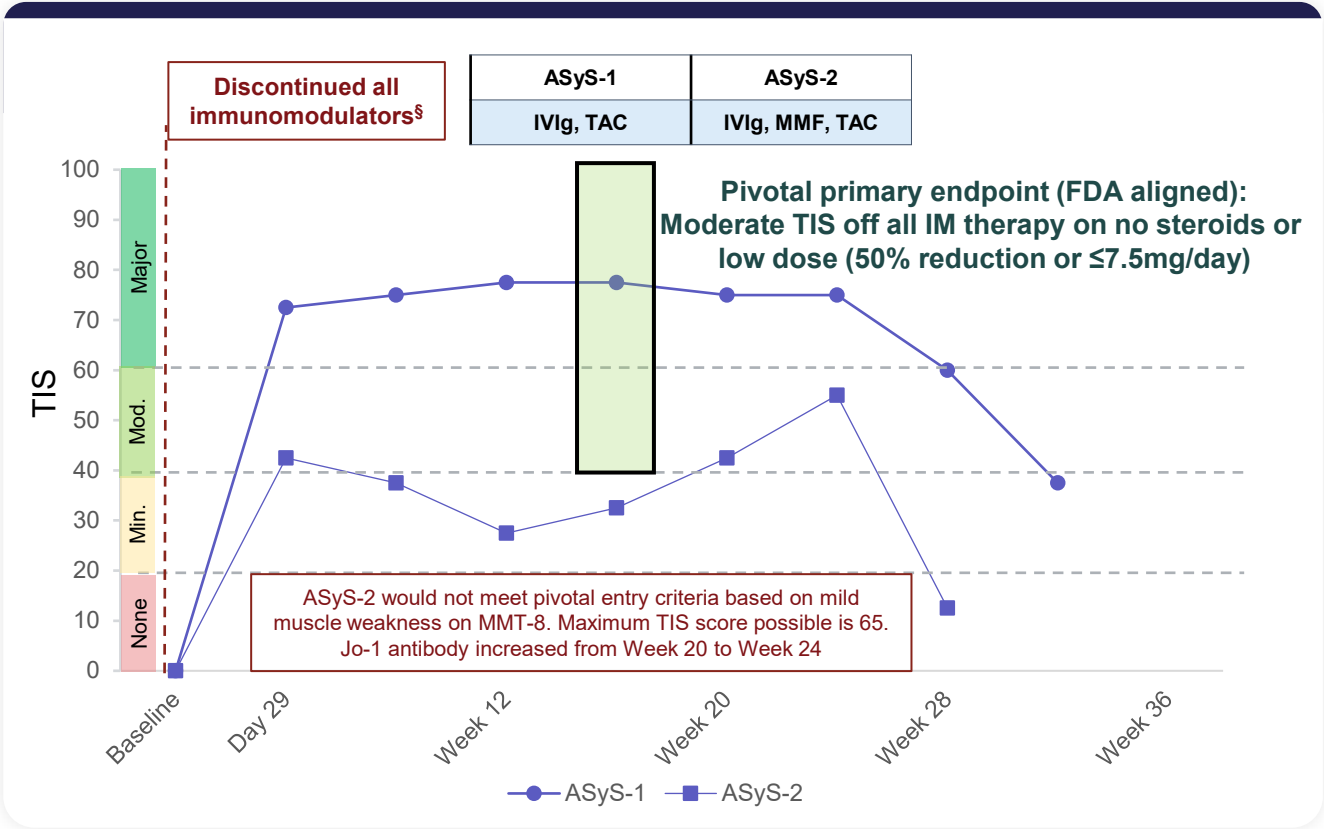
First known adult DM patients dosed with CAR T demonstrated early and clinically visible CDASI-A response off immunomodulators

*As of 11 Sep, 2025.
†Participant provided consent to optional clinical photography.
CAR, chimeric antigen receptor; CDASI-A, Cutaneous Dermatomyositis Disease Area and Severity Index – Activity; DM, dermatomyositis; rese-cel, resecabtagene autoleucel; RESET, REStoring SElf-Tolerance.
Cabaletta Bio: Data on file.

