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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 (GLOBE NEWSWIRE) -- 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.”

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.

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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