# Safety and Efficacy of Rese-cel (Resecabtagene Autoleucel) in Severe, Refractory Idiopathic Inflammatory Myopathy: Results from the Phase 1/2 cohorts of the RESET-IIM Clinical Trial

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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.

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

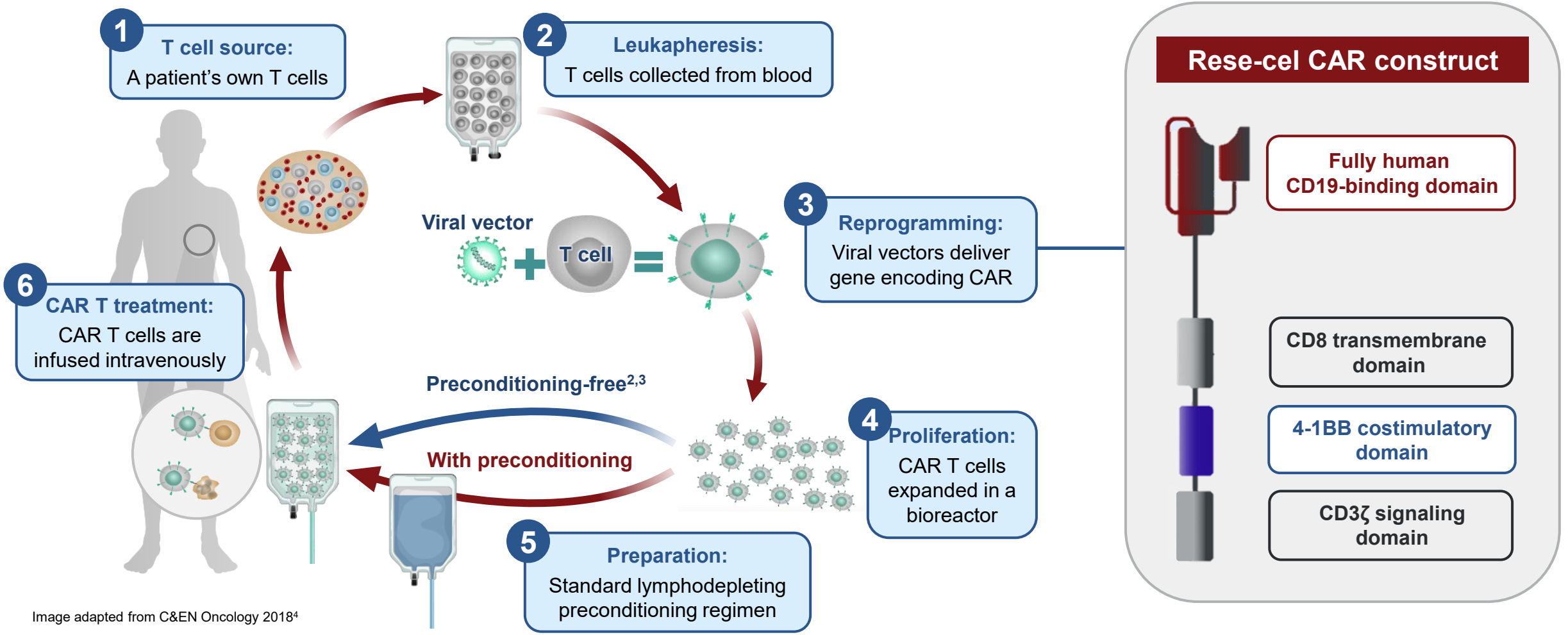


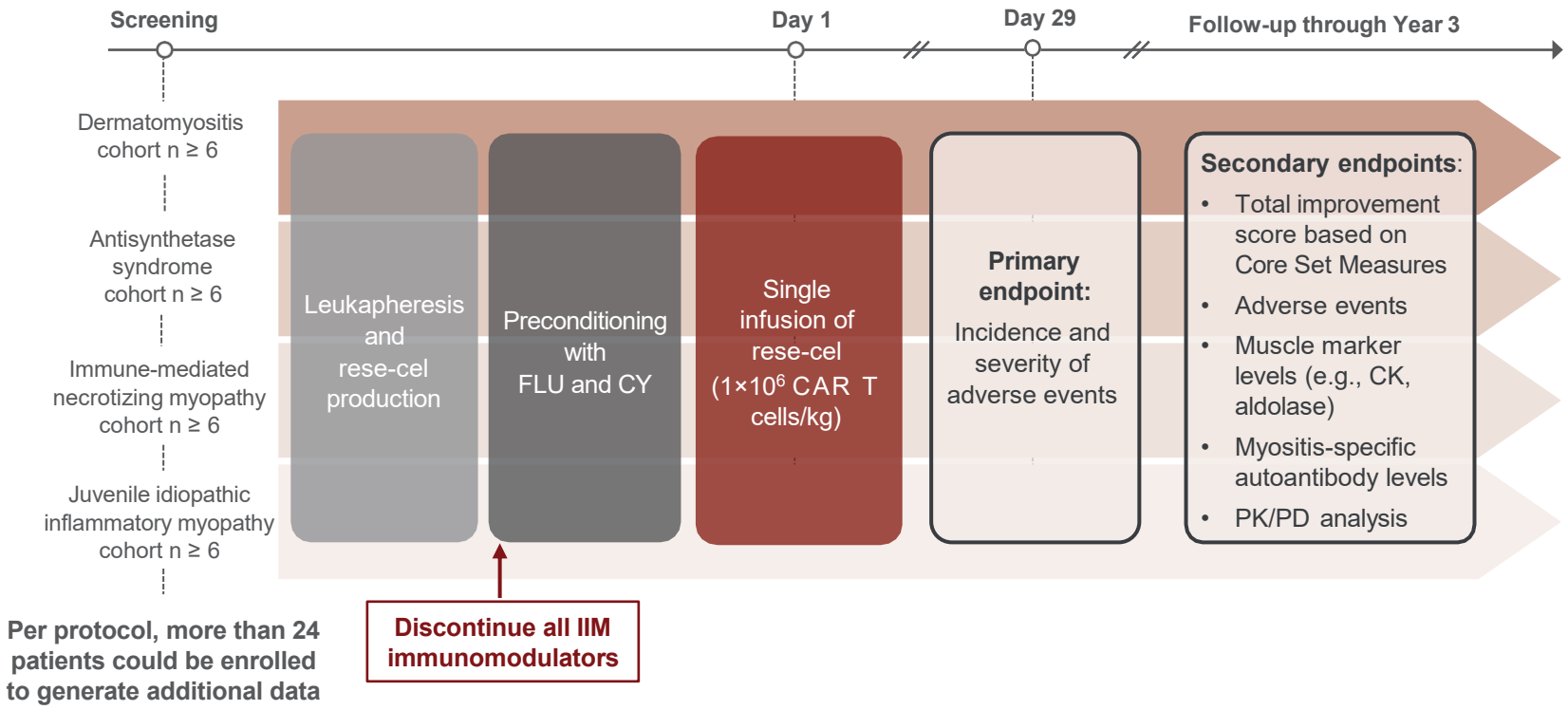

Image adapted from C&EN Oncology 2018[4]

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

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- 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 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 at: https://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<br>17%: NXP, SAE, MDA-5 | 100% Jo-1 | 67% HMGCR<br>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 (%)**<br>Grade 1 (fever only)<br>Grade 2 or above | **5 (29)**<br>5 (29)<br>0 (0) | **0 (0)**<br>0 (0)<br>0 (0) |
| Time to onset, median (range), days | 7 (4–12) | 0 |
| Duration, median (range), days | 5.0 (3–7) | 0 |
| Treatments, n (%)<br>Tocilizumab<br>Steroids<br>Anakinra | <br>5 (29)<br>1 (6)<br>0 (0) | <br>0 (0)<br>0 (0)<br>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 (%)<br>Febrile neutropenia, Grade 2 | <br>1 (6) |