Efficacy in ASyS Patients Following Rese-cel Infusion^{1*}

1 of 2 patients with ASyS achieved at least moderate TIS response at Week 16 following rese-cel infusion

Assessment at Week 16	ASyS (baseline autoantibody)	
	ASyS-1 (Jo-1)	ASyS-2 (Jo-1)
IM-free	✓	✓
Low dose or no GC	✓	✓
TIS response	Major	Minimal
Complete and transient B cells depletion	✓	✓
Antibody trend [†]	↓ [‡]	↓ [‡] → [‡]
Meets pivotal primary endpoint	✓	✗

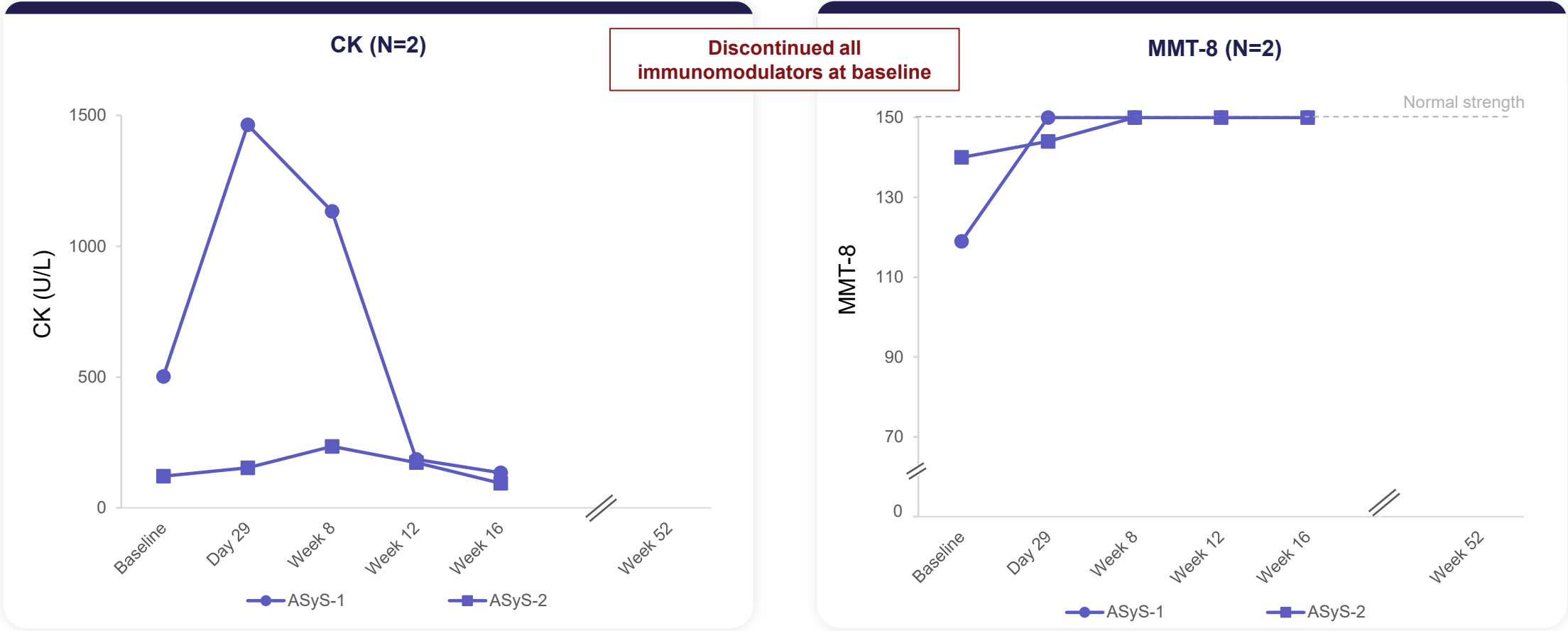


Responses to rese-cel among some ASyS patients may be time-limited by the recurrence or persistence of pathogenic autoantibodies²⁻⁴ from CD19-negative long-lived plasma cells despite complete B cell depletion

