
**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): October 29, 2025

CABALETTA BIO, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39103
(Commission File Number)

82-1685768
(IRS Employer
Identification No.)

**2929 Arch Street
Suite 600
Philadelphia, Pennsylvania**
(Address of Principal Executive Offices)

19104
(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 October 29, 2025, 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 October 2025.](#)

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.

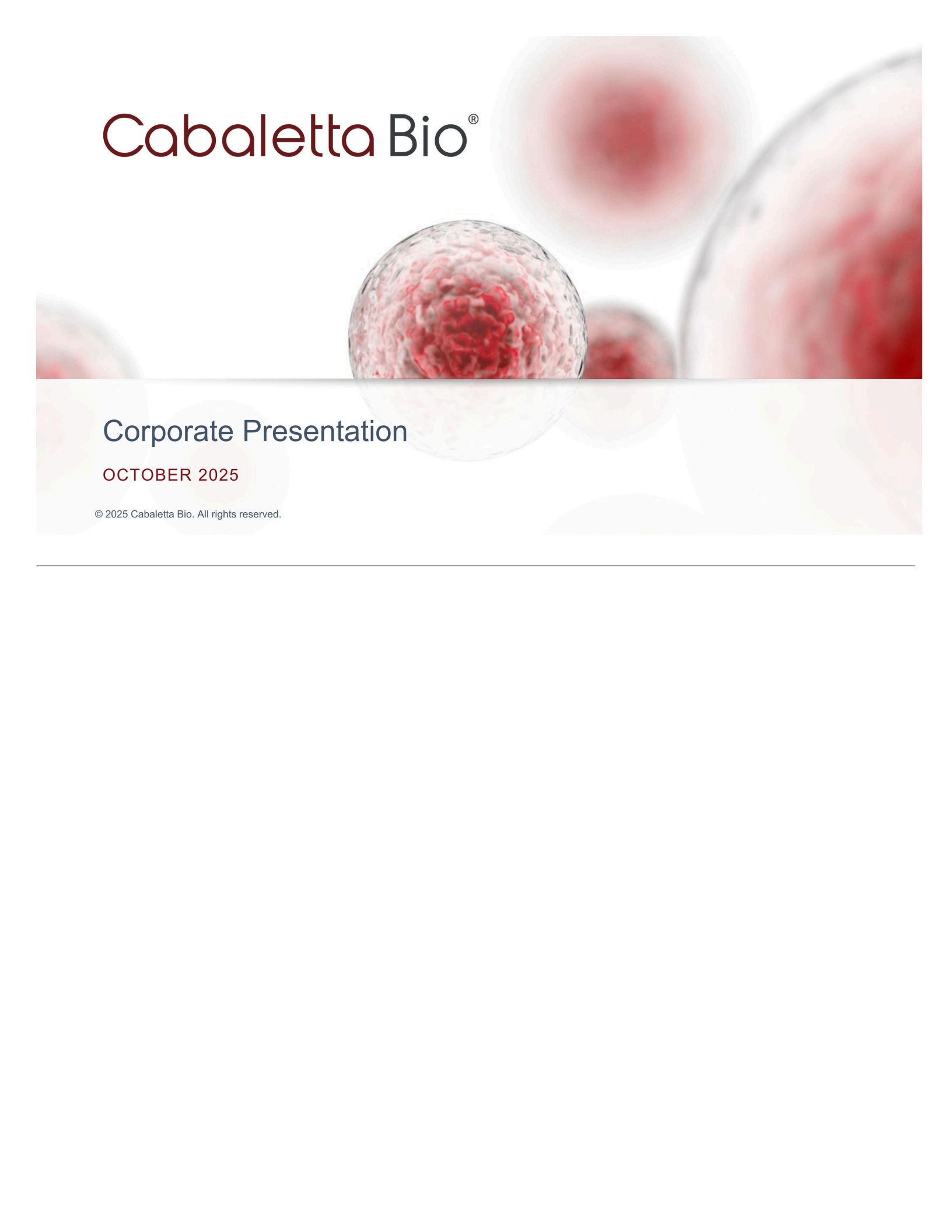
CABALETTA BIO, INC.

Date: October 29, 2025

By:

/s/ Steven Nichtberger

Steven Nichtberger
Chief Executive Officer and President
(Principal Executive Officer)



Cabaletta Bio[®]

Corporate Presentation

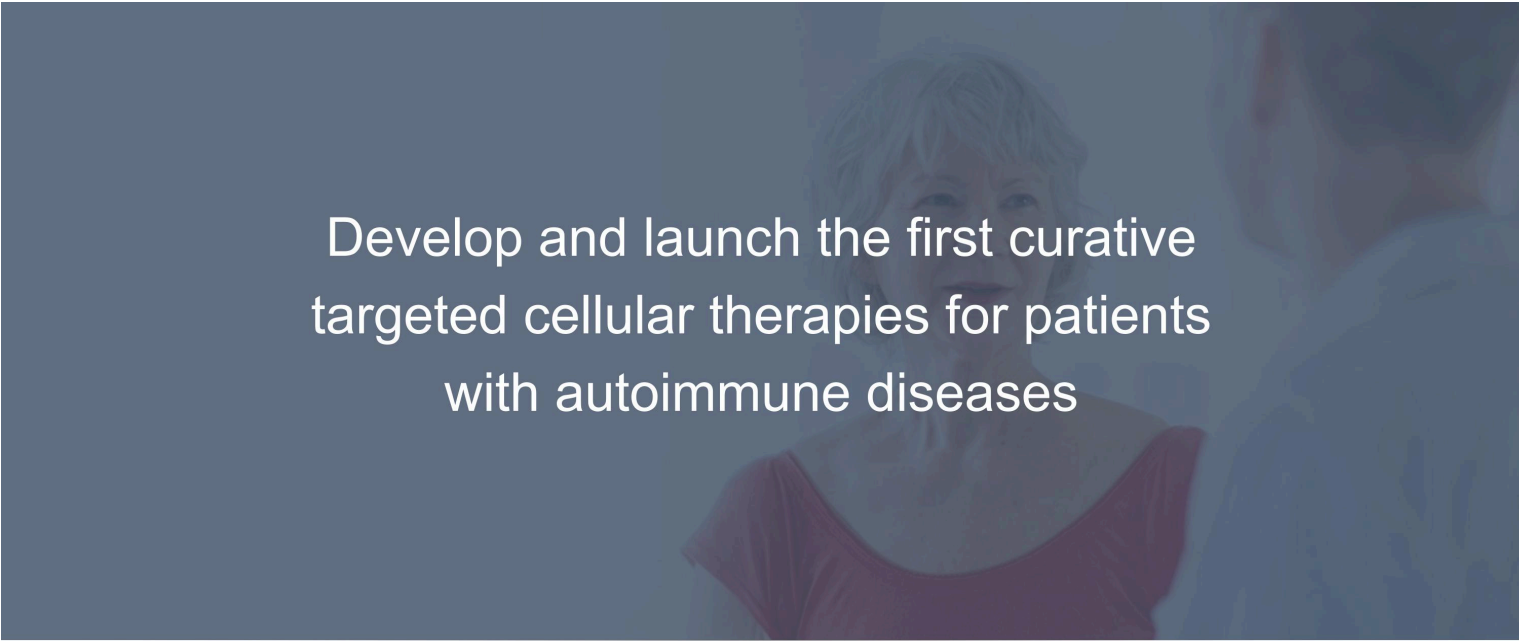
OCTOBER 2025

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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 conditions, 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, including the potential for achieving drug-free remission in patients with refractory myositis; 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 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 alignment with regulatory agencies on potential registrational pathway for rese-cel in various indications, and the timing of alignment 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; Cabaletta's advancement of the whole blood manufacturing program to remove the burden of apheresis; 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 belief regarding alignment with FDA on registrational trial design and timing thereof; 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. 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.



Develop and launch the first curative
targeted cellular therapies for patients
with autoimmune diseases

Caballetta Bio[®]

Rese-cel¹: Delivering on the promise of CD19 for autoimmune patients

Myositis registrational cohort to initiate in 4Q25; enrollment complete in phase 1/2 trials for SLE/LN, SSc & MG

- **FDA aligned with single arm DM/ASyS registrational cohort of 14 patients within RESET-Myositis trial**
 - Primary endpoint: Moderate or major TIS response at 16 weeks, off immunomodulators & on no or low dose steroids²
 - Same dose, same sites, & similar inclusion / exclusion criteria as the Phase 1/2 trial
 - FDA alignment on registrational design anticipated for systemic sclerosis and SLE/LN in 4Q25, MG in 1H26
- **Transformative clinical responses in the majority of rese-cel patients after discontinuing immunomodulators³**
 - Myositis: All DM/ASyS patients with ≥16 weeks f/u who met inclusion criteria achieved the registrational primary endpoint
 - SSc: All patients with ≥3 mo. f/u achieved an rCRISS-25 response off all immunomodulators and steroids
 - Lupus: In patients with ≥3 mo. f/u, 3/4 SLE achieved DORIS (4th with CRR) and 3/4 LN achieved renal response
- **Safety profile in first 32 patients dosed with preconditioning (PC) supports potential outpatient administration³**
 - 94% - No CRS (66%) or Grade 1 CRS (28% - fever); 94% - No ICANS
- **Rese-cel without PC: initial dose cohort with early near-complete symptom resolution in 2/3 autoimmune patients^{3,4}**
 - Accelerating plans to initiate no preconditioning cohort in RESET-SLE trial with initial clinical data expected in 2026

Myositis BLA submission on track for 2027

ASyS – antisynthetase syndrome; BLA – biologics license application; CRR – complete renal response; DM – dermatomyositis; f/u – follow-up; LN – lupus nephritis; mo. – months; MG – myasthenia gravis; PV – pemphigus vulgaris; SLE – systemic lupus erythematosus; SSc – systemic sclerosis; TIS – total improvement score.