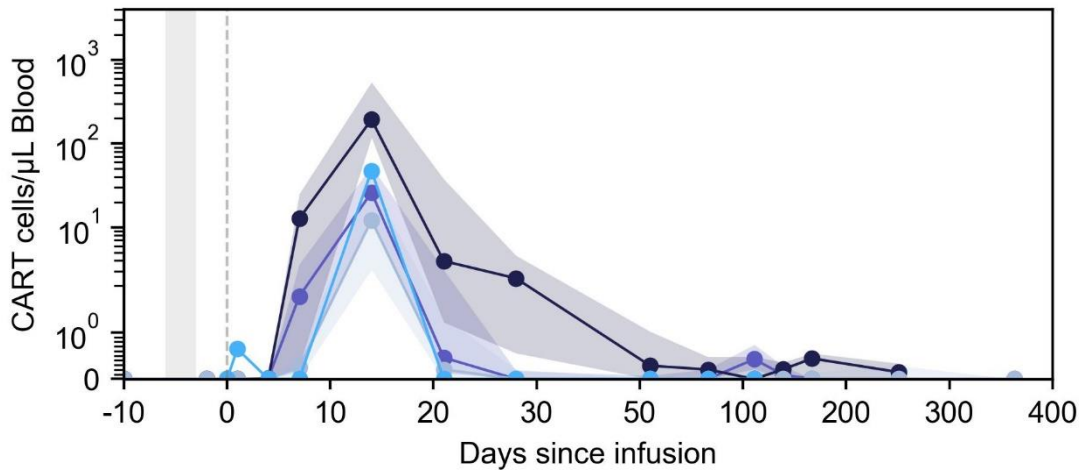
As of 16 Apr 2026.
*TEAEs of interest are reported to latest follow-up.
†Graded per ASTCT Consensus Grading Criteria.
‡Grade 3 or higher neutropenia, anemia, thrombocytopenia or pancytopenia lasting for more than 28 days.
§Grade 3 or higher (IgG level ≤400 mg/dL) and requiring treatment with external 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*

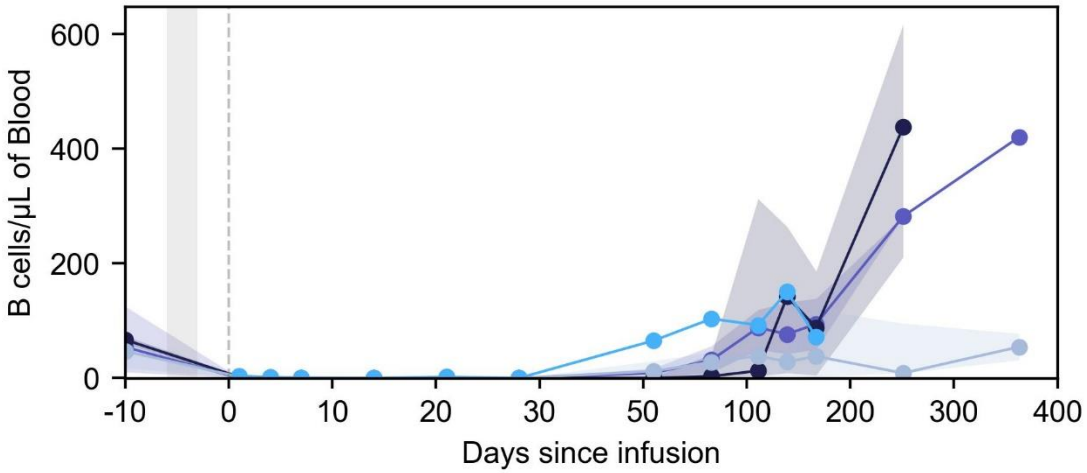
# Rese-cel Expansion and B Cell Kinetics[1,*]

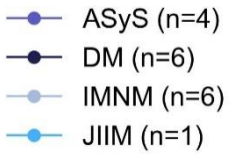
## Peak rese-cel expansion and peripheral B cell depletion occurred by 2 weeks post infusion

