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Cabaletta Bio Presents First Rese-cel Data with No Preconditioning Demonstrating Biologic Activity and Early Clinical Responses at the 2025 ESGCT Annual Congress

– Complete B cell depletion, rapid reduction in autoantibodies and near-complete resolution of clinical symptoms in two of three refractory patients; all three patients remained off immunomodulators since infusion and are off or tapering steroids as of the data cut-off –

– CAR T cell expansion in all three patients without preconditioning was similar to expansion across 30+ patients dosed with preconditioning in the other RESET™ trials –

– Initial dose data support continued exploration of rese-cel without preconditioning in pemphigus vulgaris at the current dose and evaluation of the no preconditioning regimen as an alternative treatment option in certain other autoimmune diseases –

– All adult Phase 1/2 cohorts within the myositis, lupus, scleroderma and myasthenia gravis RESET trials are fully enrolled as of September 30, 2025 –

PHILADELPHIA, Oct. 09, 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 presented initial dose data from the RESET-PV™ trial evaluating rese-cel (resecabtagene autoleucel, formerly known as CABA-201) at 1 x 10^6 cells/kg without preconditioning in three evaluable patients with pemphigus vulgaris (PV). These data are being presented in a late-breaking clinical oral presentation by Samik Basu, M.D., Chief Scientific Officer at Cabaletta, at the ongoing 2025 European Society of Gene & Cell Therapy (ESGCT) Annual Congress, which is being held in Seville, Spain, from October 7-10, 2025.

“These data provide preliminary evidence that a single infusion of rese-cel without preconditioning can achieve complete B cell depletion and meaningful early clinical responses with a simplified regimen that can expand access to patients who may desire a treatment option without preconditioning,” said David J. Chang, M.D., Chief Medical Officer of Cabaletta. “Based on the observed biologic activity and early clinical responses, we plan to first expand patient enrollment in the RESET-PV trial at the current dose and potentially evaluate higher doses of rese-cel in PV patients, as warranted. In addition, we are pursuing the incorporation of no preconditioning regimens in certain other RESET clinical trial program cohorts. We look forward to communicating updates on our no preconditioning strategy in PV as well as in other autoimmune indications, along with broader clinical updates from ongoing RESET trials, at upcoming medical meetings.”

The RESET-PV trial is the first study within Cabaletta's RESET clinical development program to evaluate rese-cel without the use of cyclophosphamide and fludarabine as preconditioning agents. Because the RESET trials share consistent study design principles, including a single, weight-based dose of rese-cel, there is relevant context to interpret the translational data without preconditioning from the RESET-PV trial. As part of Cabaletta's innovation strategy, data from this trial will help inform the potential removal of preconditioning in certain trials within the RESET program.

In the late-breaking clinical oral presentation, key clinical and translational insights from the follow-up of the patients highlighted as of the data cut-off date of September 11, 2025, include:

- **Translational Profile:** Rese-cel exhibited similar CAR T cell expansion and contraction kinetics relative to translational data reported from other RESET trials with preconditioning. All three patients experienced substantial depletion of B cells within the first month post-infusion, with patients 2 and 3 achieving complete peripheral B cell depletion. In these two patients, rapid reduction in autoantibodies to desmoglein was observed and the increase in peak B cell activating factor (BAFF) was within the range of patients dosed with rese-cel plus preconditioning from pre-infusion through the latest follow-up, suggestive of deep B cell depletion in the tissue.

- **Safety Profile:** Rese-cel was generally well tolerated with no immune effector cell-associated neurotoxicity syndrome (ICANS) reported. After infusion, patient 1 experienced transient fever (grade 1 cytokine release syndrome). Patient 2 required a course of steroids for a disease flare in the first two weeks following infusion after discontinuing immunomodulators. This steroid course was less intense than a previous course that was administered for a flare prior to infusion where limited impact on disease was observed. The patient has tapered the steroid dose to below the pre-infusion baseline dose at 3 months post-infusion.

- **Clinical Profile:** Meaningful early clinical responses were observed in all three patients starting in the first month post-infusion based on Pemphigus Disease Area Index (PDAI) score for skin, scalp and mucosal surfaces. From baseline to latest follow-up, PDAI activity scores improved as follows:

    - Patient 1 (4 mo): 24 to 10
    - Patient 2 (3 mo): 83 to 3
    - Patient 3 (1 mo): 22 to 2

    PDAI activity scores have formed the basis for the most recent regulatory approval in PV. Total PDAI scores were also reported to be consistent with the PDAI activity scores, including improvement in the PDAI damage scores, in the late-breaking clinical oral presentation. PDAI improvements were most significant in the two patients who experienced complete B cell depletion. All three patients remain off immunomodulators as of the data cut-off.

Additional information can be accessed on the website of the 2025 ESGCT Annual Congress. The Company has made available the accepted abstract and will make available oral presentation materials following their presentation on the Posters & Publications section

of its 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 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 provides preliminary evidence that a single infusion of rese-cel without preconditioning has the potential to deliver complete B cell depletion and meaningful early clinical responses with a simplified treatment regimen that can expand access to patients who may desire a treatment option without preconditioning; Cabaletta's plan to expand patient enrollment in the RESET-PV trial at the current dose, while exploring the incorporation of no preconditioning regimens in certain other RESET clinical trial program cohorts; Cabaletta's potential updates on its no preconditioning strategy in PV as well as other autoimmune indications, along with broader clinical updates from ongoing RESET trials and timing of communications of such updates;

Cabaletta's plan to remove preconditioning in certain trials within the RESET program; 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 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.

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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