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Cabaletta Bio Presents Preconditioning-free Clinical Data and Automated Manufacturing Translational Data for Rese-cel at ASGCT 2026 Annual Meeting

A single infusion of the lowest dose of rese-cel administered without preconditioning, after discontinuation of all immunomodulators, demonstrated compelling drug-free responses for 6 months in 2 of 4 refractory patients; next dose cohort actively enrolling

Translational data from the first two patients dosed with rese-cel manufactured on the automated Cell Shuttle™ platform showed pharmacokinetic and pharmacodynamic data consistent with other patients dosed in the RESET™ clinical program

ASGCT 2026 presentations reinforce Cabaletta's focus on optimizing the patient and physician experience through simplified treatment regimens and scalable reliable manufacturing

PHILADELPHIA, May 14, 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 and translational data from the first four patients in the lowest dose cohort in RESET-PV® evaluating preconditioning-free (PC-free) rese-cel (resecabtagene autoleucel) and initial manufacturing and translational data from the first two autoimmune patients treated with rese-cel manufactured using the automated Cellares Cell Shuttle platform in the RESET clinical development program. These data are being presented in separate poster presentations today at the American Society of Gene & Cell Therapy (ASGCT) 2026 Annual Meeting in Boston, MA.

"Based on our view that a higher rese-cel dose would be required in the absence of preconditioning, it is encouraging that at the lowest PC-free dose, which is the same dose used across the RESET program with preconditioning, 50% of the patients demonstrated compelling and drug-free responses through 6 months of follow-up. PC-free rese-cel has the potential to substantially expand access for patients in current CAR T centers on an outpatient basis as well as in community-based infusion centers," said David J. Chang, M.D., Chief Medical Officer of Cabaletta. "In addition, the initial automated manufacturing and translational data from patients in the RESET clinical program being presented today move us even closer to realizing a more scalable and reproducible commercial product supply for rese-cel, if approved. We believe this is central to being able to meet the potential demand for rese-cel from thousands of patients living with autoimmune diseases."

Lowest Dose Data from RESET-PV Reinforces PC-free Opportunity to Broaden Patient Reach Across Autoimmune Diseases

Cabaletta is presenting clinical and translational data from the first four patients with pemphigus vulgaris treated at the lowest dose of rese-cel without preconditioning. As of April 2, 2026, all four patients had been dosed and completed at least 24 weeks of follow-up. The PDAI Total Activity (PDAI) scores ranged from 22 to 83 at baseline. Key findings from the poster include:

- **Translational Profile:** PC-free rese-cel demonstrated similar CAR T cell expansion kinetics relative to reported translational data from RESET patients with preconditioning. In all four patients, the magnitude and timing of rese-cel expansion was consistent with RESET patients with preconditioning. Three of the four patients experienced complete peripheral B cell depletion. B cell activating factor serum levels, which may correlate with depth of B cell depletion, were increased and reached the lower end of the range achieved in RESET patients with preconditioning. In the three patients with complete peripheral B cell depletion, repopulated B cells reflected an expected transitional naïve phenotype.

- **Safety Profile:** Rese-cel was generally well tolerated with no dose-limiting toxicities (DLT) or immune effector cell-associated neurotoxicity syndrome. One patient experienced transient fever, or grade 1 cytokine release syndrome (CRS).

- **Clinical Profile:** All four patients exhibited initial improvement with clinically meaningful reductions in PDAI total activity scores as early as four weeks. Two of the four patients maintained drug-free compelling clinical responses through 6 months of follow-up. The three patients who exhibited full B cell depletion exhibited the most robust clinical improvements. Serum levels of anti-DSG3 and anti-DSG1 antibodies were reduced with initial improvement in PDAI total activity scores.

The favorable safety observations in all patients and unanticipated, compelling drug-free clinical responses in two of the four patients treated at the lowest PC-free rese-cel dose are supportive of the plan to continue to explore higher doses of PC-free rese-cel in PV and other autoimmune diseases. PC-free rese-cel data at higher doses from RESET-PV are anticipated in 2H26 and initial data at the lowest rese-cel dose from RESET-SLE™ are expected in 1H26 at the European Alliance of Associations for Rheumatology 2026 Congress, being held from June 3-6, 2026, in London, UK.

Automated Manufacturing Replicates Process Consistency and Early Clinical Experience from the First Two Autoimmune Patients to Support Future Scalable Supply with Minimal Capital Investment

Cabaletta is presenting data highlighting the initial manufacturing and translational data from the first two autoimmune patients dosed with rese-cel manufactured using the automated Cellares Cell Shuttle platform, representing the first use of the Cell Shuttle in any clinical program. As of May 6, 2026, both patients had been dosed and completed at least 4 weeks of follow-up. Key findings from the poster include:

- **Manufacturing Profile:** The Cell Shuttle process supported end-to-end, closed and automated manufacturing intended to improve reproducibility, scalability and process control while reducing manual complexity. The first two GMP doses of rese-cel manufactured on the Cell Shuttle met all release specifications with on-time delivery.

Critical product quality metrics, including purity, CAR expression, viability, vector copy number, and cytotoxic activity, were within the established quality range based on historical clinical manufacturing runs.

- **Initial Translational Profile:** Rese-cel with automated manufacturing demonstrated similar peak expansion and B cell depletion kinetics, both at similar magnitudes and timeframes, relative to its broader reported translational profile across RESET trials.

Cabaletta believes these initial findings support the continued advancement of the Cell Shuttle automated manufacturing platform as a commercial supplier for rese-cel, if approved, to improve reproducibility and scale over time while maintaining product attributes within established clinical ranges.

Additional information can be accessed on the website of theASGCT 2026 Annual Meeting. 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-

PV preconditioning-free cohort and initial automated manufacturing data from patients treated with the Cellares Cell Shuttle; 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 to implement automated manufacturing of rese-cel with Cellares' Cell Shuttle platform and expectations regarding the potential of such platform to improve reproducibility, scalability and process control, including the potential to supply rese-cel at flexible scale with minimal capital investment and among the lowest cost of goods in the industry for autologous cell therapy production; and 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.

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, persistence or clinical response may not inform long-term results or translate across programs; Cabaletta's ability to demonstrate sufficient evidence of safety, efficacy and tolerability in its preclinical studies and clinical trials of rese-cel; risks that modifications to trial design or approach may not have the intended benefits; risks related to clinical trial site activation, enrollment delays and assessment of clinical trial results; 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, 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 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; 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 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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