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 27, 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 27, 2025, Cabaletta Bio, Inc. (“Cabaletta” or the “Company”) issued a press release reporting new clinical data and development updates across the RESET-Myositis™, RESET-SSc™ and RESET-SLE™ trials 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 27, 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 data and development updates across the RESET-Myositis™, RESET-SSc™ and RESET-SLE™ trials evaluating rese-cel (resecabtagene autoleucel, formerly known as CABA-201) in multiple oral and poster presentations at the American College of Rheumatology ("ACR") Convergence 2025.

Highlights of the rese-cel clinical and translational data being presented at ACR Convergence 2025 as of the data cut-off date of September 11, 2025, and development updates include:

RESET-Myositis: Complete Adult Phase 1/2 Data and Registrational Cohort Update
Cabaletta is presenting complete adult Phase 1/2 clinical data from 6 patients in the combined DM/ASyS (4 dermatomyositis and 2 antisynthetase syndrome) cohort and 6 patients in the immune-necrotizing myopathy ("IMNM") cohort, in addition to 1 patient in the juvenile idiopathic inflammatory myopathy cohort, within the RESET-Myositis trial. Regarding safety, 4 of 13 patients experienced fever, or grade 1 cytokine release syndrome ("CRS"), and no immune effector cell-associated neurotoxicity syndrome ("ICANS") was observed.

All 4 DM/ASyS patients who met the key inclusion criteria for the registrational cohort with sufficient follow-up achieved immunomodulatory-free total improvement score ("TIS") responses of moderate or major improvement at week 16. Based on these clinical data, Cabaletta is initiating a DM/ASyS registrational cohort within the RESET-Myositis trial. There are approximately 60,000 patients with DM in the U.S. who have IVIg as their only U.S. Food and Drug Administration ("FDA")-approved treatment option and approximately 15,000 patients with ASyS in the U.S who have no FDA-approved treatment options. Consistent with the previously announced FDA alignment on registrational cohort design, Cabaletta expects to enroll 14 patients in the registrational cohort with a 16-week primary endpoint of moderate or major TIS response while off immunomodulators and on no or low-dose steroids. Cabaletta remains on track to initiate enrollment in the registrational DM/ASyS cohort this quarter.

Two of 4 IMNM patients with sufficient follow-up achieved immunomodulatory-free TIS responses at week 24. In a subset of ASyS and IMNM patients with limited durability or response, rese-cel achieved complete B cell elimination and an apparent B cell reset, but did not lead to antibody clearance, suggesting CD19-negative long-lived plasma cells may be a clinically meaningful source for potentially pathogenic autoantibodies in these patients. Prior to the potential initiation of a registrational IMNM cohort, additional patients will be enrolled in the Phase 1/2 cohort with refined entry criteria and existing patients will be followed to further evaluate efficacy and durability in this patient population.

RESET-SSc: Preliminary Phase 1/2 Data
Cabaletta is presenting preliminary Phase 1/2 clinical data from 6 RESET-SSc patients, including 3 in the severe skin (SSc-Skin) cohort and 3 in the organ (SSc-Organ) cohort. Three of these 6 patients experienced low-grade CRS (grade 1 or 2) and one ICANS event was observed (grade 3, previously reported in March 2025).

All 4 patients with at least 3 months of follow-up achieved an rCRISS-25 response off immunomodulators and steroids. These initial data suggest the potential for rese-cel to reset the immune system in systemic sclerosis, allowing patients to achieve transformative clinical responses off all immunomodulators and glucocorticoids. Cabaletta anticipates FDA alignment on the registrational cohort design this year.

RESET-SLE: Preliminary Phase 1/2 Data and Expansion of No Preconditioning Strategy
Cabaletta is presenting preliminary Phase 1/2 clinical data from 9 patients in the RESET-SLE trial, including 5 patients in the non-renal systemic lupus erythematosus ("SLE") cohort and 4 patients in the lupus nephritis ("LN") cohort. Six of 9 patients experienced no CRS (grade 1 events were reported in 3 patients) and 8 of 9 patients experienced no ICANS (grade 4 in 1 patient, previously reported in August 2024).

Three of 4 SLE patients with at least 3 months of follow-up achieved DORIS (definition of remission in SLE), and the fourth patient with pure class V LN achieved a complete renal response. Three of 4 LN patients with at least 3 months of follow-up showed renal response. All 9 patients were off all immunomodulators as of the data cut-off. Patients across both cohorts achieved a median 8-point reduction in SLEDAI-2K and a significant reduction in anti-dsDNA antibodies was observed.

Based on the clinical responses observed in lupus following complete B cell depletion after administration of rese-cel with preconditioning, and with the initial data from 3 patients in RESET-PV™ showing that potentially complete B cell depletion is possible with a single, weight-based dose of rese-cel without the use of a fludarabine and cyclophosphamide lymphodepleting regimen, Cabaletta is expanding this approach into lupus, which predominantly affects women of child-bearing potential. Cabaletta is incorporating this new dose-escalation cohort into the RESET-SLE trial with initial clinical data anticipated in 2026.

Forward-Looking Statements

The information under this Item 8.01 contains "forward-looking statements" of Cabaletta 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 alignment with regulatory authorities on potential registrational pathway for rese-cel; Cabaletta's ability to leverage its emerging clinical data and its efficient development strategy; 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, gMG and PV and advancement of the RESET-MS trial, including updates related to status, safety data, efficiency of clinical trial design and timing of data read-outs or otherwise; Cabaletta's ability to initiate the myositis registrational trial and timing thereof; Cabaletta's plans to initiate enrollment in the registrational DM / ASyS cohort in 2025; Cabaletta's plans to enroll additional patients in the phase 1/2 IMNM cohort prior to the potential initiation of a registrational IMNM cohort; Cabaletta's plans to initiate a no preconditioning cohort in RESET-SLE trial based on the consistency of clinical responses in patients with lupus and timing of data read-outs in connection thereto; Cabaletta's plans to incorporate a new dose-escalation cohort into the RESET-SLE trial with initial clinical data anticipated in 2026; Cabaletta's expectations around alignment with FDA on the registrational designs for lupus and systemic sclerosis cohorts in 2025; Cabaletta's expectations around the initial data of the RESET-SSc trial and the potential for rese-cel to reset the immune system in systemic sclerosis, allowing patients to achieve transformative clinical responses off all immunomodulators and glucocorticoids.

Any forward-looking statements in this Item 8.01 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 filings with the Securities and Exchange Commission. All information in this Item 8.01 is as of the date of this Current Report on Form 8-K, and the Company undertakes no duty to update this information unless required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release issued by the registrant on October 27, 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 27, 2025

By: /s/ Steven Nichtberger

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

Exhibit 99.1

Cabaletta Bio Presents Positive Clinical Data and Development Updates for Rese-cel at ACR Convergence 2025

– All myositis patients in the Phase 1/2 DM/ASyS cohort with sufficient follow-up who met key registrational inclusion criteria exceeded the registrational primary endpoint, demonstrating major TIS responses with no immunomodulators –

– Myositis registrational trial being initiated this quarter with a planned cohort of 14 DM/ASyS patients and a 16-week primary endpoint – moderate or major TIS while off immunomodulators and on no or low-dose steroids – consistent with FDA alignment on key trial parameters –

– All systemic sclerosis patients with sufficient follow-up demonstrated ongoing, transformative clinical responses off all immunomodulators and steroids –

– Seven of 8 lupus patients with sufficient follow-up achieved DORIS or renal response; RESET-SLE™ trial expanding to include a no preconditioning cohort with initial clinical data expected in 2026 –

– 76 patients enrolled at 77 clinical trial sites globally as of October 24, 2025 –

PHILADELPHIA, Oct. 27, 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 announced positive clinical data and development updates across the RESET-Myositis™, RESET-SSc™ and RESET-SLE trials evaluating rese-cel (resecabtagene autoleucel, formerly known as CABA-201). These data are being presented in multiple oral and poster presentations at the ongoing American College of Rheumatology (ACR) Convergence 2025, which is being held at the McCormick Place Convention Center in Chicago, Illinois, from October 24-29, 2025.

