# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): April 20, 2026**

# CABALETTA BIO, INC.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-39103** | **82-1685768** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **2929 Arch Street**<br>**Suite 600**<br>**Philadelphia, Pennsylvania** | **19104** |
| **(Address of Principal Executive Offices)** | **(Zip Code)** |

**Registrant's Telephone Number, Including Area Code: (267) 759-3100**

**Not Applicable**
**(Former Name or Former Address, if Changed Since Last Report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Securities registered pursuant to Section 12(b) of the Act:**

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $0.00001 per share | CABA | The Nasdaq Global Select Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 8.01 Other Events.**

On April 20, 2026, Cabaletta Bio, Inc. (the "Company") posted to the "Investors & Media" section of the Company's website at *www.cabalettabio.com* an updated corporate presentation (the "Corporate Presentation"). A copy of the Corporate Presentation is attached hereto as Exhibit 99.1 and is incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| | |
|---|---|
| 99.1 | Cabaletta Bio, Inc. Corporate Presentation, dated April 2026, filed herewith. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL Document). |

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**CABALETTA BIO, INC.**

Date: April 20, 2026

By: /s/ Steven Nichtberger
Steven Nichtberger
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 99.1

Cabaletta Bio®

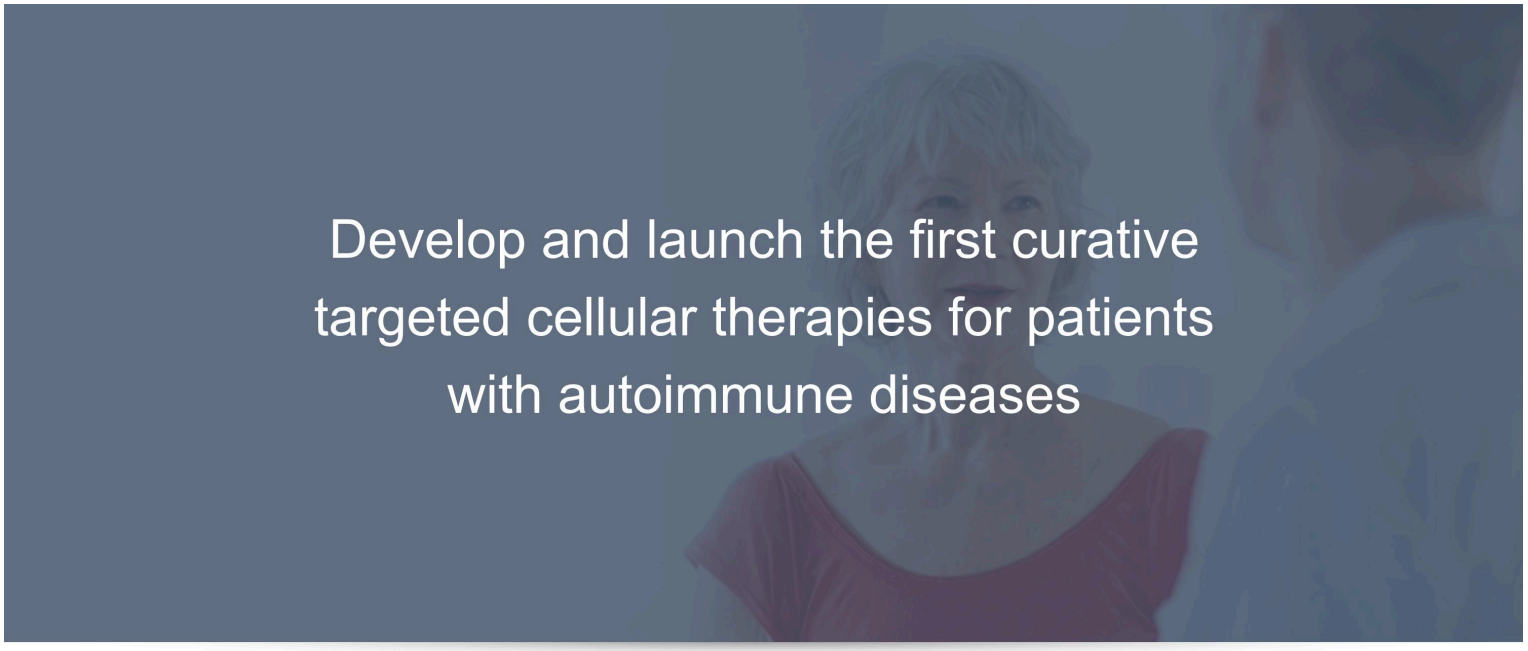
# Corporate Presentation

APRIL 2026

# Disclaimer

This presentation, including any printed or electronic copy of these slides, the talks given by the presenters, the information communicated during any delivery of the presentation and any question and answer session and any document distributed at or in connection with the presentation (collectively, the "Presentation") has been prepared by Cabaletta Bio, Inc. ("we," "us," "our," "Cabaletta" or the "Company") and may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to our business, operations, and financial condition, and include, but are not limited to, express or implied statements regarding our current beliefs, expectations and assumptions regarding: our business, future plans and strategies for our technology; our ability to grow our autoimmune-focused pipeline; the ability to capitalize on and potential benefits resulting from our research and translational insights, including those related to any similarly-designed constructs or dosing regimens; the anticipated market opportunities for rese-cel in patients with autoimmune diseases; the Company's business plans and objectives; our expectations around the potential success and therapeutic and clinical benefits of rese-cel, as well as our ability to successfully complete research and further development and commercialization of our drug candidates in current or future indications, including the timing and results of our clinical trials and our ability to conduct and complete clinical trials; expectation that clinical results will support rese-cel's safety and activity profile; our plan to leverage increasing clinical data and a unique development program for rese-cel; the timing, clinical significance and impact of clinical data read-outs, including the progress, results and clinical data from each of the patients dosed with rese-cel in the Phase 1/2 RESET-Myositis, RESET-SLE, RESET-SSc, RESET-MG and RESET-PV trials and our other planned activities with respect to rese-cel; our belief that rese-cel has the potential to provide drug-free, durable transformative clinical responses, through an immune reset; the Company's advancement of separate Phase 1/2 clinical trials of rese-cel and advancement of the RESET-PV and RESET-MS trials, with and without preconditioning, as applicable, including updates related to status, safety data, efficiency of clinical trial design and timing of data read-outs or otherwise; our ability to leverage our experience in autoimmune cell therapy; our ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner and timing thereof, and advance the trial as planned in our Phase 1/2 clinical trials of rese-cel; the timing of any planned regulatory filings for our development programs, including IND applications and interactions with regulatory authorities, including such authorities' review of safety information from our ongoing clinical trials and discussions with regulatory agencies on potential registrational pathway for rese-cel in various indications, and the timing of trial design related thereto; our ability to successfully complete our preclinical and clinical studies for our product candidates, including our ability to progress the trial; our plans and expectations regarding automated scalable manufacturing and no preconditioning and its potential to expand and accelerate access; our expectations that automation and elimination of preconditioning and apheresis will enhance patient experience; our expectation and timing for clinical manufacturing data with Cellares' automated manufacturing process and its ability to confirm GMP readiness, including supply chain logistics, as well as its potential to provide scalability for thousands of patients per year and to facilitate post-approval expansion; our ability to increase enrollment from our rapidly expanding clinical network in the RESET clinical trial program in the US and Europe; our ability to obtain and maintain regulatory approval of our product candidates, including our expectations regarding the intended incentives conferred by and ability to retain regulatory designations and the anticipated initiation of registrational cohorts and potential BLA submission; our expectation and timing for completion of dosing of most disease-specific cohorts; our expectations regarding opportunities based on market research; our ability to accelerate our pipeline to approval and launch and to develop transformative therapies for patients, including in collaboration with academic and industry partners and the ability to optimize such collaborations on, including timing thereof, our development programs; our ability to contract with third-party suppliers and manufacturers; our ability to execute our manufacturing strategy to enable expansion of clinical supply and efficiently scale commercial supply for rese-cel; our potential commercial opportunities, including value and addressable market, for our product candidates; our expectations regarding the potential commercial and economic benefits of preconditioning elimination and automated manufacturing, including its potential to reduce costs of goods, minimize capital investment requirements, and support efficient global expansion of rese-cel. 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.




Cabaletta Bio®

# Rese-cel[1]: Delivering on the promise of CD19-CAR T in autoimmunity

Pivotal myositis study enrolling; no preconditioning clinical data (PV & SLE) & automated manufacturing in 2026

- **Autologous CAR T has delivered reliable, durable, transformative outcomes for autoimmune patients[2]**
  - Rese-cel data: immunomodulator-free efficacy with a favorable safety profile using a single weight-based dose
  - Complete phase 1/2 data expected in systemic sclerosis and lupus in 1H26; myasthenia gravis data presented at AAN
- **Myositis: 17 patient single-arm study with planned 2027 BLA submission including potential for outpatient infusion**
  - Primary endpoint: moderate TIS off immunomodulators & on no or low dose steroids[3] at 16 weeks
  - All phase 1/2 patients with sufficient f/u who would have met inclusion criteria met the registrational primary endpoint[4]
- **Safety profile in first 40 patients dosed with preconditioning (PC) supports outpatient administration[4]**
  - 95% - No CRS (~67%) or Grade 1 CRS (~28% - fever); 95% - No ICANS[5]
- **No preconditioning data: early, near-complete symptom resolution in 2/3 autoimmune patients at threshold dose[4,6]**
  - Longer-term and dose-ranging data in RESET-PV and RESET-SLE anticipated throughout 2026
- **Automated manufacturing by Cellares offers potential scale to thousands of patients with minimal capital investment**
  - Initial patients dosed using automated, scalable manufacturing of rese-cel; initial data to be presented at ASGCT

**Safety profile of rese-cel in autoimmune patients supports outpatient use;**
**No preconditioning & automated scalable manufacturing can expand & accelerate access**

BLA – biologics license application; f/u – follow-up; PV – pemphigus vulgaris; SLE – systemic lupus erythematosus; TIS – total improvement score.
1. resecabtagene autoleucel; CABA-201
2. Solimani, Farzan, et al. "Clinical progress of engineered cellular immunotherapies for autoimmunity." Nature Biotechnology (2026): 1-16.
3. Low dose steroids is defined as 50% reduction from baseline or ≤7.5 mg/day.
4. As of data cut-off on September 11, 2025.
5. As of data cut-off on October 30, 2025
6. Basu, S. RESET-PV: Initial clinical and translational data evaluating rese-cel without preconditioning in pemphigus vulgaris. Presented at ESGCT 2025; October 6-10, 2025; Seville, Spain.

# Transformative value proposition with PC elimination & automation

Removing PC should expand access while automated manufacturing should reduce COGS & increase scale

**Elimination of PC**

- Expands the market
- Catalyzes outpatient use
- Reduces resource utilization
- Impacts patient and provider experience

**Automated Manufacturing**

- Minimal capital investment
- Scalability to produce thousands of patient runs per year
- Substantially reduced COGS
- Facilitates global expansion

**Transformative Value Proposition**

- Differentiated product profile
- Typical 'biologic' margins
- Potential to address larger autoimmune indications including T1D, UC and RA

**1H26**

***PV: PC free rese-cel data including longer-term follow up at the initial dose***
***SLE: PC free rese-cel data including early data at the initial dose***
***Initial clinical experience with rese-cel manufactured by Cellares***