1. resecabtagene autoleucel; CABA-201

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

3. As of data cut-off on September 11, 2025.

4. Basu, S. RESET-PV: Initial clinical and translational data evaluating rese-cel (resecabtagene autoleucel), an autologous 4-1BB CD19-CAR T cell therapy, without preconditioning, in pemphigus vulgaris. Presented at ESGCT 2025; October 6-10, 2025; Seville, Spain.

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Innovative clinical strategy to support accelerated regulatory path

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

Program ¹	Trial	Preclinical	Phase 1/2	Registrational
Rese-cel ^{FTD} (CABA-201) 4-1BB CD19-CAR T	RESET-Myositis TM ^{RMAT}	<i>Dermatomyositis</i>		
		<i>Antisynthetase syndrome</i>		
		<i>Immune-mediated necrotizing myopathy</i>		
		<i>Juvenile Myositis</i>		
	RESET-SLE TM ^{RMAT}	<i>Lupus Nephritis</i>		
		<i>Non-Renal SLE</i>		
	RESET-SSc TM	<i>Skin + Organ Cohort</i>		
		<i>Skin Cohort</i>		
	RESET-MG TM	<i>AChR-Ab pos. gMG</i>		
		<i>AChR-Ab neg. gMG</i>		
	RESET-MS TM	<i>Relapsing MS</i>		
		<i>Progressive MS</i>		
	RESET-PV TM	<i>Mucocutaneous & mucosal pemphigus vulgaris</i>		

Rheumatology²

Neurology

Dermatology

Contains cohort(s) without preconditioning

Pediatric Indication

RESETTM – REstoring SElf-Tolerance; Ab – Antibody; AChR – Acetylcholine receptor; gMG – Generalized myasthenia gravis; MS – Multiple sclerosis; SLE – Systemic lupus erythematosus

1. Additional pipeline candidate includes MuSK-CAART for MuSK-Ab positive MG, currently being evaluated in a Phase 1 trial.

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

^{FTD} FDA Fast Track Designation received in dermatomyositis, SLE and lupus nephritis, systemic sclerosis, generalized myasthenia gravis and multiple sclerosis.

^{RMAT} FDA Regenerative Medicine Advanced Therapy (RMAT) received in myositis, SLE and LN.

FDA aligned on key design elements of myositis registrational cohort

FDA alignment achieved in Type C meeting; single-arm evaluation of DM/ASyS sub-types at 16 weeks in a 14-patient cohort



- 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-dose³ steroids
- 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 program⁴

Initiating registrational trial in 4Q25 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 aligned upon with the FDA and 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.

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Anticipated Rese-cel Milestones with 2027 BLA Submission Planned

Planning to leverage myositis FDA alignment and execution across the portfolio of indications

	1H25	2H25	1H26	2H26
Align with FDA on registrational cohort designs	☒ Myositis	☐ Lupus ☐ SSc	☐ MG	
Present complete Phase 1/2 data	☒ Interim data Myositis, Lupus & SSc	☒ Myositis	☐ Lupus ☐ SSc	☐ MG
Initiate enrollment in registrational cohorts		☐ Myositis	☐ Additional indication(s):	Lupus, SSc & MG ¹
No preconditioning		☒ Initial dose data in RESET-PV	☐ Initial clinical data Lupus	☐ Additional data in RESET-PV ²
CMC commercial supply readiness & innovation	☒ FDA alignment: Safety comparability	☒ Commercial process implemented	☐ Cellares automated process ³ – Initial clinical data	

1. Subject to data and FDA alignment on proposed registrational cohort design.
2. Data from additional PV patients treated at 1×10^6 cells/kg and/or PV patients treated at a higher dose, if warranted.
3. Pending final agreement with Cellares to advance technology.

A photograph of a woman with dark hair, wearing a red top, smiling warmly. A person in a white lab coat, presumably a doctor, has their hand on her shoulder. The background is a blurred clinical or laboratory setting. The image is overlaid with a semi-transparent dark blue filter.

Rese-cel: Autologus CD19-CAR T for Autoimmunity

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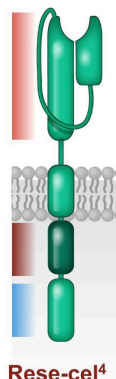
Rese-cel: CD19-CAR T specifically designed for autoimmunity

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 product design & clinical / translational data

4-1BB costimulatory domain with fully human binder

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

Same weight-based dose as in academic studies

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

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

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)

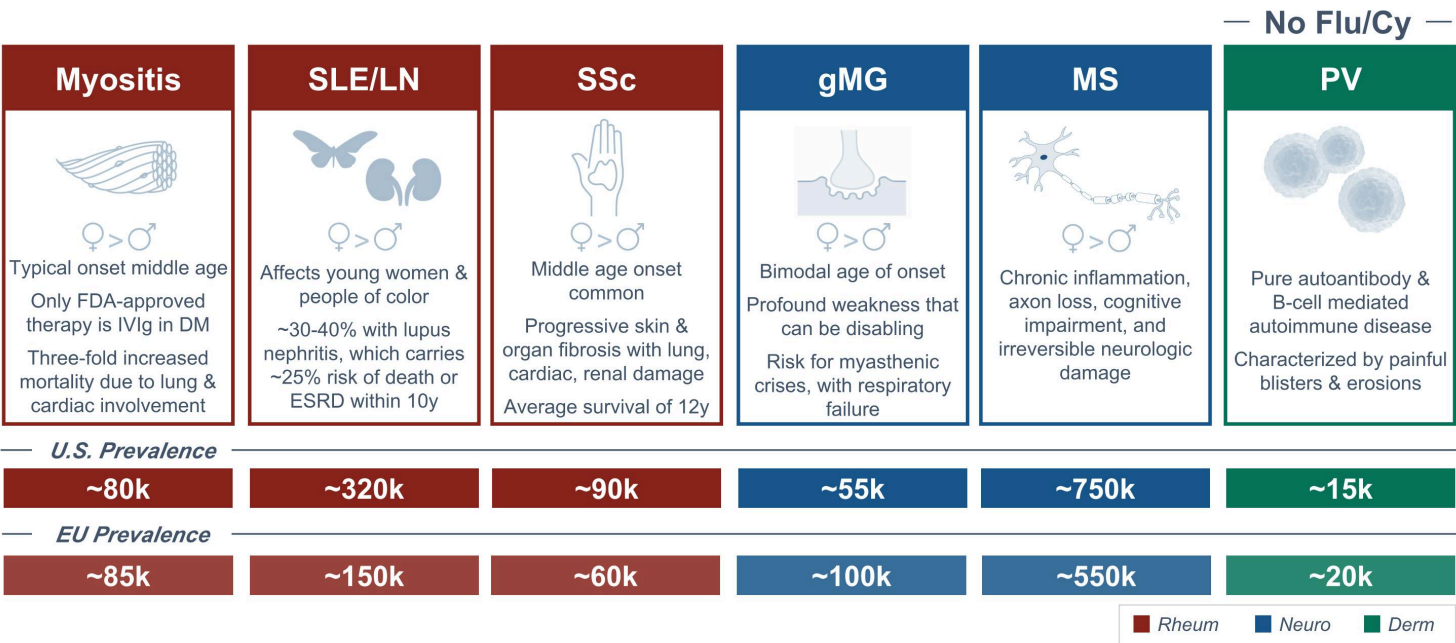
Transmembrane domain in rese-cel is CD8 α vs. TNFRSF19 (Troy) utilized in the academic construct. The two transmembrane domains have not been shown to have a significant difference in function or IFN γ production in preclinical studies. The CD8 α transmembrane domain is employed in tisagenlecleucel.

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

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

RESET™ program advancing trials in a broad portfolio of diseases

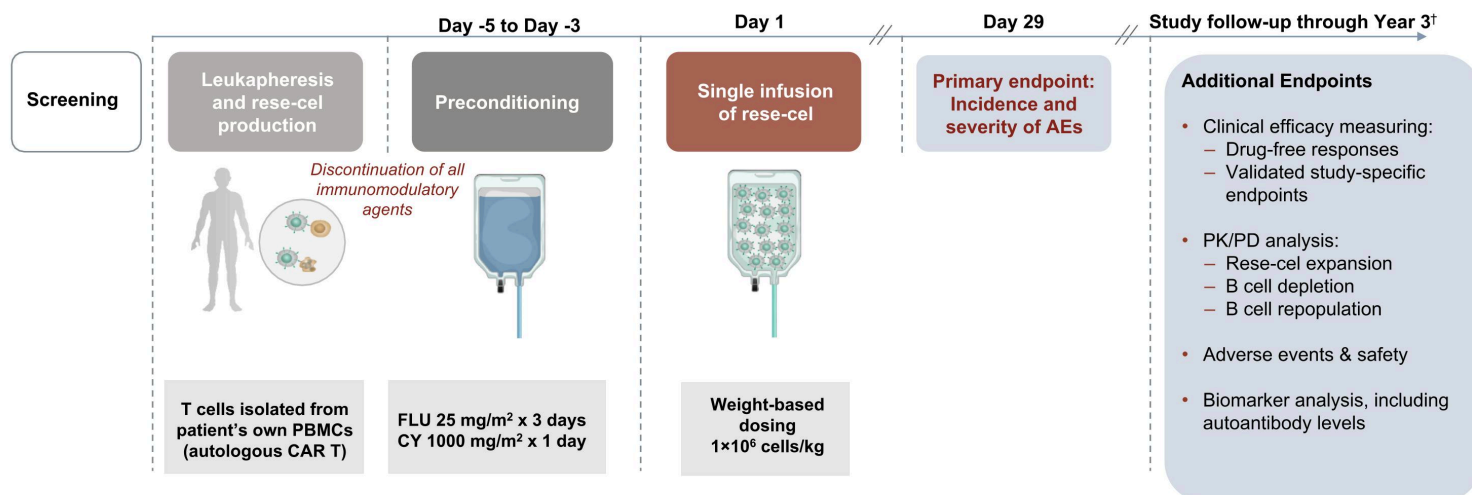
Broad portfolio with six RESET trials designed to address high unmet need and realize the potential of rese-cel



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

RESET™ clinical trials have consistent design principles¹

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



[†]Follow up period encompasses 15 years in total, aligned to regulatory guidance for CAR T cell therapies.

