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 09, 2025

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 Suite 600 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 7.01 Regulation FD Disclosure.

On October 9, 2025, Cabaletta Bio, Inc. ("Cabaletta" or the "Company") issued a press release reporting new clinical and translational data from the ongoing RESET-PV™ trial evaluating rese-cel (resecabtagene autoleucel, formerly known as CABA-201) (the "Press Release"). A copy of the Press Release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section and shall not be incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On October 9, 2025, 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 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

Cabaletta is presenting new clinical and translational data from three evaluable patients who were dosed with rese-cel in the RESET-PV trial in a late-breaking clinical oral presentation at the 2025 European Society of Gene & Cell Therapy (ESGCT) Annual Congress. The RESET-PV trial is the first study within Cabaletta's RESET clinical development program to evaluate rese-cel without the use of cyclophosphamide and fludarabine as preconditioning agents.

Key clinical and translational insights from these patients, as of the data cut-off date of September 11, 2025, include:

- **Translational Profile:** Rese-cel exhibited similar CAR T cell expansion and contraction kinetics relative to translational data reported from other RESET trials with preconditioning. All three patients experienced substantial depletion of B cells within the first month post-infusion, with patients 2 and 3 achieving complete peripheral B cell depletion. In these two patients, rapid reduction in autoantibodies to desmoglein was observed and the increase in peak B cell activating factor (BAFF) was within the range of patients dosed with rese-cel plus preconditioning from pre-infusion through the latest follow-up, suggestive of deep B cell depletion in the tissue.
- **Safety Profile:** Rese-cel was generally well tolerated with no immune effector cell-associated neurotoxicity syndrome (ICANS) reported. After infusion, patient 1 experienced transient fever (grade 1 cytokine release syndrome). Patient 2 required a course of steroids for a disease flare in the first two weeks following infusion after discontinuing immunomodulators. This steroid course was less intense than a previous course that was administered for a flare prior to infusion where limited impact on disease was observed. The patient has tapered the steroid dose to below the pre-infusion baseline dose at 3 months post-infusion.
- **Clinical Profile:** Meaningful early clinical responses were observed in all three patients starting in the first month post-infusion based on Pemphigus Disease Area Index (PDAI) score for skin, scalp and mucosal surfaces. From baseline to latest follow-up, PDAI activity scores improved as follows:
    - Patient 1 (4 mo): 24 to 10
    - Patient 2 (3 mo): 83 to 3
    - Patient 3 (1 mo): 22 to 2

  PDAI activity scores have formed the basis for the most recent regulatory approval in PV. Total PDAI scores were also reported to be consistent with the PDAI activity scores, including improvement in the PDAI damage scores, in the late-breaking clinical oral presentation. PDAI improvements were most significant in the two patients who experienced complete B cell depletion. All three patients remain off immunomodulators as of the data cut-off.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release issued by the registrant on October 9, 2025, furnished herewith.
99.2	Cabaletta Bio, Inc. Corporate Presentation, dated October 2025, 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: October 9, 2025

By: /s/ Steven Nichtberger

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

Exhibit 99.1

Cabaletta Bio®

Cabaletta Bio Presents First Rese-cel Data with No Preconditioning Demonstrating Biologic Activity and Early Clinical Responses at the 2025 ESGCT Annual Congress

– Complete B cell depletion, rapid reduction in autoantibodies and near-complete resolution of clinical symptoms in two of three refractory patients; all three patients remained off immunomodulators since infusion and are off or tapering steroids as of the data cut-off –

– CAR T cell expansion in all three patients without preconditioning was similar to expansion across 30+ patients dosed with preconditioning in the other RESET™ trials –

– Initial dose data support continued exploration of rese-cel without preconditioning in pemphigus vulgaris at the current dose and evaluation of the no preconditioning regimen as an alternative treatment option in certain other autoimmune diseases –

– All adult Phase 1/2 cohorts within the myositis, lupus, scleroderma and myasthenia gravis RESET trials are fully enrolled as of September 30, 2025 –

PHILADELPHIA, Oct. 9, 2025 -- Cabaletta Bio, Inc. (Nasdaq: CABA), a clinical-stage biotechnology company focused on developing and launching the first curative targeted cell therapies designed specifically for patients with autoimmune diseases, today presented initial dose data from the RESET-PV™ trial evaluating rese-cel (resecabtagene autoleucel, formerly known as CABA-201) at 1 x 10^6 cells/kg without preconditioning in three evaluable patients with pemphigus vulgaris (PV). These data are being presented in a late-breaking clinical oral presentation by Samik Basu, M.D., Chief Scientific Officer at Cabaletta, at the ongoing 2025 European Society of Gene & Cell Therapy (ESGCT) Annual Congress, which is being held in Seville, Spain, from October 7-10, 2025.

“These data provide preliminary evidence that a single infusion of rese-cel without preconditioning can achieve complete B cell depletion and meaningful early clinical responses with a simplified regimen that can expand access to patients who may desire a treatment option without preconditioning,” said David J. Chang, M.D., Chief Medical Officer of Cabaletta. “Based on the observed biologic activity and early clinical responses, we plan to first expand patient enrollment in the RESET-PV trial at the current dose and potentially evaluate higher doses of rese-cel in PV patients, as warranted. In addition, we are pursuing the incorporation of no preconditioning regimens in certain other RESET clinical trial program cohorts. We look forward to communicating updates on our no preconditioning strategy in PV as well as in other autoimmune indications, along with broader clinical updates from ongoing RESET trials, at upcoming medical meetings.”

The RESET-PV trial is the first study within Cabaletta’s RESET clinical development program to evaluate rese-cel without the use of cyclophosphamide and fludarabine as preconditioning agents. Because the RESET trials share consistent study design principles, including a single, weight-based dose of rese-cel, there is relevant context to interpret the translational data

without preconditioning from the RESET-PV trial. As part of Cabaletta's innovation strategy, data from this trial will help inform the potential removal of preconditioning in certain trials within the RESET program.

In the late-breaking clinical oral presentation, key clinical and translational insights from the follow-up of the patients highlighted as of the data cut-off date of September 11, 2025, include:

- **Translational Profile:** Rese-cel exhibited similar CAR T cell expansion and contraction kinetics relative to translational data reported from other RESET trials with preconditioning. All three patients experienced substantial depletion of B cells within the first month post-infusion, with patients 2 and 3 achieving complete peripheral B cell depletion. In these two patients, rapid reduction in autoantibodies to desmoglein was observed and the increase in peak B cell activating factor (BAFF) was within the range of patients dosed with rese-cel plus preconditioning from pre-infusion through the latest follow-up, suggestive of deep B cell depletion in the tissue.

- **Safety Profile:** Rese-cel was generally well tolerated with no immune effector cell-associated neurotoxicity syndrome (ICANS) reported. After infusion, patient 1 experienced transient fever (grade 1 cytokine release syndrome). Patient 2 required a course of steroids for a disease flare in the first two weeks following infusion after discontinuing immunomodulators. This steroid course was less intense than a previous course that was administered for a flare prior to infusion where limited impact on disease was observed. The patient has tapered the steroid dose to below the pre-infusion baseline dose at 3 months post-infusion.

- **Clinical Profile:** Meaningful early clinical responses were observed in all three patients starting in the first month post-infusion based on Pemphigus Disease Area Index (PDAI) score for skin, scalp and mucosal surfaces. From baseline to latest follow-up, PDAI activity scores improved as follows:

    - Patient 1 (4 mo): 24 to 10
    - Patient 2 (3 mo): 83 to 3
    - Patient 3 (1 mo): 22 to 2

    PDAI activity scores have formed the basis for the most recent regulatory approval in PV. Total PDAI scores were also reported to be consistent with the PDAI activity scores, including improvement in the PDAI damage scores, in the late-breaking clinical oral presentation. PDAI improvements were most significant in the two patients who experienced complete B cell depletion. All three patients remain off immunomodulators as of the data cut-off.

Additional information can be accessed on the website of the 2025 ESGCT Annual Congress. The Company has made available the accepted abstract and will make available oral presentation materials following their presentation on the Posters & Publications section of its website.

About rese-cel (resecabtagene autoleucel, formerly CABA-201)
Rese-cel is an investigational, autologous CAR-T cell therapy engineered with a fully human CD19 binder and a 4-1BB co-stimulatory domain, designed specifically for the treatment of autoimmune diseases. Administered as a single, weight-based infusion, rese-cel is intended to

transiently and deeply deplete CD19-positive cells, with the goal of resetting the immune system and achieving durable clinical responses without the need for chronic therapy. Cabaletta is evaluating rese-cel in the RESET (REstoring SElf-Tolerance) clinical development program, which includes multiple ongoing company-sponsored trials across a diverse and growing range of autoimmune diseases in rheumatology, neurology and dermatology.

About Cabaletta Bio

Cabaletta Bio (Nasdaq: CABA) is a clinical-stage biotechnology company focused on developing and launching the first curative targeted cell therapies designed specifically for patients with autoimmune diseases. The CABA™ platform encompasses two complementary strategies which aim to advance the discovery and development of engineered T cell therapies with the potential to become deep and durable, perhaps curative, treatments for a broad range of autoimmune diseases. The lead CARTA (Chimeric Antigen Receptor T cells for Autoimmunity) strategy is prioritizing the development of rese-cel, a 4-1BB-containing fully human CD19-CAR T cell investigational therapy. Rese-cel is currently being evaluated in the RESET™ (REstoring SElf-Tolerance) clinical development program spanning multiple therapeutic areas, including rheumatology, neurology and dermatology. Cabaletta Bio's headquarters and labs are located in Philadelphia, PA. For more information, please visit www.cabalettabio.com and connect with us on LinkedIn.

Forward-Looking Statements

This press release contains "forward-looking statements" of Cabaletta Bio within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including without limitation, express or implied statements regarding: Cabaletta's business plans and objectives as a whole; Cabaletta's ability to realize its vision of launching the first curative targeted cell therapy designed specifically for patients with autoimmune diseases; Cabaletta's ability to successfully complete research and further development and commercialization of its drug candidates in current or future indications, including the timing and results of Cabaletta's clinical trials and its ability to conduct and complete clinical trials; expectation that clinical results will support rese-cel's safety and activity profile; statements regarding the timing of interactions with regulatory authorities, including such authorities' review of safety information from Cabaletta's ongoing clinical trials and potential registrational pathway for rese-cel; Cabaletta's ability to leverage its emerging clinical data and its efficient development strategy; Cabaletta's belief that its new data provides preliminary evidence that a single infusion of rese-cel without preconditioning has the potential to deliver complete B cell depletion and meaningful early clinical responses with a simplified treatment regimen that can expand access to patients who may desire a treatment option without preconditioning; Cabaletta's plan to expand patient enrollment in the RESET-PV trial at the current dose, while exploring the incorporation of no preconditioning regimens in certain other RESET clinical trial program cohorts; Cabaletta's potential updates on its no preconditioning strategy in PV as well as other autoimmune indications, along with broader clinical updates from ongoing RESET trials and timing of communications of such updates; Cabaletta's plan to remove preconditioning in certain trials within the RESET program; Cabaletta's ability to capitalize on and potential benefits resulting from its research and translational insights; the clinical significance of the clinical data read-out at upcoming scientific meetings and timing thereof; Cabaletta's expectations around the potential success and therapeutic benefits of rese-cel, including its belief that rese-cel has the potential to reset the immune system and result in profound clinical responses without chronic therapy requirements in patients; the Company's advancement of separate Phase 1/2 clinical trials of rese-cel in patients with SLE, myositis, SSc and gMG and advancement of the RESET-PV and RESET-MS

trials, including updates related to status, safety data, efficiency of clinical trial design and timing of data read-outs or otherwise.

Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: risks related to regulatory filings and potential clearance; the risk that signs of biologic activity or persistence may not inform long-term results; Cabaletta's ability to demonstrate sufficient evidence of safety, efficacy and tolerability in its preclinical studies and clinical trials of rese-cel; the risk that the results observed with the similarly-designed construct employed in academic publications, including due to the dosing regimen, are not indicative of the results we seek to achieve with rese-cel; risks that results from one program may not translate to results for another program; 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; risks related to clinical trial site activation, delays in enrollment generally or enrollment rates that are lower than expected; delays related to assessment of clinical trial results; risks related to unexpected safety or efficacy data observed during clinical studies; risks related to volatile market and economic conditions and public health crises; Cabaletta's ability to retain and recognize the intended incentives conferred by Orphan Drug Designation and Fast Track Designation or other designations for its product candidates, as applicable; risks related to Cabaletta's ability to protect and maintain its intellectual property position; risks related to fostering and maintaining successful relationships with Cabaletta's collaboration and manufacturing partners; uncertainties related to the initiation and conduct of studies and other development requirements for its product candidates; the risk that any one or more of Cabaletta's product candidates will not be successfully developed and/or commercialized; and the risk that the initial or interim results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Cabaletta's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Cabaletta's most recent annual report on Form 10-K as well as discussions of potential risks, uncertainties, and other important factors in Cabaletta's other subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Cabaletta undertakes no duty to update this information unless required by law.

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Cabaletta Bio®

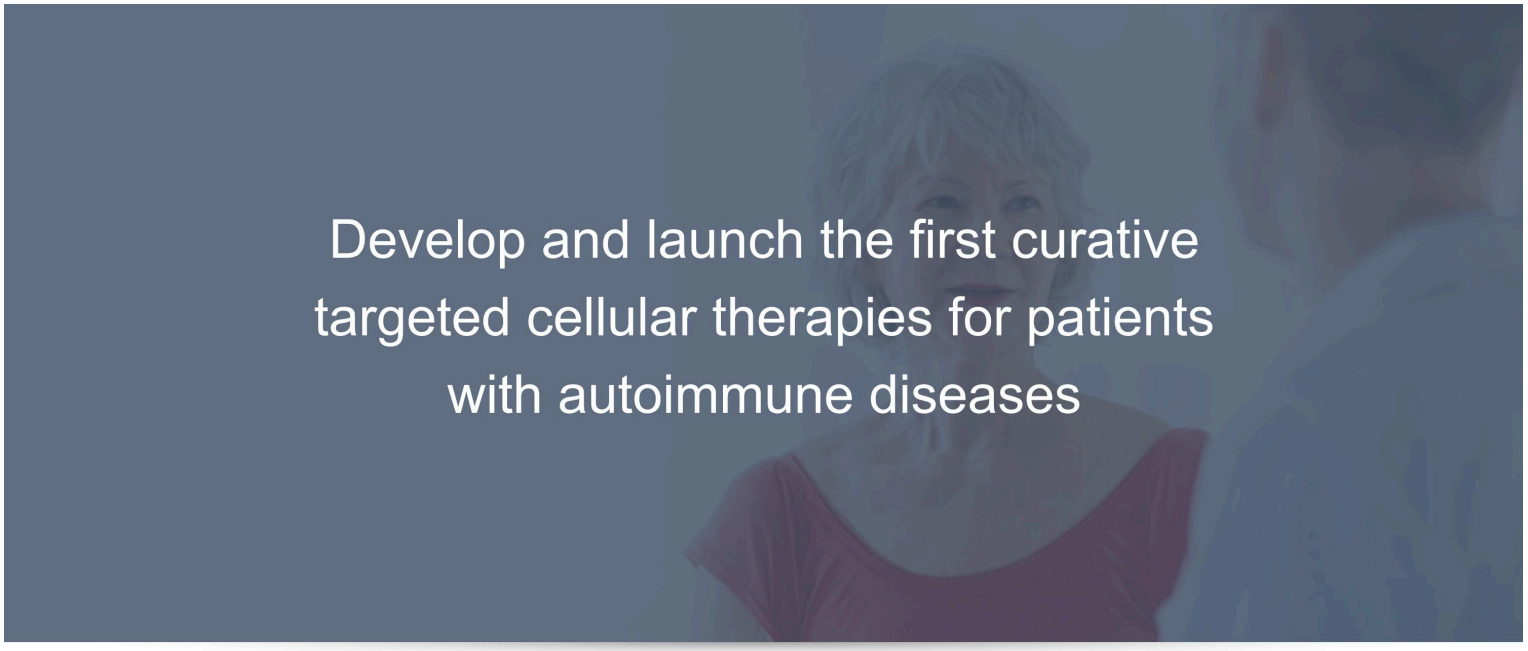
Corporate Presentation

OCTOBER 2025

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 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 belief regarding alignment with FDA on registrational trial design and timing thereof; 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.



Cabaletta Bio®

Rese-cel[1]: Delivering on the promise of CD19 for autoimmune patients

Over 70 clinical sites recruiting across 6 indications with myositis BLA submission expected in 2027

Aligned with FDA on open-label single arm evaluation of registrational cohorts in RESET-Myositis trial

- ~15 patients in each of two independent sub-type specific cohorts: DM/ASyS cohort (~60k/~15k pts) & IMNM (~7.5k pts)
  - Disease specific efficacy and safety data supplemented by safety data from ~100 RESET patients (>60% enrolled[2])
- Registrational cohorts use the same weight-based dose, similar entry criteria and same sites as Phase 1/2 cohorts

Transformative clinical responses in the vast majority of rese-cel patients after discontinuing immunomodulators[3]

- In the 1st 32 patients dosed with a single infusion of rese-cel with preconditioning (PC)[3]:
  - 94%: no CRS (66%) or grade 1 CRS (28%)
  - 94%: no ICANS

Rese-cel without preconditioning: complete B cell depletion & near-complete symptom resolution in 2 of 3 patients[3]

Multiple near-term catalysts

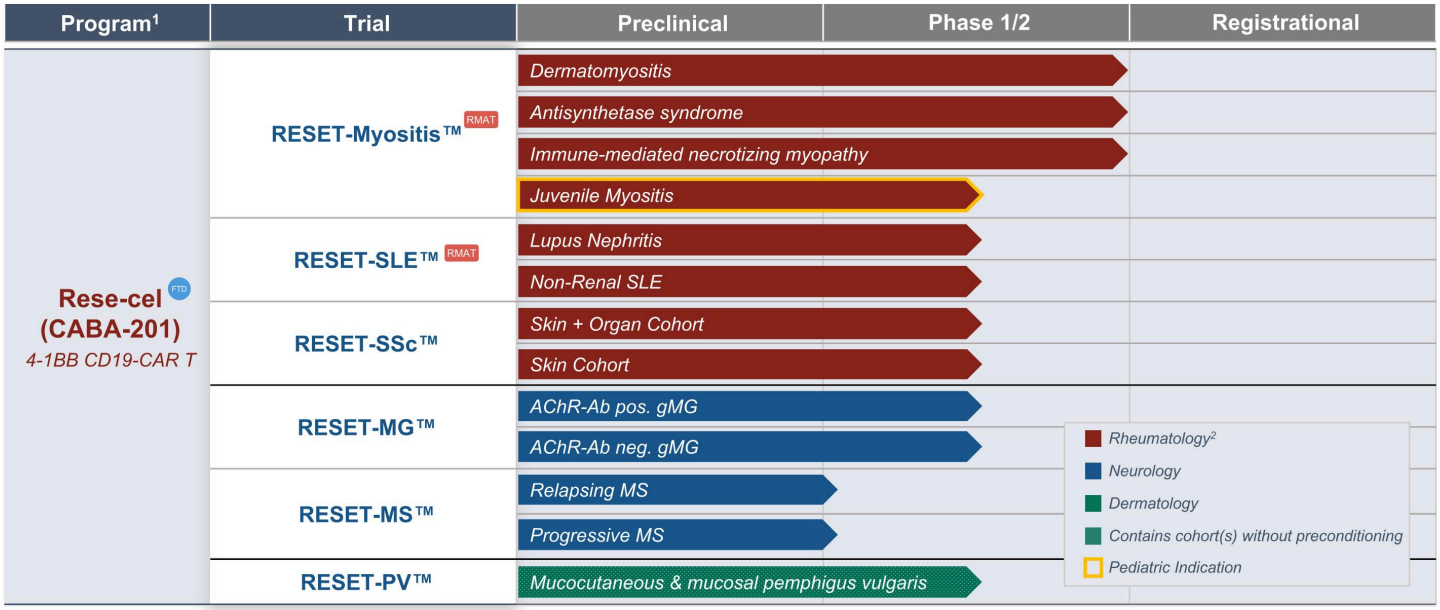
- ACR (Oct 24-29) – Complete Phase 1/2 RESET-Myositis data & interim RESET-SSc & RESET-SLE data
- AANEM (Oct 29) – RESET-MG initial clinical data
- Anticipating FDA alignment on pivotal trial design for SLE/LN and scleroderma in 2H25, MG in 1H26

Patients are seeking a drug-free, symptom-free life, which is rarely achieved with current therapies

SLE – systemic lupus erythematosus; LN – lupus nephritis; SSc – systemic sclerosis; BLA – biologics license application; PV – pemphigus vulgaris.
1. resecabtagene autoleucel; CABA-201
2. As of August 27, 2025.
3. As of data cut-off of September 11, 2025.

