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Cabaletta Bio Announces 2026 Strategic Priorities

Registrational myositis trial actively enrolling with planned 17-patient cohort and 2027 rese-cel BLA submission – including an outpatient dosing option using a single weight-based dose

IND amendment cleared to manufacture rese-cel with the automated, scalable Cellares platform based on multiple successful engineering runs; clinical manufacturing data expected in 1H26 to confirm GMP readiness, including supply chain logistics

New durability data without preconditioning and higher dose initial clinical data from RESET-PV™ expected in 1H26; dose-ranging data from RESET-SLE™ without preconditioning anticipated in 2026

Complete Phase 1/2 data anticipated in lupus, scleroderma and myasthenia gravis in 1H26

FDA alignment on registrational study achieved in SLE and LN for small single-arm cohorts; strategically prioritizing no preconditioning regimen pending dose-ranging data

PHILADELPHIA, Jan. 12, 2026 (GLOBE NEWSWIRE) -- Cabaletta Bio, Inc. (Nasdaq: CABA), a late-stage clinical biotechnology company focused on developing and launching the first curative targeted cell therapies designed specifically for patients with autoimmune diseases, today announced its 2026 strategic priorities to support development and launch of rese-cel (resecabtagene autoleucel) while advancing innovations to efficiently increase scale through automated manufacturing and expanding access for patients with autoimmune diseases.

“In 2026, we are focused on enrolling our pivotal myositis trial to support the planned rese-cel BLA submission next year while advancing paradigm-changing innovations that have the potential to generate a scalable commercial business with attractive margins and minimal capital investment. Fully automated manufacturing, the potential for outpatient use and progress on our no preconditioning approach each provide important advantages for rese-cel, for patients and for Cabaletta,” said Steven Nichtberger, M.D., Chief Executive Officer of Cabaletta. “The safety profile of a single, weight-based dose of rese-cel gives us confidence in the potential for outpatient treatment with rese-cel. In addition, the emerging clinical data in patients dosed without preconditioning, if durable, may further increase access for patients with significant unmet need.”

2026 Strategic Priorities and Recent Progress:

Translate registrational pathways with rese-cel into a pipeline in a product across autoimmune diseases

- **Initiation of myositis registrational cohort:** Cabaletta initiated the U.S. Food and Drug Administration (FDA)-aligned dermatomyositis (DM) and antisynthetase

syndrome (ASyS) registrational cohort in December 2025. These subtypes affect approximately 70,000 patients in the U.S., with DM comprising approximately 60,000 patients. The registrational cohort is expected to evaluate 17 patients with a 16-week primary endpoint of moderate or major total improvement score response while off immunomodulators and on no or low-dose steroids. Data from the Phase 1/2 RESET-Myositis® trial presented at ACR Convergence 2025 demonstrated that all DM patients with sufficient follow-up who would have met key inclusion criteria in the registrational cohort achieved the registrational primary endpoint with durability throughout the follow-up period as long as one year. Based on that data, Cabaletta elected to expand the registrational trial by 3 patients to permit enrollment of approximately 14 DM patients aligned with natural U.S. prevalence estimates. If successful, data from this cohort will support Cabaletta's first projected Biologics License Application (BLA) submission for rese-cel in myositis next year.

- **FDA alignment on new registrational cohort designs in SLE and LN:**Cabaletta has aligned with the FDA on registrational cohort designs in RESET-SLE to evaluate the current rese-cel weight-based dose of 1 million cells/kg in a single infusion with preconditioning, including two independent, single-arm cohorts, one consisting of patients with non-renal systemic lupus erythematosus (SLE) and one consisting of patients with lupus nephritis (LN), each evaluating approximately 25 patients with unique endpoints in each cohort. Cabaletta will provide an update on next steps for these cohorts later this year subject to dose-ranging data evaluating rese-cel without preconditioning in lupus patients.