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.

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Key inclusion and exclusion criteria in RESET™ Phase 1/2 trials

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

Key inclusion criteria¹⁻³

Evidence of active disease despite prior or current treatment with standard of care

RESET-Myositis™	RESET-SLE™	RESET-SSc™
• Diagnosis of IIM (ASyS, DM, or IMNM) • Age ≥18 and ≤75 • Presence of at least one myositis antibody • JIIIM: Age ≥6 and ≤17 with presence of at least one MSA or MAA	• Diagnosis of SLE (SLE or LN) • Age ≥18 and ≤65 • Positive ANA or anti-dsDNA at screening • SLE (non-renal): active, moderate to severe SLE, SLEDAI-2K ≥8; pure class V LN eligible • LN: active, biopsy-proven LN class III or IV (± class V)	• Diagnosis of SSc limited or diffuse • Age ≥18 and ≤75 • Evidence of significant skin, pulmonary, renal, or cardiac involvement

Key exclusion criteria¹⁻³

B cell-depleting agent within prior 3-6 months; Previous CAR T therapy and/or HSCT

• Cancer-associated myositis • Significant lung or cardiac impairment	• Presence of kidney disease other than LN • Current symptoms of severe, progressive, or uncontrolled pulmonary or cardiac disease	• Severe lung or cardiac impairment
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Anticipate completion of dosing in most disease-specific cohorts in 2025; similarly designed RESET-MG™ Phase 1/2 cohorts have fully enrolled

ASyS, antisynthetase syndrome; CAR, chimeric antigen receptor; DM, dermatomyositis; HSCT, hematopoietic stem cell transplantation; IIM, idiopathic inflammatory myopathy; LN, lupus nephritis; MAA, myositis-associated antibody; SLEDAI-2K, SLE disease activity index 2000; SSc, systemic sclerosis.

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

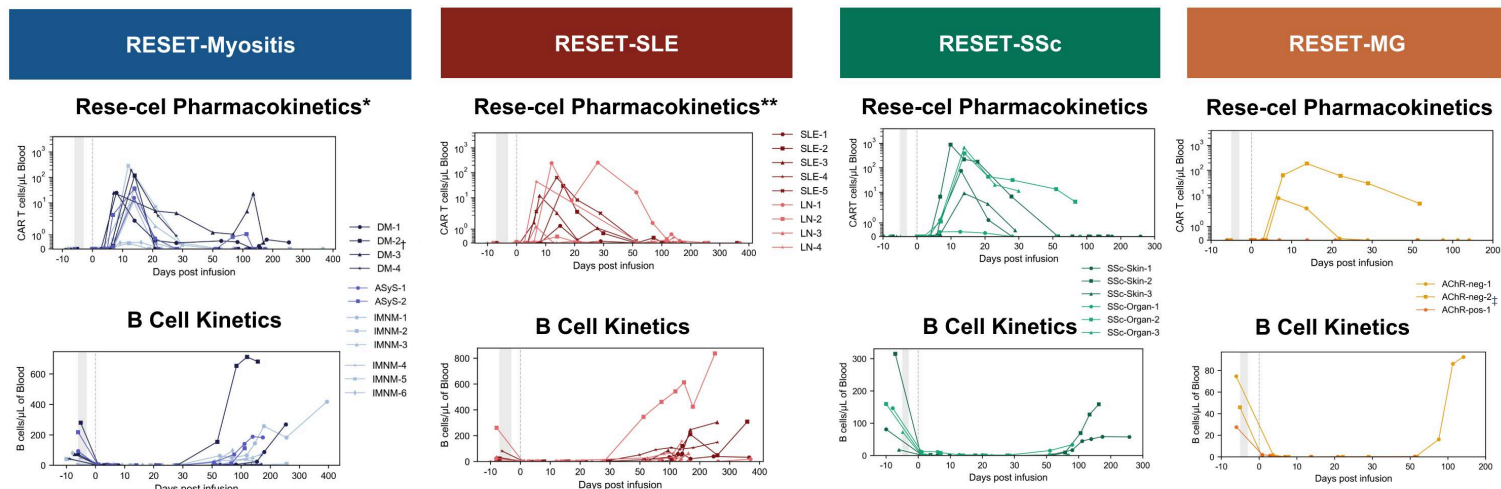
2. ClinicalTrials.gov. Available at: www.clinicaltrials.gov/study/NCT06328777 (accessed October 2024).

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

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Rese-cel expansion & B cell kinetics across indications*

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



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 autolucel; RESET,

REStoring SEIf-Tolerance; SLE, systemic lupus erythematosus, SSc, systemic sclerosis, TCR, T cell receptor.

Cabaletta Bio: Data on file.



Myositis: Unmet Need & Clinical Data

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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 complications²
 - ~20% mortality < 5 years with standard immunosuppressive treatment³

"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 ASyS⁴
~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 DM⁴
~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 options¹

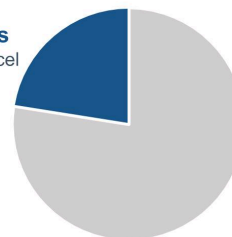
- Common therapies: steroids plus an immunomodulator (i.e. methotrexate, azathioprine, mycophenolate, rituximab)
- IVIg (intravenous immunoglobulin), the only FDA-approved therapy, is approved in adult dermatomyositis
- Therapies can carry potential long-term side effects such as serious infections and organ damage
- Despite existing therapies, disease is often refractory

Eligible U.S. myositis patients²

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

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

**~16k to 20k
U.S. myositis patients**
potentially eligible for rese-cel



~80k myositis patients

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.

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

*As of 11 Sep, 2025.

†Baseline disease activity = activity before preconditioning.

‡Reflects any exposure to RTX and IVIg prior or at time of study entry. RTX is not allowed within approximately 6 months of Screening.

ASyS, antisynthetase syndrome; CDASI-A, Cutaneous Dermatomyositis Disease Area and Severity Index – Activity; CK, creatine kinase; DM, dermatomyositis; GC, glucocorticoid; HMGCR, 3-hydroxy-3-methylglutaryl-coenzyme A reductase; IM, immunomodulatory medication; IMNM, immune-mediated necrotizing myopathy; IVIg, intravenous immunoglobulin; JlIM, juvenile idiopathic inflammatory myopathy; MMT-8, manual muscle testing 8; NXP, nuclear matrix protein; N/A, not applicable; RESET, REstoring SElf-Tolerance; RTX, rituximab; SAE, small ubiquitin-like modifier activating enzyme; SRP, signal recognition particle; TIF1, transcription intermediary factor 1; U/L, units per liter.

Cabaletta Bio – Data on File.

Cabaletta Bio®

Incidence of relevant and related serious adverse events*

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

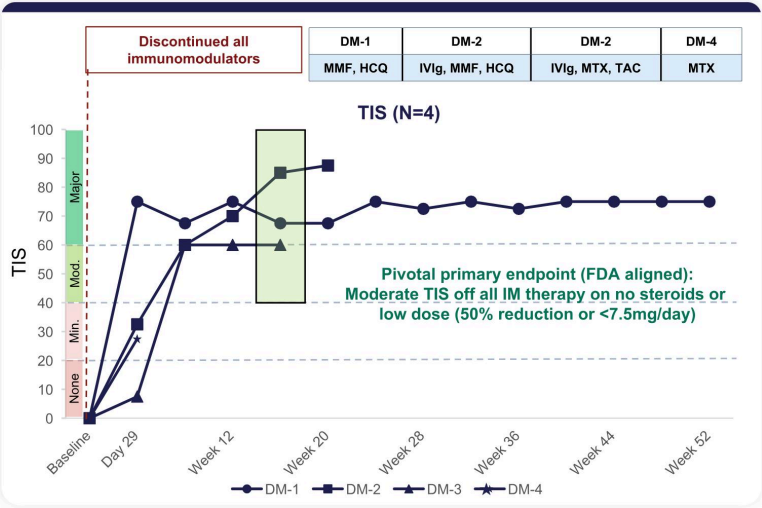
Cohort	DM				ASyS		IMNM						JIIM
Patient	DM-1	DM-2	DM-3	DM-4	ASyS-1	ASyS-2	IMNM-1	IMNM-2	IMNM-3	IMNM-4	IMNM-5	IMNM-6	JIIM-1
CRS†	None	Grade 1	None	None	Grade 1	Grade 1	None	None	Grade 1	None	None	None	None
ICANS‡	None	None	None	None	None	None	None	None	None	None	None	None	None
Serious infections‡	None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

*As of 11 Sep, 2025; primary endpoint of the Phase 1/2 study is incidence and severity of adverse events through Day 29. Serious infections and related SAEs are reported to latest follow-up.
†Graded per ASTCT Consensus Grading Criteria.
‡Coded in System Organ Class of Infections and Infestations and meets seriousness criteria.
§As assessed per US Food and Drug Administration guidelines.
ASTCT, American Society for Transplantation and Cellular Therapy; ASyS, antisynthetase syndrome; CRS, cytokine release syndrome; DM, dermatomyositis; ICANS, immune effector cell-associated neurotoxicity syndrome; IMNM, immune-mediated necrotizing myopathy; JIIM, juvenile idiopathic inflammatory myopathy; SAE, serious adverse event.
Cabaletta Bio: Data on File.

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 FDA-aligned 16-week primary endpoint for the upcoming pivotal study of at least moderate TIS response

*As of 11 Sep. 2025.