“The clinical data to be presented at ACR reinforce the potential of a single weight-based dose of rese-cel to deliver durable, drug-free clinical responses across multiple autoimmune diseases. The consistency of responses through the primary endpoint of the registrational cohort in patients meeting the key inclusion criteria is particularly encouraging. We look forward to initiating the myositis registrational trial and anticipate alignment with FDA on the designs for lupus and systemic sclerosis this year,” said David J. Chang, M.D., Chief Medical Officer of Cabaletta. “In addition, given the compelling, emerging data in the first three autoimmune patients receiving rese-cel without preconditioning, we are accelerating plans to initiate a no preconditioning dose-escalation cohort in the RESET-SLE trial. We believe this innovation can provide a simpler and more patient-focused alternative for lupus patients, many of whom are women of child-bearing potential, who may desire rese-cel without preconditioning.”

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RESET-Myositis: Complete Adult Phase 1/2 Data and Registrational Cohort Update
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Two of 4 IMNM patients with sufficient follow-up achieved immunomodulatory-free TIS responses at week 24. In a subset of ASyS and IMNM patients with limited durability or response, rese-cel achieved complete B cell elimination and an apparent B cell reset, but did not lead to antibody clearance, suggesting CD19-negative long-lived plasma cells may be a clinically meaningful source for potentially pathogenic autoantibodies in these patients. Prior to the potential initiation of a registrational IMNM cohort, additional patients will be enrolled in the Phase 1/2 cohort with refined entry criteria and existing patients will be followed to further evaluate efficacy and durability in this patient population.

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Based on the clinical responses observed in lupus following complete B cell depletion after administration of rese-cel with preconditioning, and with the initial data from 3 patients in RESET-PV™ showing that potentially complete B cell depletion is possible with a single, weight-based dose of rese-cel without the use of a fludarabine and cyclophosphamide lymphodepleting regimen, Cabaletta is expanding this approach into lupus, which predominantly affects women of child-bearing potential. Cabaletta is incorporating this new dose-escalation cohort into the RESET-SLE trial with initial clinical data anticipated in 2026.

Additional information can be accessed on the website of the ACR Convergence 2025. Presentation materials will be made available following their presentation on the Posters & Publications section of the Company's 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 alignment with regulatory authorities on 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 reinforces the potential of a single weight-based dose of rese-cel to deliver durable, drug-free clinical responses across multiple autoimmune diseases and that the consistency of responses in patients meeting the key inclusion criteria for its myositis registrational cohort is particularly encouraging; 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, gMG and PV and advancement RESET-MS trial, including updates related to status, safety data, efficiency of clinical trial design and timing of data read-outs or otherwise; Cabaletta's ability to initiate the myositis registrational trial and timing thereof; Cabaletta's plans to initiate enrollment in the registrational DM/ASyS cohort in 2025; Cabaletta's plans to enroll additional patients in the phase 1/2 IMNM cohort prior to the potential initiation of a registrational IMNM cohort; Cabaletta's plans to initiate a no preconditioning cohort in RESET-SLE trial based on the consistency of clinical responses in patients with lupus and timing of data read-outs in connection thereto; Cabaletta's expectations that the no preconditioning innovation can provide a simpler and more patient-focused alternative for many lupus patients; Cabaletta's plans to incorporate a new dose-escalation cohort into the RESET-SLE trial with initial clinical data anticipated in 2026; Cabaletta's expectations around alignment with FDA on the registrational designs for lupus and systemic sclerosis cohorts in 2025; Cabaletta's expectations around the initial data of the RESET-SSc trial and the potential for rese-cel to reset the immune system in systemic sclerosis, allowing patients to achieve transformative clinical responses off all immunomodulators and glucocorticoids.

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

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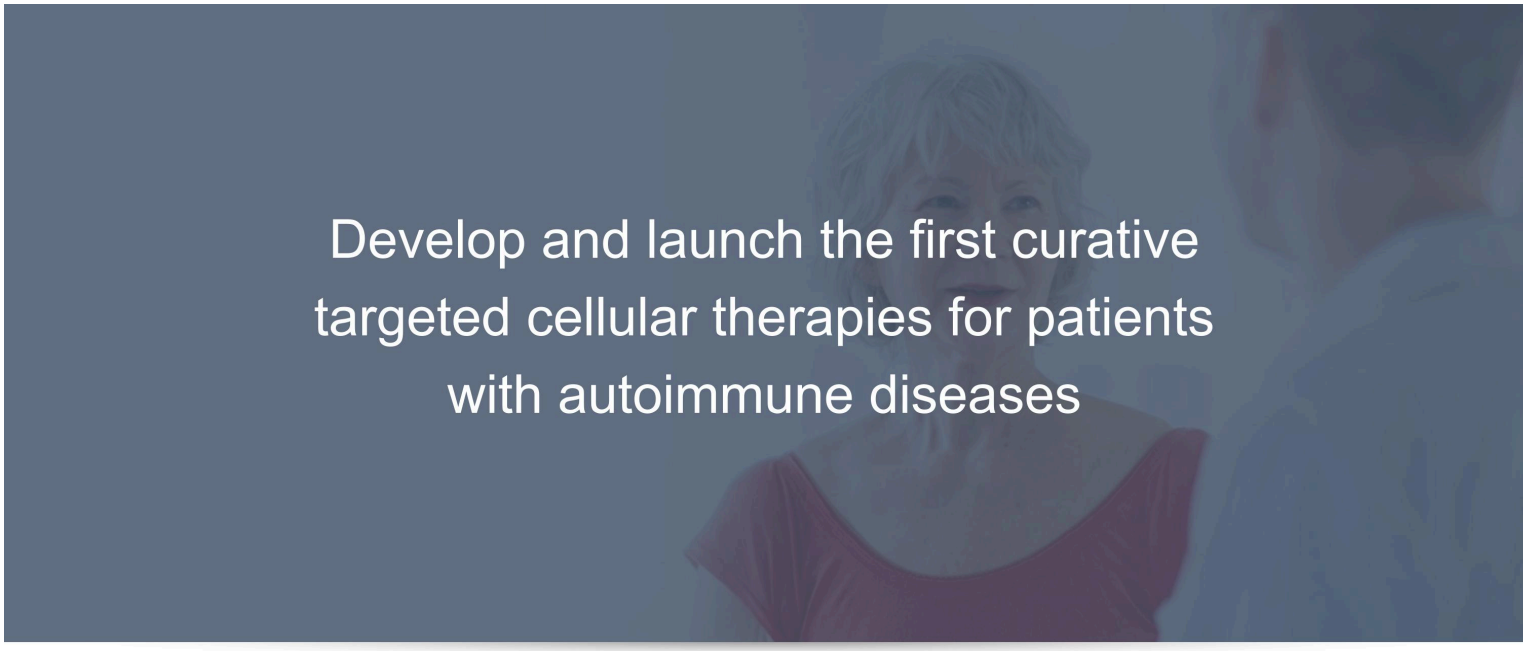
Various risks, uncertainties and assumptions could cause actual results to differ materially from those anticipated or implied in our forward-looking statements. Such risks and uncertainties include, but are not limited to, risks related to the success, cost, and timing of our development activities and clinical trials, risks related to our ability to demonstrate sufficient evidence of safety, efficacy and tolerability in our clinical trials, the risk that the results observed with the similarly-designed construct, including, but not limited to, dosing regimen, are not indicative of the results we seek to achieve with rese-cel, the risk that signs of biologic activity or persistence may not inform long-term results, risks related to clinical trial site activation or enrollment rates that are lower than expected, risks that modifications to trial design or approach may not have the intended benefits and that the trial design may need to be further modified; our ability to protect and maintain our intellectual property position, risks related to our relationships with third parties, uncertainties related to regulatory agencies' evaluation of regulatory filings and other information related to our product candidates, our ability to retain and recognize the intended incentives conferred by any regulatory designations, risks related to regulatory filings and potential clearance, the risk that any one or more of our product candidates will not be successfully developed and commercialized, the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies, risks related to volatile market and economic conditions and our ability to fund operations and continue as a going concern. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause our actual results to differ materially from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent annual report on Form 10-K and quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the Securities and Exchange Commission. Certain information contained in this Presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company's own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of this Presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. The Company is the owner of various trademarks, trade names and service marks. Certain other trademarks, trade names and service marks appearing in this Presentation are the property of third parties. Solely for convenience, the trademarks and trade names in this Presentation are referred to without the ® and TM symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.