- **Additional RMAT designation granted and registrational cohort alignments and initiations anticipated in 2026:** The FDA has recently granted a Regenerative Medicine Advanced Therapy (RMAT) designation to rese-cel for the treatment of systemic sclerosis. Cabaletta is continuing to engage with the FDA to align on registrational cohort designs for RESET-SSc™ and anticipates providing an update regarding registrational alignment for RESET-SSc in 1H26 and RESET-MG™ in mid-2026.

Advance fully automated, scalable manufacturing with Cellares to support the anticipated post-approval market expansion of rese-cel

- **Automated manufacturing of rese-cel using the Cellares Cell Shuttle™ and Cellares Cell Q™ to initiate imminently:** Investigational New Drug (IND) amendment clearance has been obtained to use the Cellares Cell Shuttle to manufacture rese-cel. This is a first for any autologous CAR T program. The IND submission included three engineering runs that demonstrated product consistency compared to existing rese-cel manufacturing runs at current contract development and manufacturing organizations (CDMOs) and is the result of the collaboration between Cabaletta and Cellares since 2023. This follows the previously announced completion of the Technology Adoption Program which successfully demonstrated the ability of Cellares' Cell Shuttle to automate the rese-cel manufacturing process. Cabaletta anticipates clinical manufacturing data in the first half of 2026, which is intended to confirm overall supply chain GMP readiness, including supply chain logistics, for Cellares-produced rese-cel implementation across the rese-cel portfolio. The Company continues to work with its

existing manufacturing partners to support the myositis registrational trial and launch-readiness efforts for rese-cel. The Cellares Integrated Development and Manufacturing Organization (IDMO) Smart Factory can enable unprecedented scale with minimal capital investment, rapid expansion to global capacity, lower manufacturing cost and improve scheduling flexibility for rese-cel after commercialization.

Expand the clinical experience of rese-cel and in combination with process innovations to deliver an industry-leading therapy for patients and physicians

- **No preconditioning dose-escalation ongoing in RESET-PV:** Following the presentation of the first rese-cel data demonstrating biologic activity and early clinical responses without preconditioning at the 2025 European Society of Gene & Cell Therapy Annual Congress, Cabaletta is now evaluating rese-cel at a higher dose without preconditioning in patients with pemphigus vulgaris with additional patients currently enrolled. Additional durability data from patients dosed at the initial dose and initial clinical data from patients dosed at the higher dose are expected in 1H26.

- **No preconditioning cohort added in RESET-SLE:** Cabaletta has incorporated a dose-escalation cohort without preconditioning in RESET-SLE, which is the current focus for the trial. This decision was based on the safety and activity data at the initial dose evaluating rese-cel without preconditioning in the RESET-PV study and the clinical responses observed in lupus following complete B cell depletion after administration of rese-cel with preconditioning. Pending dose-ranging clinical data anticipated in 2026, Cabaletta will evaluate pursuing alignment with the FDA on a registrational pathway for the no preconditioning cohort.

- **Complete Phase 1/2 data readouts across three RESET™ trials expected in 1H26:** Following the presentation of complete Phase 1/2 clinical data from RESET-Myositis cohorts in 2025, Cabaletta anticipates complete Phase 1/2 clinical data from cohorts in RESET-SLE, RESET-SSc and RESET-MG in 1H26.

About rese-cel (resecabtagene autoleucel)
Rese-cel (formerly referred to as CABA-201) 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 late-stage clinical 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 plans to advance a new generation of autologous innovations that can support scalable outpatient use with attractive margins and minimal capital investment; Cabaletta's belief that clinical data without preconditioning, if durable, may further increase access for patients; 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 achieve durable clinical responses without the need for chronic therapy; 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, enrollment, safety data, efficiency of clinical trial design and timing of data read-outs or otherwise; Cabaletta's plans to submit a BLA for rese-cel in myositis in 2027 and obtain regulatory approval from the FDA and other regulatory authorities, among others.

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, Fast Track Designation and 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; 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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