Innovative clinical strategy to support accelerated regulatory path

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



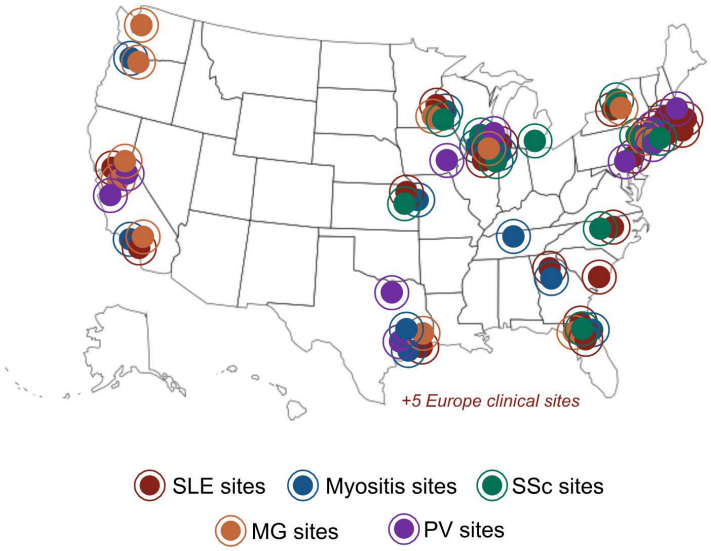
RESET™ – **RE**storing **SE**lf-**T**olerance; Ab – Antibody; AChR – Acetylcholine receptor; gMG – Generalized myasthenia gravis; MS – Multiple sclerosis; SLE – Systemic lupus erythematosus

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.

● FDA Fast Track Designation received in dermatomyositis, SLE and lupus nephritis, systemic sclerosis, and multiple sclerosis.
■ FDA Regenerative Medicine Advanced Therapy (RMAT) received in myositis, SLE and LN.

Rapidly completing enrollment in Phase 1/2 RESET™ trial cohorts

Enrollment continues in expansion cohorts until pivotal cohorts start enrolling

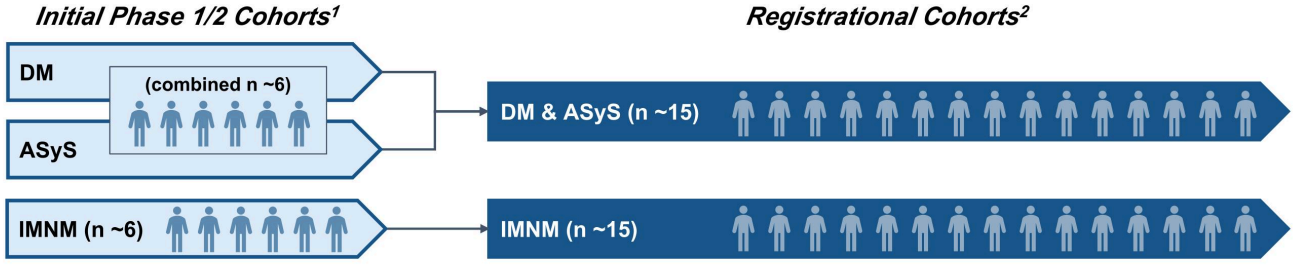


- Industry-leading US clinical site footprint[1] with 73 clinical sites recruiting in the US & Europe[2]
- 65 patients actively enrolled & 38 dosed[2]

1. As compared to companies with actively recruiting U.S. clinical sites for autoimmune cell therapy trials under company-sponsored INDs per clinictrials.gov.
2. As of August 27, 2025.

FDA aligned on key design elements of myositis registrational cohorts

FDA alignment achieved in Type C meeting for rese-cel; two open-label, single-arm cohorts to evaluate outcomes



- Expansion of current RESET-Myositis trial to include two registrational cohorts
- Evaluating a primary endpoint based on the **TIS**, a validated endpoint in myositis, within 26 weeks of rese-cel infusion
- 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)
  - Over 60% of the safety database already enrolled across the RESET clinical development program[3]
- **BLA for either registrational cohort may be submitted independently[4]**

2027 BLA submission planned in myositis; initiation of registrational cohorts anticipated in 2025

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 cohorts based on key statistical parameters aligned upon with the FDA and background remission rate in myositis.
3. As of August 27, 2025.
4. Subsequent indications anticipated to be submitted as an sBLA (Supplemental Biologics License Application).

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	☑ EULAR 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 in additional indication(s)**	
CMC commercial supply readiness & innovation	☑ FDA alignment: Safety comparability	☑ Commercial process implemented	☐ Initial clinical data w/ Cellares process[2]	

1. Subject to data and FDA alignment on proposed registrational cohort design.
2. Pending final agreement with Cellares to advance technology.

Rese-cel: Autologus CD19-CAR T for Autoimmunity

Cabaletta Bio®

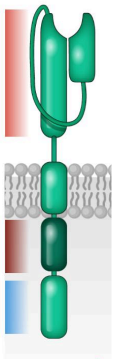
Rese-cel: CD19-CAR T specifically designed for autoimmunity

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

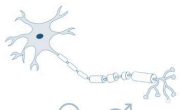
- **4-1BB costimulatory domain with fully human binder**
  - **Binder with similar affinity & biologic activity to academic FMC63 binder while binding to the same epitopes[1,2]**
- **Same weight-based dose as in academic studies**
  - **Potential to provide immune reset based on initial clinical and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

1. Peng, Binghao J, et al. "Preclinical specificity and activity of CABA-201, a fully human 4-1BB containing CD19 CAR T therapy for treatment-resistant autoimmune disease." Poster presented at: American Society Gene and Cell Therapy 26th Annual Meeting; 2023 May 19; Los Angeles, CA.
2. Dai, Zhenyu, et al. "Development and functional characterization of novel fully human anti- CD19 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™ 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

— No Flu/Cy —

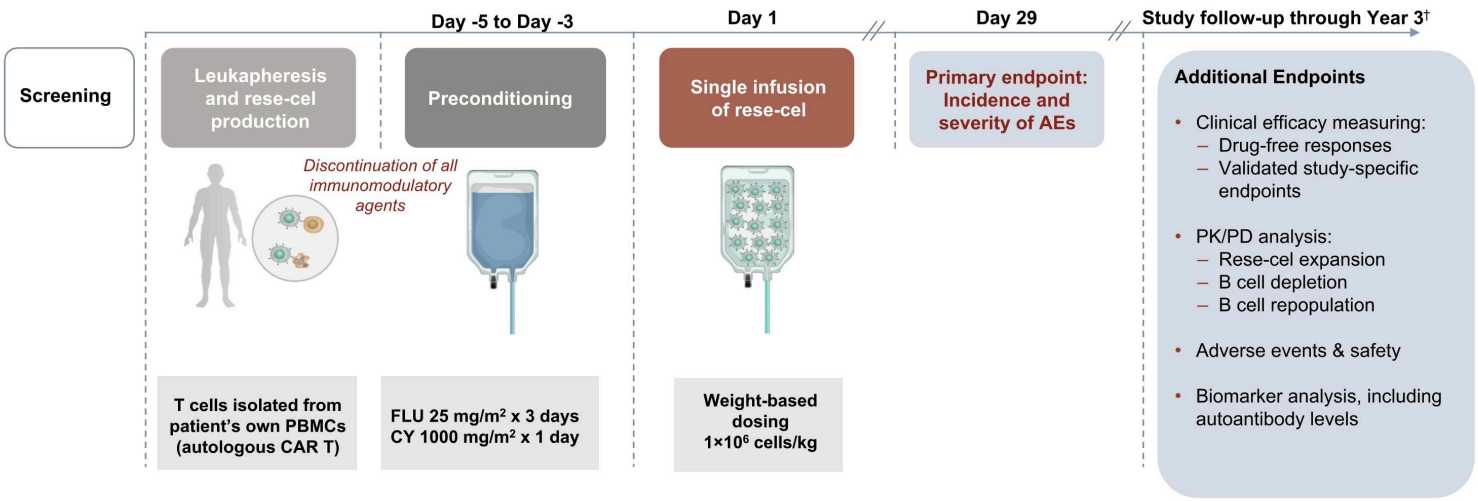
Myositis	SLE/LN	SSc	gMG	MS	PV
					
♀>♂	♀>♂	♀>♂	♀>♂	♀>♂	
Typical onset middle age Only FDA-approved therapy is IVIg in DM Three-fold increased mortality due to lung & cardiac involvement	Affects young women & people of color ~30-40% with lupus nephritis, which carries ~25% risk of death or ESRD within 10y	Middle age onset common Progressive skin & organ fibrosis with lung, cardiac, renal damage Average survival of 12y	Bimodal age of onset Profound weakness that can be disabling Risk for myasthenic crises, with respiratory failure	Chronic inflammation, axon loss, cognitive impairment, and irreversible neurologic damage	Pure autoantibody & B-cell mediated autoimmune disease Characterized by painful blisters & erosions
U.S. Prevalence					
~80k	~320k	~90k	~55k	~750k	~15k
EU Prevalence					
~85k	~150k	~60k	~100k	~550k	~20k

Rheum *Neuro* *Derm*

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 principles[1]

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.

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 criteria[1–3]

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

RESET-Myositis™

- Diagnosis of IIM (**ASyS, DM, or IMNM**)
- Age ≥18 and ≤75
- Presence of at least one myositis antibody
- **JIIM**: Age ≥6 and ≤17 with presence of at least one MSA or MAA

RESET-SLE™

- 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)

RESET-SSc™

- Diagnosis of **SSc limited or diffuse**
- Age ≥18 and ≤75
- Evidence of significant skin, pulmonary, renal, or cardiac involvement

Key exclusion criteria[1–3]

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

Anticipate completion of dosing in multiple 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; JIIM, juvenile idiopathic inflammatory myopathy; LN, lupus nephritis; MAA, myositis-associated antibody; SLEDAI-2k, SLE disease activity index 2000; SSc, systemic sclerosis.

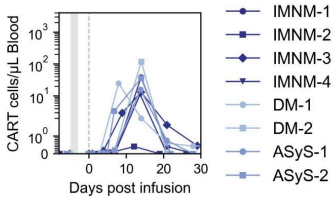
1. ClinicalTrials.gov. Available at: www.clinicaltrials.gov/study/NCT06121297 (accessed October 2024).
2. ClinicalTrials.gov. Available at: www.clinicaltrials.gov/study/NCT06328777 (accessed October 2024).
3. ClinicalTrials.gov. Available at: www.clinicaltrials.gov/study/NCT06154252 (accessed October 2024).

Rese-cel expansion & B cell kinetics across indications

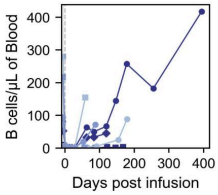
Peak rese-cel expansion and transient peripheral B cell depletion occurred within ~2 weeks post infusion

RESET-Myositis

Rese-cel Pharmacokinetics

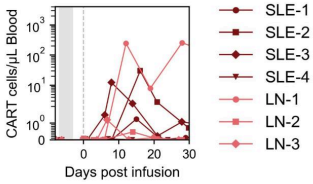


B Cell Kinetics

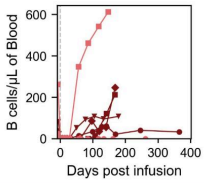


RESET-SLE

Rese-cel Pharmacokinetics*

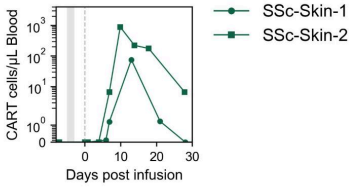


B Cell Kinetics

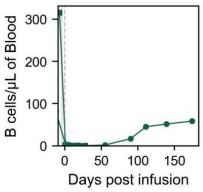


RESET-SSc

Rese-cel Pharmacokinetics



B Cell Kinetics



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

*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
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.