Cabaletta Bio®

Rese-cel[1]: 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 steroids[2]
  - 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 immunomodulators[3]**
  - 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 administration[3]**
  - 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

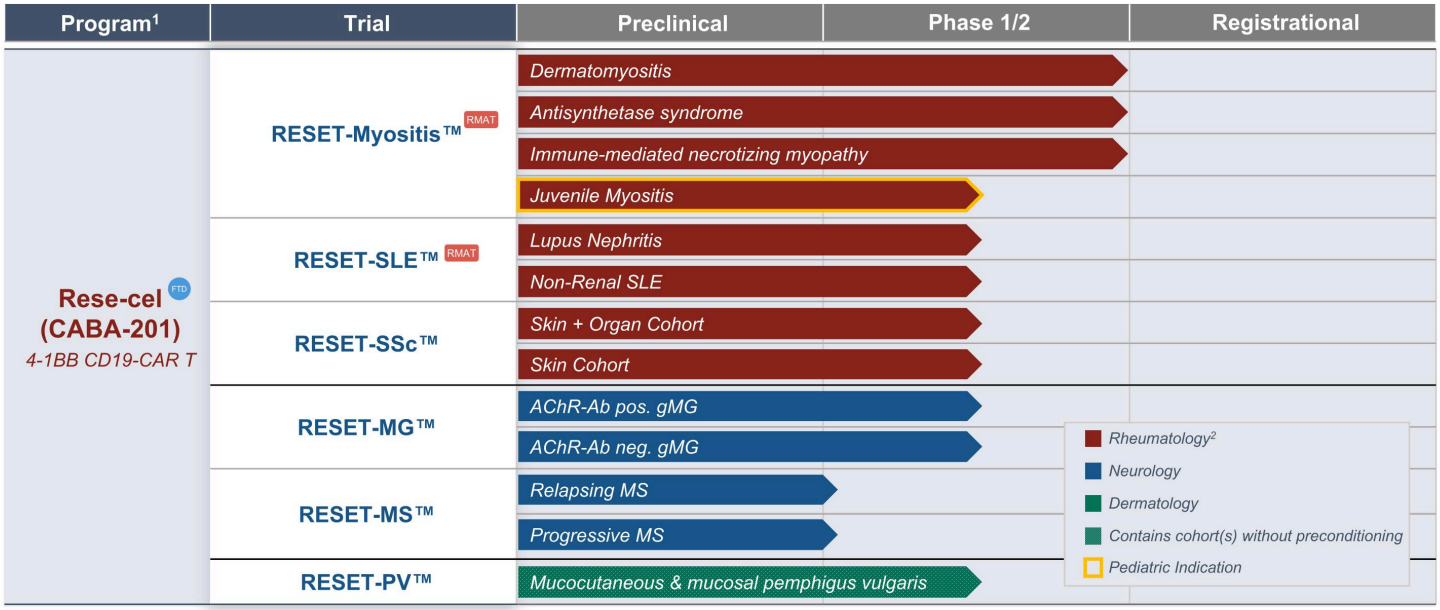
Myositis BLA submission on track for 2027

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.

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, generalized myasthenia gravis and multiple sclerosis.
■ 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-dose[3] 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 program[4]

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.

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 x 10^6 cells/kg and/or PV patients treated at a higher dose, if warranted.
3. Pending final agreement with Cellares to advance technology.

Rese-cel: Autologus CD19-CAR T for Autoimmunity

Cabaletta Bio®

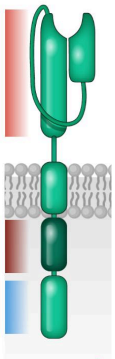
Rese-cel: CD19-CAR T specifically designed for autoimmunity

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

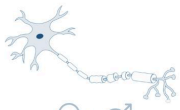
- **4-1BB costimulatory domain with fully human binder**
  - **Binder with similar affinity & biologic activity to academic FMC63 binder while binding to the same epitopes[1,2]**
- **Same weight-based dose as in academic studies**
  - **Potential to provide immune reset based on initial clinical and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