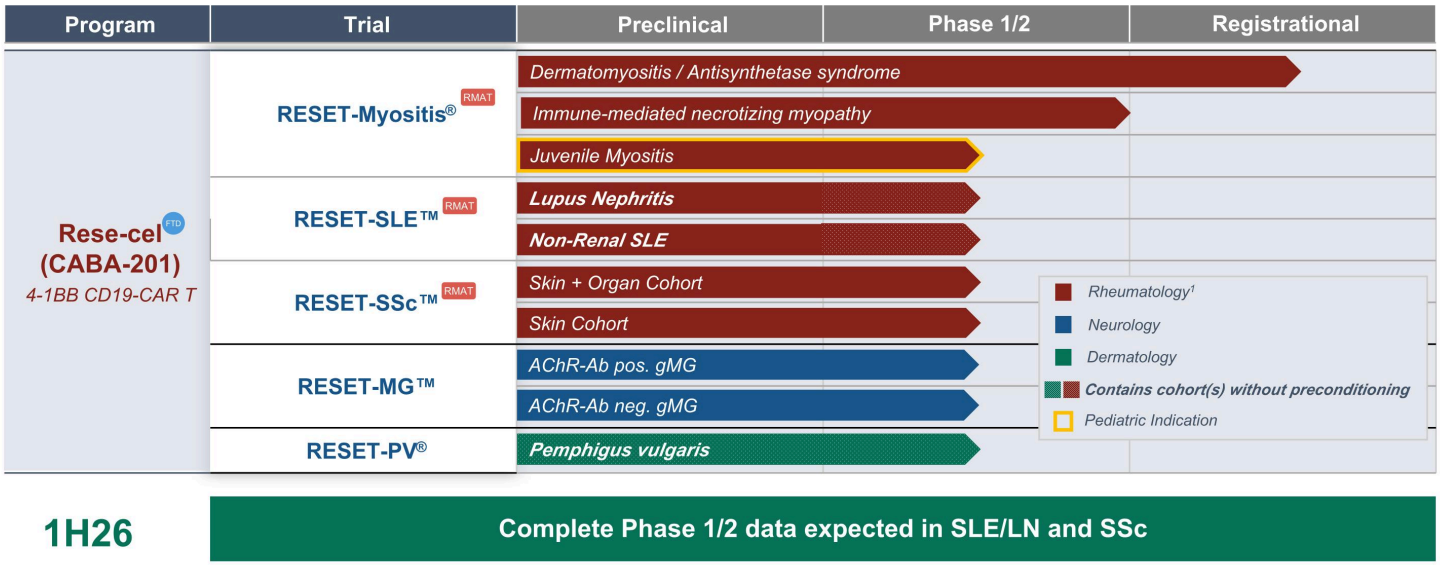
**2H26**

***Longer-term PC free rese-cel data from the PV & SLE dose cohorts and from patients receiving rese-cel manufactured by Cellares***

COGS – Cost of goods sold; PC – Preconditioning; PV – Pemphigus vulgaris; SLE – Systemic lupus erythematosus; RA – Rheumatoid arthritis; T1D – Type 1 diabetes; UC – Ulcerative colitis.

# Innovative clinical strategy to support accelerated regulatory path

SLE registrational design in hand; SSc pivotal design anticipated 1H26 and MG anticipated mid-2026



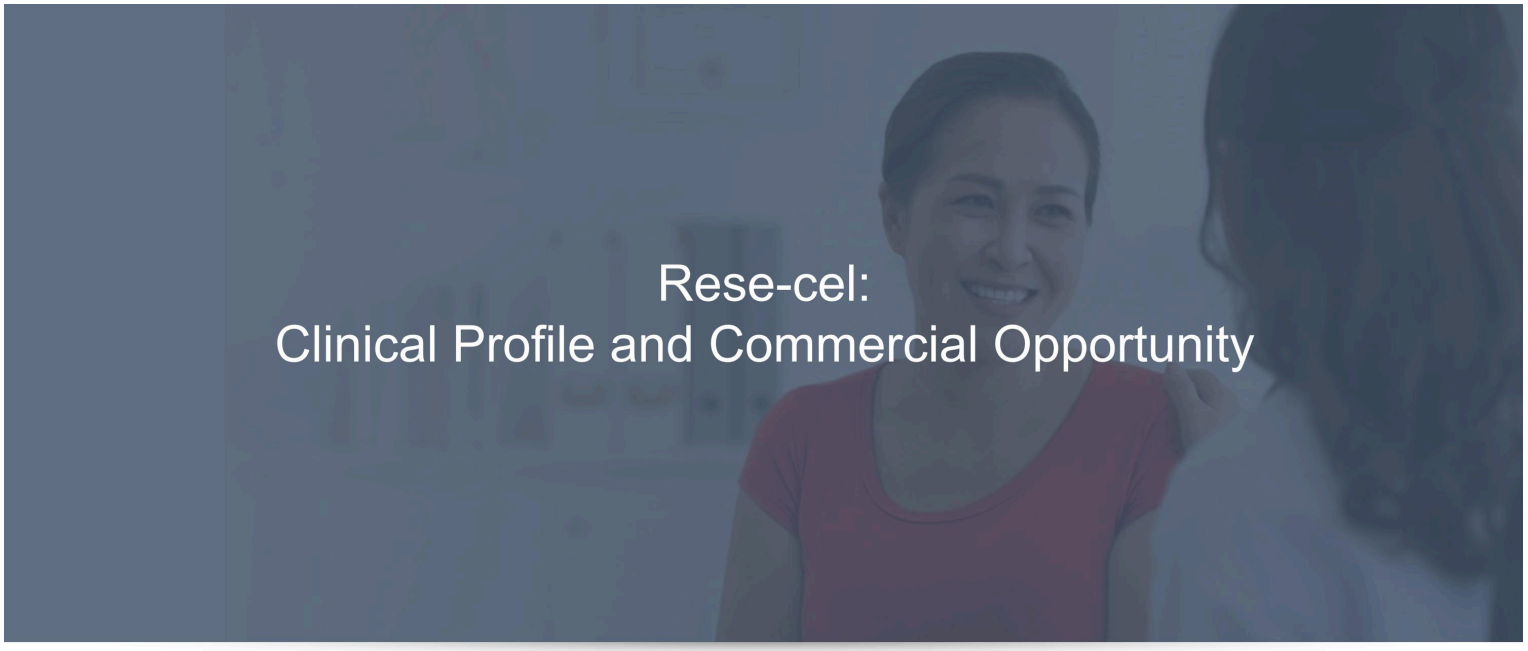

**1H26** — **Complete Phase 1/2 data expected in SLE/LN and SSc**

RESET™ – **RE**storing **SE**lf-**T**olerance; Ab – Antibody; AChR – Acetylcholine receptor; gMG – Generalized myasthenia gravis; 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.



# Rese-cel:
# Clinical Profile and Commercial Opportunity

Cabaletta Bio®

# RESET™ program advancing trials in a broad portfolio of diseases

Broad portfolio of trials designed to address high unmet need and realize the potential of rese-cel

— No PC Cohorts —

— No PC only –

| Myositis | SLE/LN | SSc | gMG | PV |
|---|---|---|---|---|
|  |  |  |  |  |
| ♀>♂ | ♀>♂ | ♀>♂ | ♀>♂ | |
| Typical onset middle age | Affects young women & people of color | Middle age onset common | Bimodal age of onset | Pure autoantibody & B-cell mediated autoimmune disease |
| Only FDA-approved therapy is IVIg in DM | ~30-40% with lupus nephritis, which carries ~25% risk of death or ESRD within 10y | Progressive skin & organ fibrosis with lung, cardiac, renal damage | Profound weakness that can be disabling | Characterized by painful blisters & erosions |
| Three-fold increased mortality due to lung & cardiac involvement | | Average survival of 12y | Risk for myasthenic crises, with respiratory failure | |
| ***U.S. Prevalence*** | | | | |
| ~80k | ~320k | ~90k | ~100k | ~15k |

*Rheum* *Neuro* *Derm*

SLE – Systemic lupus erythematosus; DM – Dermatomyositis; SSc – Systemic sclerosis; gMG – Generalized myasthenia gravis; PC – Preconditioning; ESRD – End-stage renal disease; PV – pemphigus vulgaris

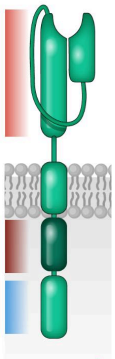
# Rese-cel: CD19-CAR T specifically designed for autoimmunity

Rese-cel binder with similar *in vitro* & *in vivo* activity to construct used in academic studies in autoimmunity[1,3]

Fully human anti-CD19 binder

4-1BB costimulatory domain

CD3-ζ signaling domain



Rese-cel[4]

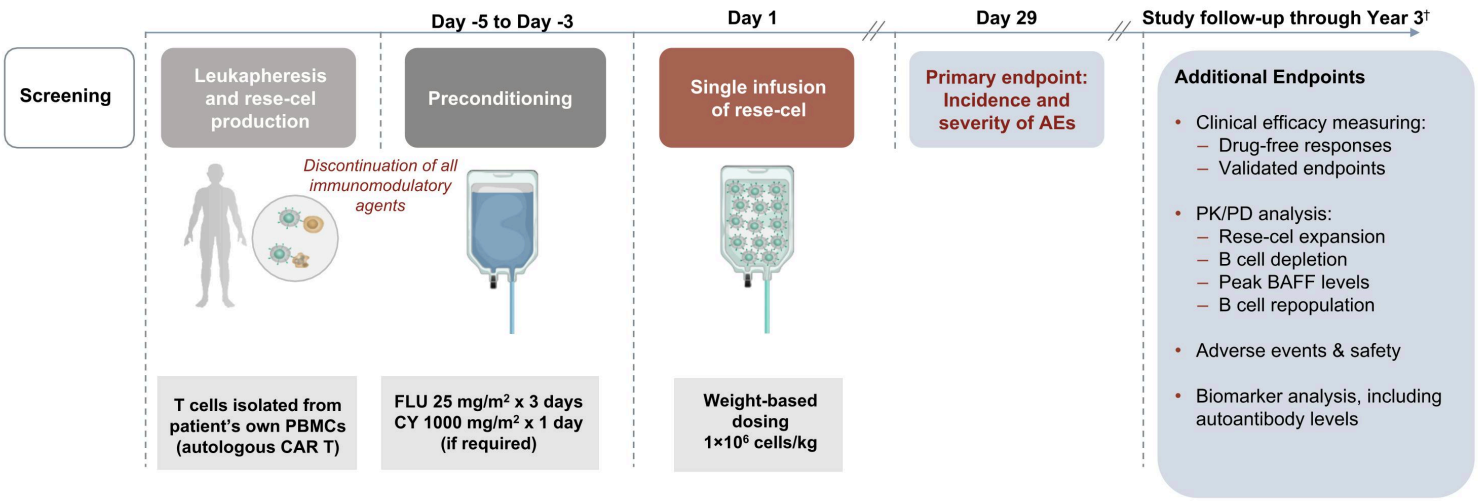
**Rese-cel product design & clinical / translational data**

- **4-1BB costimulatory domain with fully human binder**
  - **Binder with similar affinity & biologic activity to academic FMC63 binder while binding to the same epitopes[1,2]**
- **Same weight-based dose as in academic studies**
  - **Potential to provide immune reset based on clinical and translational data[5]**
- **Patients treated with rese-cel have shown compelling clinical responses with safety data that supports outpatient use for autoimmune patients[6]**


1. Peng BJ, et al. Mol Ther Methods Clin Dev. 2024;32(2):101267.
2. Dai, Zhenyu, et al. "Development and functional characterization of novel fully human antiCD19 chimeric antigen receptors for T-cell therapy." Journal of Cellular Physiology 236.8 (2021): 5832-5847.
3. Müller, Fabian, et al. "CD19 CAR T-Cell Therapy in Autoimmune Disease—A Case Series with Follow-up." New England Journal of Medicine 390.8 (2024): 687-700.
4. Maschan, Michael, et al. "Multiple site place-of-care manufactured anti-CD19 CAR-T cells induce high remission rates in B-cell malignancy patients." Nature Communications 12, 7200 (2021) Transmembrane domain in rese-cel is CD8α vs. TNFRSF19 (Troy) utilized in the academic construct. The two transmembrane domains have not been shown to have a significant difference in function or IFNγ production in preclinical studies. The CD8α transmembrane domain is employed in tisagenlecleucel.
5. Volkov, Jenell, et al. "Case study of CD19 CAR T therapy in a subject with immune-mediate necrotizing myopathy treated in the RESET-Myositis phase I/II trial." Molecular Therapy 32.11 (2024): 3821-3828.
6. Abstract 1733: Safety and Efficacy of CABA-201, a Fully Human, Autologous 4-1BB Anti-CD19 CAR T Cell Therapy in Patients with Immune-Mediated Necrotizing Myopathy and Systemic Lupus Erythematosus from the RESET-Myositis™ and RESET-SLE™ Clinical Trials. ACR 2024.

# RESET™ clinical trials have consistent design principles[1]

## Many of the RESET trials share common elements of preconditioning, dose, and study design



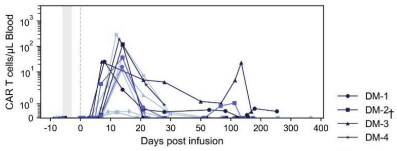

†Follow up period encompasses at least 15 years in total, ed to regulatory guidance for CAR T cell therapies.
AE, adverse event; CABA, Cabaletta Approach to B cell Ablation; FLU, fludarabine; CY, cyclophosphamide; PBMC, peripheral blood mononuclear cell; PD, pharmacodynamics; PK, pharmacokinetics; RESET, REstoring SElf-Tolerance; SLE, systemic lupus erythematosus; SSc, systemic sclerosis.
Cabaletta Bio: Data on file; 1. Peng BJ, et al. Mol Ther Methods Clin Dev. 2024;32(2):101267.