† Historical NXP-2 autoantibody, but none detected at Pre-preconditioning (Baseline visit). ‡ At latest follow-up (Day 29). § Insufficient follow-up. ¶ Reflects trend from baseline to latest timepoint.

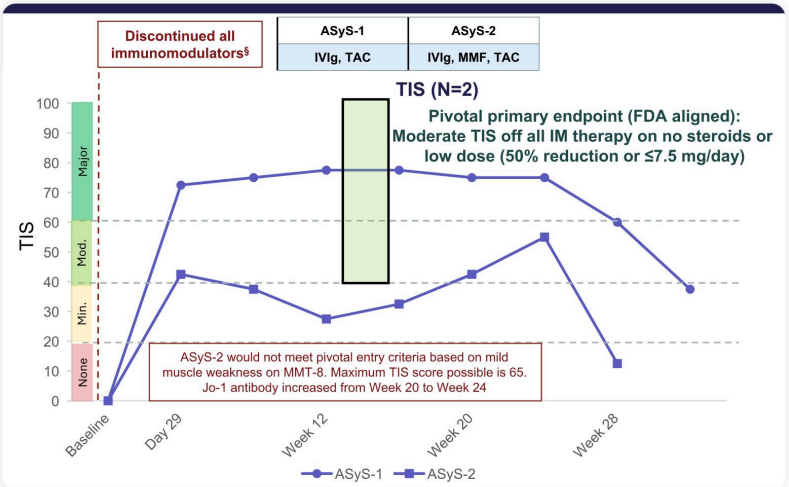
DM, dermatomyositis; FDA, Food and Drugs Administration; GC, glucocorticoids; HCQ, hydroxychloroquine; IM, immunomodulatory medication; IVIg, intravenous immunoglobulin; mg, milligrams; MMF, mycophenolate mofetil; MTX, methotrexate; N/A, not available; NXP, nuclear matrix protein; rese-cel, rescecabtagene 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.

Cabaletta Bio®

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 autoantibodies¹⁻³ 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.

A photograph of a woman with dark hair pulled back, wearing a red top, smiling warmly. A hand is resting on her right shoulder. The background is slightly blurred, showing what appears to be a kitchen or home interior. The image is overlaid with a semi-transparent dark blue filter.

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 system¹

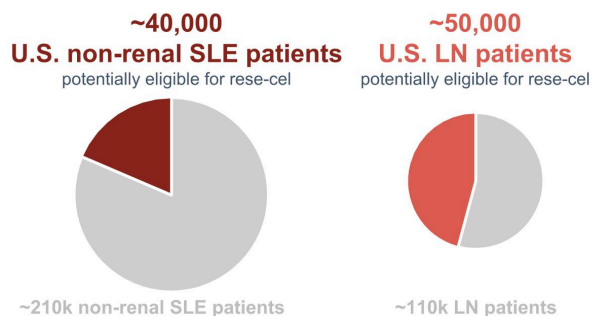
- Most common in women, with disease onset generally between ages of 20-40 years
- Common symptoms include severe fatigue, joint pain and swelling, skin rashes, ulcers & Raynaud's phenomenon
- >50% of patients develop permanent widespread organ damage, caused by disease & current treatments²
- Standardized 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 patients⁷

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)



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, L, 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.

Cabaletta Bio®

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% Sm: 60%	dsDNA: 75% Sm: 75%
Baseline disease activity†	SLEDAI-2K (median)	
	10	16
	UPCR (mg/mg) (median)	
	1.09§	3.45
Therapies at screening:		
Systemic GCs	80%	50%
≤2 SLE immunomodulators‡	60%	50%
≥3 SLE immunomodulators‡	40%	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.

Cabaletta Bio®

23

Incidence of relevant and related serious adverse events*

Fever (Grade 1 CRS) reported in 3 of 9 patients & ICANS reported in 1 of 9 patients

Cohort	Non-renal SLE (n=5)					LN (n=4)			
Patient	SLE-1	SLE-2	SLE-3	SLE-4	SLE-5	LN-1	LN-2	LN-3	LN-4
CRS†	None	Grade 1	None	None	Grade 1	Grade 1	None	None	None
ICANS‡	None	None	None	None	None	Grade 4	None	None	None
Serious infections‡	None	None	None	None	None	None	None	None	None
Related SAEs (Grade)§ (Excluding CRS/ICANS)	None	None	None	None	None	Fever (1) Neutropenic fever (1) Pancytopenia‡ (4)	None	None	None

*As of 11 Sep, 2025; primary endpoint is incidence and severity of adverse events through Day 29. Serious infections and related SAEs are reported to latest follow-up. No patient experienced clinical sequelae from CRS, ICANS or related SAEs.
†Graded per ASTCT Consensus Grading Criteria. 7 of 9 patients received anti-seizure prophylaxis. Tocilizumab was administered for CRS in one patient.
‡Coded in System Organ Class of Infections and Infestations and meets seriousness criteria.
§As assessed per US Food and Drug Administration guidelines.
¶Consistent with "Prolonged Cytopenias," which is a labeled warning and precaution for approved oncology CAR T products.
CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; LN, lupus nephritis; SAE, serious adverse event; SLE, systemic lupus erythematosus.
Cabaletta Bio: Data on File.

Non-renal SLE: Efficacy data following rese-cel infusion*

As of the data cut-off, 3 of 4 SLE patients with ≥6 months follow-up achieved DORIS (4th in CRR)

	Non-renal SLE				
Patient	SLE-1 [†]	SLE-2	SLE-3	SLE-4	SLE-5 [†]
Latest follow-up	Week 68	Week 52	Week 44	Week 40	Week 8
IM-free	✓	✓	✓	✓	✓
GC-free	✓	✓	✓	No	No
DORIS [‡] (at latest follow-up)	☐ [§]	✓	✓	✓	Too early
PGA (% improvement from baseline)	93	100	100	64	40
SLEDAI-2K improvement (baseline to latest follow-up)	21	8	6	4	7
Anti-dsDNA antibody (change from baseline)	↓	↔ Transiently negative	↓	↓	↓
Complement (C3 or C4) (baseline to latest follow-up)	Improving	Normalized	Normal at baseline	Transiently normalized (up until week 28)	Normalized
CRR [‡] (at latest follow-up)	✓	N/A	N/A	N/A	☐
PRR [‡] (at latest follow-up)	✓	N/A	N/A	N/A	☐
UPCR (mg/mg) (baseline to latest follow-up)	1.08→0.35	N/A	N/A	N/A	1.09→0.81
eGFR (mL/min/1.73m ²) (baseline to latest follow-up)	132.7→109.7	N/A	N/A	N/A	108.7→99.2

*As of 11 Sep, 2025.
[†]SLE-1 had pure Class V LN and extra-renal SLE disease activity and SLE-5 had Class II LN with moderate-severe chronicity and extra-renal disease activity that met inclusion criteria for the non-renal cohort.
[‡]DORIS = Clinical SLEDAI-2K=0 (irrespective of serology); Physician Global Assessment <0.5; antimalarials; low-dose GCs (prednisolone ≤5 mg/day); stable immunosuppressives including biologics. CRR = UPCR ≤0.5 mg/mg; ≥60 mL/min or no confirmed eGFR decrease of >20% from baseline; no receipt of rescue therapy. PRR = ≥50% reduction from baseline UPCR.
[§]SLE-1 achieved DORIS at Week 48; on cyclosporine therapy between Week 41 and Week 60 for a non-SLE-related, non-rese-cel-related safety event (macrophage activation syndrome with onset at Week 40).
CRR, complete renal response; DORIS, definition of remission in SLE; eGFR, estimated glomerular filtration rate; GC, glucocorticoid; IM, immunomodulatory; LN, lupus nephritis; N/A, not applicable; PGA, physician's global assessment; PRR, partial renal response; rese-cel, rescabtagene autoleucel; SLE, systemic lupus erythematosus; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000; UPCR, urine protein-creatinine ratio.
Cabaletta Bio: Data on File.

LN: Efficacy data following rese-cel infusion*

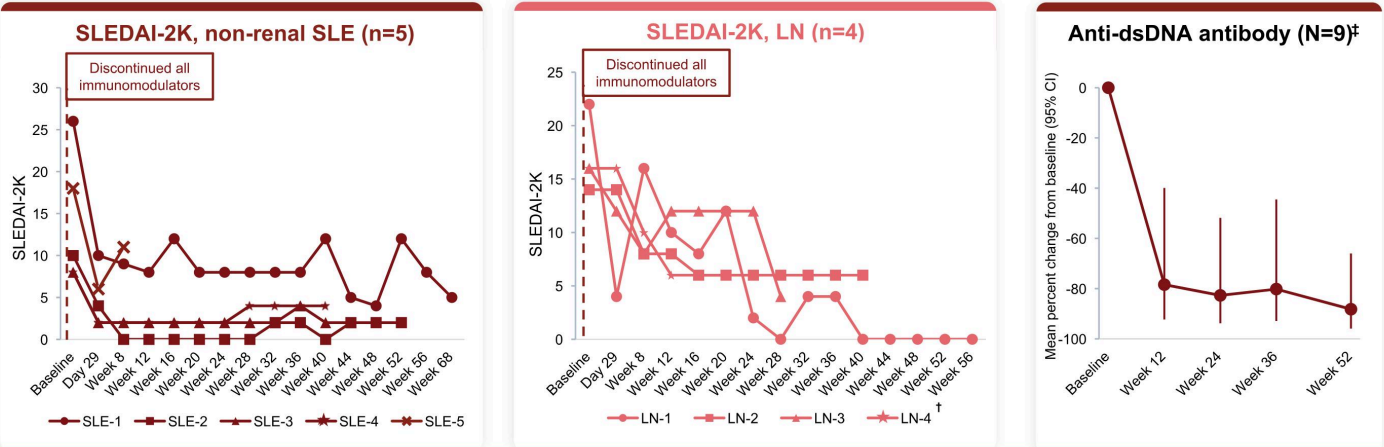
As of the data cut-off, LN-1 in CRR, LN-2 in PRR and LN-3 with histologic response on repeat renal biopsy