### Rese-cel Pharmacokinetics




### Pharmacodynamics
(B Cell Counts)†



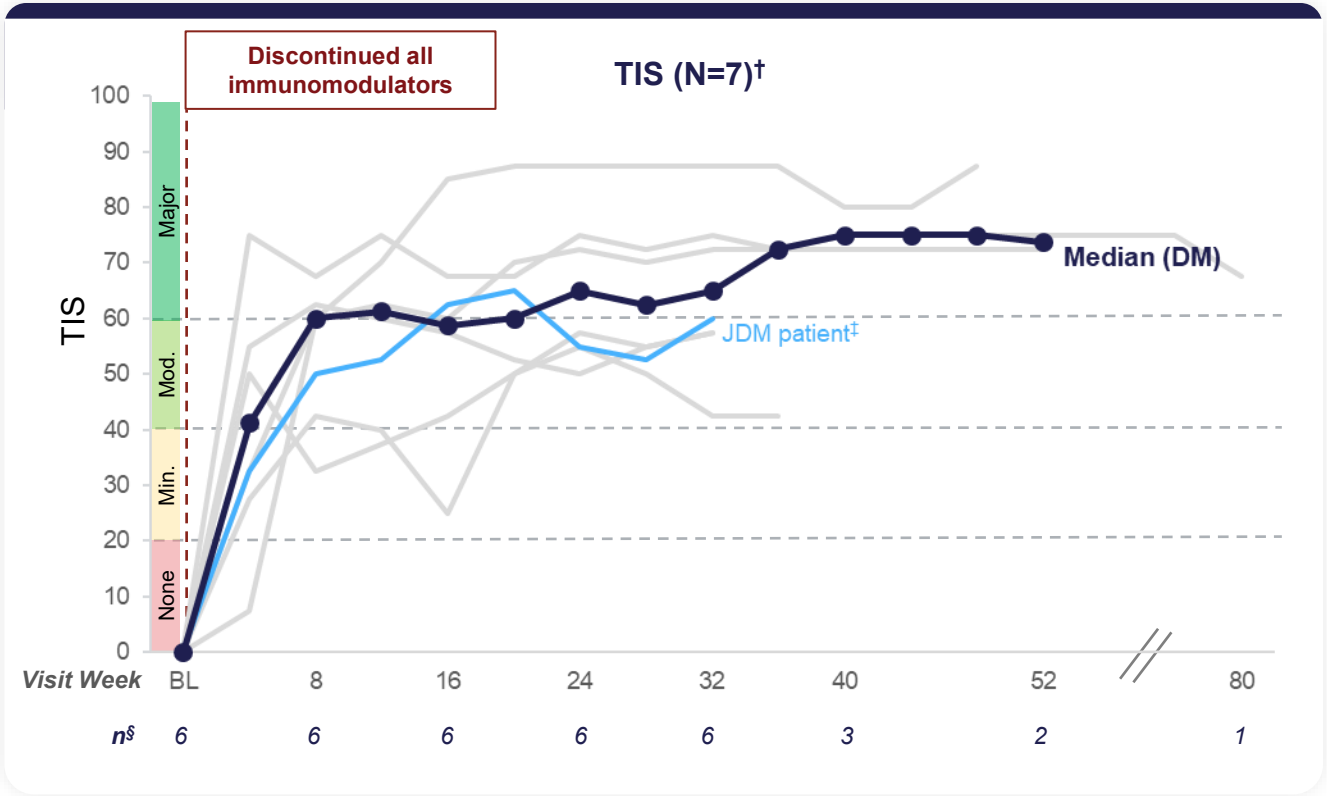

**Median time to B cell repopulation was approximately 2.3 months;**
**Repopulating B cells were predominantly transitional naïve, indicating deep B cell depletion and B cell reset[2]**

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 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%** |