# Rese-cel expansion & B cell kinetics across indications*

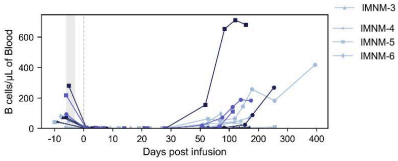
Peak rese-cel expansion and transient peripheral B cell depletion occurred within ~2 weeks post infusion

## RESET-Myositis

### Rese-cel Pharmacokinetics*

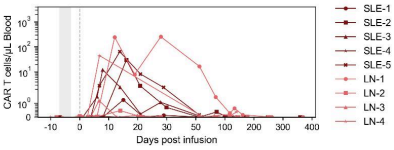



### B Cell Kinetics

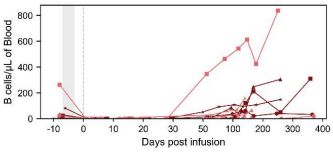



## RESET-SLE

### Rese-cel Pharmacokinetics**

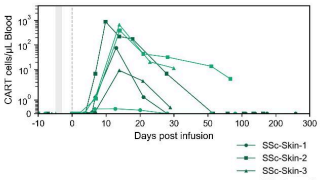



### B Cell Kinetics

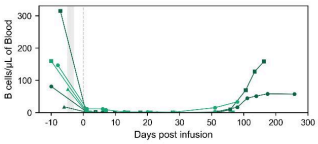



## RESET-SSc

### Rese-cel Pharmacokinetics

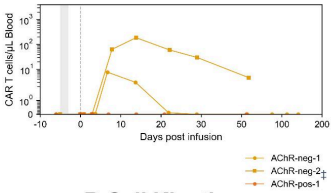



### B Cell Kinetics

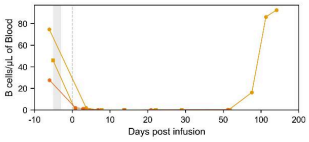



## RESET-MG

### Rese-cel Pharmacokinetics




### B Cell Kinetics




**Peripheral B cells begin repopulating ~2 to 3 months after rese-cel in patients with sufficient follow-up***

*All data is as of 11 Sep, 2025, except DM-3 which includes Week 24 data as of 08 Oct 2025.
**LN-1 had prolonged rese-cel detection due to TCR activation that corresponded to longer time to B cell repopulation. LN-4: follow up ongoing
† DM-3 rese-cel PK at Week 20 was artifactually elevated due to low circulating lymphocyte counts.
‡ Reduced rese-cel expansion observed in AChR-pos-1 may be attributed to patient's continued use of azathioprine, a prohibited medication, until day of infusion (Day 1).
ASyS, antisynthetase syndrome; CAR, chimeric antigen receptor; DM, dermatomyositis; IMNM, immune-mediated necrotizing myopathy; LN, lupus nephritis; rese-cel, resecabtagene autoleucel; RESET, REstoring SElf-Tolerance; SLE, systemic lupus erythematosus, SSc, systemic sclerosis, TCR, T cell receptor.
Cabaletta Bio: Data on file.

# Demographics & CRS/ICANS in 1st 40 rese-cel patients by indication

Across 4 RESET™ studies, 95% of patients with no CRS or Grade 1 CRS (fever) and 95% with no ICANS[1]

**Baseline characteristics of autoimmune disease patients treated with rese-cel**

| | RESET-Myositis | RESET-SLE | RESET-SSc | RESET-MG |
|---|---|---|---|---|
| Number of patients | 15 | 10 | 9 | 6 |
| Age, years, mean (SD) | 51.7 (14.6) | 30.4 (7.6) | 53.1 (12.3) | 57.5 (9.8) |
| Sex, % female | 53.3 | 80.0 | 66.7 | 66.7 |
| Duration of disease, years, mean (SD) | 5.4 (3.7) | 9.8 (5.0) | 2.2 (1.3) | 5.1 (5.3) |

**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 (33.3) | 3 (30.0) | 4 (44.4) | 1 (16.7) | 13 (32.5% CRS) |
| CRS Grade 1, n (%) | 5 (33.3) | 3 (30.0) | 3 (33.3) | 0 (0.0) | 11 (27.5% G1 CRS) |
| CRS Grade 2, n (%) | – | – | 1 (11.1) | 1 (16.7) | 2 (5% G2 CRS) |
| Time to CRS onset, days* (mean) | 7.4 | 7.3 | 8.5 | 7.0 | 7.7 days |
| CRS duration†, days (mean) | 4.6 | 3.0 | 3.0 | 2.0 | 3.5 days |
| ICANS‡ n (%) (Grade) | – | 1 (10) (G4) | 1 (11.1) (G3) | – | 2 (5% 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 ASH 2025 with data cut-off as of October 30, 2025.

# CAR T may eliminate active disease & use of expensive medications

Rese-cel safety profile permits outpatient administration which can facilitate favorable reimbursement

## Cancer CAR T: Safety profile often requires inpatient infusion, affecting reimbursement

**Cancer patients experience early and frequent CRS/ICANS following CAR T therapy, which increases inpatient admissions and shifts Medicare reimbursement to the DRG system.**

Majority of oncology patients treated with CAR T therapy experience CRS within first 5 days post-infusion[1]

Many cancer patients are insured under Medicare, which has inpatient **DRG-018** reimbursement

## Rese-cel: Safety profile facilitates outpatient infusion, which can favorably impact reimbursement

**Commercial**

Myositis & SSc patients often commercially insured (60%-75%)[2,3]

CRS less frequent & severe, delayed onset → potential outpatient administration

Outpatient CAR T infrastructure exists at many centers

**Medicare**

Outpatient administration supports viable Part B Medicare payments

RESET clinical site footprint can be leveraged to generate early adopters

1. Ferreri, Christopher J., and Manisha Bhutani. "Mechanisms and management of CAR T toxicity." Frontiers in Oncology 14 (2024): 1396490.
2. Smoyer-Tomic KE, et al. BMC Musculoskelet. Disord. 2012 Jun 15;13:103. doi: 10.1186/1471-2474-13-103.
3. Gale, Sara L., et al. "Characterizing disease manifestations and treatment patterns among adults with systemic sclerosis: a retrospective analysis of a US healthcare claims population." Rheumatology and therapy 7.1 (2020): 89-99.

# RESET™ program designed for outpatient administration at launch

Outpatient administration reduces administrative burden and improves patient and provider accessibility

**INPATIENT MODEL**

Limited patient beds
and resource infrastructure

- Increases inpatient resource pressure: ↑ total cost of care, human resource and bed space demands
- Reduces eligible patients treated

**OUTPATIENT MODEL**

More favorable safety profile
reduces need for inpatient admission

- Reduces use of hospital resources; Increases throughput
- Reduces conflicts with cancer patient use of in-patient beds

# Rese-cel commercial model – manufacturing and COGM

Health status of patient population and slower disease progression improve manufacturing cost efficiency

## In oncology, disease progress & out of specification (OOS) rates increase costs and reduce margins

**Late-stage oncology patients have high drop-off rate due to rapid disease progression and compromised T cell fitness, leading to higher manufacturing OOS rates[1,2,3]**

Increased OOS rates; ↑ COGM + ↓ revenue since out of spec products not reimbursed

+

Disease progression reduces revenue capture because unused product not reimbursed

+

Reduced eligible patients, resulting in economies of scale not being achieved

+

Manufacturing capacity constraints → delayed commercial ramp-up

## In autoimmunity, healthier patients & fully automated rese-cel mfg, should support lower COGM

Autoimmune patients are not heavily pretreated with chemotherapy → more fit immune cells that support reliable manufacture, reducing COGM

Autoimmune patients rarely progress as rapidly as cancer patients → more reliable revenue realization for manufactured product

Building manufacturing capacity at CDMOs to support successful launch; Cellares automation has the potential to facilitate post-approval expansion

COGM – Cost of goods manufactured


1. U.S. Food and Drug Administration. Kymriah (tisagenlecleucel) Prescribing Information. Revised 2025, U.S. Food and Drug Administration.https://www.fda.gov/media/107296/download
2. U.S. Food and Drug Administration. Breyanzi (lisocabtagene maraleucel) Prescribing Information. Revised 2025, U.S. Food and Drug Administration.https://www.fda.gov/media/145711/download
3. U.S. Food and Drug Administration. Yescarta (axicabtagene ciloleucel) Prescribing Information. Revised 2025, U.S. Food and Drug Administration.https://www.fda.gov/media/108377/download

# Myositis: Unmet Need & Clinical Data

Cabaletta Bio®

# Myositis: High rates of disability & increased risk of mortality

Highly concentrated treatment network in the US; dermatomyositis represents ~75% of this market

## High disease burden: disability & mortality

- Typical patient is a middle-aged female who experiences muscle weakness, fatigue, pain, shortness of breath and difficulty swallowing
  - Moderate to severe disability (40% to 65%)[1]
  - Assisted walking devices (18% to 38%)[1]
- The **risk of mortality is ~3 times higher** than the general population, primarily due to cancer and lung & cardiac complications[2]
  - ~20% mortality < 5 years with standard immunosuppressive treatment[3]

*"I find it **very difficult to get up from a regular chair**, I need boosters or assistance from somebody else. Walking, my **gait has really suffered**. My stability walking has suffered as well, and I **can't lift anything more than five or eight pounds**. So doing stuff is difficult. Bending down is very difficult. **I can't get up from the floor if I fall.**"*

**"John"**
*61-year-old male with ASyS[4]*
*~10 yrs since diagnosis*

*"It just **affected every aspect of my life. Just work, family, social life, own wellbeing.** It just pours into everything else with that."*

**"Erica"**
*44-year-old female with DM[4]*
*~2.5 yrs since diagnosis*

**Subtype prevalence in the U.S.**

**~60,000 pts**[5,6]
Dermatomyositis (DM)

**~15,000 pts**[7,8]
Anti-synthetase syndrome (ASyS)

**~7,500 pts**[5,9]
Immune-mediated necrotizing myopathy (IMNM)


1. Opinc AH, Brzezinska OE, Makowska JS. Disability in idiopathic inflammatory myopathies: questionnaire-based study. Rheumatol Int. 2019;39(7):1213-1220.
2. Marie I. Morbidity and mortality in adult polymyositis and dermatomyositis. Curr Rheumatol Rep. 2012;14(3):275-285.
3. Schiopu E, Phillips K, MacDonald PM, Crofford LJ, Somers EC. Predictors of survival in a cohort of patients with polymyositis and dermatomyositis: effect of corticosteroids, methotrexate and azathioprine. Arthritis Res Ther. 2012;14(1):R22.
4. Primary market research conducted via third-party, blinded interviews with myositis patients, conducted in 2024.
5. Khoo 2023 6. Kronzer 2023 7. Coffey 2021 8. Dahal 2022 9. Shelley 2022

# Myositis: Limited treatment options for ~80k U.S. patients

IVIg is the only approved therapy (only for patients with the adult dermatomyositis subtype)

## Autoimmune disease with B cells component

- Idiopathic inflammatory myopathies (IIMs, or myositis) are a group of autoimmune diseases characterized by inflammation and muscle weakness

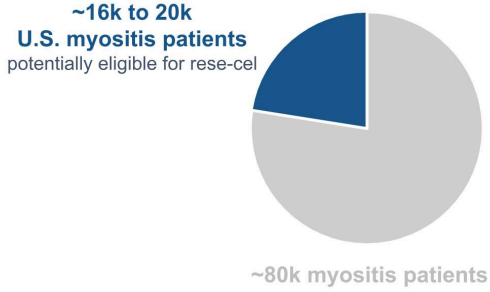
## Limited treatment options[1]

- Common therapies: steroids plus an immunomodulator (i.e. methotrexate, azathioprine, mycophenolate, rituximab)
- IVIg (intravenous immunoglobulin), the only FDA-approved therapy, is approved in adult dermatomyositis
- Therapies can carry potential long-term side effects such as serious infections and organ damage
- Despite existing therapies, disease is often refractory
- Two therapies in Phase 3 development, Brepocitinib and Vyvgart®, demonstrated improvement with chronic administration added onto existing immunomodulatory medications

**Eligible U.S. myositis patients[2]**

***Myositis patients with moderate to severe, refractory disease potentially eligible for rese-cel***

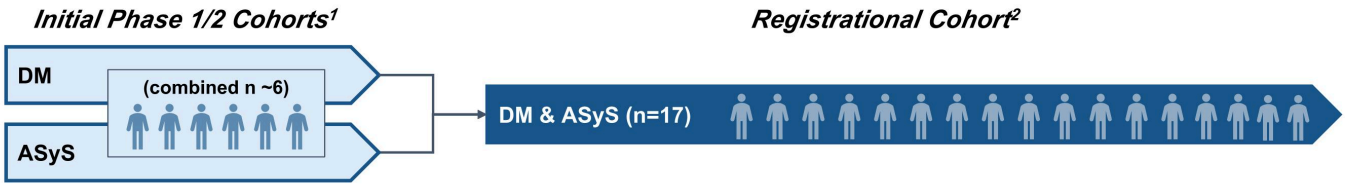
*(per analysis of quantitative research with ~240 myositis-treating physicians)*




1. Lundberg, Ingrid E., et al. "Idiopathic inflammatory myopathies." Nature Reviews Disease Primers 7.1 (2021): 86.
2. Analysis from quantitative survey of U.S. myositis-treating physicians, conducted 2Q25. N = ~240.

