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Cabaletta Bio Announces New Rese-cel Safety and Efficacy Data in Patients with Myositis, Lupus and Scleroderma to Be Presented at the EULAR 2025 Congress

– 7 of 8 myositis patients achieved clinically meaningful TIS responses after discontinuation of all immunomodulators, while off or actively tapering steroids; responses were sustained throughout the follow-up period in all responding patients –

– All SLE patients without nephropathy achieved definition of remission in SLE (DORIS) as of the latest follow-up, and all 7 SLE and LN patients experienced SLEDAI-2K reductions, while off all immunomodulators and steroids –

– Both scleroderma patients demonstrated clinically compelling mRSS improvement after discontinuation of all immunomodulators and steroids –

– In 18 patients with follow-up of 4 weeks or more, 94% had either no CRS or Grade 1 CRS (transient fever) and 89% had no ICANS (2 patients with previously reported ICANS events) –

– Two registrational myositis cohorts with ~15 patients each are on track to initiate enrollment this year; registrational discussions with FDA are scheduled for SLE/LN in 3Q25, and anticipated for scleroderma in 4Q25 and myasthenia gravis in 1H26 –

– RESET™ clinical trial program enrollment continues to accelerate, with 51 patients now actively enrolled and 24 patients dosed across industry leading US clinical site network as of May 30, 2025 –

PHILADELPHIA, June 11, 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 new clinical and translational data from the ongoing RESET-Myositis™, RESET-SLE™ and RESET-SSc™ trials evaluating rese-cel (resecabtagene autoleucel, formerly known as CABA-201). These data are being presented in three oral presentations at the ongoing European Alliance of Associations for Rheumatology (EULAR) 2025 Congress, which is being held from June 11-14, 2025, in Barcelona, Spain.

“These new clinical and translational findings reinforce our belief that a single, weight-based dose of rese-cel leads to deep B cell depletion and compelling clinical data in patients with myositis, lupus and systemic sclerosis, with nearly all patients off immunomodulators and steroids. Patients are seeking a drug-free, symptom-free life, which is rarely, if ever, achieved with currently approved therapies. We believe the clinical data on rese-cel indicate its potential to achieve this aspiration and ultimately change treatment paradigms for autoimmune diseases,” said David J. Chang, M.D., Chief Medical Officer of Cabaletta. “As

we continue to execute across the RESET clinical development program with accelerating enrollment across a broad portfolio of indications with over 50 patients actively enrolled at more than 65 active clinical sites, we plan to leverage our recent FDA alignment on a registrational pathway in myositis to engage in near-term interactions with the FDA on registrational program designs for SLE/LN, SSc and MG and move closer to our goal of launching rese-cel as the first targeted curative cell therapy for patients with autoimmune diseases."

Cabaletta is presenting new clinical and translational data from 18 evaluable patients who were dosed with rese-cel across the RESET-Myositis, RESET-SLE and RESET-SSc trials at the EULAR 2025 Congress in three oral presentations. As of the data cut-off dates of May 6, 2025, for the RESET-Myositis and RESET-SSc trials and June 2, 2025, for the RESET-SLE trial, key clinical and translational insights from these patients include:

- **RESET-Myositis:** 7 out of 8 patients achieved a clinical response off all immunomodulators, while off or actively tapering steroids. All 4 antisynthetase syndrome (ASyS) and dermatomyositis (DM) patients achieved a clinically meaningful total improvement score (TIS) response, with 3 of these patients having achieved a major TIS response as of the data cut-off date. Clinically meaningful drug-free responses were observed in 3 of 4 refractory patients with immune-mediated necrotizing myopathy (IMNM), which are consistent with published data. These findings continue to reflect the more modest TIS responses in IMNM compared to other myositis subtypes. Regarding safety, 4 of 8 patients experienced grade 1 CRS (fever), and no ICANS was observed.