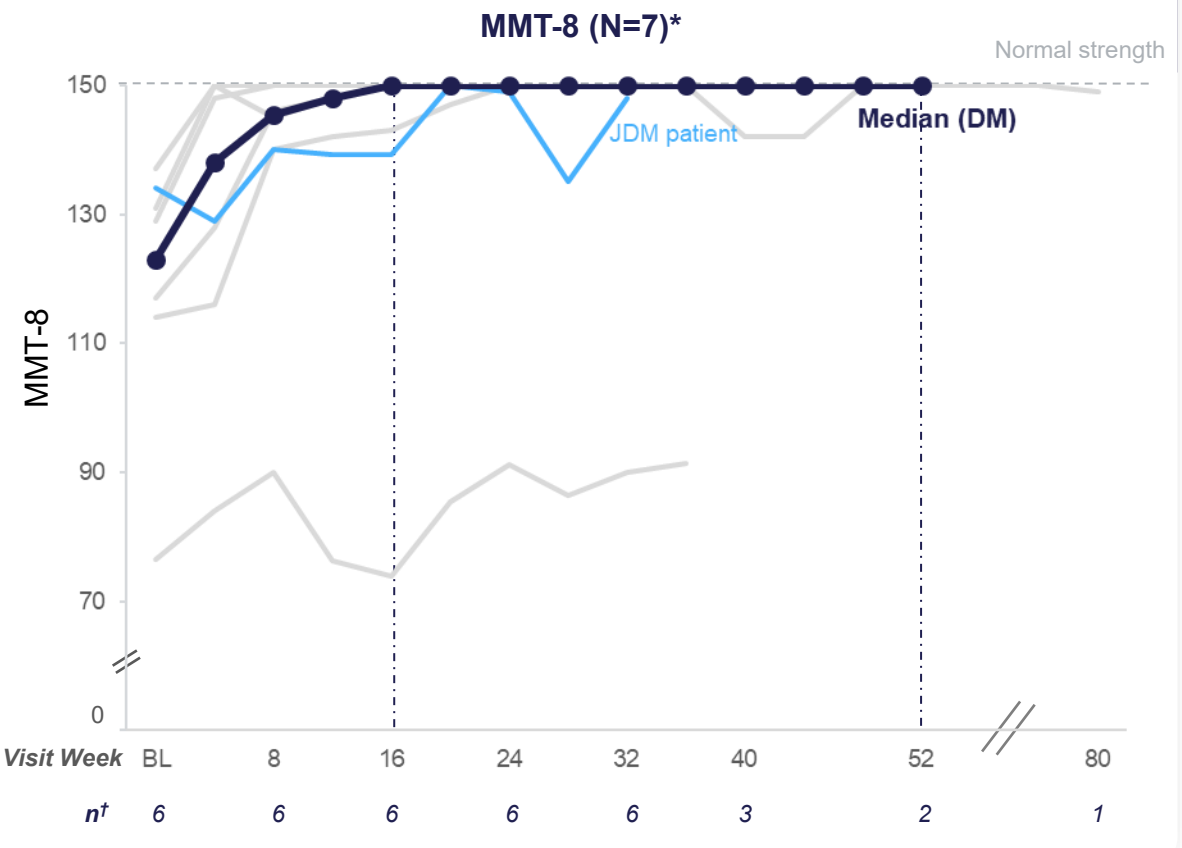



**5 of 6 DM patients and the JDM patient achieved the 16-week primary endpoint for the ongoing pivotal study and all of these patients maintained IM-free TIS response through latest follow-up, as long as 1.5 years**

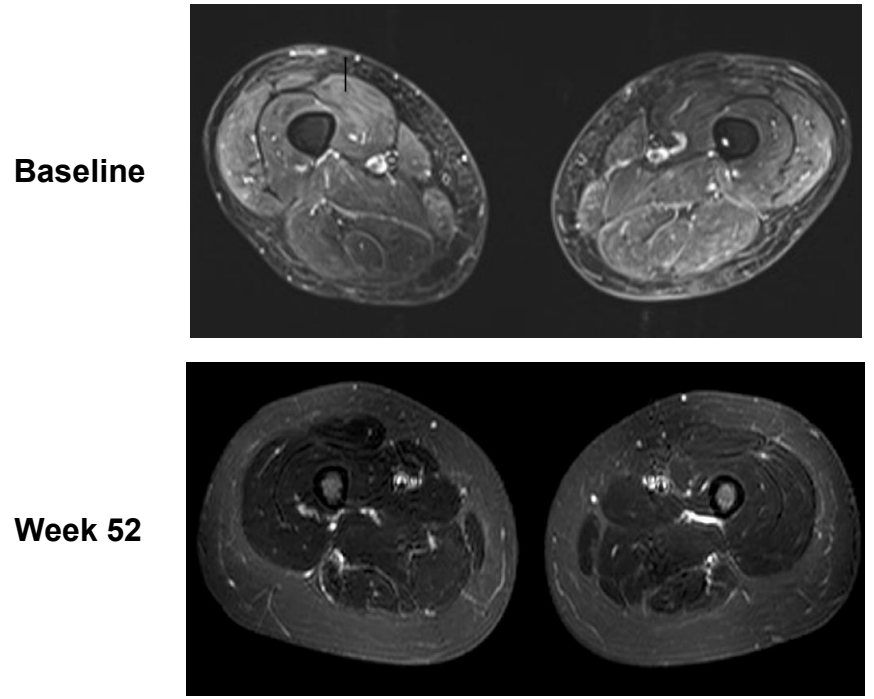
As of 16 Apr 2026.
*Low-dose steroids is defined as 50% reduction from baseline or ≤7.5 mg/day. †Missing data were imputed using last observation carried forward. ‡TIS threshold for a moderate response is ≥45 in patients with JIIM; TIS scale on the Y-axis reflects adult thresholds.
§Median and n numbers 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




MRI STIR imaging of Thigh (DM-2)