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]

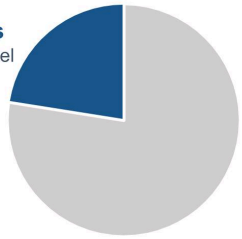
- Common therapies: steroids plus an immunomodulator (i.e. methotrexate, azathioprine, mycophenolate, rituximab)
- IVIg (intravenous immunoglobulin), the only FDA-approved therapy, is approved in adult dermatomyositis
- Therapies can carry potential long-term side effects such as serious infections and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

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)

~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 8 Patients in RESET-Myositis*

All patients had active, refractory disease and most had failed IVIg; an expensive & burdensome B cell therapy

	RESET-Myositis™							
Cohort	**DM**		**ASyS**		**IMNM**			
Patient	**DM-1^**	**DM-2**	**ASyS-1**	**ASyS-2**	**IMNM-1^**	**IMNM-2^**	**IMNM-3**	**IMNM-4**
Age, sex	57 M	45 F	39 M	48 F	33 M	60 M	55 M	64 M
Disease duration (y)	~4	~2	~4	~15	~2	~4	~1	~6
Autoantibodies	SAE	NXP-2; Ro	Jo-1; Ro-52	Jo-1; Ro-52	SRP	HMGCR	SRP; Ro-52	HMGCR
Baseline disease activity†	**MMT-8**							
	131	117	119	140	130	126	105	108
	CK (U/L)							
	94	39	502	121	617	4725	1447	529
Therapies at Screening	GC, MMF, HCQ	**IVIg**, MMF, HCQ	GC, **IVIg**, TAC	GC, **IVIg**, MMF, TAC	GC, MTX	GC, **IVIg**	MTX, AZA	GC, **IVIg**, MMF
Other prior therapies	**IVIg**	GC, **RTX**, TAC	**RTX**, MMF, TOC, AZA	**RTX**, MTX, MMF, AZA	**RTX, IVIg**	**RTX**, MTX, MMF	GC	AZA
GC dose at Screening (mg/day)	20	NA	10	5	5	5	NA	10

*As of May 6, 2025.
^Patient(s) who had clinical data presented in February 2025 scientific meetings.
†Baseline disease activity = activity before preconditioning.
ASyS, antisynthetase syndrome; AZA, azathioprine; CK, creatine kinase; DM, dermatomyositis; GC, glucocorticoid; HCQ, hydroxychloroquine; HMGCR, 3-hydroxy-3-methylglutaryl-coenzyme A reductase; IMNM, immune-mediated necrotizing myopathy; IVIg, intravenous immunoglobulin; MMF, mycophenolate mofetil; MMT-8, manual muscle testing 8; MTX, methotrexate; NXP, nuclear matrix protein; RESET, REstoring SElf-Tolerance; RTX, rituximab; SAE, small ubiquitin-like modifier activating enzyme; SRP, signal recognition particle; TAC, tacrolimus; TOC, tocilizumab; U/L, units per liter; y, years.
Cabaletta Bio: Data on File.

Incidence of relevant and related serious adverse events*

Fever (Grade 1 CRS) in 4 of 8 patients and no ICANS in any patients

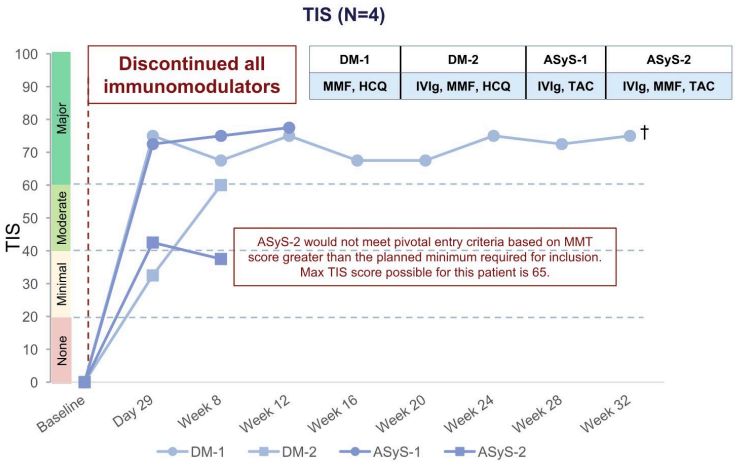
	RESET-Myositis™							
Cohort	**DM**		**ASyS**		**IMNM**			
Patient	**DM-1^**	**DM-2**	**ASyS-1**	**ASyS-2**	**IMNM-1^**	**IMNM-2^**	**IMNM-3**	**IMNM-4**
CRS†	None	Grade 1	Grade 1	Grade 1	None	None	Grade 1	None
ICANS†	None	None	None	None	None	None	None	None
Serious infections‡	None	None	None	None	None	None	None	None
Related SAEs (Grade)§ (excluding CRS and ICANS)	None	None	None	None	None	None	None	None

*As of May 6, 2025; primary endpoint is incidence and severity of adverse events through Day 29.
^Patient(s) who had clinical data presented in February 2025 scientific meetings.
†Graded per ASTCT Consensus Grading Criteria. DM-1, DM-2, ASyS-1, ASyS-2, and IMNM-3 received medication for seizure prophylaxis. Tocilizumab was administered for CRS for DM-2, ASyS-1, ASyS-2, and IMNM-3.
‡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; SAE, serious adverse event; RESET, REstoring SElf-Tolerance.
Cabaletta Bio: Data on File.

DM & ASyS: Efficacy data following rese-cel infusion*

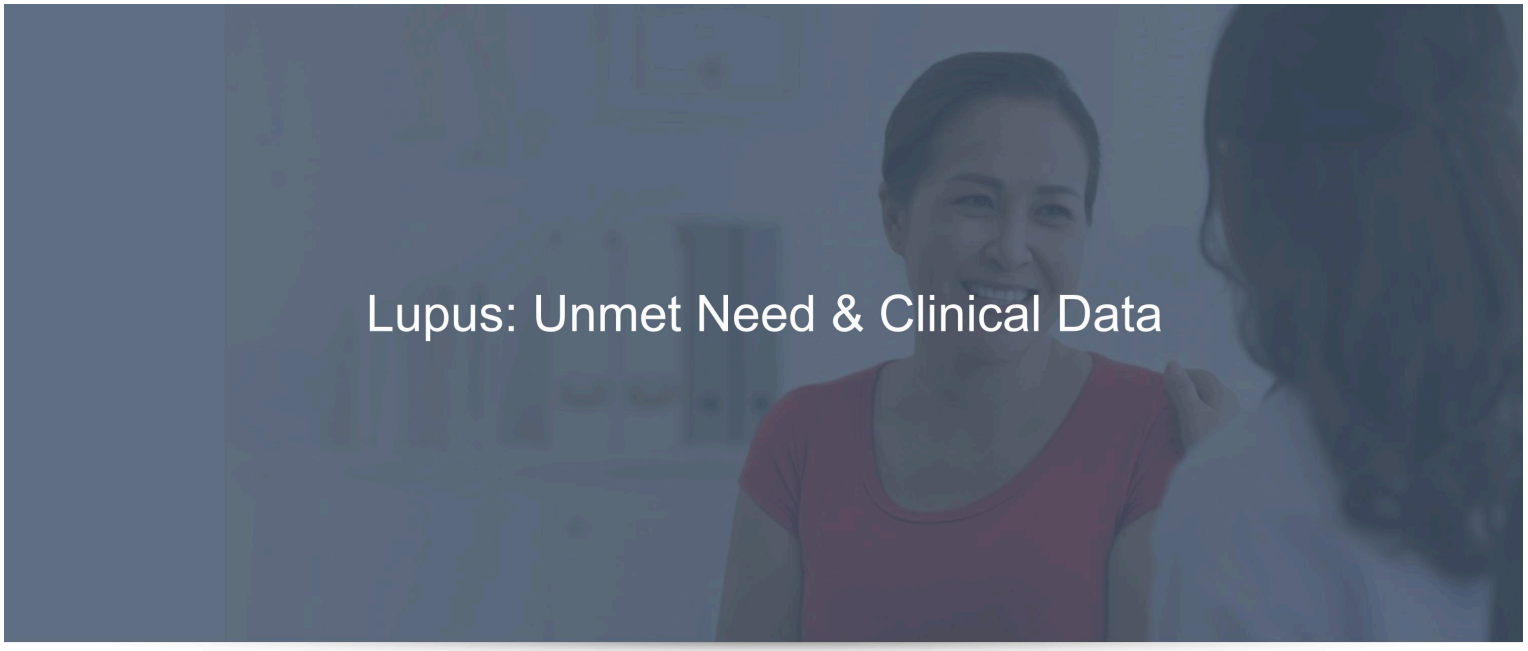
Clinical responses have been observed off immunomodulators and glucocorticoids in all patients

	DM		ASyS	
Patient	**DM-1^**	**DM-2**	**ASyS-1**	**ASyS-2**
Latest follow-up	32 weeks	8 weeks	12 weeks	8 weeks
TIS Response	Major	Major	Major	Minimal to moderate
GC-free	✓	✓	✓	✓
IM-free	✓	✓	✓	✓



TIS responses to rese-cel among all DM and ASyS patients show potential for achieving drug-free remission in patients with refractory myositis

*As of May 6, 2025. †DM-1 Week 32 CK value not available; Week 28 CK value used for TIS calculation.
^Patient(s) who had clinical data presented in February 2025 scientific meetings.
ASyS, antisynthetase syndrome; CK, creatine kinase; DM, dermatomyositis; HCQ, hydroxychloroquine; IVIg, intravenous immunoglobulin; MMF, mycophenolate mofetil; MMT-8, manual muscle testing 8; rese-cel, resecabtagene autoleucel; TAC, tacrolimus; TIS, total improvement score; U/L, units per liter.
Cabaletta Bio: Data on File.