	LN			
Patient	LN-1	LN-2	LN-3	LN-4
Latest follow-up	Week 56	Week 40	Week 28	Week 20
IM-free	✓	✓	✓	✓
GC-free	✓	✓	✓	✓
DORIS† (at latest follow-up)	✓	N/A	N/A	N/A
PGA (% improvement from baseline)	100	100	100	100
SLEDAI-2K improvement (baseline to latest follow-up)	22	8	12	10§
Anti-dsDNA antibody (change from baseline)	↓ Negative	↓	Negative at baseline	↓
Complement (C3 or C4) (baseline to latest follow-up)	Normalized	Normalized	Normal at baseline	Normal at baseline
CRR† (at latest follow-up)	✓	□	□‡	□
PRR† (at latest follow-up)	✓	✓	□	□
UPCR (mg/mg) (baseline to latest follow-up)	7.22→0.18	4.85→2	2.04→1.13	1.69→1.83
eGFR (mL/min/1.73m²) (baseline to latest follow-up)	72.3→123.5	127.2→122.8	133.2→131.8	82.7→60.5

*As of 11 Sep, 2025.
†DORIS = Clinical SLEDAI-2K=0 (irrespective of serology); Physician Global Assessment <0.5; antimalarials; low-dose GCs (prednisolone ≤5 mg/day); stable immunosuppressives including biologics. CRR = UPCR ≤0.5 mg/mg; ≥60 mL/min or no confirmed eGFR decrease of >20% from baseline; no receipt of rescue therapy. PRR = ≥50% reduction from baseline UPCR.
‡LN-3 achieved histologic response (activity index 0/12) on repeat kidney biopsy at 26 weeks post-infusion despite partial reduction in proteinuria.
§Week 20 urinalysis components of the SLEDAI-2K (WBC, RBC and casts) imputed from Week 16 for total SLEDAI-2K score.
CRR, complete renal response; DORIS, definition of remission in SLE; eGFR, estimated glomerular filtration rate; GC, glucocorticoid; IM, immunomodulatory; LN, lupus nephritis; N/A, not applicable; PGA, physician's global assessment; PRR, partial renal response; RBC, red blood cell; rese-cel, rescabtagene autoleucel; SLE, systemic lupus erythematosus; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000; UPCR, urine protein-creatinine ratio; WBC, white blood cell.
Cabaletta Bio: Data on File.

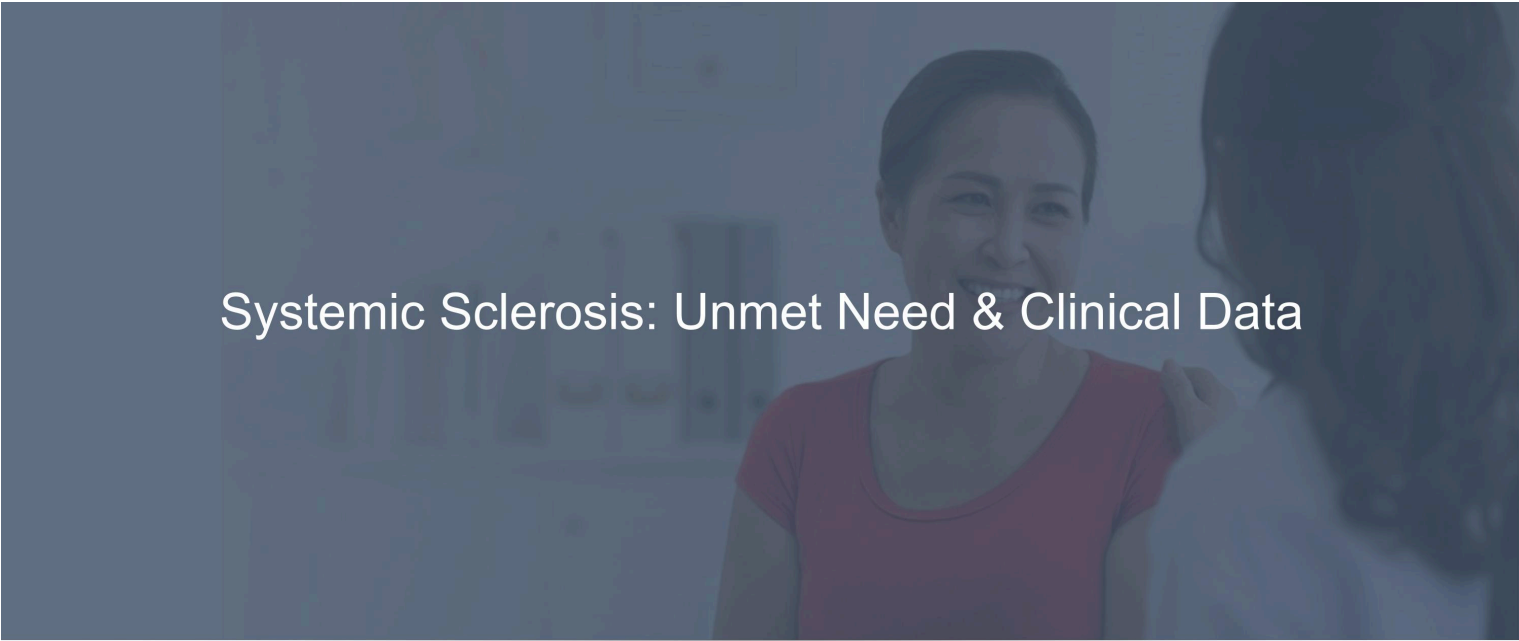
Efficacy data following rese-cel infusion*

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 2026

*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; RBC, red blood cell; rese-cel, resecabtagene autoleucel; SLE, systemic lupus erythematosus; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000; WBC, white blood cell.
Cabaletta Bio: Data on File.

A photograph of a woman with dark hair, wearing a red top, smiling warmly. Another person's hand is visible on her right shoulder, suggesting a supportive or comforting gesture. The background is slightly blurred, showing what appears to be a home or office setting.

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 disease¹

- Characterized by progressive skin & internal organ fibrosis¹
- Deep, tissue-level B cell-driven autoimmunity, with activated B cells & autoantibodies, promotes inflammation & organ damage³

> Patients experience a progressive & often fatal course

- Typically, middle age onset and more common in females¹
- 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 subsets⁵
 - 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 patients⁶

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

AHSCT, autologous hematopoietic stem cell transplantation; 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 DLCO: 70	FVC: 93 DLCO: 58	FVC: 50 DLCO: 89	FVC: 69 DLCO: 58	FVC: 76 DLCO: 66	FVC: 83 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, mycophenolic 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.

Incidence of relevant and related serious adverse events*

CRS reported in 3 of 6 patients and ICANS reported in 1 of 6 patients

	Severe Skin cohort			Organ Cohort		
Patient	SSc-Skin-1	SSc-Skin-2	SSc-Skin-3	SSc-Organ-1	SSc-Organ-2	SSc-Organ-3
CRS†	Grade 2‡	None	Grade 1	None	None	Grade 1
ICANS†	None	Grade 3**	None	None	None	None
Serious infections‡	None	None	None	None	None	None
Related SAEs (Grade)§ (Excluding CRS/ICANS)	None	Neutropenic fever (1)	Hypercapnic Respiratory Failure (4) Encephalopathy (4)	None	None	None

*As of 11 Sep, 2025; primary endpoint of the Phase 1/2 study is incidence and severity of adverse events through Day 29. No patient experienced clinical sequelae from CRS, ICANS or related SAEs.

†Graded per ASTCT Consensus Grading Criteria.

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

§As assessed per US Food and Drug Administration guidelines.

‡Transient hypotension on Day +10 resolved with IV hydration; no tocilizumab administered.

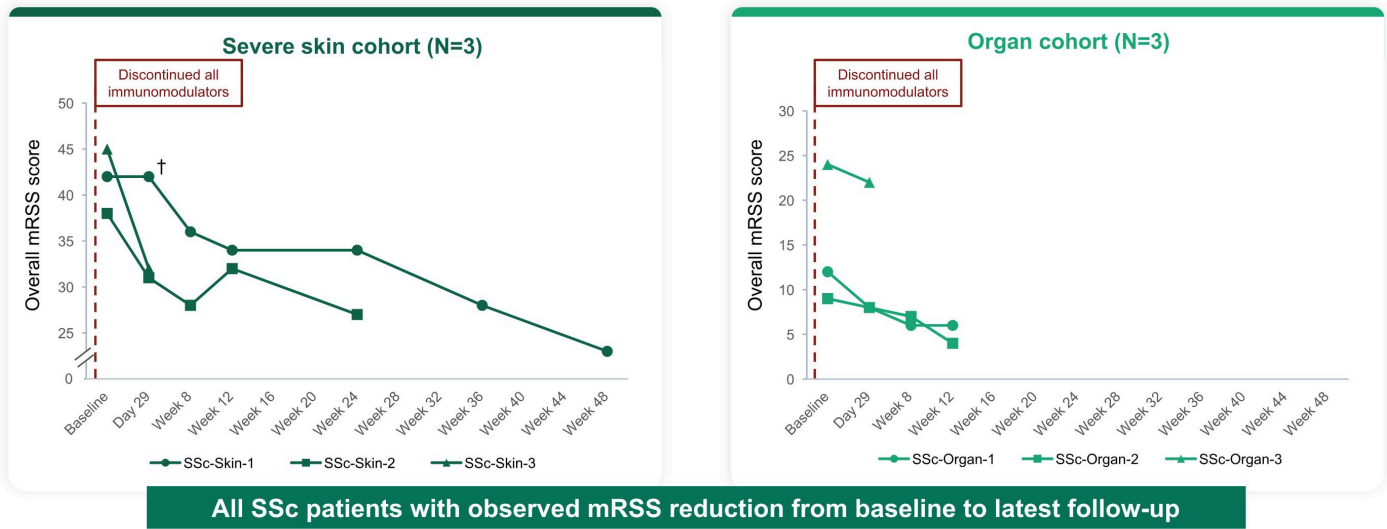
**Productive cough & fever prior to infusion. Low grade fever & rigors on Day +8, treated with IV cefepime, vancomycin, and morphine. ICE 3 score on Day +9, progressed to ICE 1 on Day +10: arousable; able to speak and follow commands but answered all questions to the ICE assessment incorrectly; no evidence of seizure, elevated intracranial pressure or cerebral edema; resolved within 2 days following dexamethasone.

ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; IV, intravenous; SAE, serious adverse event; SSc, systemic sclerosis.

Cabaletta Bio: Data on File.

SSc: Efficacy data following rese-cel infusion*

Improvements in overall mRSS score in SSc patients off all immunomodulators and off or tapering steroids



*As of 11 Sep, 2025.
†Assessed at Week 3.
mRSS, modified Rodnan Skin Score (measure of skin thickness in SSc across 17 body areas, with a maximum score of 51); rese-cel, resecabtagene autoleucel; SSc, systemic sclerosis.
Cabaletta Bio: Data on File.

SSc: Efficacy data following rese-cel infusion*

As of the data cut-off, 4 of 4 SSc patients with at least 12 weeks follow-up achieved rCRISS-25 response

	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.

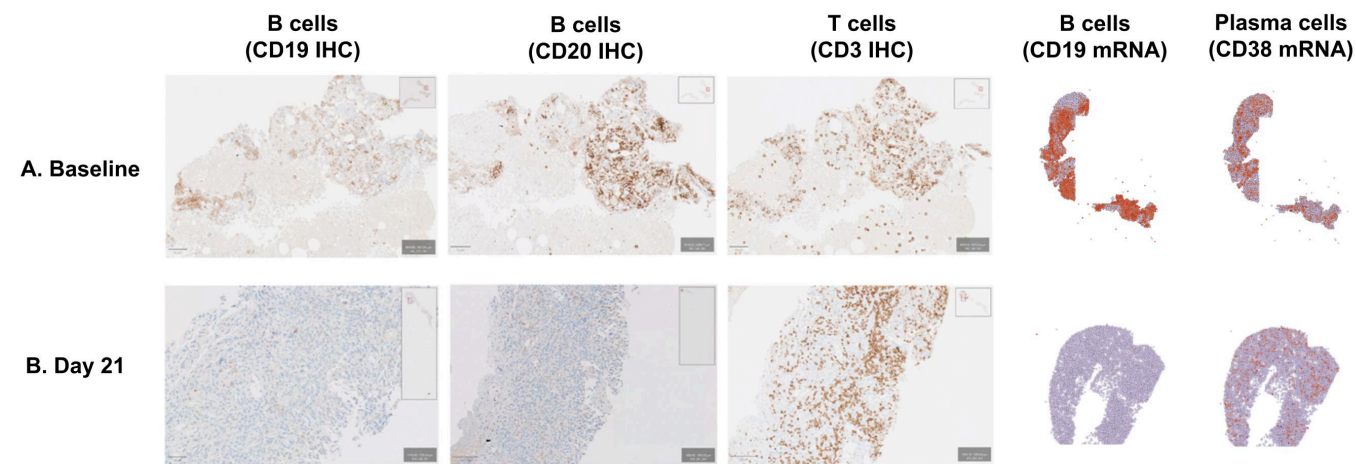
††Tapering GC.

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, rescabtagene autoleucel; RNA Pol III/RP11, ribonucleic acid polymerase III; Scl-70, anti-topoisomerase I antibody; SSc, systemic sclerosis.

Cabaletta Bio: Data on File.

Lymph node B cell depletion in SSc-Skin-1^{1*}

Tissue resident depletion, consistent with the deep B cell depletion in circulation, observed via lymph node biopsy



B cell depletion observed to date is consistent with an academic study in autoimmune disease showing CD19-CAR T cell therapy achieves deeper depletion than mAbs²

*Lymph node biopsies were from the left inguinal area using USG at U. Mich. by Dr. Khanna.
CAR, chimeric antigen receptor; rese-cel, resecabtagene autoleucel; IHC, immunohistochemistry; mAb, monoclonal antibody; mRNA, messenger ribonucleic acid; SSc, systemic sclerosis.
1. Cabaletta Bio: Data on File. 2. Tur C, et al. Ann Rheum Dis. 2025;84(1):106–114.

A photograph of a woman with dark hair pulled back, wearing a red top, smiling warmly. A hand is resting on her right shoulder. The background is slightly blurred, showing what appears to be a kitchen or home interior. The entire image is overlaid with a semi-transparent dark blue filter.

Myasthenia Gravis: Unmet Need

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Myasthenia gravis: Significant disease & treatment burden

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

> Serious, chronic autoimmune neuromuscular disorder¹

- 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 ventilation²

> Treatments have transient effect & involve long-term broad immunosuppression¹

- 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 patients³

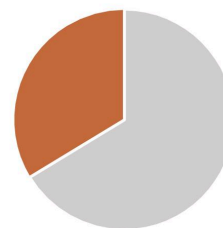
Generalized MG patients with refractory disease potentially eligible for rese-cel

(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: First 4 patients in RESET-MG*

	AChR Positive		AChR Negative	
Patient / Cohort (latest follow-up)	AChR-pos-1 (Week 8)	AChR-pos-2 (Week 4)	AChR-neg-1 (Week 20)	AChR-neg-2 (Week 8)
Age, sex	62, M	44, F	54, F	70, F
Disease duration (approx. years)	1	6	4	1
Autoantibodies	AChR	AChR	Seronegative‡	Seronegative‡
QMG†	11	18	22	21
MG-ADL†	15	13	17	14
Therapies at screening	GC, AZA, IVIg, PYR	EFG, PYR	GC, PYR, PLA	PYR, MMF, ROZ
Other prior therapies	–	GC, IVIg, MMF, AZA, ECU, PLA	IVIg, AZA, RTX, ECU, EFG	IVIg
GC dose at screening (mg/day)	25	–	15	–

*As of 11 Sep, 2025.

†Baseline disease activity = activity before preconditioning.

‡Seronegative = no anti-AChR, anti-MuSK and anti-LRP4 antibodies

AChR, acetylcholine receptor; AZA, azathioprine; ECU, eculizumab; EFG, efgartigimod; GC, glucocorticoid; IVIg, intravenous immunoglobulin; MG, myasthenia gravis; MG-ADL, MG – Activities of Daily Living; MMF, mycophenolate mofetil; PLA, plasmapheresis; PYR, pyridostigmine; ROZ, rozanolixizumab; RTX, rituximab; QMG, Quantitative Myasthenia Gravis Score; RESET, REstoring SElf-Tolerance.

Cabaletta Bio: Data on File.

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Incidence of relevant and related serious adverse events*

No CRS reported in 3 of 4 patients & no ICANS in any patients

	AChR Positive		AChR Negative	
Patient / Cohort	AChR-pos-1	AChR-pos-2†	AChR-neg-1	AChR-neg-2
CRS‡	None	Grade 2	None	None
ICANS‡	None	None	None	None
Serious infections‡	None	None	None	None
Related SAEs (Grade)§ (Excluding CRS/ICANS)	None	Anorexia (Grade 3) Physical deconditioning (Grade 3)	None	None

*As of 11 Sep, 2025; primary endpoint of the Phase 1/2 study is incidence and severity of adverse events through Day 29. Serious infections and related SAEs are reported to latest follow-up. No patient experienced clinical sequelae from CRS, ICANS or related SAEs.

†Graded per ASTCT Consensus Grading Criteria.

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

§As assessed per US Food and Drug Administration guidelines.

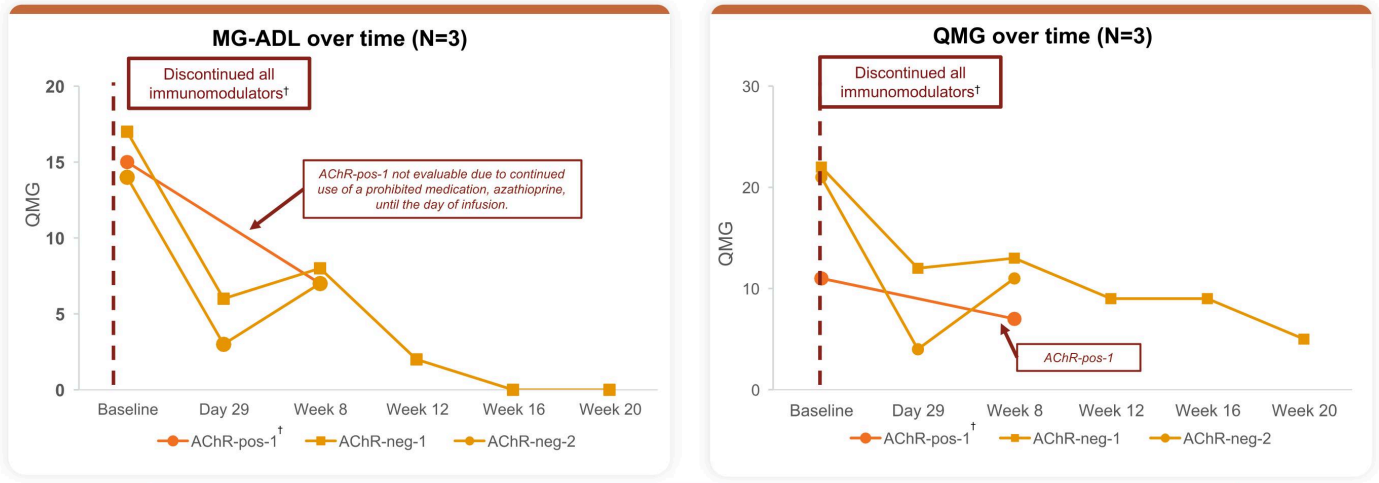
¶AChR-pos-2: Week 4 safety data presented; efficacy follow-up ongoing.