^{*}As of 11 Sep, 2025.
[†]Reflects trend from baseline to latest timepoint antibody results are available (Week 24 for both patients). In ASyS-2, Jo-1 antibody level trended up from Week 20 to Week 24 but was lower than baseline. [‡]Based on the research-based, qualified, quantitative Luminex assay.
[§]ASyS-1 to minimal response at latest follow-up (Week 32); treated with GC bursts and obinutuzumab; ASyS-2 to no response at latest follow-up (Week 28); treated with GC burst.
ASyS, antisynthetase syndrome; FDA, Food and Drugs Administration; GC, glucocorticoids; IM, immunomodulatory medication; IVIg, intravenous immunoglobulin; mg, milligrams; MMF, mycophenolate mofetil; N/A, not available; rese-cel, resecatagene autoleucel; TAC, tacrolimus; TIS, total improvement score.
1. Cabaletta Bio: Data on File. 2. Pinal-Fernandez I, et al. *Ann Rheum Dis*. 2024;83(11):1549–1560. 3. Galindo-Feria AS, et al. *Best Pract Res Clin Rheumatol*. 2022;36(2):101767. 4. Müller, F, et al. *Nat Med*. 2025;31(6):1793–1797.

Efficacy in ASyS Patients Following Rese-cel Infusion*

Patients with ASyS achieve improvements in CK levels and normalization of MMT-8 following rese-cel by Week 16



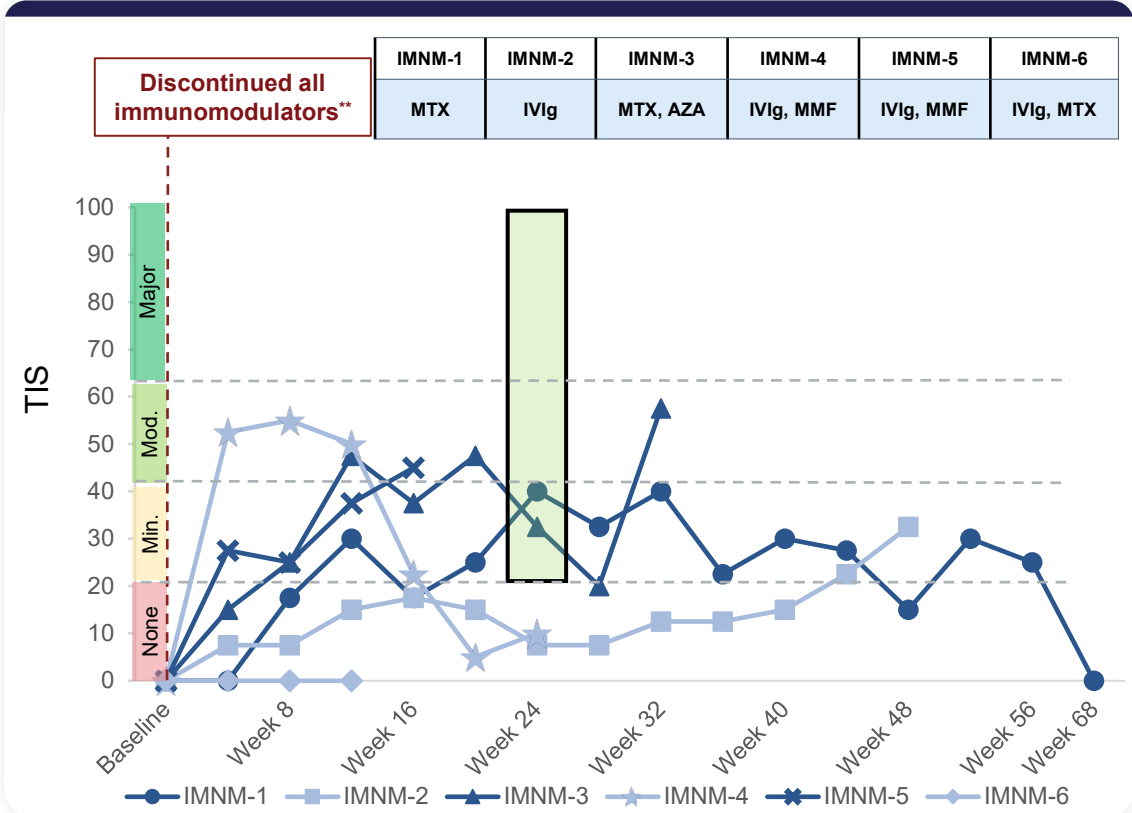
*As of 11 Sep, 2025.
ASyS, antisynthetase syndrome; CK, creatine kinase; FDA, Food and Drugs Administration; MMT-8, manual muscle testing 8; rese-cel, reseccabtagene autoleucel; U/L, units per liter.
Cabaletta Bio: Data on File.