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

RESET™ 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 —

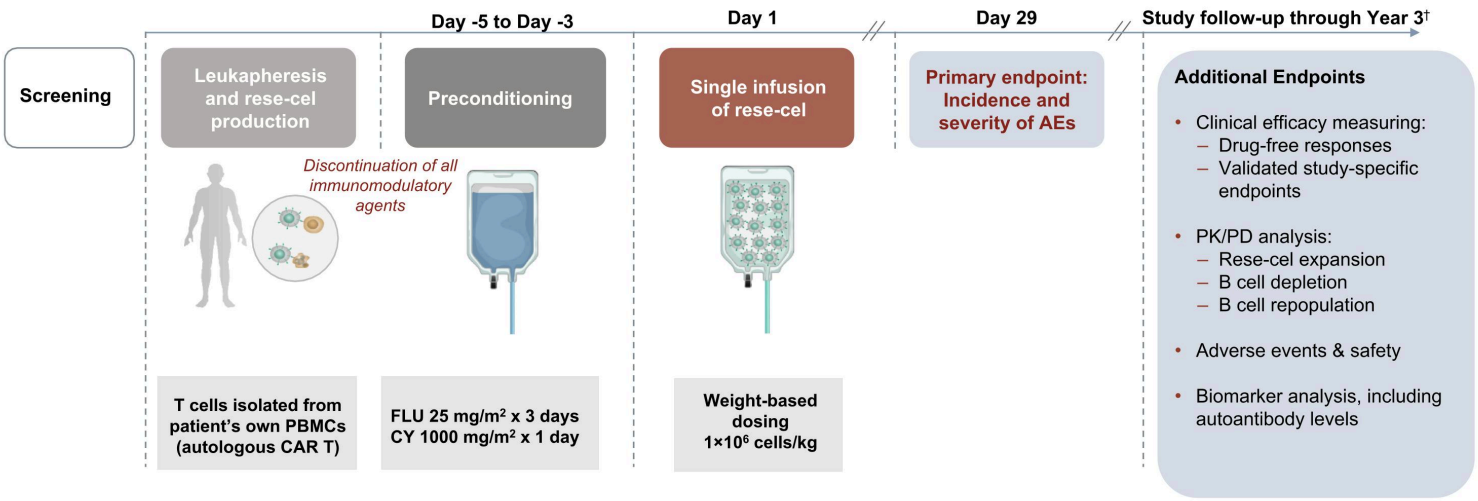
Myositis	SLE/LN	SSc	gMG	MS	PV
					
♀>♂	♀>♂	♀>♂	♀>♂	♀>♂	
Typical onset middle age	Affects young women & people of color	Middle age onset common	Bimodal age of onset	Chronic inflammation, axon loss, cognitive impairment, and irreversible neurologic damage	Pure autoantibody & B-cell mediated autoimmune disease
Only FDA-approved therapy is IVIg in DM	~30-40% with lupus nephritis, which carries ~25% risk of death or ESRD within 10y	Progressive skin & organ fibrosis with lung, cardiac, renal damage	Profound weakness that can be disabling		Characterized by painful blisters & erosions
Three-fold increased mortality due to lung & cardiac involvement		Average survival of 12y	Risk for myasthenic crises, with respiratory failure		
U.S. Prevalence					
~80k	~320k	~90k	~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 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; JIIM, juvenile idiopathic inflammatory myopathy; LN, lupus nephritis; MAA, myositis-associated antibody; SLEDAI-2k, SLE disease activity index 2000; SSc, systemic sclerosis.

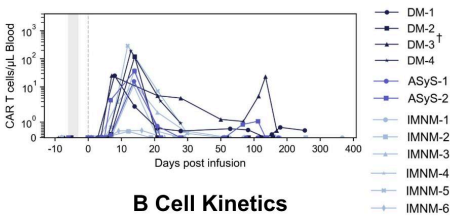
1. ClinicalTrials.gov. Available at: www.clinicaltrials.gov/study/NCT06121297 (accessed October 2024).
2. ClinicalTrials.gov. Available at: www.clinicaltrials.gov/study/NCT06328777 (accessed October 2024).
3. ClinicalTrials.gov. Available at: www.clinicaltrials.gov/study/NCT06154252 (accessed October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

Rese-cel expansion & B cell kinetics across indications*

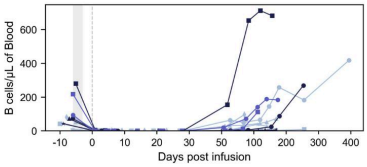
Peak rese-cel expansion and transient peripheral B cell depletion occurred within ~2 weeks post infusion

RESET-Myositis

Rese-cel Pharmacokinetics*

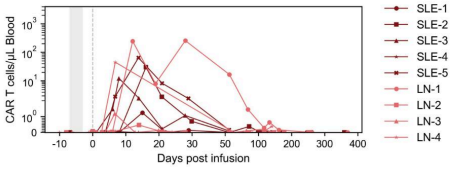


B Cell Kinetics

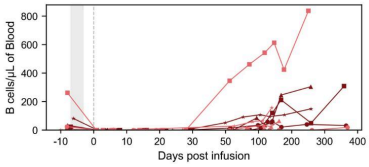


RESET-SLE

Rese-cel Pharmacokinetics**

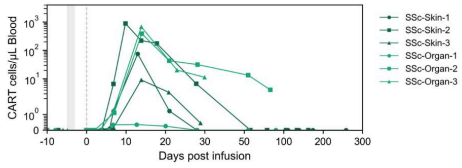


B Cell Kinetics

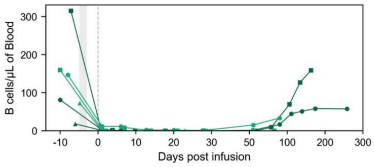


RESET-SSc

Rese-cel Pharmacokinetics



B Cell Kinetics



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

*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.
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

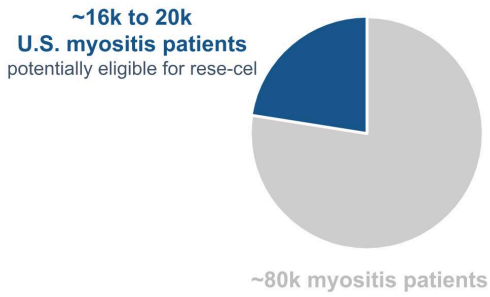
Limited treatment options[1]

- 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)



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

*As of 11 Sep, 2025.
†Baseline disease activity = activity before preconditioning.
‡Reflects any exposure to RTX and IVIg prior or at time of study entry. RTX is not allowed within approximately 6 months of Screening.
ASyS, antisynthetase syndrome; CDASI-A, Cutaneous Dermatomyositis Disease Area and Severity Index – Activity;CK, creatine kinase; DM, dermatomyositis; GC, glucocorticoid; HMGCR, 3-hydroxy-3-methylglutaryl-coenzyme A reductase; IM, immunomodulatory medication; IMNM, immune-mediated necrotizing myopathy; IVIg, intravenous immunoglobulin; JIIM, juvenile idiopathic inflammatory myopathy; MMT-8, manual muscle testing 8; NXP, nuclear matrix protein; N/A, not applicable; RESET, REstoring SElf-Tolerance; RTX, rituximab; SAE, small ubiquitin-like modifier activating enzyme; SRP, signal recognition particle; TIF1, transcription intermediary factor 1; U/L, units per liter.
Cabaletta Bio – Data on File.

Incidence of relevant and related serious adverse events*

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

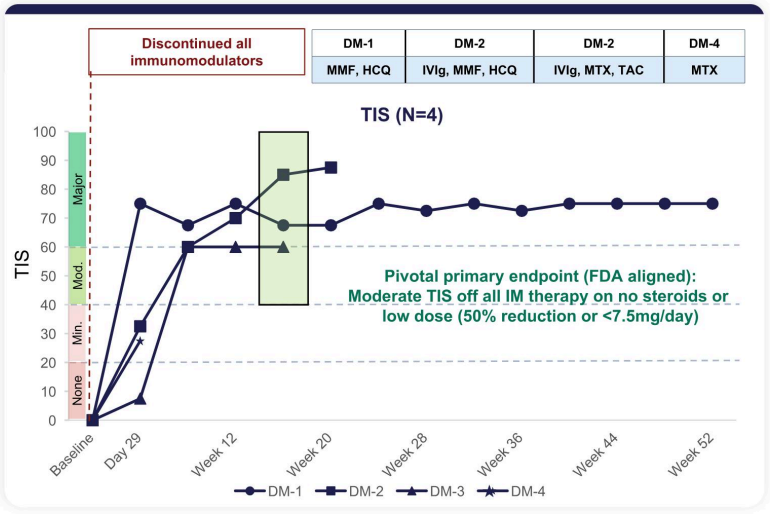
Cohort	DM				ASyS		IMNM						JIIM
Patient	**DM-1**	**DM-2**	**DM-3**	**DM-4**	**ASyS-1**	**ASyS-2**	**IMNM-1**	**IMNM-2**	**IMNM-3**	**IMNM-4**	**IMNM-5**	**IMNM-6**	**JIIM-1**
CRS†	None	Grade 1	None	None	Grade 1	Grade 1	None	None	Grade 1	None	None	None	None
ICANS†	None	None	None	None	None	None	None	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§



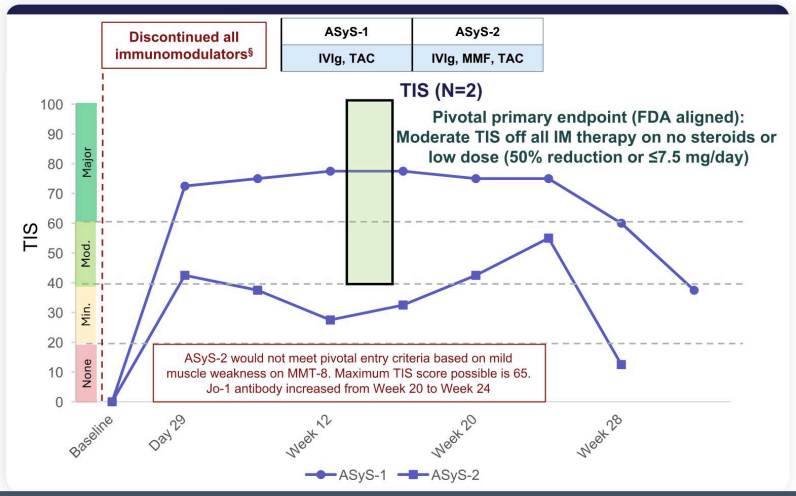
After discontinuation of all IM medications, 3 of 3 DM patients achieved the FDA-aligned 16-week primary endpoint for the upcoming pivotal study of at least moderate TIS response

*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, resecabtagene autoleucel; SAE, small ubiquitin-like modifier activating enzyme; TAC, tacrolimus; TIF1-γ, transcription intermediary factor 1 gamma; TIS, total improvement score.
Cabaletta Bio: Data on File.

ASyS: Efficacy data following rese-cel infusion*

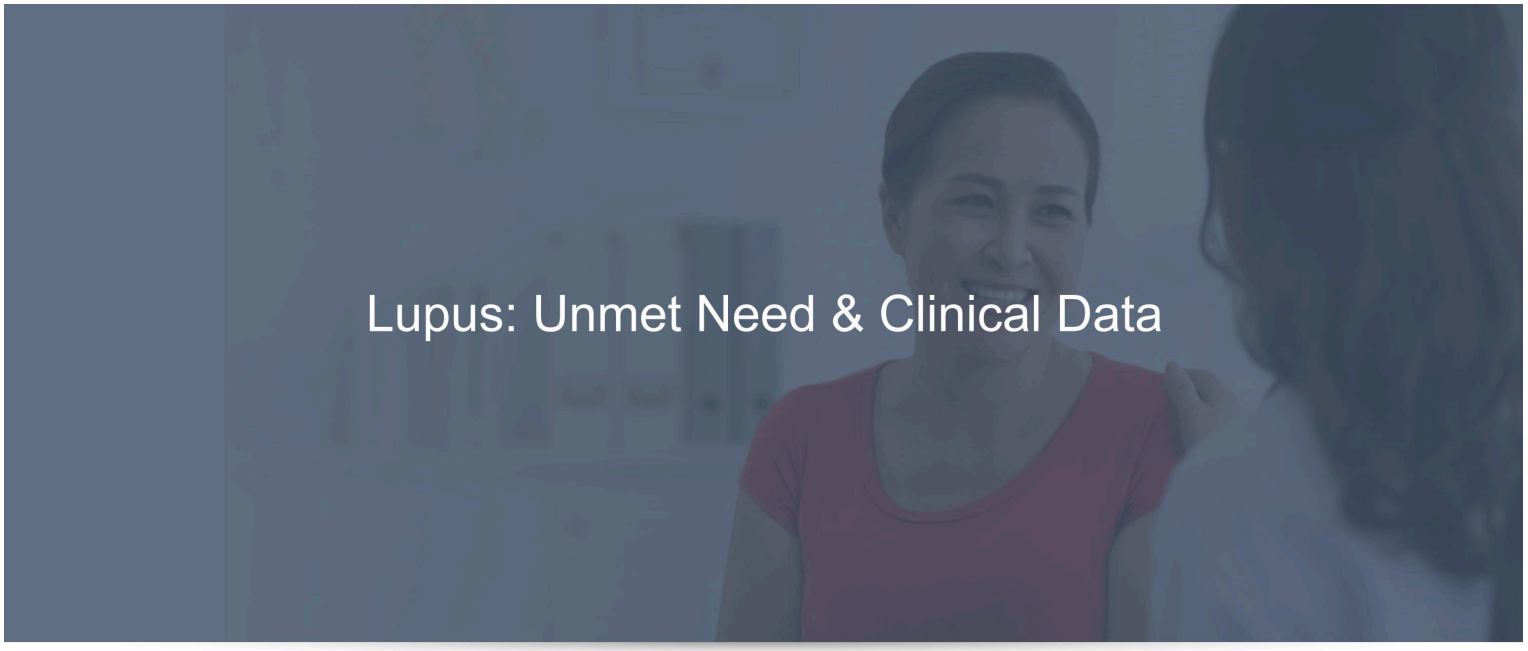
Patient who would meet key inclusion criteria in registrational cohort achieved a major TIS response at Week 16

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



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

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



Lupus: Unmet Need & Clinical Data

Cabaletta Bio®

SLE & LN: Represent a high unmet clinical need

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

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

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

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

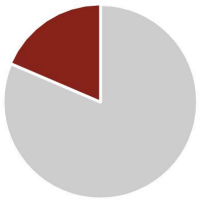
- LN may present silently or with symptoms such as proteinuria, hematuria, swelling & elevated blood pressure
- 10-30% of patients with LN will progress to ESRD, requiring dialysis or transplantation within the first decade of their disease[5,6]

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

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

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

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



~210k non-renal SLE patients

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

~110k LN patients

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

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

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

Baseline characteristics: First 9 patients in RESET-SLE*

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

Cohort	**Non-renal SLE (n=5)**	**LN (n=4)**
Age, years, mean (min, max)	~34 (26, 44)	~26 (18, 35)
Female, n (%)	4 (80)	3 (75)
Time from diagnosis to screening, years, mean (min, max)	11.5 (6.1, 17.3)	7.3 (2.2, 15.7)
Autoantibodies (%)	dsDNA: 100% 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** **≤2 SLE immunomodulators‡** **≥3 SLE immunomodulators‡**	 80% 60% 40%	 50% 50% 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.

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/1.73m²) (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, resecabtagene 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*

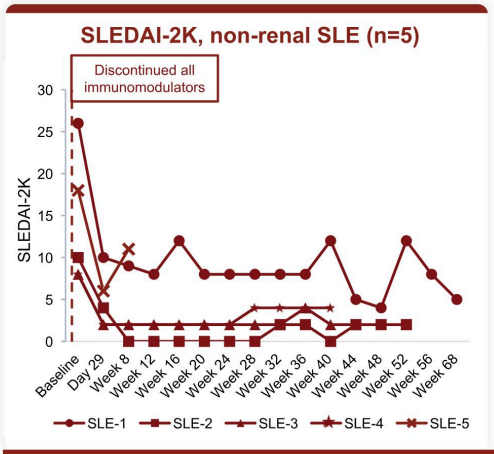
As of the data cut-off, LN-1 in CRR, LN-2 in PRR and LN-3 with histologic response on repeat renal biopsy

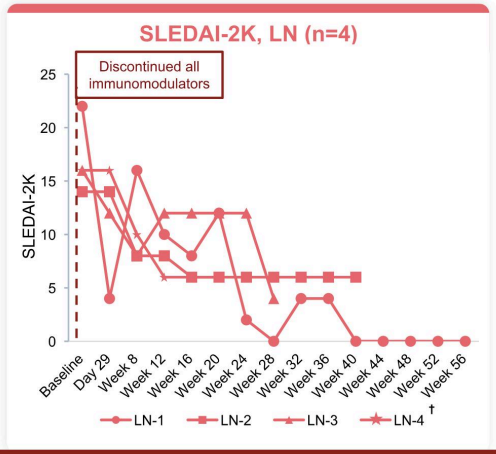
	LN			
Patient	**LN-1**	**LN-2**	**LN-3**	**LN-4**
Latest follow-up	Week 56	Week 40	Week 28	Week 20
IM-free	✓	✓	✓	✓
GC-free	✓	✓	✓	✓
DORIS† (at latest follow-up)	✓	N/A	N/A	N/A
PGA (% improvement from baseline)	100	100	100	100
SLEDAI-2K improvement (baseline to latest follow-up)	22	8	12	10§
Anti-dsDNA antibody (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

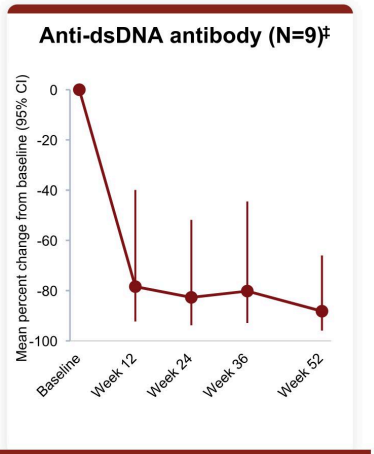
*As of 11 Sep, 2025.
†DORIS = Clinical SLEDAI-2K=0 (irrespective of serology); Physician Global Assessment <0.5; antimalarials; low-dose GCs (prednisolone ≤5 mg/day); stable immunosuppressives including biologics. CRR = UPCR ≤0.5 mg/mg; ≥60 mL/min or no confirmed eGFR decrease of >20% from baseline; 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, resecabtagene 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

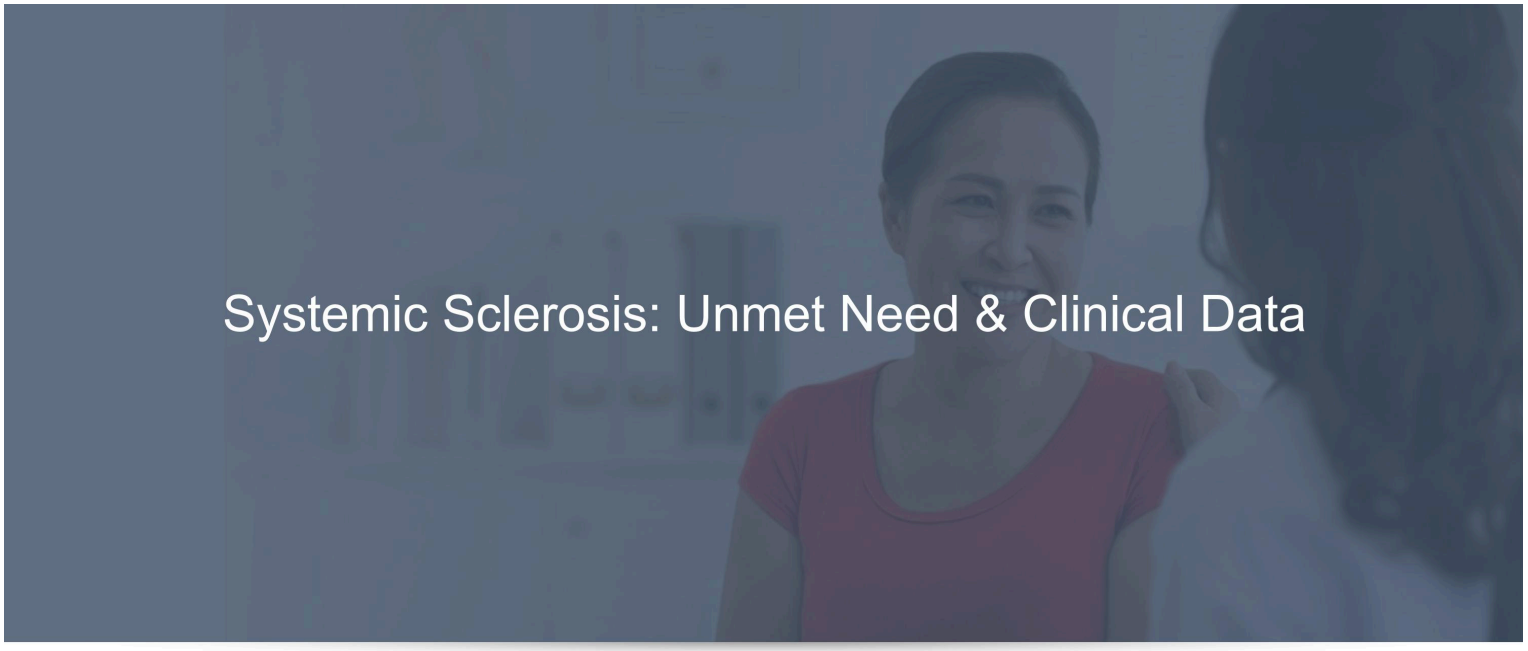






Clinical & translational data in lupus for rese-cel with preconditioning (PC) along with initial no PC data in PV support expansion of simplified no PC regimen into lupus; initial clinical data anticipated in 2026

*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.



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

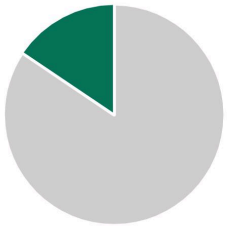
- Typically, middle age onset and more common in females[1]
- Highest mortality of all rheumatological diseases & significant burden from persistent skin & organ manifestations[4,5]
  - Mean survival is ~12 years from diagnosis
- Need for disease-modifying therapies across all SSc subsets[5]
  - FDA-approved 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: 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, mycophenoloic acid; mRSS, modified Rodnan skin score; NIN, nintedanib; SAE, serious adverse event; PFT, pulmonary function test; RESET, REstoring SElf-Tolerance; RNA Pol III, ribonucleic acid polymerase III; Scl-70, anti–topoisomerase I antibody; SSc, systemic sclerosis; TOC, tocilizumab; y, years.
Cabaletta Bio: Data on File.

Incidence of relevant and related serious adverse events*

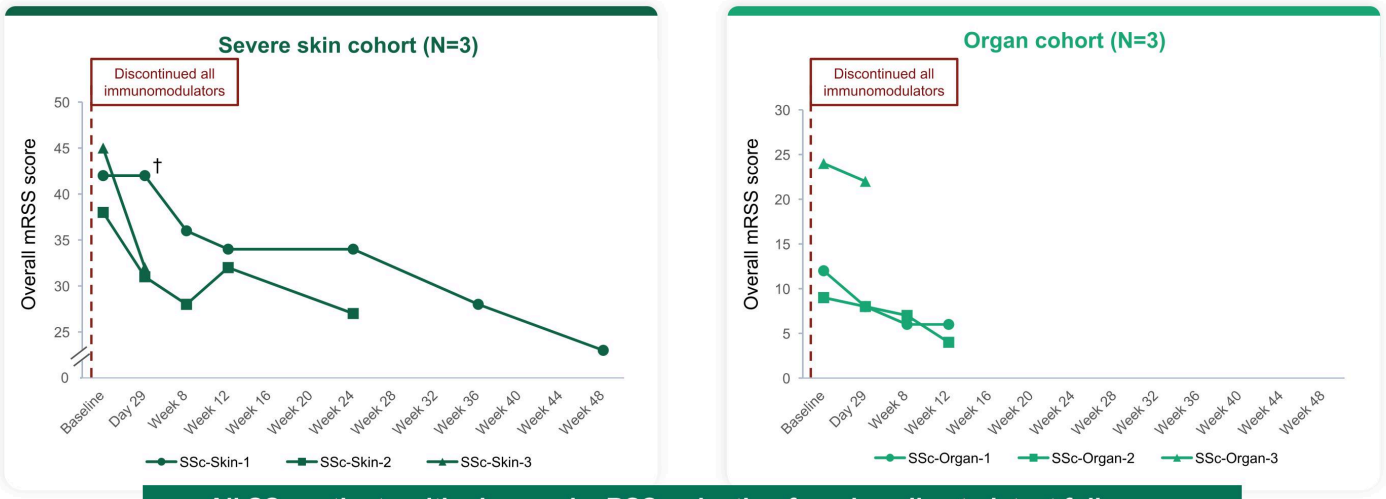
CRS reported in 3 of 6 patients and ICANS reported in 1 of 6 patients

	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



All SSc patients with observed mRSS reduction from baseline to latest follow-up

*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

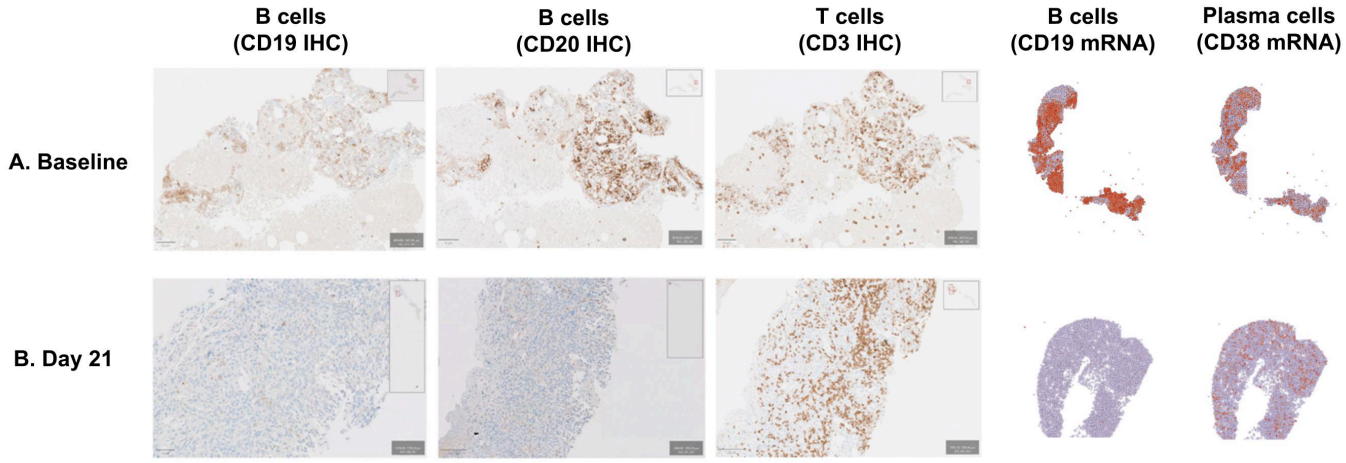
	Severe Skin Cohort			Organ Cohort		
Patient / Cohort	**SSc-Skin-1**	**SSc-Skin-2**	**SSc-Skin-3**	**SSc-Organ-1**	**SSc-Organ-2**	**SSc-Organ-3**
Latest follow-up	Week 48	Week 24	Day 29	Week 16	Week 12	Day 29
GC-free	✓	✓	✓	✓	✓	–‡‡
IM-free	✓	✓	✓	✓	✓	✓
Antibody and trend†	RNA Pol III ↓	Scl-70 ↓**	RNA Pol 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, resecabtagene 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 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; 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.

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 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]

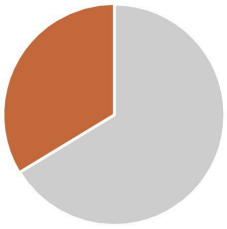
- Available therapeutic options focus on specific symptoms and can be associated with serious long-term side effects
- Mainstays include steroids, immunosuppressants (e.g., mycophenolate), FcRn antagonists, complement inhibitors and rituximab
- MG represents a significant healthcare cost burden in the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

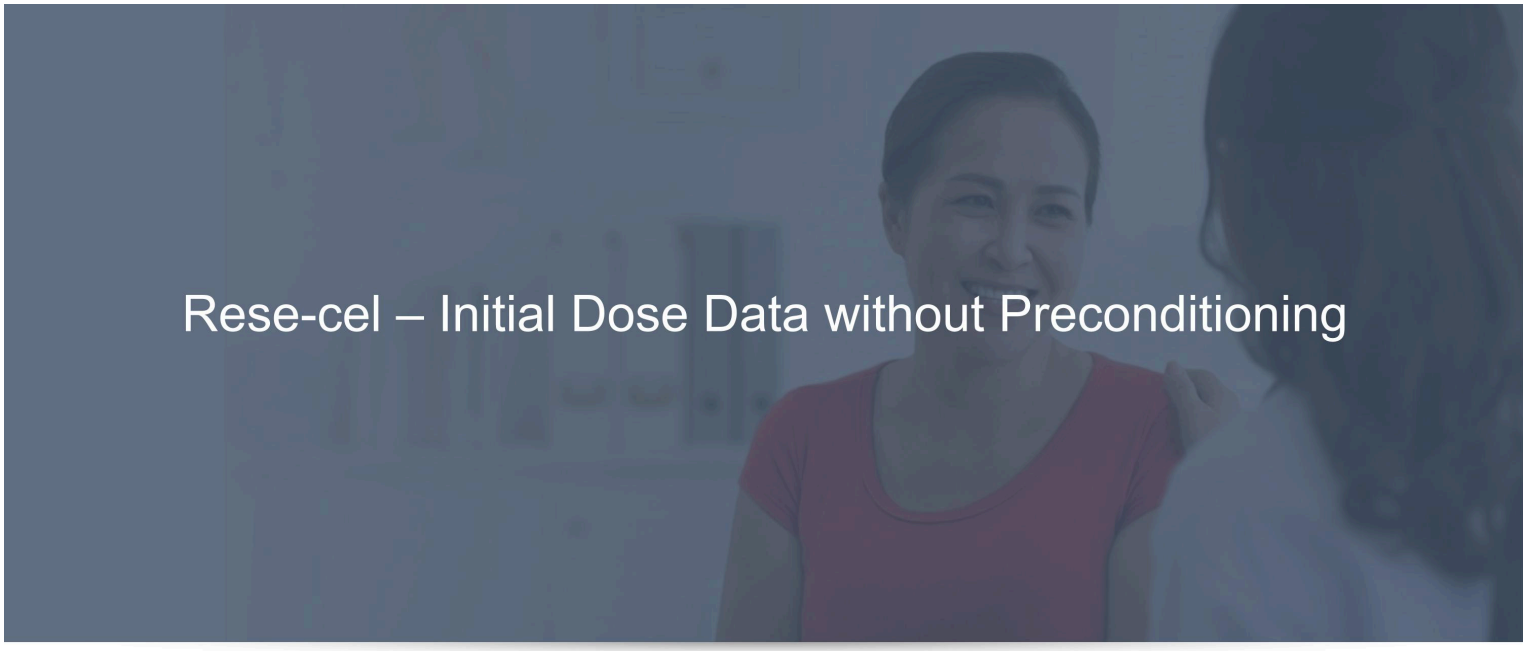
(per quantitative research with ~100 MG-treating physicians)

~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

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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
- 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.

Baseline characteristics of first 3 patients in RESET-PV™

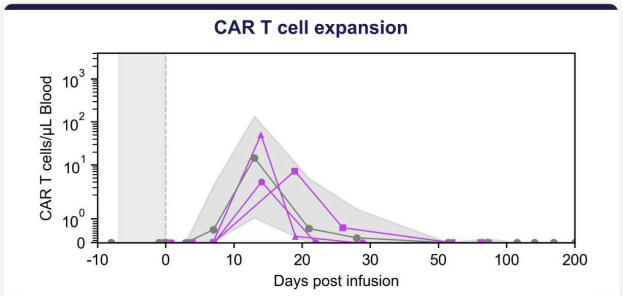
All pts had moderate to severe, active, refractory disease & failed B cell-targeting therapies, including RTX

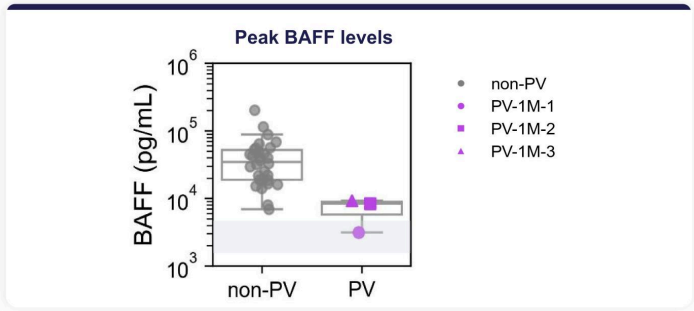
	RESET-PV™		
Patient	**PV-1M-1**	**PV-1M-2**	**PV-1M-3**
Age, sex	48, M	64, M	53, F
PV type	Mucosal	Mucocutaneous	Mucosal with minor skin involvement
Disease duration (approx. years)	7	3	8
Autoantibodies	DSG3	DSG3, DSG1	DSG3, DSG1
Baseline* PDAI Total	**24**	**95**	**23**
Baseline* PDAI Skin Activity	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]

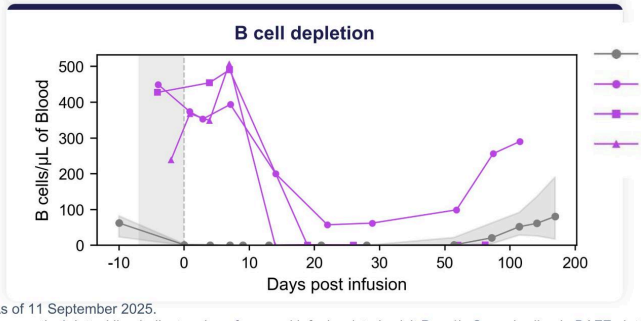
As of 11 September 2025. Cabaletta Bio: Data on file.
1M, 1 million CAR T cells/kg; DSG1, desmoglein 1; DSG3, desmoglein 3; GC, glucocorticoid; IVIg, intravenous immunoglobulin; MMF, mycophenolate mofetil; MTX, methotrexate; PDAI, Pemphigus Disease Area Index; PV, pemphigus vulgaris; RESET, REstoring 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

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

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







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

PV-1M-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*

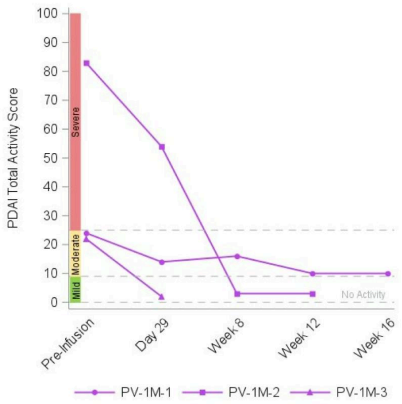
	RESET-PV™ without preconditioning (PC)			Non-PV RESET™ Trials with PC^ n/N (%)
Patient	**PV-1M-1**	**PV-1M-2**	**PV-1M-3**	
Latest follow up	Week 16	Week 12	Day 29	Safety summary through first 29 Days
CRS**	Grade 1	None	None	11 / 32 (34%)
ICANS**	None	None	None	2 / 32 (6%)
Serious infections‡	None	None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

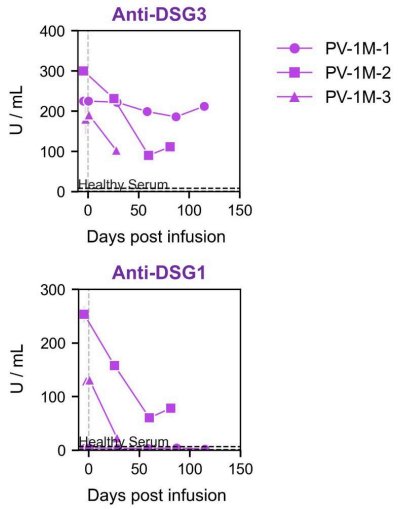
Early clinical activity of rese-cel without preconditioning*

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

PDAI Total Activity Score



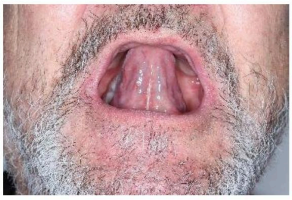
Anti-DSG3 and Anti-DSG1 Titers



Images PV-1M-2

Baseline

Week 12



PDAI improvements were most significant in the two patients who experienced 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).

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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 Oxford[1]

  2) Drug product process at Lonza[2]

- 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

Cabaletta 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

SCIENTIFIC ADVISORY BOARD

Aimee Payne, M.D., Ph.D.
Co-Founder and Co-Chair

Carl June, M.D.

Iain McInnes, Ph.D., FRCP, FRSE, FMedSci

Michael C. Milone, M.D., Ph.D.
Co-Founder and Co-Chair

Georg Schett, M.D.

Jay Siegel, M.D.

Drew Weissman, M.D., Ph.D.

Appendix

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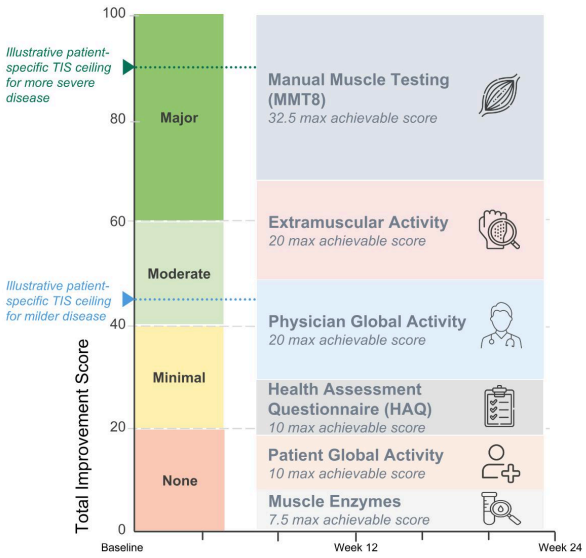
Myositis outcomes captured through validated composite endpoint

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