AChR, acetylcholine receptor; 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.

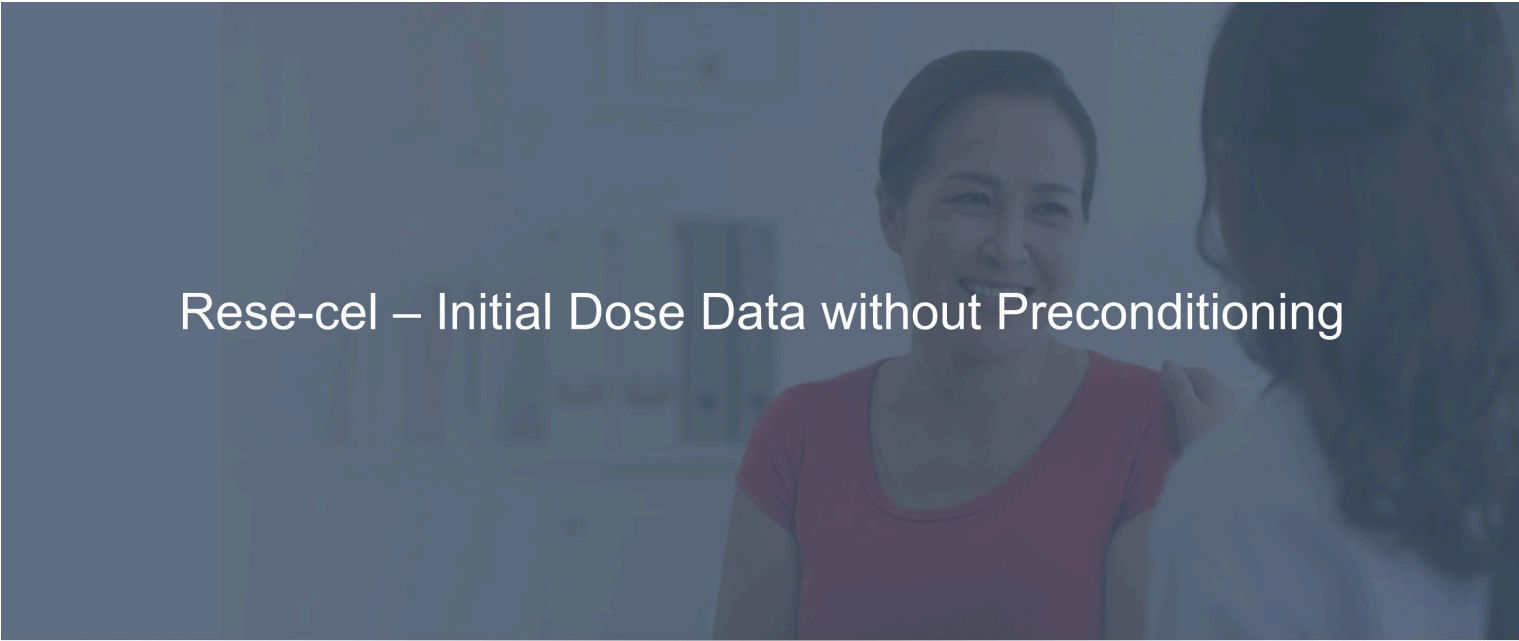
MG: Efficacy data following rese-cel infusion*

As of latest follow-up, both evaluable patients showed improvement off immunomodulators and steroids



RESET-MG is now fully enrolled in both cohorts
Cabaletta plans to align with FDA on the registrational cohort design in 1H26

*As of 11 Sep. 2025.
†AChR-pos-1, Day 29 visit data unavailable. In AChR-pos-1, azathioprine, 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.
AChR, acetylcholine receptor; AZA, azathioprine; IVIg, intravenous immunoglobulin; MG, myasthenia gravis; MG-ADL, MG – Activities of Daily Living; QMG, Quantitative Myasthenia Gravis Score; rese-cel, resecabtagene autoleucel.
Cabaletta Bio: Data on file.



Rese-cel – Initial Dose Data without Preconditioning

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Rese-cel without preconditioning (PC), initial dose cohort*

Summary of early clinical and translational data

- 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
- Complete B cell depletion 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
- IFN γ 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 PC¹
 - 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; IFN γ , interferon-gamma

1. Standard preconditioning in RESET trials consists of fludarabine 25 mg/m² x 3 days and cyclophosphamide 1000 mg/m² x 1 day.

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Baseline characteristics of first 3 patients in RESET-PV™

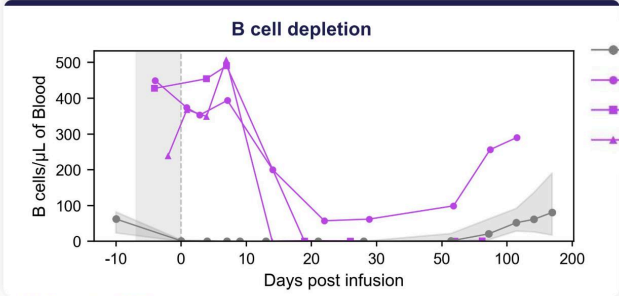
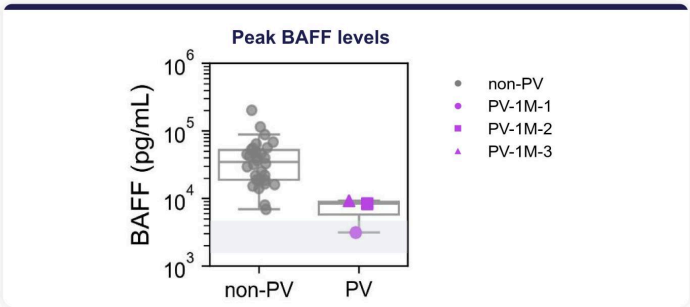
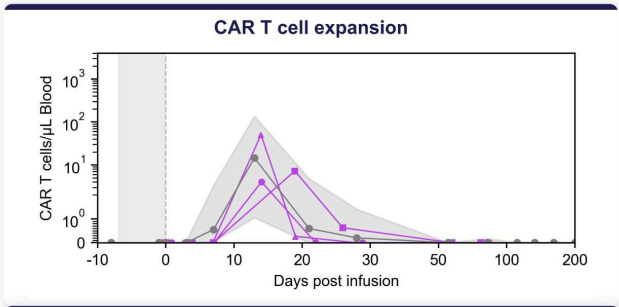
All pts had moderate to severe, active, refractory disease & failed B cell-targeting therapies, including RTX

Patient	RESET-PV™		
	PV-1M-1	PV-1M-2	PV-1M-3
Age, sex	48, M	64, M	53, F
PV type	Mucosal	Mucocutaneous	Mucosal with minor skin involvement
Disease duration (approx. years)	7	3	8
Autoantibodies	DSG3	DSG3, DSG1	DSG3, DSG1
Baseline* PDAI Total	24	95	23
Baseline* PDAI Skin Activity	0	44	1
Baseline* PDAI Scalp Activity	0	4	0
Baseline* PDAI Mucous Membrane Activity	24	35	21
Baseline* PDAI Damage (Skin + Scalp)	0	12	1
Systemic therapies at screening	None	MMF	None
Other prior therapies	RTX ¹ , MMF, MTX, GC	GC, IVIg, RTX ¹ , MMF	RTX ¹ , MMF, IVIg
GC dose at screening (mg/day)	None	None ²	None ³

As of 11 September 2025. Cabaletta Bio: Data on file.
1M, 1 million CAR T cells/kg; DSG1, desmoglein 1; DSG3, desmoglein 3; GC, glucocorticoid; IVIg, intravenous immunoglobulin; MMF, mycophenolate mofetil; MTX, methotrexate; PDAI, Pemphigus Disease Area Index; PV, pemphigus vulgaris; RESET, REStoring SElf-Tolerance; RTX, rituximab.
Baseline disease scores at pre-infusion visit
1. RTX last received ~13 months (PV-1M-1), ~29 months (PV-1M-2), and >6 years (PV-1M-3) prior to infusion
2. Prednisone 20 mg/day at Baseline
3. Prednisone 10 mg/day at Baseline

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



**PV-1M-1 had an ~ 87% reduction;
PV-1M-2 & PV-1M-3 had 100% reduction
of B cells at initial rese-cel dose**

*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.