Efficacy in IMNM Patients Following Rese-cel Infusion*

Minimal to moderate TIS response in patients whose antibodies decreased; lower and/or less consistent responses in patients without autoantibody decrease

Assessment at Week 24†	IMNM (baseline autoantibody)					
	IMNM-1 (SRP)	IMNM-2 (HMGCR)	IMNM-3 (SRP)	IMNM-4 (HMGCR)	IMNM-5 (HMGCR)	IMNM-6 (HMGCR)
IM-free	✓	-	✓	-	✓‡	-
Low dose or no GC	✓	-	✓	-	✓‡	-
TIS Response	Moderate	None	Minimal	None	Moderate‡	None‡
Complete and transient B cell depletion	✓	✓	✓	✓	✓‡	✓‡
Antibody trend§	↓→¶	→	↓¶	→	↓	→

Patients with antibodies decreased are in dark blue

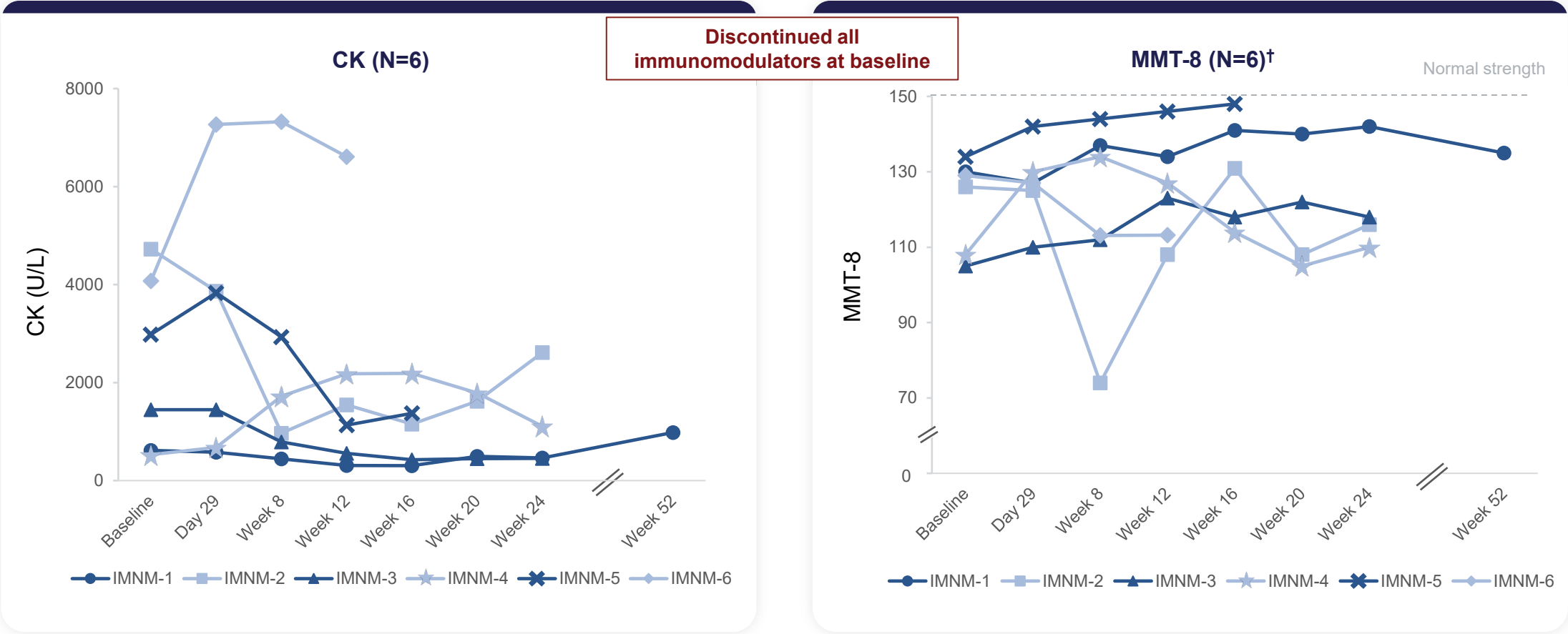


Modest and/or less consistent response in IMNM patients may be due to persistence of pathogenic autoantibodies²⁻⁴ from CD19-negative long-lived plasma cells despite complete B cell depletion. Additional patients are being evaluated in the Phase 1/2 study using modified entry criteria