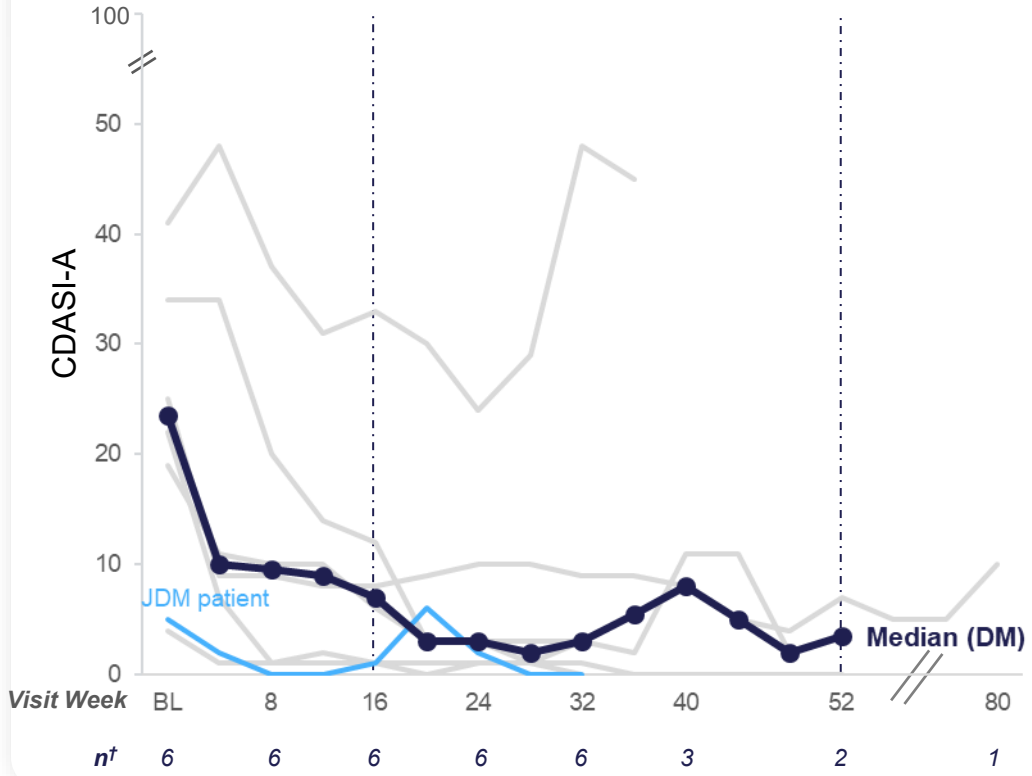

**Markedly reduced hyperintense signals at Week 52 indicate improvement of muscle inflammation**

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.

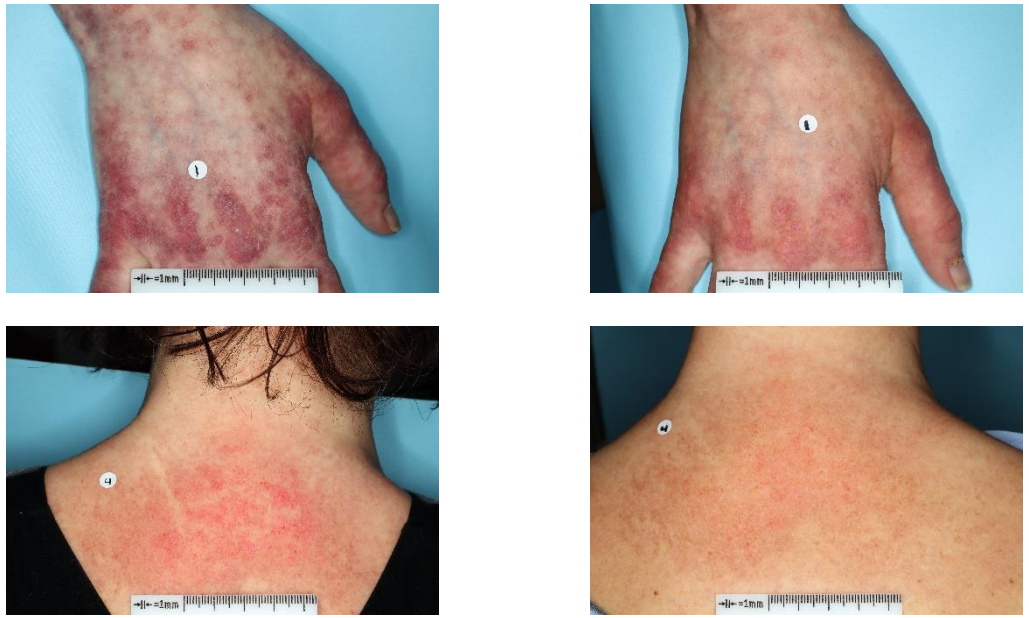
# Efficacy Data in DM and JDM Patients Following Rese-cel Infusion