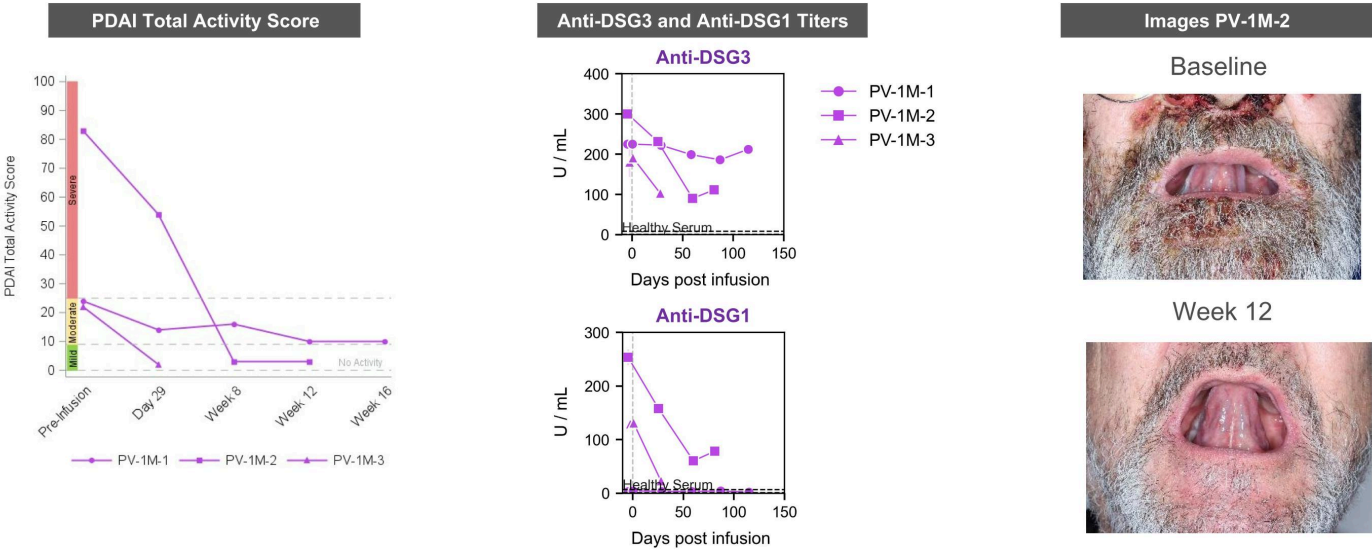
Incidence of relevant and related serious adverse events*

Patient	RESET-PV™ without preconditioning (PC)			Non-PV RESET™ Trials with PC^ n/N (%)
	PV-1M-1	PV-1M-2	PV-1M-3	
Latest follow up	Week 16	Week 12	Day 29	Safety summary through first 29 Days
CRS**	Grade 1	None	None	11 / 32 (34%)
ICANS**	None	None	None	2 / 32 (6%)
Serious infections‡	None	None	None	0 / 32 (0%)
Related SAEs (Grade)§ (excluding CRS and ICANS)	None	None	None	5 / 32 (16%)#

*As of 11 September 2025. Cabaletta Bio; Data on file.
Primary endpoint is incidence and severity of adverse events through Day 29.
**Graded per ASTCT Consensus Grading Criteria.
‡Coded in System Organ Class of Infections and Infestations and meets seriousness criteria.
§As assessed per FDA guidelines.
#Events include fever (Grade 1), febrile neutropenia (Grade 1 & 2), pancytopenia (Grade 4), encephalopathy (Grade 4)¶, respiratory failure (Grade 4)¶, physical deconditioning (Grade 3), and anorexia (Grade 3). All SAEs were transient with no sequelae.
¶One patient experienced encephalopathy and respiratory failure, which was confounded by the patient's use of several sedating medications and concurrent medical conditions.
^Non-PV RESET™ Trials include RESET-Myositis™, RESET-SLE™, RESET-SSc™, and RESET-MG™ which all include preconditioning lymphodepletion with rese-cel infusion.
1M, 1 million CAR T cells / kg; ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; PV, pemphigus vulgaris; RESET, REstoring SElf-Tolerance; SAE, serious adverse event.

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 improvements were most significant in the two patients who experienced complete B cell depletion; 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).

A photograph of a woman with dark hair, wearing a red top, smiling warmly. She is in a laboratory or office setting with shelves of equipment in the background. Another person's shoulder is visible on the right side of the frame. The image has a dark blue overlay.

Rese-cel Manufacturing

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Manufacturing strategy to BLA submission

Clinical Supply:

- Penn has reliably provided timely product for years
- Minaris Advanced Therapies (MAT) (formerly WuXi) partnership provides additional rese-cel supply

Innovative Manufacturing:

- Expanded partnership for automated manufacturing with Cellares and completed Technology Adoption Program



- Evaluating whole blood process to eliminate apheresis

Commercial Supply:

- Commercial supply strategy in hand, with process qualification and validation activities, required for BLA submission, planned:

1) LVV process at Oxford¹



2) Drug product process at Lonza²



- Commercial-ready drug product tech transfer process completed with Lonza
- Opportunity for additional manufacturing partners

LVV – lentiviral vector

1. Oxford is a commercial supplier for lentiviral vector utilized in approved CAR T products.

2. Lonza has extensive experience manufacturing commercial cell and gene therapies.



Corporate Summary

Caballetta Bio[®]

Cabaletta Bio leadership

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

LEADERSHIP TEAM



Steven Nichtberger, M.D.
President, CEO & Chairman



Samik Basu, M.D.
Chief Scientific Officer



Gwendolyn Binder, Ph.D.
President, Science & Technology



David J. Chang, M.D., M.P.H., FACR
Chief Medical Officer



Arun Das, M.D.
Chief Business Officer



Steve Gavel
Chief Commercial Officer



Michael Gerard
General Counsel



Heather Harte-Hall
Chief Compliance Officer



Anup Marda
Chief Financial Officer



Nicolette Sherman
Chief HR Officer



Sarah Yuan
Chief Technology Officer



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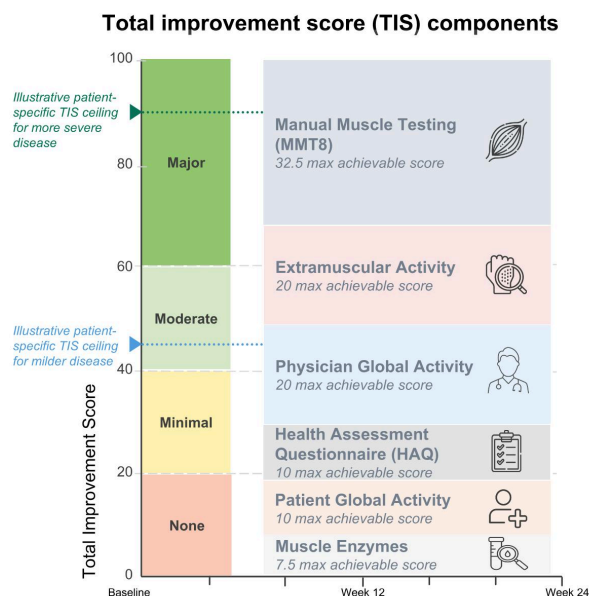


Appendix

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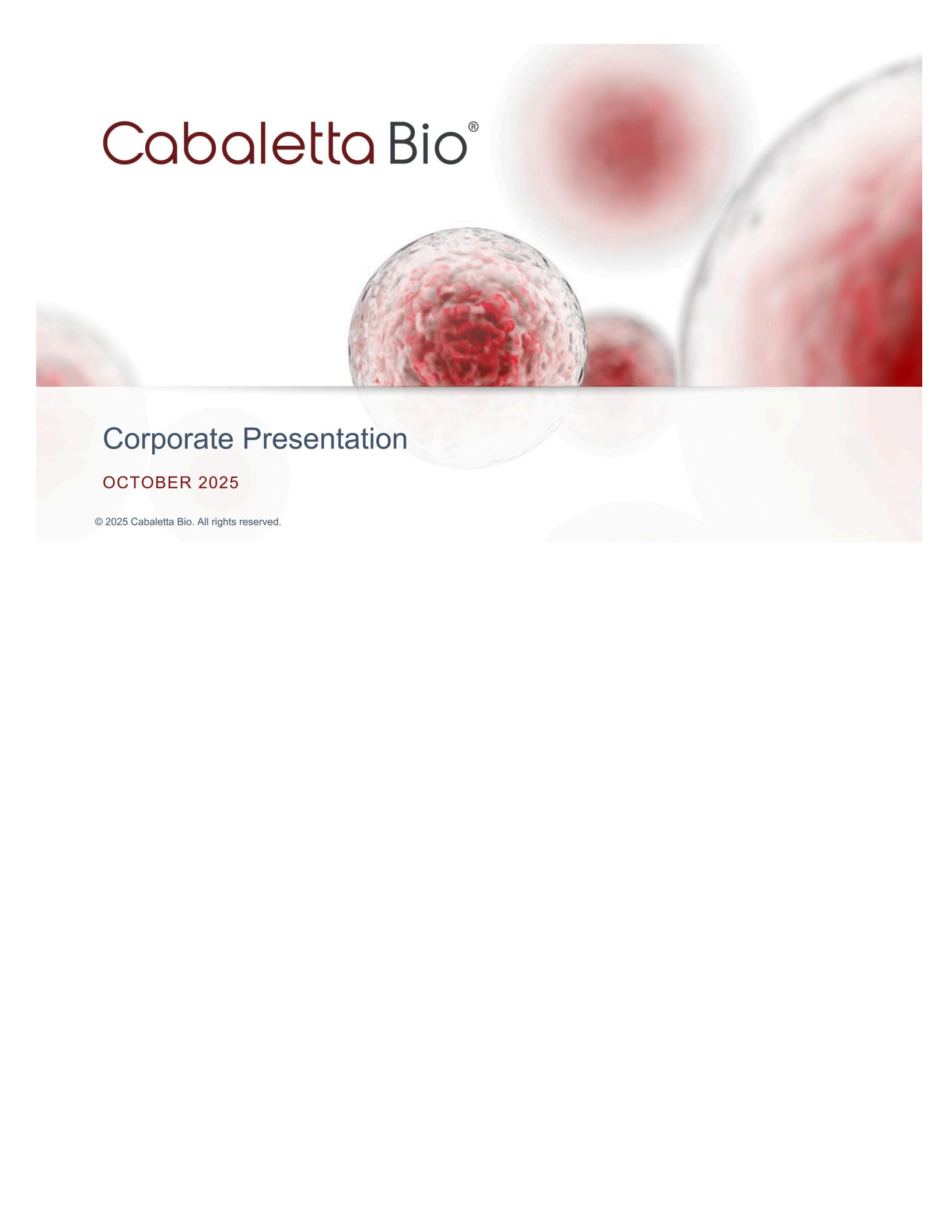
Myositis outcomes captured through validated composite endpoint

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



- 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

OCTOBER 2025

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