*As of 11 Sep, 2025.
† Following agreement with the FDA, the primary endpoint for the upcoming pivotal study in IMNM is minimal TIS off all IM therapies and on low dose steroids (50% reduction or ≤ 7.5 mg/day) at Week 24; Week 52 will be evaluated as a secondary endpoint.
‡ At latest follow-up (IMNM-5: Week 16 and IMNM-6: Week 12). § Reflects trend from baseline to latest timepoint or timepoint prior to initiating confounding rescue medication. In IMNM-1, SRP antibody level trended up Week 36 to Week 52 but was lower than baseline.
¶ Based on the research-based, qualified, quantitative Luminex assay.
** IMNM-1 started IVIg after Week 68; IMNM-2 received GC between Weeks 4 and 8 and started IVIg after Week 12; IMNM-4 received GC burst after Week 12 and started IVIg and RTX at Week 24; IMNM-6 started MTX, IVIg, PEX, DARA after Day 29.
DARA, daratumumab; FDA, Food and Drugs Administration; GC, glucocorticoids; HMGCR, 3-hydroxy-3-methylglutaryl-coenzyme A reductase; IM, immunomodulatory medication; IMNM, immune-mediated necrotizing myopathy; IVIg, intravenous immunoglobulin; MMF, mycophenolate mofetil; MTX, methotrexate; N/A, not available; PEX, plasma exchange; rese-cel, resecabtagene autoleucel; SRP, signal recognition particle; TIS, total improvement score.
1. Cabaletta Bio: Data on File. 2. Pinal-Fernandez I, et al. Ann Rheum Dis. 2024;83(11):1549–1560. 3. Galindo-Feria AS, et al. Best Pract Res Clin Rheumatol. 2022;36(2):101767. 4. Müller, F, et al. Nat Med. 2025;31(6):1793–1797.

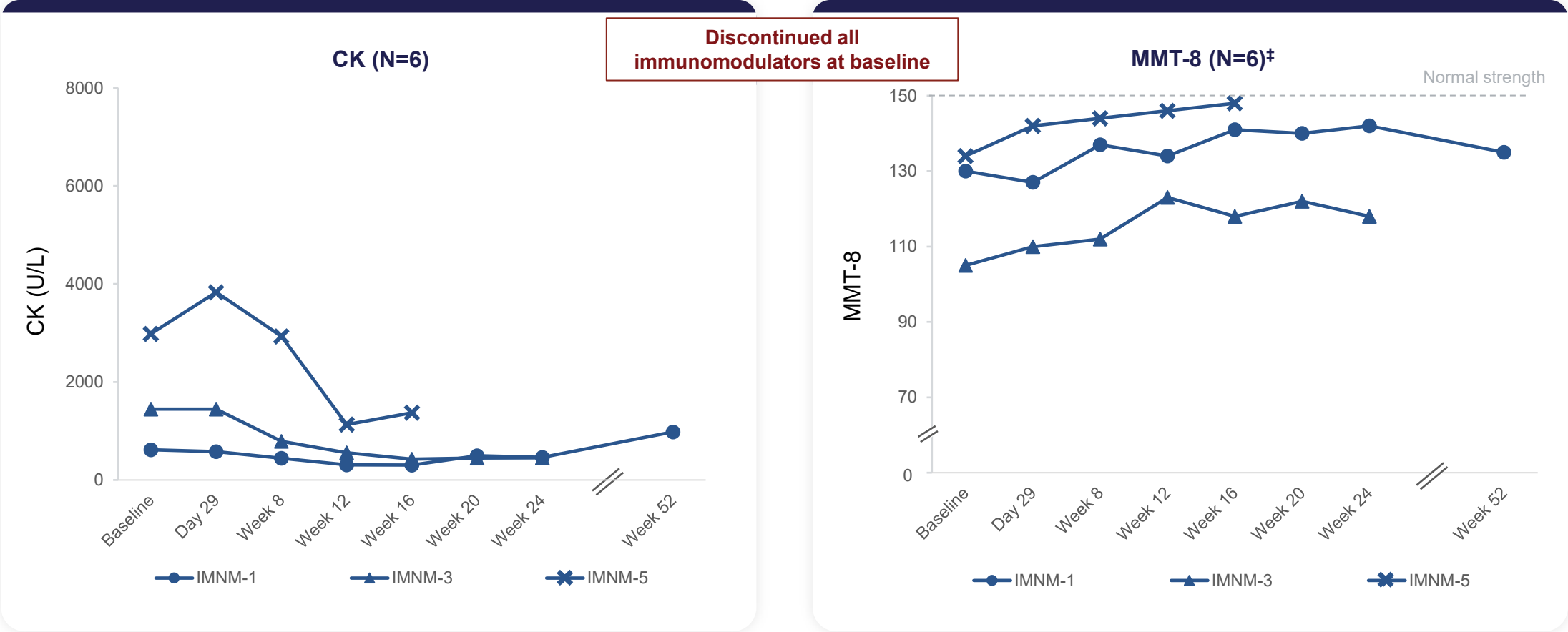
Efficacy in IMNM Patients Following Rese-cel Infusion*