## 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

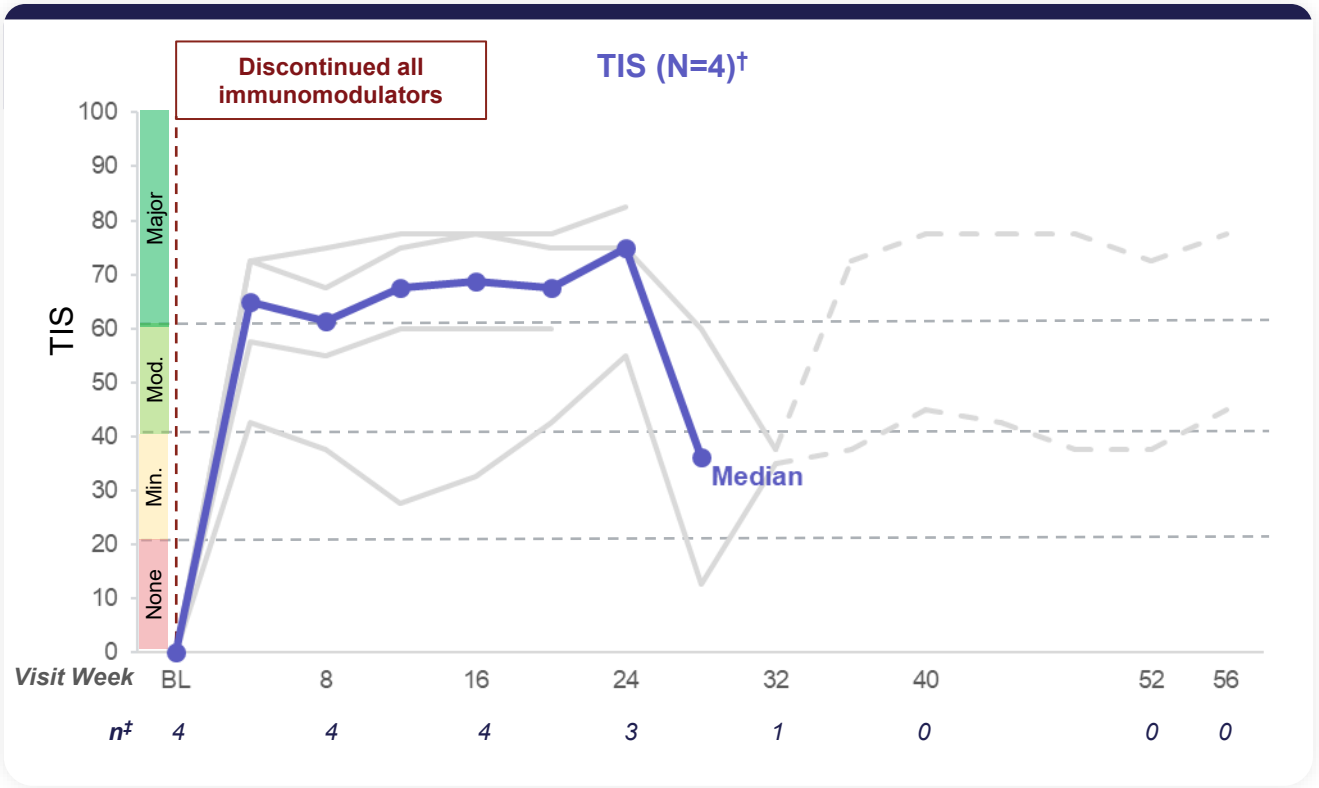
**Median 16.5-point improvement in CDASI-A at Week 16 among adults with DM with associated clinically visible improvement in skin manifestations off immunomodulators**