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]

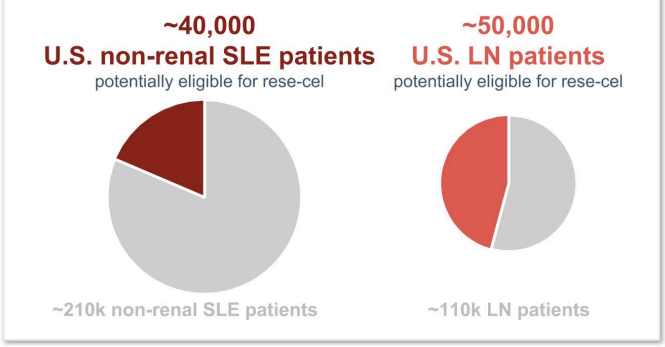
~30-40% of SLE patients develop LN, with inflammation & damage within the kidneys

- 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)



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 8 patients in RESET-SLE*

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

	Non-renal SLE				LN			
Patient / Cohort	**SLE-1‡^**	**SLE-2^**	**SLE-3^**	**SLE-4^**	**LN-1^**	**LN-2^**	**LN-3**	**LN-4**
Age, sex	26 M	36 F	44 F	37 F	24 F	35 F	26 F	18 M
Disease duration (y)	~6	~17	~9	~10	~2	~8	~16	~4
Autoantibodies§	dsDNA, Sm	dsDNA	dsDNA	dsDNA, Sm	dsDNA, Sm	dsDNA, Sm	Sm	dsDNA
LN class	V	N/A	N/A	N/A	III	IV + V	III + V	IV
SLEDAI-2K†	26	10	8	8	22	14	16	16
UPCR (mg/mg)†	1.08†	N/A	N/A	N/A	7.22	4.85	2.04	1.69
Therapies at screening	HCQ, GC, MMF	GC, AZA	HCQ, MMF, BEL	HCQ**	HCQ, GC, MMF, ANI, VOC	MMF	HCQ, MMF	HCQ, GC, MMF,TAC, BEL
Other prior therapies	CYC, BEL, VOC, TAC	HCQ, MTX, ANI, BEL, MSC, RTX, ADA	GC, MTX	GC, MTX, BEL	BEL, LEF	HCQ, GC, AZA, RTX	GC, MTX, AZA, TOC, UST, RTX, OBI	CYC, RTX, OBI
GC dose at screening (mg/day)	10	7	N/A	N/A**	20	N/A	N/A	5

*As of June 2, 2025.
^Patient(s) who had clinical data presented in February 2025 scientific meetings.
†Baseline disease activity = activity before preconditioning.
‡Inclusion criteria for LN cohort requires class III/IV LN (± class V).
§All patients were antinuclear antibody positive at screening.
**SLE-4 initiated 20 mg/day of prednisone after screening and before leukapheresis, tapering off by Week 12.
ADA, adalimumab; ANI, anifrolumab; AZA, azathioprine; BEL, belimumab; CYC, cyclophosphamide; dsDNA, double-stranded DNA; GC, glucocorticoid; HCQ, hydroxychloroquine; LEF, leflunomide; LN, lupus nephritis; MMF, mycophenolate mofetil; MSC, mesenchymal stem cell; MTX, methotrexate; N/A, not applicable; OBI, obinutuzumab; RESET, REstoring SElf-Tolerance; RTX, rituximab; SLE, systemic lupus erythematosus; SLEDAI-2K, SLE Disease Activity Index 2000; Sm, Smith; TAC, tacrolimus; TOC, tocilizumab; UPCR, urine protein-to-creatinine ratio; UST, ustekinumab; VOC, voclosporin, y, years.
Cabaletta Bio: Data on File.

Incidence of relevant and related serious adverse events*

Fever (Grade 1 CRS) reported in 2 of 8 patients & ICANS reported in 1 of 8 patients

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

*As of June 2, 2025; Primary endpoint is incidence and severity of adverse events through Day 29.
^Patient(s) who had clinical data presented in February 2025 scientific meetings.
†Graded per ASTCT Consensus Grading Criteria. All patients except SLE-1 and LN-1 received medication for seizure prophylaxis. Tocilizumab was administered for CRS in SLE-2.
‡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.
**LN-4: Week 4 safety data presented; efficacy follow up ongoing.
ASTCT, American Society for Transplantation and Cellular Therapy; CAR, chimeric antigen receptor; 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§ achieved DORIS

	Non-renal SLE			
Patient	**SLE-1†^**	**SLE-2^**	**SLE-3^**	**SLE-4^**
Latest follow-up	Week 52	Week 32	Week 28	Week 24
DORIS (at latest follow-up)	☐§	✓	✓	✓
SLEDAI-2K score‡ (baseline to latest follow-up)	26→12	10→2	8→2	8→2
UPCR (mg/mg) (baseline to latest follow-up)	1.08→1.71	N/A	N/A	N/A
eGFR (mL/min/1.73m²) (baseline to latest follow-up)	132.7→118.5	N/A	N/A	N/A
CRR (at latest follow-up)	☐§	N/A	N/A	N/A
GC-free	✓	✓	✓	✓
IM-free	✓§	✓	✓	✓

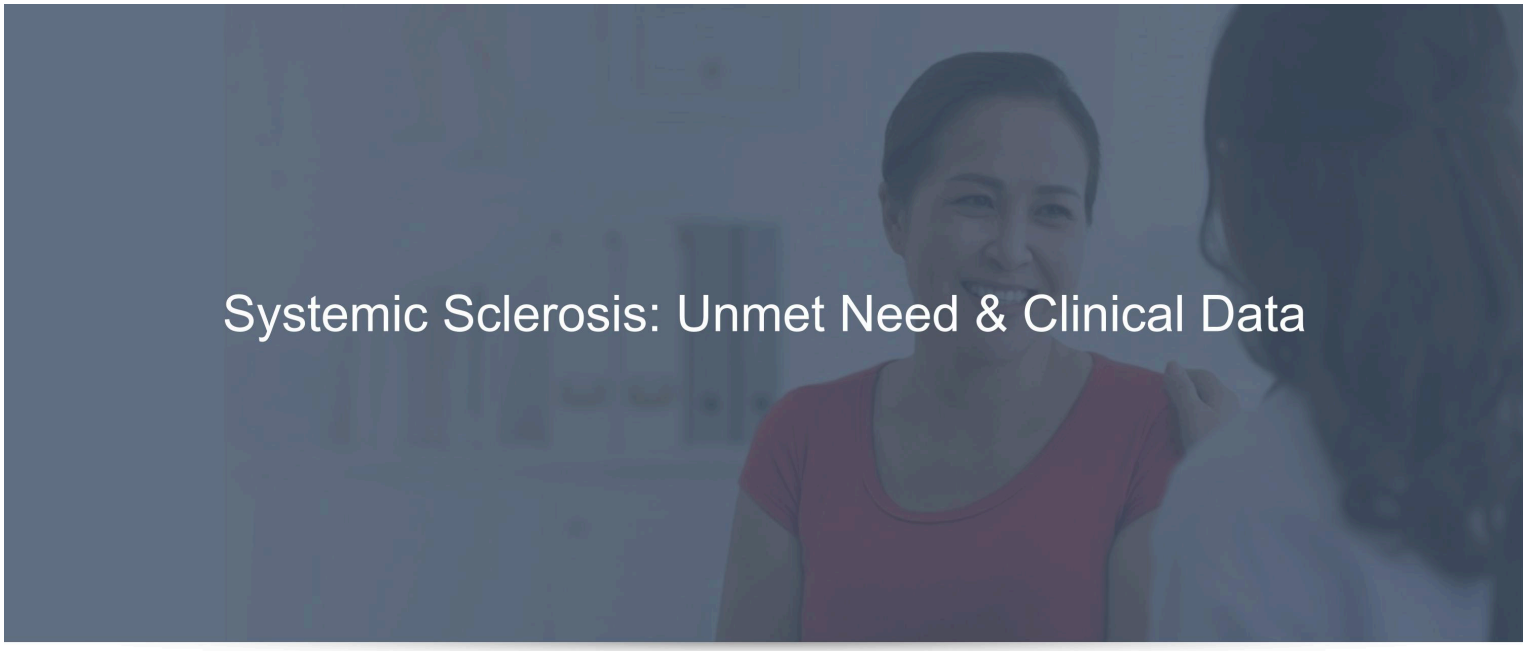
*As of June 2, 2025.
^Patient(s) who had clinical data presented in February 2025 scientific meetings.
†Enrollment in the LN cohort requires class III/IV +/- V LN. SLE-1 had pure class V LN and extra-renal SLE disease activity that met inclusion criteria for the non-renal cohort.
‡SLEDAI-2K components present at latest follow up (SLEDAI-2K contribution score in parenthesis): SLE-1: hematuria (4), proteinuria (4), complement (2), increased DNA binding (2); SLE-2: increased DNA binding (2); SLE-3: increased DNA binding (2); SLE-4: increased DNA binding (2).
§SLE-1 achieved DORIS at Week 48 and CRR at Week 44 and Week 48; on cyclosporine therapy since Week 41 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; rese-cel, resecabtagene autoleucel; SLE, systemic lupus erythematosus; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000; UPCR, urine protein-creatinine ratio.
DORIS = Clinical SLEDAI-2K=0 (irrespective of serology); Physician Global Assessment <0.5; antimalarials; low-dose glucocorticoids (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.
Cabaletta Bio: Data on File.

LN: Efficacy data following rese-cel infusion*

As of the data cut-off, 1st LN patient achieved CRR

	LN††		
Patient	**LN-1^**	**LN-2^**	**LN-3**
Latest follow-up	Week 44	Week 24	Week 12
DORIS (at latest follow-up)	✓	N/A	N/A
SLEDAI-2K score‡ (baseline to latest follow-up)	22→0	14→6	16→12
UPCR (mg/mg) (baseline to latest follow-up)	7.22→0.24	4.85→2.72**	2.04→2.02
eGFR (mL/min/1.73m²) (baseline to latest follow-up)	72.3→130.9	127.2→125.8	133.2→128.8
CRR (at latest follow-up)	✓	□	□
GC-free	✓	✓	✓
IM-free	✓	✓	✓

*As of June 2, 2025.
^Patient(s) who had clinical data presented in February 2025 scientific meetings.
‡SLEDAI-2K components present at latest follow up (SLEDAI-2K contribution score in parenthesis): LN-2: proteinuria (4), increased DNA binding (2); LN-3: hematuria (4), proteinuria (4), pyuria (4).
**LN-2 Week 24 UPCR = 24hr UPCR.
††LN-4: efficacy follow up ongoing.
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; rese-cel, resecabtagene autoleucel; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000; UPCR, urine protein-creatinine ratio.
DORIS = Clinical SLEDAI-2K=0 (irrespective of serology); Physician Global Assessment <0.5; antimalarials; low-dose glucocorticoids (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.
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

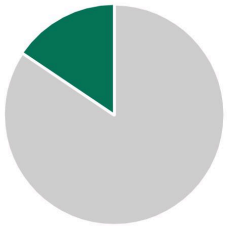
- Typically, middle age onset and more common in females[1]
- Highest mortality of all rheumatological diseases & significant burden from persistent skin & organ manifestations[4,5]
  - Mean survival is ~12 years from diagnosis
- Need for disease-modifying therapies across all SSc subsets[5]
  - FDA-approved agents for SSc-ILD slow but do not stabilize or improve lung progression
  - 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

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 & serious adverse events in first 2 SSc patients*

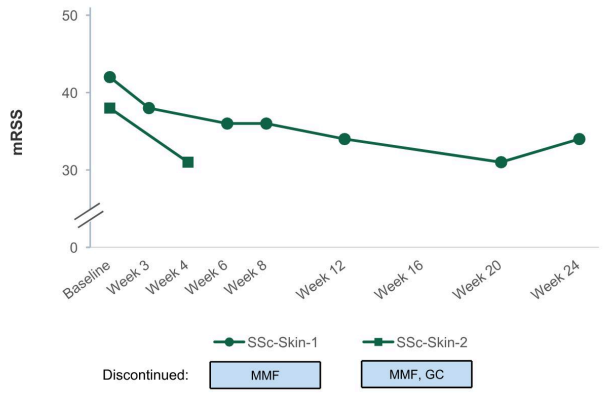
	RESET-SSc™	
Patient / Cohort	**SSc-Skin-1**^ (Severe skin cohort)	**SSc-Skin-2** (Severe skin cohort)
Age, sex	66 F	55 F
Disease duration (y)	~2	~0.5
Autoantibodies	RNA Pol III	Scl-70
Baseline mRSS**	**42**	**38**
Baseline HAQ-DI**	2.25	2.125
Baseline PFTs (% predicted)**	FVC: 91; DLCO: 70	FVC: 93; DLCO: 58
ILD presence†**	✓	-
Therapies at Screening	MMF (1500 mg BID)	MMF (1500 mg BID), GC
Other prior therapies	HCQ, BRX (Investigational)	None
Glucocorticoid dose at Screening (mg/day)	0	5
	Incidence of relevant and related serious adverse events*	
CRS††	Grade 2	None
ICANS††	None	Grade 3
Serious infections	None	None
Related SAEs‡ (Grade) ***(excluding CRS & ICANS)***	None	Neutropenic fever (1)

*As of May 6, 2025; primary endpoint is incidence and severity of adverse events through Day 29.
^Patient(s) who had clinical data presented in February 2025 scientific meetings.
**Baseline disease activity = activity before preconditioning. †Per patient history and HRCT
†† Graded per ASTCT Consensus Grading Criteria. Both patients received medication for seizure prophylaxis.
‡As assessed per US Food and Drug Administration guidelines.
ASTCT, American Society for Transplantation and Cellular Therapy; BID, twice per day; BRX, brentuximab vedotin; CRS, cytokine release syndrome; DLCO, % predicted diffusing capacity for carbon monoxide; FVC, forced vital capacity; GC, glucocorticoid; HAQ-DI, Health Assessment Questionnaire Disability Index; HCQ, hydroxychloroquine; ICANS, immune effector cell-associated neurotoxicity syndrome; ICE, immune effector cell-associated encephalopathy; ILD, interstitial lung disease; MMF, mycophenolate mofetil; mRSS, modified Rodnan skin score; SAE, serious adverse event; PFT, pulmonary function test; RESET, REstoring SElf-Tolerance; RNA Pol III, ribonucleic acid polymerase III; SSc, systemic sclerosis; y, years.
Cabaletta Bio: Data on File.

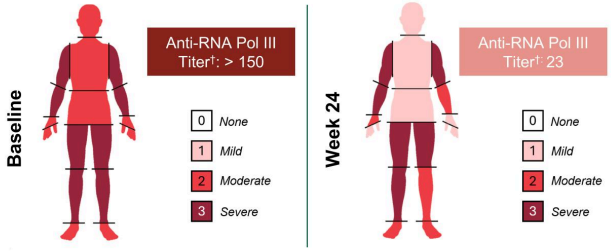
RESET-SSc™: Efficacy data following rese-cel infusion[1]

Improvements in both SSc patients after discontinuing immunomodulatory drugs and steroids

Overall mRSS (N=2)



mRSS by body area (SSc-Skin-1)



Pulmonary Evaluations (SSc-Skin-1)‡

	Baseline	Week 12	Week 24
DLCO	70%	85%	81%
FVC	91%	97%	105%
ILD	Mild stabilization on HRCT		

SSc-Skin-1 met revised CRISS response criteria starting at Week 12, supporting potential for a drug-free clinical response*

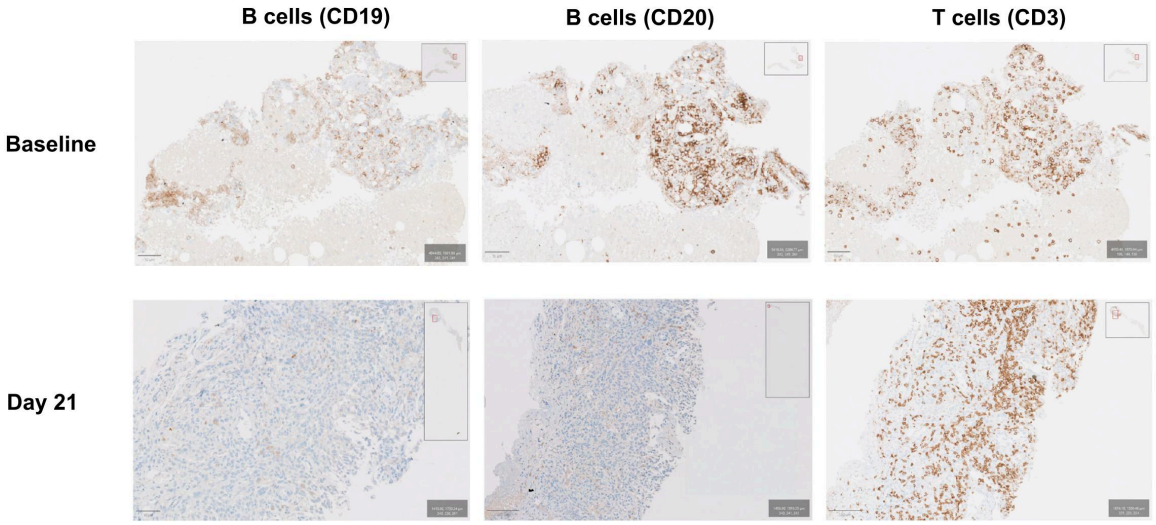
*As of May 6, 2025. †RNA Pol III IgG level performed locally at U Mich. ‡ Pulmonary evaluations not available for SSc-Skin-2 at Week 4.
CRISS, Composite Response Index in Systemic Sclerosis; DLCO, % predicted diffusing capacity for carbon monoxide; FVC, % predicted forced vital capacity; GC, glucocorticoid; HRCT, high-resolution computed tomography; ILD, interstitial lung disease; MMF, mycophenolate mofetil; mRSS, modified Rodnan Skin Score (measure of skin thickness in SSc across 17 body areas, with a maximum score of 512); RNA Pol III, ribonucleic acid polymerase III; rese-cel, resecabtagene autoleucel; SSc, systemic sclerosis.

1. Cabaletta Bio: Data on File. 2. Khanna D, et al. J Scleroderma Relat Disord. 2017;2(1):11–18;.

Cabaletta Bio®

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 mAbs[2]

*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; mAb, monoclonal antibody; RESET, REstoring SElf-Tolerance; SSc, systemic sclerosis.
1. Cabaletta Bio: Data on File. 2. Tur C, et al. Ann Rheum Dis. 2025;84(1):106–114.

Myasthenia Gravis: Unmet Need

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]

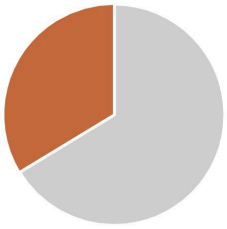
- Available therapeutic options focus on specific symptoms and can be associated with serious long-term side effects
- Mainstays include steroids, immunosuppressants (e.g., mycophenolate), FcRn antagonists, complement inhibitors and rituximab
- MG represents a significant healthcare cost burden in the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

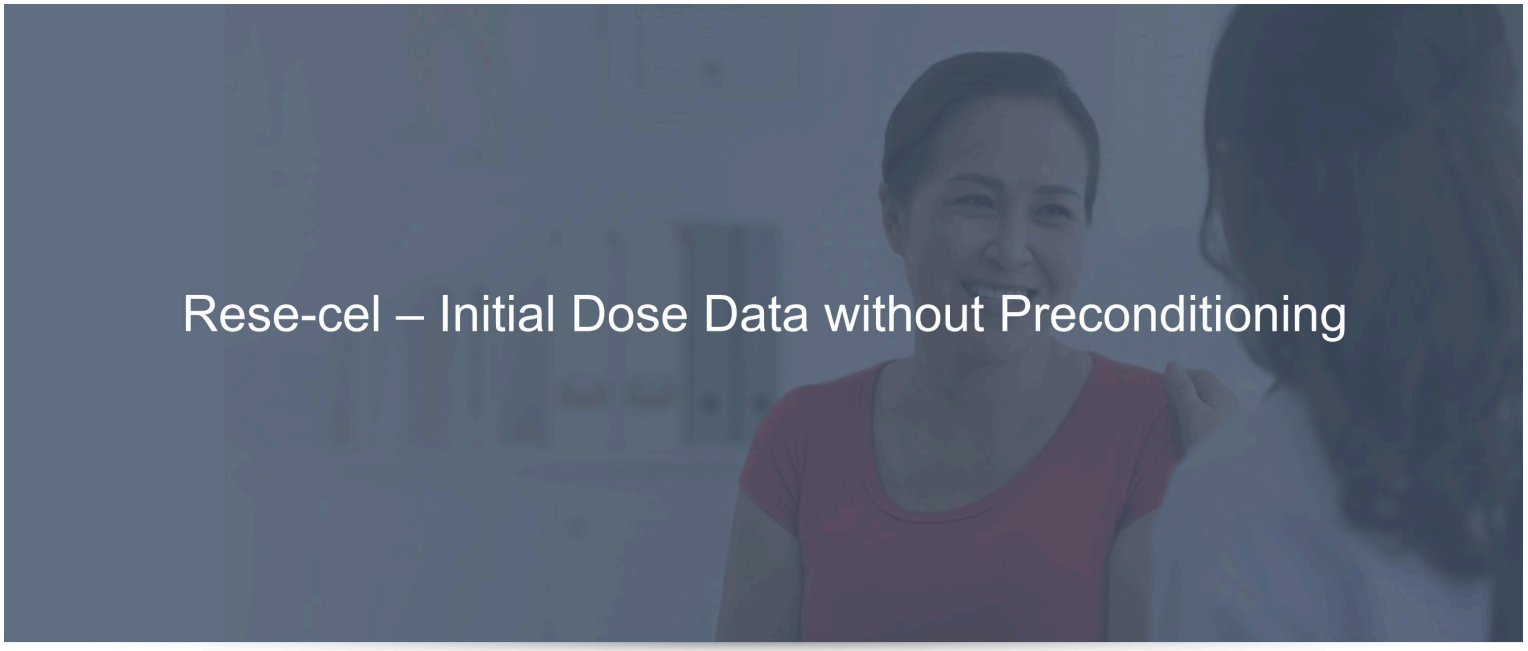
(per quantitative research with ~100 MG-treating physicians)

~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.



Rese-cel – Initial Dose Data without Preconditioning

Cabaletta Bio®

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 within 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.

RESET-PV™ phase 1/2 trial: key inclusion & exclusion criteria[1]

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

Key inclusion criteria

- Age ≥ 18
- Confirmed diagnosis of PV by prior or screening biopsy and prior DSG3 antibody positive (reconfirmed during screening)
- PV inadequately managed by at least one standard immunomodulatory therapy
- Active PV at screening

Key exclusion criteria

- Have paraneoplastic pemphigus or active malignancy (not including non-melanoma skin cancer)
- Have received rituximab or other anti-CD20 or anti-CD19 therapies in last 12 months unless anti-DSG3 antibody titers have recently increased or PV symptoms have recently worsened
- Prednisone > 0.25mg/kg/day
- Other autoimmune disorder requiring immunomodulatory therapies

As of 11 September 2025. DSG3, desmoglein 3; PV, pemphigus vulgaris; RESET™, REstoring SElf-Tolerance.
1. Cabaletta Bio: Data on file

Baseline characteristics of first 3 patients in RESET-PV™

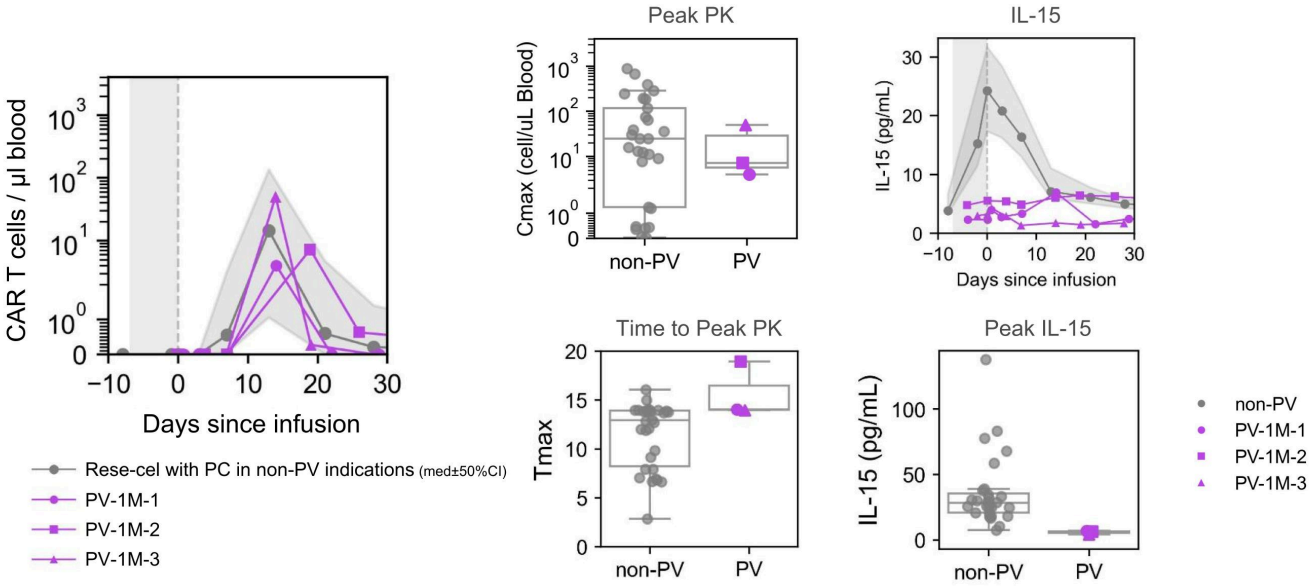
All pts had moderate to severe, active, refractory disease & failed B cell-targeting therapies, including RTX

	RESET-PV™		
Patient	**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

Peak expansion occurred slightly later in patients without PC

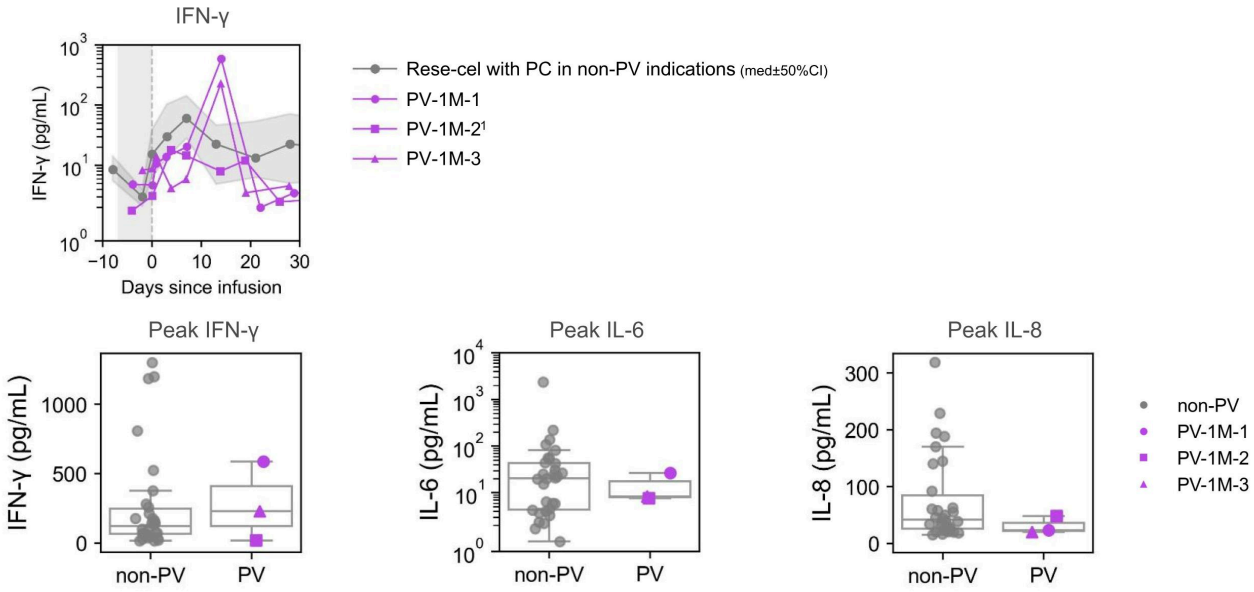
Similar rese-cel expansion observed in PC and non-PC cohorts in the absence of elevated serum IL-15



As of 11 September 2025. Cabaletta Bio: Data on file.
Gray vertical dotted line indicates day of rese-cel infusion (study visit Day 1). Gray vertical shading indicates PC window relative to infusion. 1M, 1 million CAR T cells / kg; CAR, chimeric antigen receptor; CI, confidence interval; IL, interleukin; PC, preconditioning; PK, pharmacokinetics; PV, pemphigus vulgaris; rese-cel, resecabtagene autoleucel.

IFN-γ induction observed ~ 2 weeks after infusion

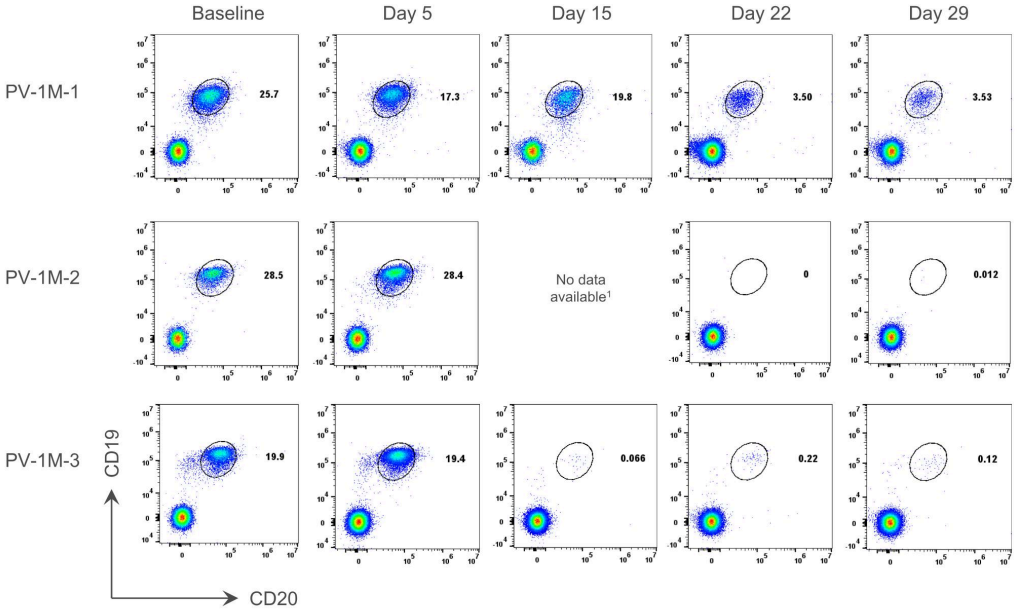
IFN-γ induction occurred ~ 1 week later in PV subjects without PC than in rese-cel patients with PC

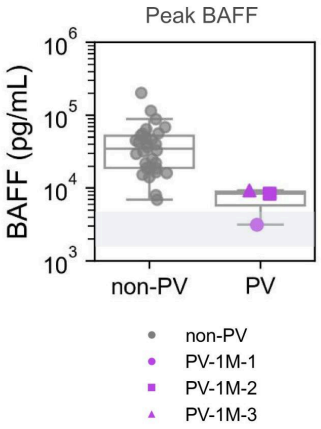


As of 11 September 2025. Cabaletta Bio: Data on file. Gray vertical dotted line indicates day of rese-cel infusion (study visit Day 1). Gray vertical shading indicates PC window relative to infusion. 1M, 1 million CAR T cells / kg; CI, confidence interval; IFN, interferon; IL, interleukin; PC, preconditioning; PV, pemphigus vulgaris; rese-cel, resecabtagene autoleucel. 1PV-1M-2 received high dose steroids approximately 12 days after infusion (Day 13 study visit) due to disease flare.

B cell depletion & serum BAFF induction observed in all subjects

PV-1M-1 had an ~ 84% reduction, PV-1M-2 & PV-1M-3 had 100% reduction of B cells at initial rese-cel dose





As of 11 September 2025. Cabaletta Bio: data on file.
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*). 1M, 1 million CAR T cells / kg; BAFF, B cell activating factor; PV, pemphigus vulgaris.
1. Sample collection issue.

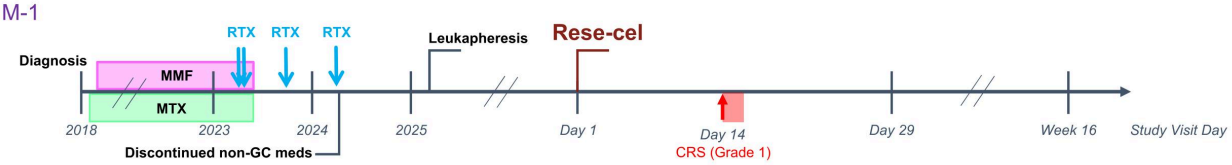
Incidence of relevant and related serious adverse events*

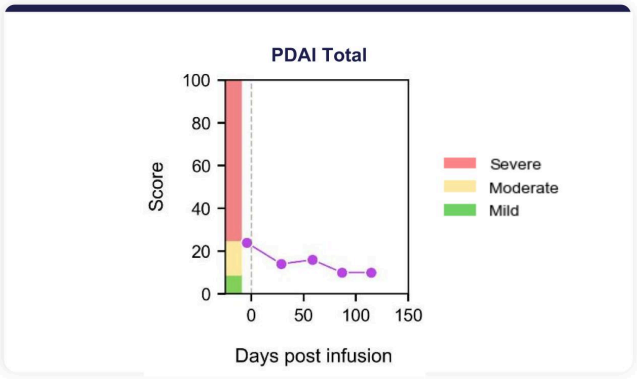
	RESET-PV™ without preconditioning (PC)			Non-PV RESET™ Trials with PC^ n/N (%)
Patient	**PV-1M-1**	**PV-1M-2**	**PV-1M-3**	
Latest follow up	Week 16	Week 12	Day 29	Safety summary through first 29 Days
CRS**	Grade 1	None	None	11 / 32 (34%)
ICANS**	None	None	None	2 / 32 (6%)
Serious infections‡	None	None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

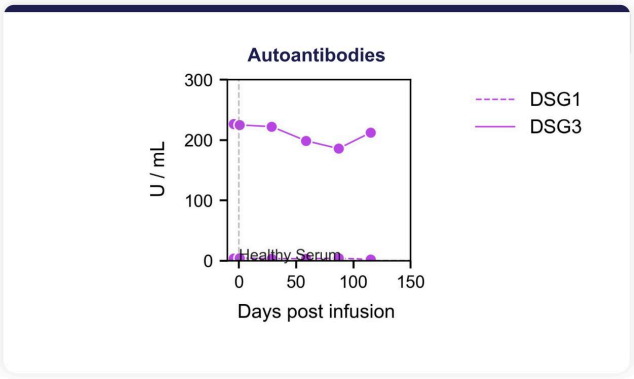
*As of 11 September 2025. Cabaletta Bio: Data on file.
Primary endpoint is incidence and severity of adverse events through Day 29.
**Graded per ASTCT Consensus Grading Criteria.
‡Coded in System Organ Class of Infections and Infestations and meets seriousness criteria.
§As assessed per FDA guidelines.
#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 patent'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.

Patient 1: Early efficacy data following rese-cel infusion without PC*

PV-1M-1





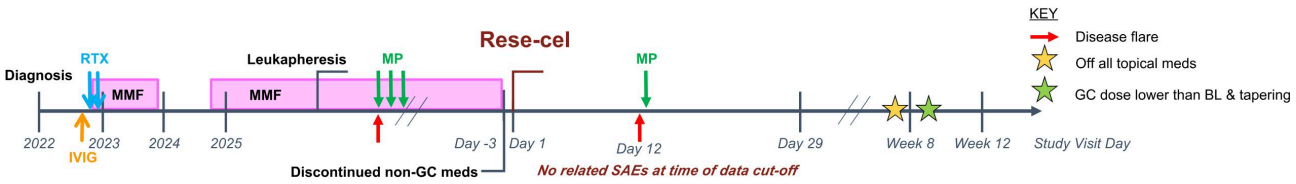


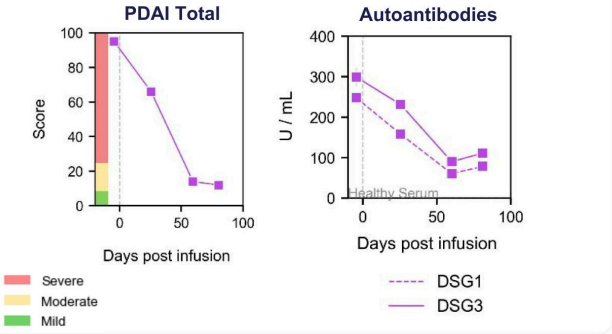
Reduction in PDAI Total in PV-1M-1 at this initial dose supports meaningful early clinical activity with limited impact on autoantibodies in this patient with refractory pemphigus

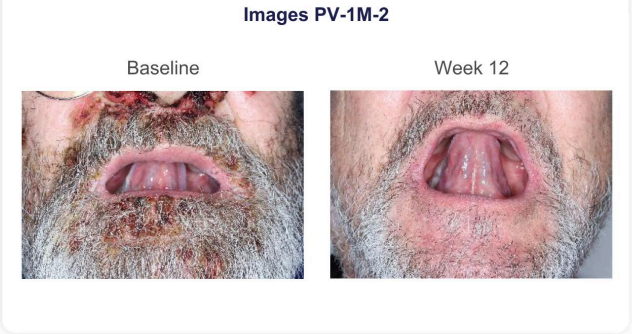
*As of 11 September 2025. Cabaletta Bio: Data on file. Disease severity intervals as defined Krain RL, et al. Br J Dermatol. 2021;184(5): 975–977.
Gray vertical dotted line indicates day of rese-cel infusion (study visit Day 1). 1M, 1 million CAR T cells / kg; CRS, cytokine release syndrome; DSG1, desmoglein 1; DSG3, desmoglein 3; GC, glucocorticoid; MMF, mycophenolate mofetil; MTX, methotrexate; PC, preconditioning; PDAI, pemphigus disease area index; PV, pemphigus vulgaris; rese-cel, resecabtagene autoleucel; RTX, rituximab.
Note: Timeline not to scale and shows select medications not including low-dose GCs and topical medications.

Patient 2: Early efficacy data following rese-cel infusion without PC*

PV-1M-2





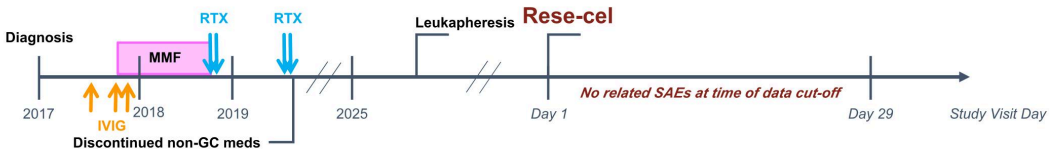


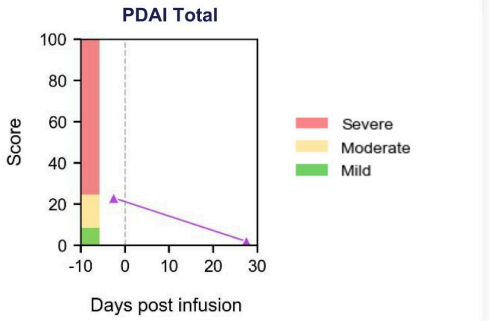
Reduction in PDAI Total in PV-1M-2 from 95 to 12 within three months reflects profound clinical activity with rapid and robust elimination of autoantibodies in this refractory patient

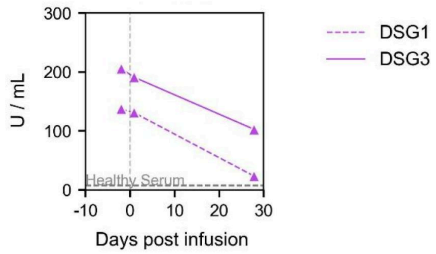
*As of 11 September 2025. Cabaletta Bio: Data on file. Disease severity intervals as defined in Krain RL, et al. Br J Dermatol. 2021;184(5): 975–977.
Gray vertical dotted line indicates day of rese-cel infusion (study visit Day 1). 1M, 1 million CAR T cells / kg; BL, baseline; DSG1, desmoglein 1; DSG3, desmoglein 3; GC, glucocorticoid; IVIG, intravenous immunoglobulin; MMF, mycophenolate mofetil; MP, methylprednisolone; PC, preconditioning; PDAI, pemphigus disease area index; PV, pemphigus vulgaris; rese-cel, resecabtagene autoleucel; RTX, rituximab; SAE, Serious Adverse Event. Note: Timeline not to scale and shows select medications not including GCs and topical medications.

Patient 3: Early efficacy data following rese-cel infusion without PC*

PV-1M-3







Reduction in PDAI Total in PV-1M-3 from 23 to 2 within one month reflects profound clinical activity with rapidly declining levels of autoantibodies in this refractory patient

*As of 11 September 2025. Cabaletta Bio: Data on file. Disease severity intervals as defined in 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). 1M, 1 million CAR T cells / kg; DSG1, desmoglein 1; DSG3, desmoglein 3; GC, glucocorticoid; IVIG, intravenous immunoglobulin; MMF, mycophenolate mofetil; PC, preconditioning; PDAI, pemphigus disease area index; PV, pemphigus vulgaris; rese-cel, resecabtagene autoleucel; RTX, rituximab. Note: Timeline not to scale and shows select medications not including low-dose GCs and topical medications.

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Manufacturing strategy to BLA submission

Clinical Supply:

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

Innovative Manufacturing:

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

CELLARES

- 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 Oxford[1], and

Oxford Biomedica

  2) Drug product process at Lonza[2]

Lonza

- 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.

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Cabaletta Bio leadership

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

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Appendix

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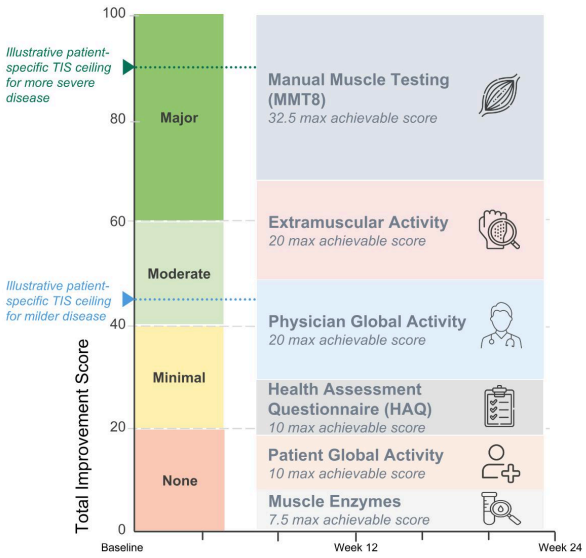
Myositis outcomes captured through validated composite endpoint

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

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

OCTOBER 2025