CK and MMT-8 in patients with IMNM following rese-cel infusion



Efficacy in IMNM Patients with Autoantibody Decreases Following Rese-cel Infusion*

Improvement in CK and MMT-8 seen in three patients with IMNM, who also experienced reduction in autoantibody levels



*As of 11 Sep, 2025.
CK, creatine kinase; IMNM, immune-mediated necrotizing myopathy; MMT-8, manual muscle testing 8; rese-cel, resecabtagene autoleucel; TIS, total improvement score; U/L, units per liter.
Cabaletta Bio: Data on File.

Summary from Clinical and Translational Data: RESET Myositis™*



- Rese-cel was generally well tolerated across 13 IIM patients treated to date, including one patient with JIIM
 - Grade 1 CRS in 4 of 13 patients
 - No ICANS in any of the 13 patients
- Rese-cel peak expansion was observed at approximately 12 days after infusion
- B cells were completely and transiently depleted in peripheral blood within 1-2 weeks following rese-cel infusion
 - Transitional naïve B cells began repopulating within 2 to 3 months, indicating B cell reset
- The persistence or recurrence of autoantibodies suggests CD19-negative long-lived plasma cells may be the primary source of pathogenic autoantibodies in a subset of ASyS and IMNM patients with limited durability or response
- After discontinuing IM medications, patients demonstrated compelling clinical responses following rese-cel infusion
 - DM: 3 of 3 patients with sufficient follow-up achieved IM-free moderate TIS response or greater at Week 16
 - ASyS: 1 of 2 patients achieved IM-free moderate TIS response or greater at Week 16
 - In the setting of persistence or recurrence of autoantibodies, responses were not durable
 - IMNM: 2 of 4 patients with sufficient follow-up achieved IM-free TIS response at Week 24.
 - Antibodies persist in 3 of 6 patients who either did not achieve or maintain response

**Based on these data, Cabaletta is planning to initiate a pivotal cohort in DM & ASyS this year (FDA-aligned):
14 patients with 16-week primary endpoint of moderate TIS off IM & on no steroids or low dose†**

*As of 11 Sep, 2025.

†Low dose steroids is defined as 50% reduction from baseline or ≤7.5 mg/day

ASyS, antisynthetase syndrome; CRS, cytokine release syndrome; DM, dermatomyositis; FDA, US Food and Drug Administration; ICANS, immune effector cell-associated neurotoxicity syndrome; IIM, idiopathic inflammatory myopathy; IM, immunomodulatory medication; IMNM, immune-mediated necrotizing myopathy; JIIM, juvenile idiopathic inflammatory myopathy; rese-cel, rescabtagene autoleucel; RESET, REStoring SElf-Tolerance; TIS, total improvement score.

Cabaletta Bio: Data on File.

Acknowledgments

This is the collective work of many individuals



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- Mayo Clinic, Rochester
- Oregon Health & Science University
- Vanderbilt University Medical Center
- MD Anderson Cancer Center
- University of Chicago

Cabaletta Bio team

- Biometrics
- Clinical Development & Operations
- Computational Biology
- Manufacturing
- Medical Affairs
- Translational Medicine
- Quality and Compliance
- Regulatory Affairs

Bone marrow

Peripheral blood