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

| 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%** |

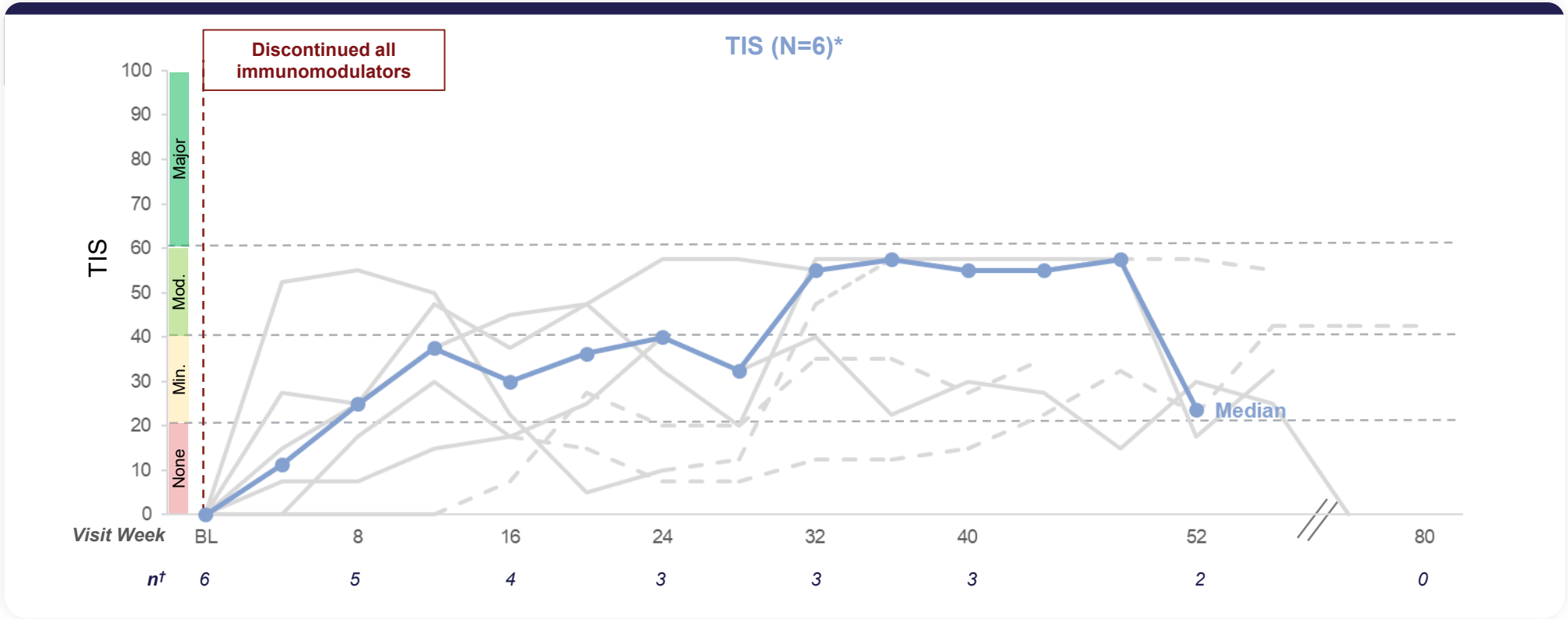



**Consistent with other CD19 CAR T data in ASyS patients, after a robust initial response, durability may be variable despite complete B cell depletion potentially due to persistent CD19-negative long-lived plasma cells**

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.
Cabaletta Bio: Data on File.

# Efficacy Data in IMNM Patients Following Rese-cel Infusion

3 of 6 patients with IMNM achieved minimal or moderate IM-free TIS response at Week 24




**Modest responses in IMNM patients could be potentially due to irreversible muscle damage or persistent CD19-negative long-lived plasma cells. Additional patients with confirmed evidence of muscle inflammation and less muscle damage are being evaluated**

As of 16 Apr 2026.
*Missing data were imputed using last observation carried forward. Dashed single patient trend lines represent patients receiving rescue immunomodulatory medications. †Median and n numbers are based on IMNM patients not receiving rescue immunomodulatory medications.
BL, baseline; IM, immunomodulatory medication; IMNM, immune-mediated necrotizing myopathy; rese-cel, resecabtagene autoleucel; TIS, total improvement score.
Cabaletta Bio: Data on File.

# Summary from Clinical and Translational Data: RESET-Myositis

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- 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 one 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
- IMNM: 3 of 6 patients achieved IM-free minimal or moderate TIS response at Week 24
  - Additional patients are being evaluated

**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; 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.

# Acknowledgments

This is the collective work of many individuals

**Patients and caregivers involved in the RESET-Myositis® clinical program**

**Site investigators and staff involved with these patients from the RESET-Myositis® clinical program**

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

**Cabaletta Bio team**

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

**Cabaletta Bio is currently enrolling a Registrational Open-Label Cohort of Rese-cel in Dermatomyositis and Antisynthetase Syndrome Adult Patients**

Scan to learn more about the RESET-Myositis trial: