June 3, 2026

Cabaletta Bio Announces New Rese-cel Data and Development Updates Across Autoimmune Portfolio, Including Encouraging Early PC-Free Lupus Findings, at EULAR 2026 Congress

83% of dermatomyositis patients in the Phase 1/2 RESET-Myositis study would have met the registrational primary endpoint; all these patients maintained their response off immunomodulators through latest follow-up, as long as 1.5 years

First juvenile dermatomyositis (JDM) patient demonstrated moderate TIS response off immunomodulators and maintained their response through latest follow-up at 32 weeks; JDM expected to be included in 2H27 myositis BLA submission, facilitating the potential for a priority review voucher

Systemic sclerosis (SSc) announced as second pivotal indication based on convincing Phase 1/2 data after a single dose of rese-cel upon discontinuation of immunomodulators; single-arm registrational study initiation anticipated in 4Q26 in ~25 SSc patients with interstitial lung disease (ILD)

Lowest dose of PC-free rese-cel achieved deep B cell depletion in one of the first two lupus patients treated based on translational data similar to RESET-SLE patients who achieved immune reset after a single dose of rese-cel with preconditioning; second, higher dose PC-free cohorts enrolling in lupus and PV

EULAR presentations demonstrate that for most patients, a single dose of rese-cel provided an immune system reset and compelling immunomodulator-free outcomes that persisted over time

PHILADELPHIA, June 03, 2026 (GLOBE NEWSWIRE) -- Cabaletta Bio, Inc. (Nasdaq: CABA), a late-stage clinical biotechnology company focused on developing and launching targeted cell therapies designed specifically for patients with autoimmune diseases, today announced new clinical data supporting rese-cel (resecabtagene autoleucel) as a potential treatment for multiple autoimmune diseases, including findings that further inform Cabaletta's registrational strategy in myositis and systemic sclerosis as well as its preconditioning-free (PC-free) program in lupus. These data are being presented in multiple oral and poster presentations, as well as in a company-sponsored satellite symposium, at the European Alliance of Associations for Rheumatology (EULAR) 2026 Congress, being held June 3-6, 2026, in London, UK.

"Over 80% of the Phase 1/2 dermatomyositis patients would have achieved the pivotal primary endpoint and all five of these patients maintained their response through the latest follow-up as long as 1.5 years. Based on a conservatively high control group response rate,

the registrational cohort requires no more than 50% of patients to achieve the 16-week primary endpoint for a positive study," said David J. Chang, M.D., Chief Medical Officer of Cabaletta Bio. "In addition, the emerging durability of rese-cel is promising. The vast majority of dermatomyositis and lupus patients maintained their immunomodulator-free responses and most systemic sclerosis patients demonstrated continued increases in the magnitude of response with longer follow-up. Beyond the emerging durability data, we are encouraged by the safety profile of rese-cel, which we believe supports outpatient administration. The unanticipated clinical activity at the lowest dose of PC-free rese-cel further supports the potential to expand the market, and we believe that with the optimal dose, preconditioning may not be required for many patients to achieve immune reset in lupus and other autoimmune diseases."

At the EULAR 2026 Congress, Cabaletta's presentations include data from 52 evaluable autoimmune disease patients living with myositis (17), lupus (20) and systemic sclerosis (15) who were treated with rese-cel, including the first juvenile dermatomyositis (JDM) patient and the first two lupus patients treated with PC-free rese-cel. Rese-cel exhibited a predictable translational profile when administered with and without preconditioning, consistent across each indication evaluated. In addition, patients were generally able to discontinue all immunomodulators (IM) and require no or only low-doses of steroids while achieving significant improvement in disease activity following rese-cel treatment. As of the cut-off dates of April 16, 2026, for patients treated with rese-cel and preconditioning and May 15, 2026, for patients treated with PC-free rese-cel, key data insights include:

RESET-Myositis®: Phase 1/2 cohort data demonstrate 80% (8/10) of dermatomyositis (DM) and antisynthetase syndrome (ASyS) patients would have met the primary endpoint of the registrational cohort. After discontinuation of all immunomodulators:

- 83% (5/6) of DM patients achieved an immunomodulator-free (IM-free), moderate-to-major Total Improvement Score (TIS) response at 16 weeks; all patients maintained their IM-free response through latest follow-up as long as 1.5 years.
- 75% (3/4) of ASyS patients achieved an IM-free, moderate-to-major TIS response at 16 weeks. Durability in these patients was variable, consistent with the reported academic CD19-CAR T data.
- The first JDM patient achieved an IM-free, moderate TIS response at 16 weeks, with response maintained through latest follow-up at 32 weeks.
- 100% (17/17) of patients experienced either no CRS or transient fever (Grade 1 CRS) and no immune effector cell-associated neurotoxicity syndrome (ICANS) of any grade was observed in any patient.

RESET-SSc™: Phase 1/2 cohort patients showed overall improvement in skin and lung disease activity and achieved clinical responses while off IMs and off or tapering steroids that appear to improve with longer follow-up

- Patients with ILD at screening demonstrated an IM-free improvement in percent predicted FVC, with a median improvement of 7.5% in patients with 36 weeks of follow-up.
- 83% (5/6) of patients achieved revised Composite Response Index in Systemic Sclerosis (rCRISS)-25 and 67% (4/6) of patients achieved rCRISS-50 at 36 weeks while off all immunomodulators and off or tapering steroids.

- 87% (13/15) of patients experienced either no CRS or transient fever (Grade 1 CRS); 93% (14/15) of patients experienced no ICANS (one Grade 3 ICANS previously reported March 2025).

RESET-SLE™: Based on data from the first two PC-free patients, the lowest dose of PC-free rese-cel appears to be a threshold dose; patients who received rese-cel with preconditioning achieved meaningful clinical responses off IMs with no or low-dose steroids at 12 months

- In the first two PC-free lupus patients, initial pharmacokinetic/pharmacodynamic (PK/PD) findings suggest the lowest PC-free rese-cel dose may represent a threshold dose, as seen in the PC-free pemphigus vulgaris study, where some patients achieved deep B cell depletion with substantial clinical benefit.
    - One of the two lupus patients experienced deep B cell depletion, similar to what has been observed in lupus patients treated with rese-cel plus preconditioning who achieved an immune reset. The second patient experienced a reduction in peripheral B cells of ~90%.
    - One patient experienced grade 1 CRS and no ICANS was observed.
- In the preconditioning cohorts:
    - In patients with 12 months of follow-up, 75% (6/8) of patients achieved Definition of Remission in SLE (DORIS) while remaining off IMs for the duration of follow-up.
    - 83% (15/18) of patients remain IM-free and on no or low-dose steroids at latest follow-up.
    - 94% (17/18) of patients experienced either no CRS or transient fever (Grade 1 CRS); 94% (17/18) of patients experienced no ICANS (one Grade 4 ICANS reported in August 2024).

In addition, pan-translational findings to be presented at the conference highlight that PK/PD dynamics show a short-term rese-cel activity phase that results in evidence of deep B cell depletion and immune system reset, while minimizing the potential for prolonged B cell aplasia and other delayed adverse events as B cells repopulate with a median time of approximately 2 months.

Anticipated Development Plans and Upcoming Milestones for Rese-cel

- **Initiate SSc registrational program with preconditioning in 4Q26, leveraging Phase 1/2 RESET-SSc data and FDA discussions:** Based on the complete Phase 1/2 cohort data and FDA feedback, Cabaletta is conducting a single-arm registrational study of approximately 25 patients with SSc-associated ILD using an FVC-based primary endpoint at 52 weeks. Cabaletta anticipates initiating this study in 4Q26.
- **Report topline data from registrational DM/ASyS cohort in mid-2027:** Patient enrollment is progressing in the registrational, single-arm DM/ASyS cohort in RESET-Myositis, which includes an outpatient dosing option. The primary endpoint will assess whether a moderate or major TIS response after discontinuation of all IMs can be achieved at 16 weeks while remaining off IMs and on no or low-dose steroids.
- **Advance enrollment in JDM to support incorporation in 2H27 BLA submission:** Based on data from the ongoing phase 1/2 study and the academic literature, Cabaletta's BLA submission strategy is planned to include JDM and adult DM. This strategy may allow the Company to receive a priority review voucher as Cabaletta has

been granted Rare Pediatric Disease Designation for the treatment of JDM.
- **Present PC-free dose-ranging data in multiple autoimmune diseases, as warranted:** Based on the safety profile and unanticipated activity of the lowest PC-free rese-cel dose in lupus and pemphigus vulgaris patients, Cabaletta plans to generate and report dose-ranging data across multiple autoimmune indications.

Additional information can be accessed on the website of theEULAR 2026 Congress. Presentation materials will be made available on the Posters & Publications section of the Company's website following their presentation.

About rese-cel
Rese-cel (resecabtagene autoleucel) 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 has demonstrated the ability to transiently, reliably 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 broad range of autoimmune diseases in rheumatology, neurology and dermatology.

About Cabaletta Bio
Cabaletta Bio (Nasdaq: CABA) is a late-stage clinical biotechnology company focused on developing and launching 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 curative targeted cell therapies designed specifically for patients with autoimmune diseases; the clinical significance of the data presented, including clinical and translational data from the RESET clinical trials; Cabaletta's expectations regarding the potential of preconditioning-free rese-cel to expand patient access and plans to explore higher doses across autoimmune diseases, including the anticipated timing of data therefrom; 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 its clinical trials; Cabaletta's plans regarding the initiation of a SSc registrational program in 4Q26 and expectations regarding the timing of topline data from the DM/ASyS registrational cohort in

mid-2027; Cabaletta's expectations around the potential success and therapeutic benefits of rese-cel, including the potential demand from thousands of patients living with autoimmune diseases; Cabaletta's expectations regarding its BLA submission strategy for adult DM and JDM in 2H27, and the potential eligibility for a priority review voucher based on Rare Pediatric Disease Designation for JDM; and Cabaletta's plans to generate and report PC-free dose-ranging data across multiple autoimmune indications.

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, approvals and designations; the risk that preclinical or clinical data, including signs of biologic activity or clinical response, may not be predictive of long-term results or translate across programs; Cabaletta's ability to demonstrate sufficient safety, efficacy and tolerability of rese-cel in its clinical trials; risks related to clinical trial enrollment, conduct and assessment of results; risks related to Cabaletta's ability to retain and recognize the intended incentives conferred by Orphan Drug Designation, Fast Track Designation, Regenerative Medicine Advanced Therapy Designation or other designations for its product candidates, as applicable; risks related to Cabaletta's ability to protect its intellectual property position and maintain successful relationships with its collaboration and manufacturing partners; and the risk that any one or more of Cabaletta's product candidates will not be successfully developed and/or commercialized. 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 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.

Contacts:

Anup Marda
Chief Financial Officer
investors@cabalettabio.com

Cabaletta Bio®

Source: Cabaletta Bio