# Myositis registrational cohort – Key design elements

Single-arm cohort including DM/ASyS patients with a primary endpoint at 16 weeks




- Expansion of current RESET-Myositis trial to include registrational cohort in DM / ASyS (~60k / ~15k US patients)
- **Primary Endpoint**: Moderate or Major TIS response @ Week 16 off all immunomodulators and off or on low-dose[3] steroids
- Expanded trial to 17 patients to ensure approximately 14 DM patients can enroll based on natural U.S. prevalence estimates
- Confirmed current dose of 1 million cells/kg in a single infusion
- Safety database ~100 autoimmune patients at ≥1-month of follow-up (with at least 35 myositis patients)
  - ~70% of the safety database already enrolled across the RESET clinical development program[4]

**Registrational trial initiated with planned 2027 BLA submission**

TIS, total improvement score.
1. Pediatric submission based on data available at the time of adult submission from ongoing Ph 1/2 study (no new study) to support pediatric label claim
2. Size of myositis registrational cohort based on key statistical parameters and estimated background remission rate in myositis.
3. Low dose steroids is defined as 50% reduction from baseline or ≤7.5 mg/day.
4. As of October 24, 2025.

# Baseline characteristics: First 13 patients in RESET-Myositis*

## All patients had active, refractory disease despite multiple immunomodulatory agents, including IVIg

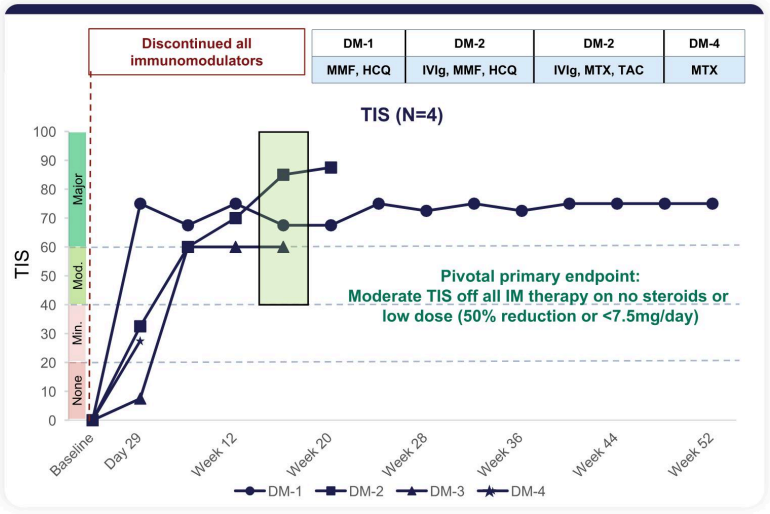
| | DM N=4 | ASyS N=2 | IMNM N=6 | JIIM N=1 |
|---|---|---|---|---|
| **Mean age, years (min, max)** | ~58 (45, 72) | ~44 (39, 48) | ~55 (33, 64) | 14 |
| **Female, n (%)** | 3 (75) | 1 (50) | 1 (17) | 1 (100) |
| **Years since diagnosis, mean (min, max)** | 3.0 (2.0, 3.6) | 9.2 (3.6, 14.8) | 4.5 (1.4, 8.8) | 8.5 |
| **Myositis-specific autoantibody** | 50% TIF1-γ<br>25% NXP, 25% SAE | 100% Jo-1 | 67% HMGCR<br>33% SRP | NXP-2 |
| **Baseline disease activity†** | | | | |
| **Mean MMT-8** | 109.6 | 129.5 | 122.0 | 134.0 |
| **Median CK, U/L** | 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; JIIM, 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.

# DM: Efficacy data following rese-cel infusion*

## 3 of 3 patients with DM with sufficient follow-up achieved major TIS responses at Week 16

| 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§ |



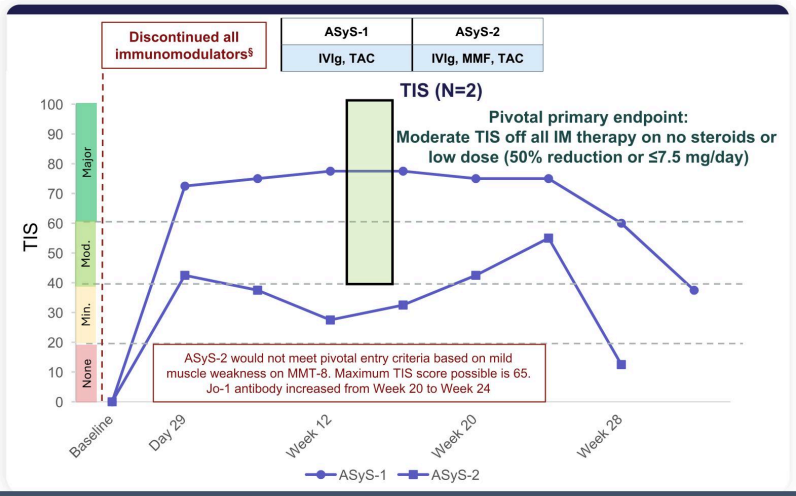

**After discontinuation of all IM medications, 3 of 3 DM patients achieved the 16-week primary endpoint for the upcoming pivotal study of at least moderate TIS response**

*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, resecabtagene 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.

# ASyS: Efficacy data following rese-cel infusion*

## Patient who would meet key inclusion criteria in registrational cohort achieved a major TIS response at Week 16

| 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 | ✓ | ✗ |



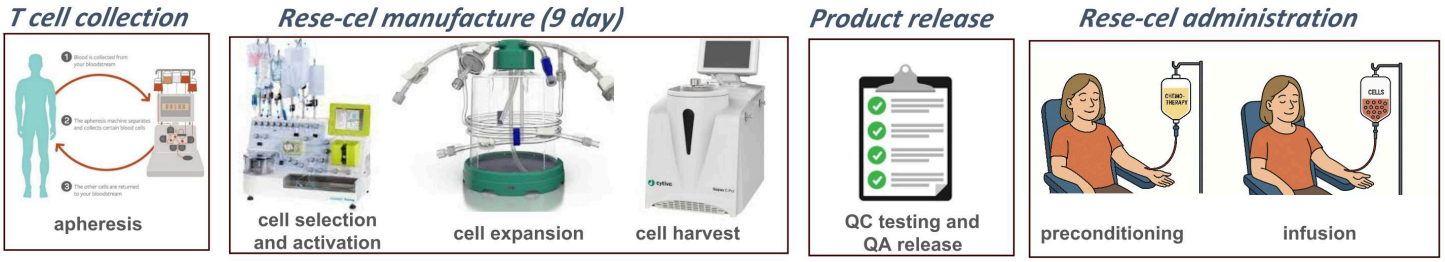

**Responses to CD19-CAR T among some ASyS patients may be time-limited by the recurrence or persistence of pathogenic autoantibodies[1–3] from CD19-negative long-lived plasma cells despite complete B cell depletion**

*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, resecabtagene 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.


Cabaletta Bio®

# Rese-cel commercial process preliminary comparability established

Reliable process with >90% manufacturing success rate in first ~70 patients[1]

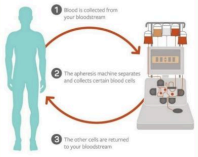
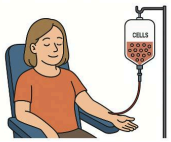
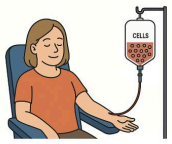



- Process A - Early clinical process
- Process B – Commercial-ready manufacturing process
  - Substantially closed process reducing contamination risk
  - Partially automated manufacturing process improving process consistency
  - 3-fold higher capacity per facility footprint than original Process A
- FDA feedback received on comparability between Process A and Process B
  - Preliminary data enables use of previously dosed patients in safety database

1. Across Process A and Process B; only 1 failure attributed to patient starting material.

# Advancing breakthrough innovations to improve scalability and costs

Automation and elimination of preconditioning and apheresis could enhance patient experience

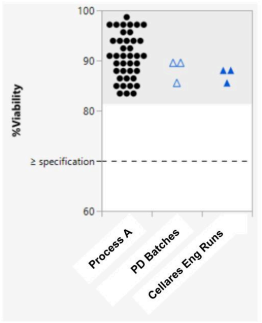
| | *T cell collection* | *Rese-cel manufacture and harvest (9 day)* | *Product release* | *Rese-cel administration* |
|---|---|---|---|---|
| CURRENT |  apheresis |  cell selection and activation  cell expansion  cell harvest |  post-production testing and QA review |  preconditioning  infusion |
| INNOVATIONS | ***Blood draw to replace apheresis[1,2]*** |    ***Cellares Cell Shuttle[3]*** • ***Fully closed, end-to-end automation*** • ***Rapid & global scalability*** • ***Shorter turn-around-time*** | |  ***One outpatient infusion without preconditioning[4]*** |

1. Stratton et al, ESGCT 2024. Poster available at https://www.cabalettabio.com/technology/posters-publications
2. (https://d1io3yog0oux5.cloudfront.net/_cdcc45a1b07d9c1e0fc529e815f21ec3/cabalettabio/db/947/8240/pdf/Whole+Blood+Mfg+Poster+ESGCT+2024.pdf)
3. Automation run feasibility completed under TAP program. Video on Cellares technology can be viewed here: https://vimeo.com/947203843/cd59569f16.
4. Under evaluation in an ongoing study in Pemphigus Vulgarus (NCT004422912); presented at ESGCT Conference 2025, presentation is available at https://www.cabalettabio.com/technology/posters-publications.

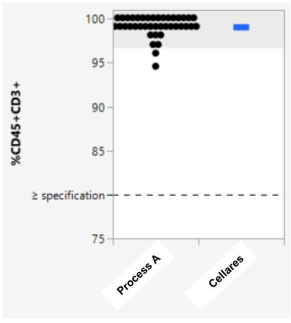
# Rese-cel engineering runs with Cellares supported INDa clearance

## Three successful engineering runs[3] completed in 2025 led to IND amendment (INDa) clearance

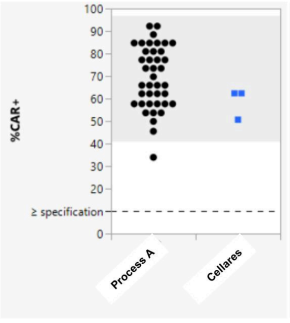
**Viability[1]**
(assesses T cell health)



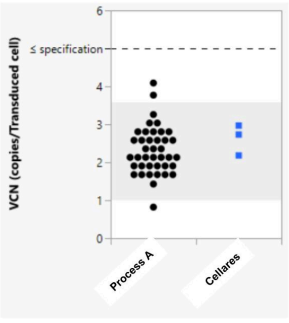

**%CD45+ CD3+**
(Total T cells produced)



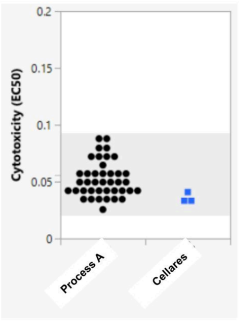

**%CD3+ CAR+**
(Total CAR-T cells produced)




**Vector copy number**
(Amount of vector per cell)

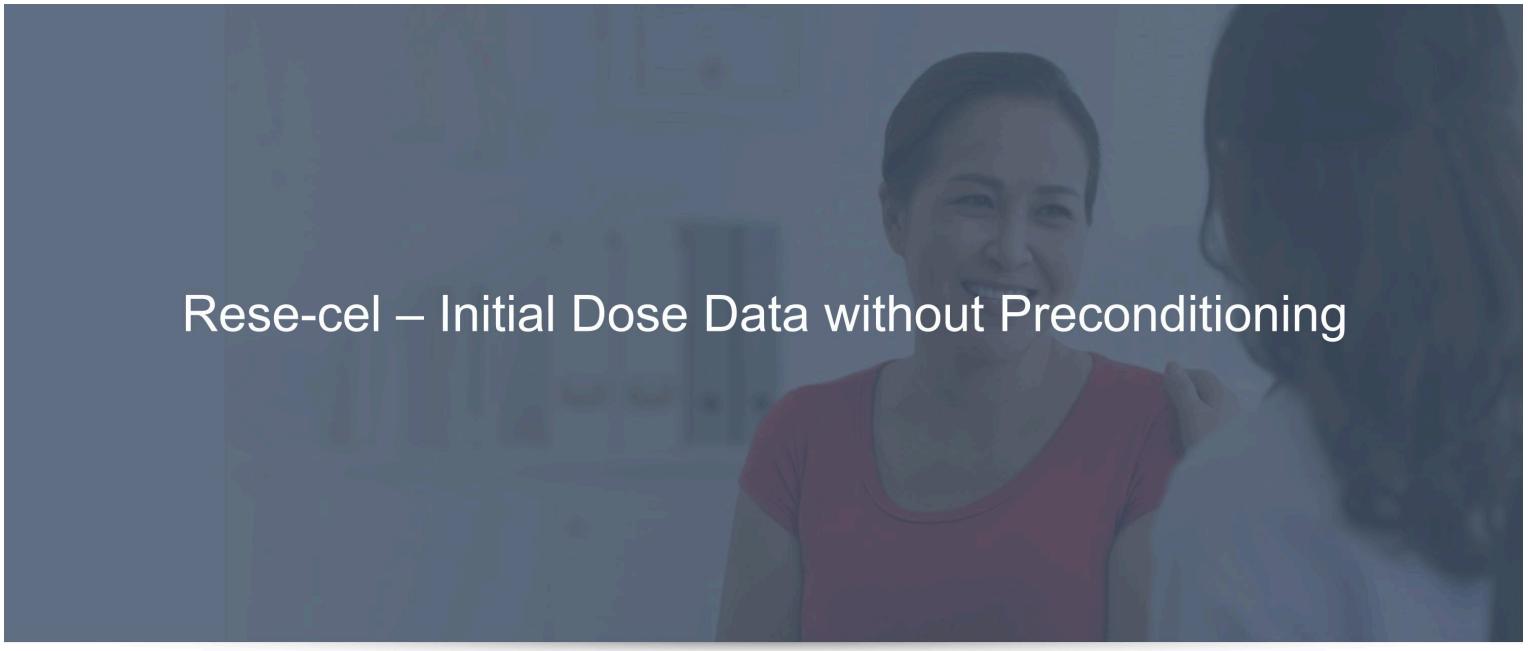



**EC 50[2]**
(Product potency)




**Clinical manufacturing experience with Cellares' automated manufacturing process anticipated in 1H26 to confirm GMP readiness, including supply chain readiness, with the Cellares manufacturing platform**

Note: Shaded areas represent historical ranges defined by tolerance intervals that covers 90% of the population with 95% confidence.
1. Cellares used Celleca for cell count to enable automated testing, while historical Process A data were collected using NC200. Data generated in Cabaletta Analytical Development lab using NC200 showed Engineering batches are within historical ranges.
2. Effective Concentration 50, which is a measurement of product potency in a validated luciferase-based assay, designed for potency release testing on manufactured product. Lower EC50 indicates greater potency of product.
3. Shaded area in the graphs indicate range of process comparability, based on historic process data.



# Rese-cel – Initial Dose Data without Preconditioning

Cabaletta Bio®

# Summary of rese-cel without preconditioning (PC), initial dose cohort*

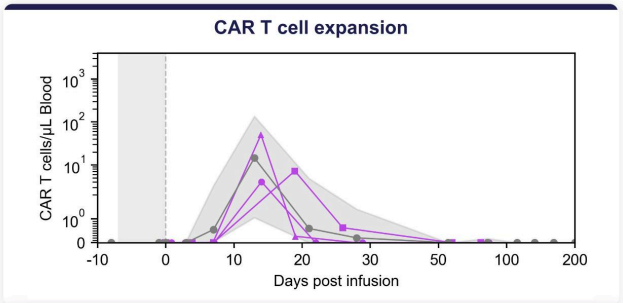
Early clinical activity observed without preconditioning; low dose rese-cel may be a 'threshold' dose

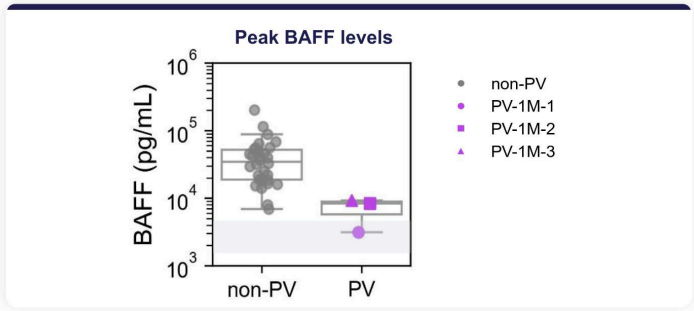
- Clear evidence of biologic and clinical activity in all three PV patients in the initial dose cohort
  - PDAI improvements were present in all three and were compelling in two of the three patients
  - All patients remain off all immunomodulators while GCs are being tapered from low doses
- Peripheral B cell elimination was observed in the two patients with the greatest clinical response
  - BAFF induction in these two patients was at the low end of the range of rese-cel with PC
- Rese-cel persistence without PC was similar to patients who received rese-cel with PC
  - Peak persistence was not impacted by absence of PC and occurred slightly later without PC
- IFNγ induction in non-PC patients was at the higher end of the range observed in PC patients
  - Higher levels may be attributable to higher B cell burden in PV patients and/or absence of preconditioning
- Rese-cel was generally well tolerated in PV patients without PC[1]
  - Based on limited data in the first three patients without PC, CRS rate was similar in rese-cel patients with PC

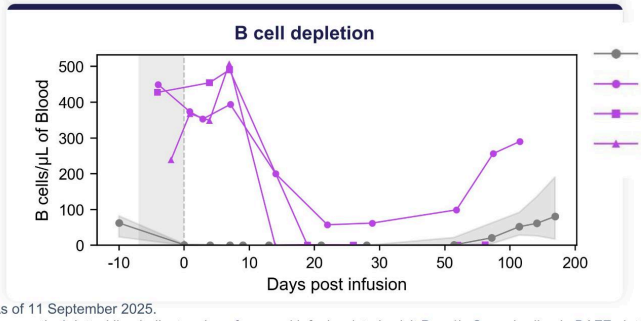
*As of 11 September 2025. Cabaletta Bio: Data on file.
BAFF, B cell activating factor; CRS, cytokine release syndrome; GC: glucocorticoids; PDAI, pemphigus disease area index; PV, pemphigus vulgaris; rese-cel, resacabtagene autoleucel; IFNγ, interferon-gamma
1. Standard preconditioning in RESET trials consists of fludarabine 25 mg/m$^2$ x 3 days and cyclophosphamide 1000 mg/m$^2$ x 1 day.

# Similar PK & B cell depletion in rese-cel treated patients without PC*

## Similar magnitude of rese-cel expansion & B cell depletion kinetics in patients treated with and without PC




Rese-cel with PC in non-PV indications (med±50%CI)
PV-1M-1
PV-1M-2
PV-1M-3

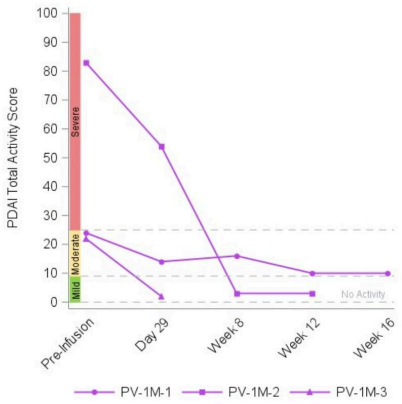
- **PV-1M-2 & PV-1M-3 had 100% reduction of peripheral B cells at initial rese-cel dose**
- **BAFF levels in these two patients were at the low end of the range observed with rese-cel with PC**

*As of 11 September 2025.
Gray vertical dotted line indicates day of rese-cel infusion (study visit Day 1). Gray shading in BAFF plot is range of median serum BAFF induction observed in PV patients following rituximab (Nagel et. al, 2009 *Journal of Investigative Dermatology* and Hébert et. al, 2021 *Frontiers in Immunology*).
Cabaletta Bio: Data on file.

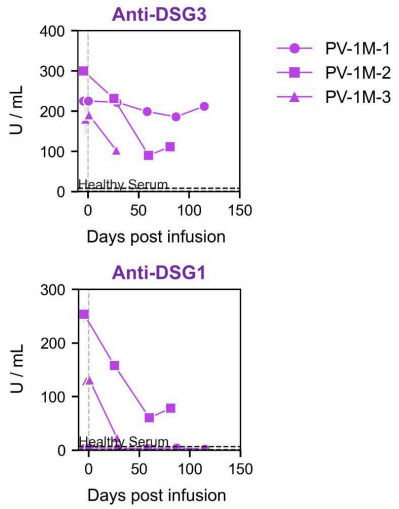
# Early clinical activity of rese-cel without preconditioning*

## Near complete resolution of clinical symptoms and rapid reduction in autoantibodies in 2 of 3 patients

**PDAI Total Activity Score**



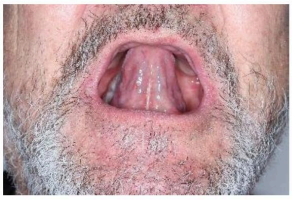

**Anti-DSG3 and Anti-DSG1 Titers**




**Images PV-1M-2**

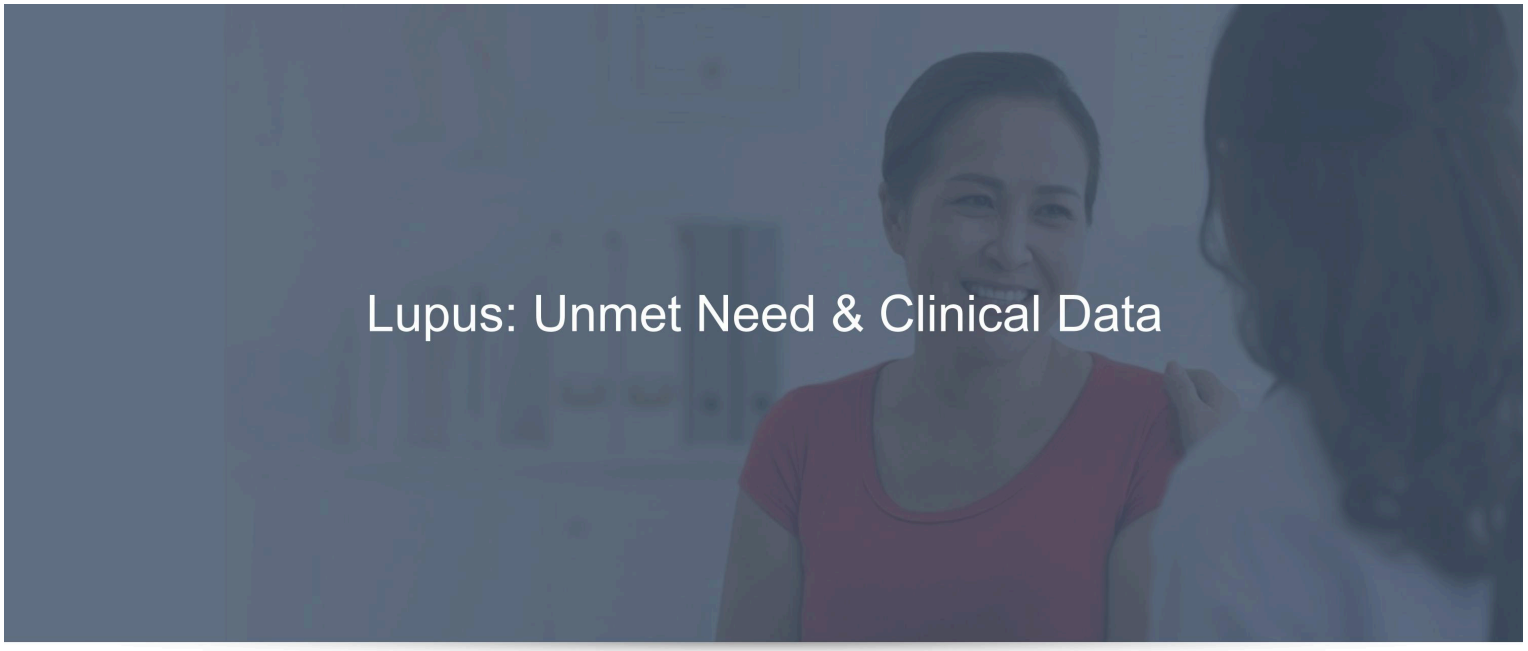
Baseline

Week 12



**PDAI improvements were most significant in the two patients who experienced peripheral B cell elimination; all three patients were off immunomodulators as of the data cut-off**

*As of 11 September 2025. Cabaletta Bio: Data on file. Disease severity intervals as defined Krain RL, et al. Br J Dermatol. 2021;184(5): 975–977.
Gray vertical dotted line indicates day of rese-cel infusion (study visit Day 1).



# Lupus: Unmet Need & Clinical Data

Cabaletta Bio®

# SLE & LN: Represent a high unmet clinical need

Increased mortality risk & negative impact on quality of life for patients with SLE & LN

## SLE is a chronic autoimmune condition that can affect nearly every organ system[1]

- Most common in women, with disease onset generally between ages of 20-40 years
- Common symptoms include severe fatigue, joint pain and swelling, skin rashes, ulcers & Raynaud's phenomenon
- >50% of patients develop permanent widespread organ damage, caused by disease & current treatments[2]
- Standardized mortality ratio from 2.4-4.5 for SLE patients[3,4]

## ~30-40% of SLE patients develop LN, with inflammation & damage within the kidneys

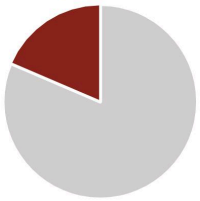
- LN may present silently or with symptoms such as proteinuria, hematuria, swelling & elevated blood pressure
- 10-30% of patients with LN will progress to ESRD, requiring dialysis or transplantation within the first decade of their disease[5,6]

### Eligible U.S. Non-Renal SLE & LN patients[7]

***SLE patients with moderate to severe, refractory disease & LN patients with refractory disease potentially eligible for rese-cel***

*(per analysis of quantitative research with ~150 lupus-treating physicians)*

**~40,000**
**U.S. non-renal SLE patients**
potentially eligible for rese-cel



~210k non-renal SLE patients

**~50,000**
**U.S. LN patients**
potentially eligible for rese-cel

~110k LN patients

**Market research indicates opportunity to achieve superior penetration and potentially further expand the market through introducing a no preconditioning CAR T alternative for patients**

ESRD, end-stage renal disease; LN, lupus nephritis; SLE, systemic lupus erythematosus.

1. Zen M, et al. Eur J Intern Med. 2023;112:45–51. 2. Rahman P, et al. Lupus. 2001;10(2):93-96. 3. Singh, R, et al. Lupus 27.10 (2018): 1577-1581.4. Murimi-Worstell, I., et al. BMJ 10.5 (2020): e031850. 5. Lichtnekert, J. Nature reviews rheumatology 20.11 (2024): 699-711. 6. Tektonidou, M. Arthritis & rheumatology 68.6 (2016): 1432-1441. 7. Results from quantitative survey of U.S. lupus-treating physicians (rheumatologists & nephrologists), conducted 2Q25. N = ~150.

# Baseline characteristics: First 9 patients in RESET-SLE*

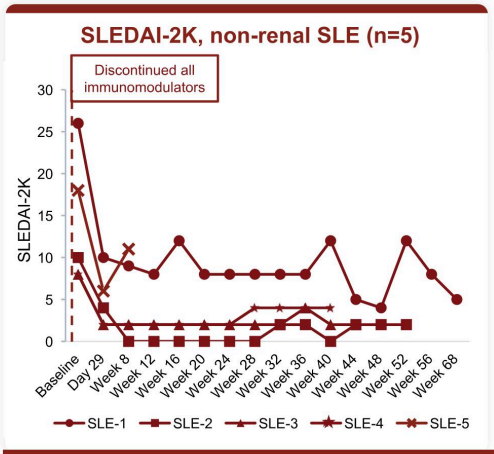
## All patients had active, refractory disease and had failed multiple B cell-targeted therapies

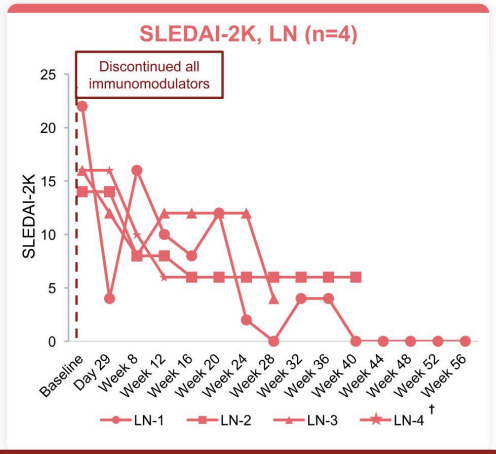
| **Cohort** | **Non-renal SLE (n=5)** | **LN (n=4)** |
|---|---|---|
| **Age,** years, mean (min, max) | ~34 (26, 44) | ~26 (18, 35) |
| **Female,** n (%) | 4 (80) | 3 (75) |
| **Time from diagnosis to screening,** years, mean (min, max) | 11.5 (6.1, 17.3) | 7.3 (2.2, 15.7) |
| **Autoantibodies (%)** | dsDNA: 100%<br>Sm: 60% | dsDNA: 75%<br>Sm: 75% |
| **Baseline disease activity†** | **SLEDAI-2K** (median) | |
| | 10 | 16 |
| | **UPCR (mg/mg)** (median) | |
| | 1.09§ | 3.45 |
| **Therapies at screening:**<br>**Systemic GCs**<br>**≤2 SLE immunomodulators‡**<br>**≥3 SLE immunomodulators‡** | <br>80%<br>60%<br>40% | <br>50%<br>50%<br>50% |
| **GC dose at screening**, mg/day, mean (min, max) | 13.4 (0, 30) | 6.25 (0, 20) |

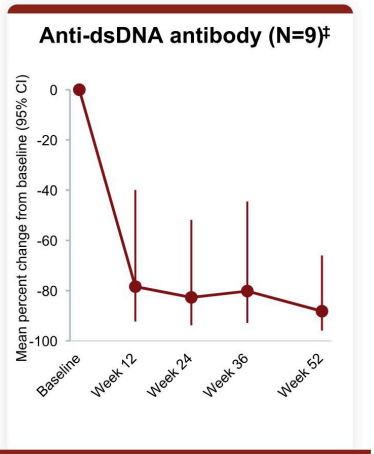
*As of 11 Sep, 2025.
†Baseline disease activity = activity before preconditioning.
‡SLE medications may include biologics, anti-malarials, and immunosuppressants.
§N=2 patients included in UPCR analysis: SLE-1 had pure Class V LN and extra-renal SLE disease activity and SLE-5 had Class II LN with moderate to severe chronicity and extra-renal disease activity that met inclusion criteria for the non-renal cohort.
dsDNA, double-stranded DNA; GC, glucocorticoid; LN, lupus nephritis; RESET, REstoring SElf-Tolerance; SLE, systemic lupus erythematosus; SLEDAI-2K, SLE Disease Activity Index 2000; Sm, Smith; UPCR, urine protein-to-creatinine ratio.
Cabaletta Bio: Data on File.

# Efficacy data following rese-cel infusion*

Improvements in SLEDAI-2K over time and significant reduction in anti-dsDNA antibodies after discontinuing immunomodulators

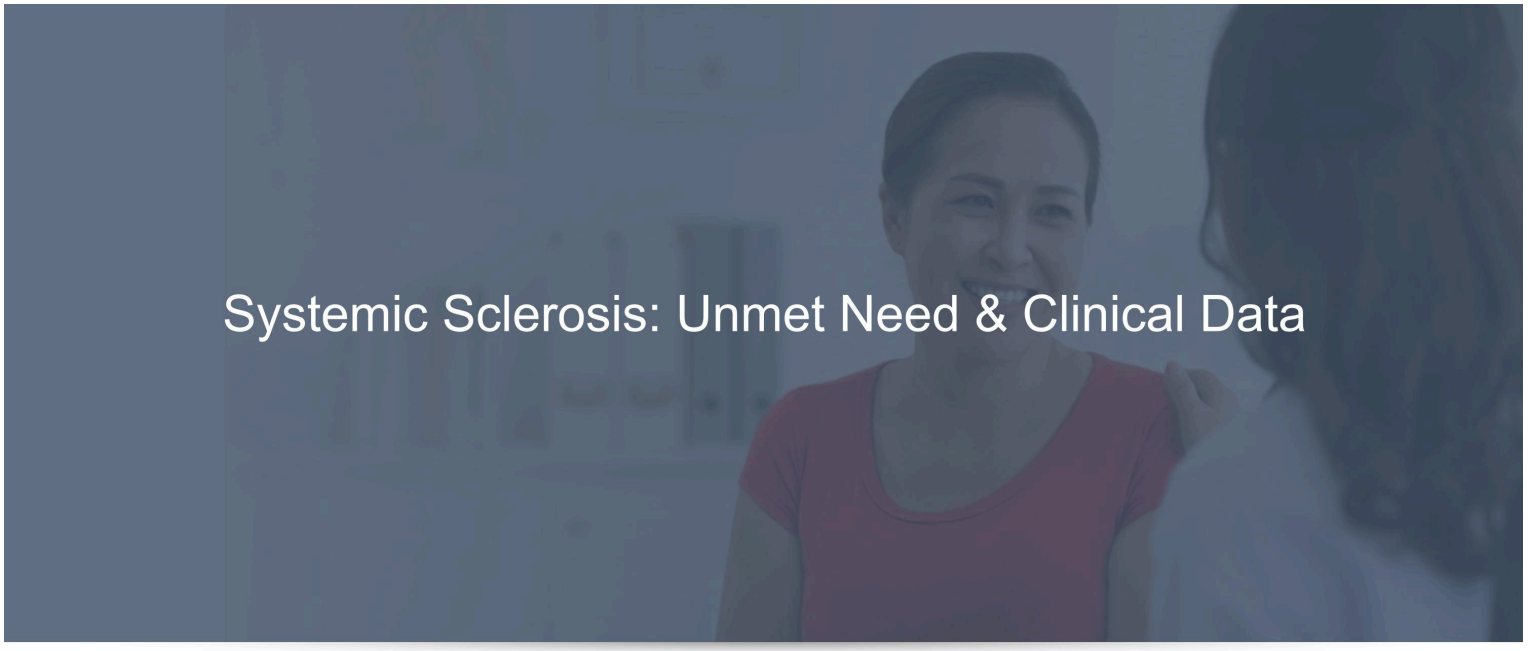



**Clinical & translational data in lupus for rese-cel with preconditioning (PC) along with initial no PC data in PV support expansion of simplified no PC regimen into lupus; initial clinical data anticipated in 1H26**

*As of 11 Sep, 2025.
†Week 20 urinalysis components of the SLEDAI-2K (WBC, RBC and casts) imputed from Week 16 for total SLEDAI-2K score.
‡Assessed by ELISA at a central lab at baseline, weeks 12, 24, 36 and 52.
dsDNA, double-stranded DNA; LN, lupus nephritis; rese-cel, resecabtagene autoleucel; SLE, systemic lupus erythematosus; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000.
Cabaletta Bio: Data on File.



# Systemic Sclerosis: Unmet Need & Clinical Data

Cabaletta Bio®

# Systemic sclerosis: Profound unmet need & limited options

Associated with progressive morbidity and high mortality[1,2]

## Rare, potentially life-threatening autoimmune disease[1]

- Characterized by progressive skin & internal organ fibrosis[1]
- Deep, tissue-level B cell-driven autoimmunity, with activated B cells & autoantibodies, promotes inflammation & organ damage[3]

## Patients experience a progressive & often fatal course

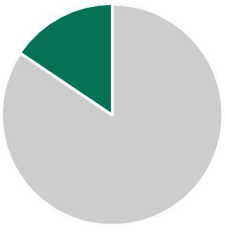
- Typically, middle age onset and more common in females[1]
- Highest mortality of all rheumatological diseases & significant burden from persistent skin & organ manifestations[4,5]
  - Mean survival is ~12 years from diagnosis
- Need for disease-modifying therapies across all SSc subsets[5]
  - FDA-approved agents for SSc-ILD slow but do not stabilize or improve lung progression
    - Approved based on 1-year primary endpoints
  - No existing treatments capable of halting SSc pathology other than AHSCT, which carries high risk

**Eligible U.S. SSc patients[6]**

***SSc patients with early, active disease potentially eligible for rese-cel***

*(per quantitative research with ~100 SSc-treating physicians)*

**~12,000-15,000**
**U.S. SSc patients**
potentially eligible for rese-cel



**~90k SSc patients**
**(~40% with clinically significant ILD)**

AHSCT, autologous hematopoietic stem cell transplantation; ILD, interstitial lung disease; SSc, systemic sclerosis.

1. Allanore Y, et al. Nat Rev Dis Primers. 2015;1:15002. 2. Denton CP, et al. Lancet. 2017;390(10103):1685–1699. 3. Thoreau B, et al. Front Immunol. 2022;13:933468. 4. Truchetet ME, et al. Clin Rev Allergy Immunol. 2023;64(3):262–283. 5. Pope JE, et al. Nat Rev Rheumatol. 2023;19(4):212–226. 6. Results from quantitative survey of U.S. SSc-treating physicians (rheumatologists), conducted 3Q25. N = ~100.

# Baseline characteristics: First 6 Patients in RESET-SSc*

## All patients had active, refractory disease and were on 1 to 3 disease-specific therapies at screening

| | Severe Skin Cohort | | | Organ Cohort | | |
|---|---|---|---|---|---|---|
| **Patient / Cohort** | **SSc-Skin-1** | **SSc-Skin-2** | **SSc-Skin-3** | **SSc-Organ-1** | **SSc-Organ-2** | **SSc-Organ-3** |
| Age, sex | 66 F | 55 F | 59 M | 70 M | 43 F | 60 F |
| Disease duration (y) | ~2 | ~0.5 | ~2 | ~5 | ~2 | ~1 |
| Autoantibodies | RNA Pol III | Scl-70 | RNA Pol III | □ | Scl-70 | Scl-70 |
| **Baseline† mRSS** | **42** | **38** | **45** | **12** | **9** | **24** |
| **Baseline† HAQ-DI** | 2.25 | 2.125 | 2.875 | 0.75 | 0.50 | 2.50 |
| **Baseline† PFTs (% predicted)** | FVC: 91<br>DLCO: 70 | FVC: 93<br>DLCO: 58 | FVC: 50<br>DLCO: 89 | FVC: 69<br>DLCO: 58 | FVC: 76<br>DLCO: 66 | FVC: 83<br>DLCO: 78 |
| **ILD presence‡** | ✓ | □ | □ | ✓ | ✓ | ✓ |
| **Therapies at Screening** | MMF | GC, MPA | MMF | MMF, TOC, NIN | GC, TOC | MMF, IVIg, HCQ |

*As of 11 Sep, 2025; primary endpoint is incidence and severity of adverse events through Day 29
†Baseline disease activity = activity before preconditioning.
‡Per patient history and HRCT.
DLCO, % predicted diffusing capacity for carbon monoxide; FVC, forced vital capacity; GC, glucocorticoid; HAQ-DI, Health Assessment Questionnaire Disability Index; HCQ, hydroxychloroquine; HRCT, high-resolution computed tomography; ILD, interstitial lung disease; IVIg, intravenous immune globulin; MMF, mycophenolate mofetil; MPA, mycophenoloic acid; mRSS, modified Rodnan skin score; NIN, nintedanib; SAE, serious adverse event; PFT, pulmonary function test; RESET, REstoring SElf-Tolerance; RNA Pol III, ribonucleic acid polymerase III; Scl-70, anti–topoisomerase I antibody; SSc, systemic sclerosis; TOC, tocilizumab; y, years.
Cabaletta Bio: Data on File.

# SSc: Efficacy data following rese-cel infusion*

## As of the data cut-off, 4 of 4 SSc patients with ≥12 weeks follow-up had FVC stabilization or improvement

| | Severe Skin Cohort | | | Organ Cohort | | |
|---|---|---|---|---|---|---|
| **Patient / Cohort** | **SSc-Skin-1** | **SSc-Skin-2** | **SSc-Skin-3** | **SSc-Organ-1** | **SSc-Organ-2** | **SSc-Organ-3** |
| **Latest follow-up** | Week 48 | Week 24 | Day 29 | Week 16 | Week 12 | Day 29 |
| **GC-free** | ✓ | ✓ | ✓ | ✓ | ✓ | –‡‡ |
| **IM-free** | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| **Antibody and trend†** | RNA Pol III ↓ | Scl-70 ↓** | RNA Pol III; *too early* | None detected | Scl-70 ↓ | Scl-70; *too early* |
| **Revised CRISS-25‡** (time to response) | ✓ **Week 12** | ✓ **Week 24** | N/A | ✓ **Week 12** | ✓ **Week 12** | N/A |
| **Revised CRISS-50‡** (time to response) | ✓ **Week 12**§ | ✓ **Week 24** | N/A | – | ✓ **Week 12** | N/A |
| **mRSS** (baseline to latest follow-up) | 42→23 | 38→27 | 45→32 | 12→6 | 9→4 | 24→22 |
| **FVC¶ [%] (baseline to latest follow-up)** | **91→105** | **93→100** | **N/A** | **69→72** | **76→77** | **N/A** |
| **DLCO¶ [%]** (baseline to latest follow-up) | 70→81 | 58→75 | N/A | 58→58 | 66→75 | N/A |

**SSc patients were able to achieve meaningful clinical responses off all immunomodulators and off or tapering steroids**

*As of 11 Sep, 2025; primary endpoint is incidence and severity of adverse events through Day 29.
†Reflects trend from baseline to latest available timepoint.
‡Revised CRISS is evaluated at Weeks 12, 24, 36, and 52. PFTs from Week 24 are carried forward for Week 36 evaluation.
§Revised CRISS-50 met at Weeks 12 and 36. Not met at Week 24.
¶DLCO and FVC are evaluated at Weeks 12 and 24.
**Based on the research-based, qualified, quantitative Luminex assay.
‡‡Tapering GC.
CRISS, Composite Response Index in Systemic Sclerosis; DLCO, % predicted diffusing capacity for carbon monoxide; FVC, forced vital capacity; GC, glucocorticoid; IM, immunomodulatory medication; mRSS, modified Rodnan Skin Score (measure of skin thickness in SSc across 17 body areas, with a maximum score of 51); N/A, not applicable; rese-cel, resecabtagene autoleucel; RNA Pol III/RP11, ribonucleic acid polymerase III; Scl-70, anti–topoisomerase I antibody; SSc, systemic sclerosis.
Cabaletta Bio: Data on File.

# Myasthenia Gravis: Unmet Need & Clinical Data

Cabaletta Bio®

# Myasthenia gravis: Significant disease & treatment burden

High impact of disease due to patient symptoms & cost burden, particularly for refractory patients

## Serious, chronic autoimmune neuromuscular disorder[1]

- Characterized by defective transmission at the neuromuscular junction, resulting in weakness of the skeletal muscles
- Typically associated with autoantibodies (e.g. AChR, MuSK, LRP4)
- Symptoms range from ocular involvement, including double vision and ptosis, to severe weakness of the limb, bulbar, trunk, and respiratory muscles, which is worsened with exertion
- Mortality rate estimated to be 5-9%, primarily driven by myasthenic crises, or respiratory crises requiring ventilation[2]

## Treatments have transient effect & involve long-term broad immunosuppression[1]

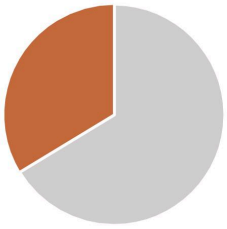
- Available therapeutic options focus on specific symptoms and can be associated with serious long-term side effects
- Mainstays include steroids, immunosuppressants (e.g., mycophenolate), FcRn antagonists, complement inhibitors and rituximab
- MG represents a significant healthcare cost burden in the US, particularly for patients whose disease is inadequately controlled

**Eligible U.S. MG patients[3]**

***Generalized MG patients with refractory disease potentially eligible for rese-cel***

*(per quantitative research with ~100 MG-treating physicians)*

**~35,000**
**U.S. MG patients**
potentially eligible for rese-cel



~100k MG patients

1. Gilhus NE, et al. *Eur J Neurol.* 2024 2. Dresser L, et al. *J Clin Med.* May 2021. 3. Results from quantitative survey of U.S. MG-treating physicians (neurologists), conducted 3Q25. N = ~100.

# Baseline Characteristics: 13 RESET-MG Patients*

## All patients had active, refractory disease despite multiple immunomodulatory agents

| | AChR Positive (n=7) | AChR Negative (n=6) |
|---|---|---|
| **Age,** years, mean (min, max) | 54.0 (41, 65) | 53.3 (37, 70) |
| **Female,** n (%) | 3 (42.9%) | 6 (100.0%) |
| **Time from diagnosis to screening,** years, mean (min, max) | 7.10 (1.4, 19.1) | 6.83 (0.6, 16.2) |
| **Autoantibodies (%)** | AChR: 100% | Seronegative: 50%<br>MuSK: 33.3%<br>LRP4: 16.7% |
| **Baseline disease activity†** | **MG-ADL (mean)** | |
| | 12.3 | 12.8 |
| | **QMG (mean)** | |
| | 14.1 | 16.8 |
| **Prior MG therapies (excluding GCs),** mean (min, max) | 4.6 (0, 8) | 3.5 (1, 6) |
| **Therapies at screening:**<br>**Systemic GCs**<br>**≤2 MG therapies‡**<br>**≥3 MG therapies‡** | <br>57%<br>71%<br>29% | <br>50%<br>83%<br>17% |
| **GC dose at screening§**, mg/day, mean (min, max) | 10 (0, 25) | 10.8 (0, 30) |

*As of 6 March, 2026.
†Baseline disease activity = activity before preconditioning.
‡MG therapies include acetylcholinesterase inhibitors, FcRn inhibitors, biologics, IVIg, and immunosuppressants.
§GC dose = glucocorticoid dose expressed in equivalent dose of prednisone (mg/day).
AChR, acetylcholine receptor; FcRn, neonatal Fc receptor; GC, glucocorticoid; IVIg, intravenous immunoglobulin; LRP4, low-density lipoprotein receptor-related protein 4; MG, myasthenia gravis; MG-ADL, MG – Activities of Daily Living; MuSK, muscle-specific tyrosine kinase; QMG, Quantitative Myasthenia Gravis Score; RESET, REstoring SElf-Tolerance; rese-cel, resecabtagene autoleucel.
Cabaletta Bio – Data on File.

Cabaletta Bio®

# Incidence of Relevant and Related Serious Adverse Events*

## No CRS was observed in 11 of 13 patients; CRS was mild and resolved with no sequelae; no ICANS observed

| Cohort | AChR Positive | | | | | | | AChR Negative | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Patient** | AChR-pos-1 | AChR-pos-2 | AChR-pos-3 | AChR-pos-4 | AChR-pos-5 | AChR-pos-6 | AChR-pos-7 | AChR-neg-1 | AChR-neg-2 | AChR-neg-3 | AChR-neg-4 | AChR-neg-5 | AChR-neg-6 |
| **CRS**† | None | Grade 2‡ | None | None | None | None | Grade 1‡ | None | None | 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/ICANS) | None | Physical deconditioning, anorexia (3) | None | None | None | None | None | None | None | None | None | Neutropenic fever (3) | None |

*As of 6 March, 2026; (N=13 dosed); primary endpoint is incidence and severity of adverse events through Day 29.
†Graded per ASTCT Consensus Grading Criteria.
‡The median time to onset of observed CRS was 5 days (range 2–8 days) relative to the rese-cel infusion (events occurring within 7 days of each other were considered a single event).
§Coded in System Organ Class of Infections and Infestations and meets seriousness criteria.
¶As assessed per US Food and Drug Administration guidelines.
AChR, acetylcholine receptor; AE, adverse event; ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; SAE, serious adverse event.
Cabaletta Bio – Data on File.

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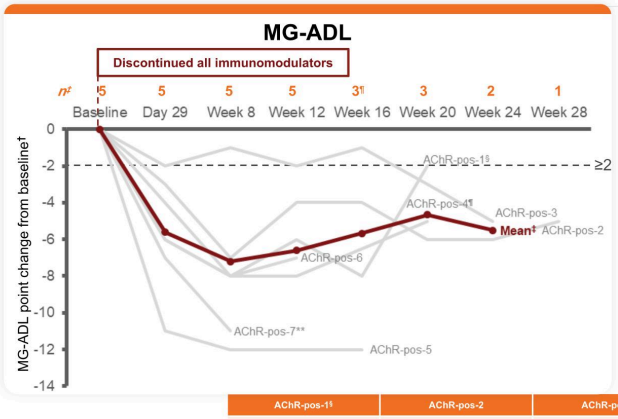
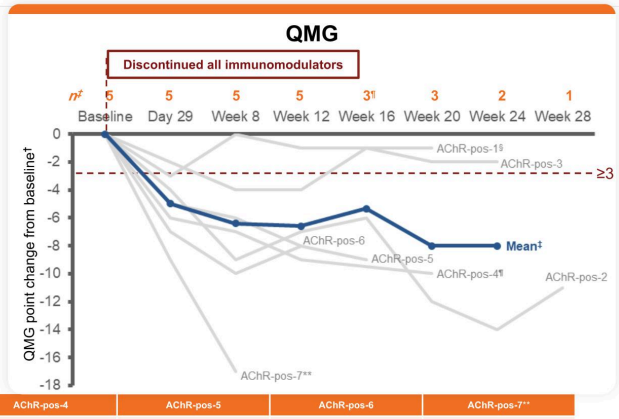
# Efficacy data in AChR-positive patients following rese-cel infusion[1]*

## After discontinuation of all immunomodulators



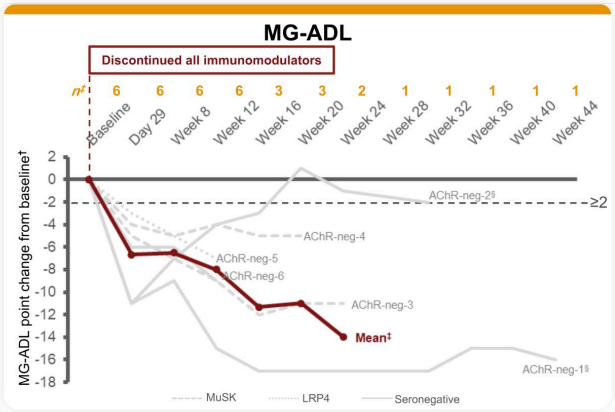

| | AChR-pos-1§ | AChR-pos-2 | AChR-pos-3 | AChR-pos-4 | AChR-pos-5 | AChR-pos-6 | AChR-pos-7** |
|---|---|---|---|---|---|---|---|
| **MG medications (screening visit)** | AZA, IVIg, GC, PYR | EFG, PYR | EFG, MMF, GC | EFG, MMF, GC, PYR | PYR | GC, PYR | IVIg |
| **GC-free (latest follow-up)** | *Taper* | ✓ | *Taper* | ✓ | ✓ | *Taper* | ✓ |
| **AChEI-free (latest follow-up)** | *Ongoing* | ✓ | ✓ | ✓ | *Taper* | ✓ | ✓ |
| **MG-ADL response** | Received IVIg | ✓ | ✓ | ✓ | ✓ | ✓ | Received IVIg |

**After discontinuation of all immunodulators,**
**5 of 7 AChR-positive patients showed clinically meaningful improvements on the MG-ADL scale**
**Cabaletta anticipates announcing registrational plans and trial design in mid-26**

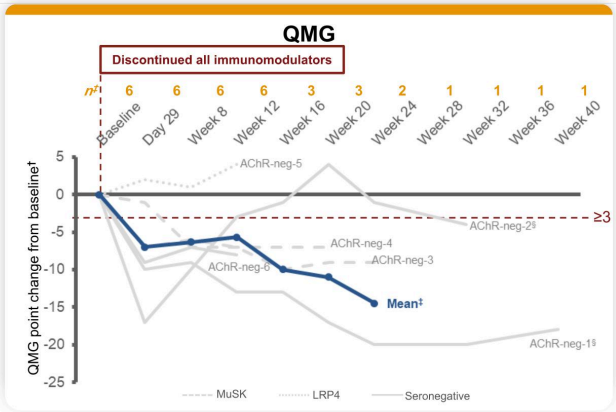
*As of 6 March, 2026.
†Baseline disease activity = activity before preconditioning. ‡Mean and n numbers are based on dosed patients not receiving rescue medication for MG. §AChR-pos-1: AZA, a prohibited medication, was continued until the day of infusion (Day 1). IVIg was stopped prior to rese-cel infusion and restarted 4 weeks after infusion for continued MG symptoms; patient discontinued study at Week 20 due to visit refusal. AChR-pos-1, Day 29 visit data unavailable. ¶AChR-pos-4 missed Week 16 visit. **AChR-pos-7 received rescue IVIg due to MG exacerbation 3 days post rese-cel infusion; IVIg rescue therapy ongoing.
AChEI, acetylcholinesterase inhibitors (i.e PYR); AChR, acetylcholine receptor; AZA, azathioprine; EFG, efgartigimod; GC, glucocorticoid; IM, immunomodulatory medication; IVIg, intravenous immunoglobulin; MG, myasthenia gravis; MG-ADL, MG – Activities of Daily Living; MMF, mycophenolate mofetil; PYR, pyridostigmine; QMG, Quantitative Myasthenia Gravis Score; rese-cel, resecabtagene autoleucel.
1. Cabaletta Bio – Data on File. 2. Muppidi S, et al. Muscle Nerve. 2022;65(6):630–639.
3. EMA. Available at: www.ema.europa.eu/en/documents/overview/soliris-epar-medicine-overview_en.pdf (accessed April 2026). 4. Barnett C, et al. Neurol Clin. 2018;36(2):339–353.

# Efficacy data in AChR-negative patients following rese-cel infusion[1]*

## After discontinuation of all immunomodulators




Clinically meaningful improvement threshold[2,3]




Clinically meaningful improvement threshold[4]

| | AChR-neg-1§ (seronegative) | AChR-neg-2§ (seronegative) | AChR-neg-3 (MuSK) | AChR-neg-4 (MuSK) | AChR-neg-5 (LRP4) | AChR-neg-6 (seronegative) |
|---|---|---|---|---|---|---|
| MG medications (screening visit) | PLA, GC, PYR | MMF, ROZ, PYR | PLA,GC | AZA | EFG | EFG, GC, PYR |
| GC-free (latest follow-up) | ✓ | ✓ | No¶ | ✓ | ✓ | *Taper* |
| AChEI-free (latest follow-up) | ✓ | ✓ | ✓ | ✓ | ✓ | *Taper* |
| MG-ADL response | ✓ | Received EFG and IVIg | ✓ | ✓ | ✓ | ✓ |

**After discontinuation of all immunomodulators,**
**5 of 6 AChR-negative patients showed clinically meaningful improvements on the MG-ADL scale;**
**Cabaletta anticipates announcing registrational plans and trial design in mid-26**

*As of 6 March, 2026.
†Baseline disease activity = activity before preconditioning. ‡Mean and n numbers are based on dosed patients not receiving rescue medication for MG. §AChR-neg-1, no Week 44 QMG performed (unrelated AE prevented assessment being completed); AChR-neg-2, no Week 28 visit data available (missed visit).¶AChR-neg-1 receiving low dose IVIg for ongoing hypogammaglobinemia every 2 months from Week 8; AChR-neg-2 received rescue EFG from Week 13 through Week 16 and IVIg every 3 weeks from Week 24 visit due to MG symptoms; AChR-neg-3 receiving chronic GC for adrenal insufficiency. AChEI, acetylcholinesterase inhibitors (i.e PYR); AChR, acetylcholine receptor; AZA, azathioprine; EFG, efgartigimod; GC, glucocorticoid; IM, immunomodulatory medication; IVIg, intravenous immunoglobulin; LRP4, low-density lipoprotein receptor-related protein 4; MG, myasthenia gravis; MG-ADL, MG – Activities of Daily Living; MMF, mycophenolate mofetil; MuSK, muscle-specific tyrosine kinase; PLA, plasmapheresis; PYR, pyridostigmine; QMG, Quantitative Myasthenia Gravis Score; rese-cel, resecabtagene autoleucel; ROZ, rozanolixizumab.

1. Cabaletta Bio – Data on File. 2. Muppidi S, et al. Muscle Nerve. 2022;65(6):630–639. 3. EMA. Available at: www.ema.europa.eu/en/documents/overview/soliris-epar-medicine-overview_en.pdf (accessed April 2026).
4. Barnett C, et al. Neurol Clin. 2018;36(2):339–353.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# Cabaletta Bio leadership

Track record of operational success evaluating & developing novel cell therapy candidates in autoimmunity

## LEADERSHIP TEAM

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**Gwendolyn Binder, Ph.D.**
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**Jay Siegel, M.D.**

# Transformative value proposition with PC elimination & automation

Removing PC should expand access while automated manufacturing should reduce COGS & increase scale

**Elimination of PC**

- Expands the market
- Catalyzes outpatient use
- Reduces resource utilization
- Impacts patient and provider experience

**Automated Manufacturing**

- Minimal capital investment
- Scalability to produce thousands of patient runs per year
- Substantially reduced COGS
- Facilitates global expansion

**Transformative Value Proposition**

- Differentiated product profile
- Typical 'biologic' margins
- Potential to address larger autoimmune indications including T1D, UC and RA

**1H26**

***PV: PC free rese-cel data including longer-term follow up at the initial dose***
***SLE: PC free rese-cel data including early data at the initial dose***
***Initial clinical experience with rese-cel manufactured by Cellares***

**2H26**

***Longer-term PC free rese-cel data from the PV & SLE dose cohorts and from patients receiving rese-cel manufactured by Cellares***

COGS – Cost of goods sold; PC – Preconditioning; PV – Pemphigus vulgaris; SLE – Systemic lupus erythematosus; RA – Rheumatoid arthritis; T1D – Type 1 diabetes; UC – Ulcerative colitis.

# Appendix

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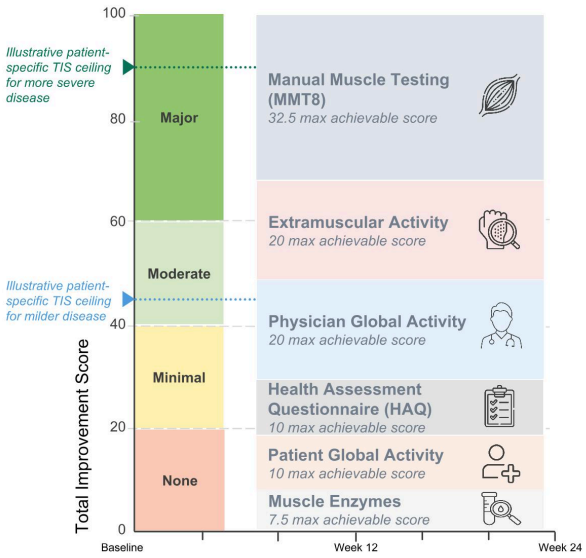
# Myositis outcomes captured through validated composite endpoint

TIS is a composite tool measuring a patient's relative improvement from their baseline

**Total improvement score (TIS) components**




- TIS developed via conjoint analysis based continuous model using **absolute percentage change** in 6 core set measures (CSM): MMT8, Extramuscular Activity, Physician Global Activity, Health Assessment Questionnaire, Patient Global Activity, and Muscle Enzymes
- TIS is the sum of improvement scores in the 6 CSMs, with **ceiling of potential effect likely higher in DM and ASyS than in IMNM given minimal extramuscular involvement**

1. ASyS – antisynthetase syndrome; CSM – core set measure; DM – dermatomyositis; IMNM – immune-mediated necrotizing myopathy; IVIg – intravenous immunoglobulin.
2. Aggarwal R et al. NEJM. 2022;387(14):1264-1278.

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# Corporate Presentation

APRIL 2026