- **RESET-SLE:** 7 out of 7 patients achieved a clinical response off all immunomodulators and glucocorticoids. All non-renal systemic lupus erythematosus (SLE) patients without nephropathy achieved DORIS as of the latest follow-up. The first lupus nephritis (LN) patient achieved DORIS and a complete renal response, while follow-up is continuing on the other two LN patients who were treated more recently. In the 8 patients with safety follow-up, 2 of 8 experienced grade 1 CRS (fever) and 1 ICANS event was observed (grade 4, previously reported).

- **RESET-SSc:** Both of the patients reported in the severe skin cohort had meaningful modified Rodnan Skin Score (mRSS) improvements after discontinuing immunomodulatory drugs and steroids, which was sustained out to 6 months in the first patient. The first patient also met the revised Composite Response Index in Systemic Sclerosis (CRISS) criteria starting at 3 months, highlighting the potential of rese-cel to provide a drug-free, clinical response in patients with systemic sclerosis (SSc). One patient experienced transient grade 2 CRS and one ICANS event was observed (grade 3, previously reported).

- **Rese-cel Translational Profile:** Peak rese-cel expansion was observed within approximately two weeks. B cells were rapidly and transiently reduced in peripheral blood within the first month and their repopulation was observed beginning approximately two months after infusion, generally expressing a transitional, naïve phenotype. Tissue-resident B cell depletion was confirmed via a lymph node biopsy in the first systemic sclerosis patient.

Additional information can be accessed on the website of the EULAR 2025 Congress. Presentation materials will be made available after they occur on the Posters & Publications section of the Company's website.

About rese-cel (formerly referred to as CABA-201)
Rese-cel is a 4-1BB-containing fully human CD19-CAR T cell investigational therapy for patients with autoimmune diseases where B cells contribute to the initiation and/or maintenance of disease. Following a one-time infusion of a weight-based dose, rese-cel is designed to transiently and deeply deplete all CD19-positive cells in both the peripheral circulation and within tissues. Cabaletta believes this approach has the potential to reset the immune system and result in profound clinical responses without chronic therapy requirements in patients. Cabaletta is currently evaluating rese-cel in the RESET™ (REstoring SElf-Tolerance) clinical development program which includes multiple disease-specific, company-sponsored clinical trials across expanding portfolios of autoimmune diseases in a broad range of therapeutic areas, including 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 is planning to evaluate rese-cel in two, independent registrational cohorts within myositis, and anticipates aligning with the FDA on the registrational cohort design for studies in SLE/LN, SSc, and MG. 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 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; including those related to any

similarly-designed constructs or dosing regimens; Cabaletta's expectation regarding the clinical data to be presented at the EULAR congress; Cabaletta's expectations around the potential success and therapeutic benefits of rese-cel; the Company's advancement of separate Phase 1/2 clinical trials of rese-cel in patients with SLE, myositis, SSc and gMG and advancement of the RESET-PV and RESET-MS trials, including updates related to status, safety data, efficiency of clinical trial design and timing of data read-outs or otherwise; Cabaletta's expectations to initiate enrollment in two myositis registrational cohorts in 2025; Cabaletta's belief that the clinical data on rese-cel indicates its potential for patients to achieve a drug-free, symptom-free life and ultimately change treatment paradigms for autoimmune diseases; Cabaletta's plans to leverage its recent FDA alignment on a registrational pathway in myositis to engage in near-term interactions with the FDA on registrational program designs for SLE/LN, SSc and MG, and move closer to its goal of launching rese-cel as the first targeted curative cell therapy for patients with autoimmune diseases; Cabaletta's timing of registrational discussions with FDA for SLE/LN in 3Q25 and anticipated timing of registrational discussions with FDA for scleroderma in 4Q25 and myasthenia gravis in 1H26.

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 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 Regenerative Medicine Advanced Therapy, 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; 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; the Company's ability to fund its operations and continue as a going concern. 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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