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Cabaletta Bio Reports Clinical Data from the Second Dose Cohort in DesCAARTes™ Trial in Patients with mPV

– No dose-limiting toxicities (DLTs) or clinically relevant adverse events observed as of August 17 using 100 million cells in the second dose cohort –

– DSG3-CAART persistence observed in all three patients in the second dose cohort during the 28 days following infusion –

– Dosing initiated in third cohort at 500 million cells, with biologic activity data from the first two dosing cohorts and third cohort safety data anticipated in 4Q21 –

PHILADELPHIA, Aug. 18, 2021 (GLOBE NEWSWIRE) -- Cabaletta Bio, Inc. (Nasdaq: CABA), a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies for patients with B cell-mediated autoimmune diseases, today announced 28-day data from the second dose cohort, at the 100 million cell dose level, in the DesCAARTes™ Phase 1 clinical trial of DSG3-CAART for the treatment of patients with mucosal-dominant pemphigus vulgaris (mPV).

“We continue to be encouraged by the safety profile of DSG3-CAART in all patients dosed to date. In the second cohort, with patients receiving 100 million DSG3-CAART cells – a five-fold higher dose than the initial cohort – there were no clinically relevant adverse events or DLTs observed either acutely or in the 28-day DLT monitoring period following infusion,” said David J. Chang, M.D., Chief Medical Officer of Cabaletta. “Similar to the first cohort, this safety profile was observed in the presence of circulating anti-DSG3 antibodies. In the absence of preconditioning, DSG3-CAART persistence was observed via quantitative polymerase chain reaction in peripheral blood samples of all three patients in the second dose cohort during the 28 days following infusion.”

In addition to assessing the safety and tolerability of DSG3-CAART, the trial is designed to evaluate early signs of efficacy through clinical outcomes, such as persistent decline in disease activity, reduction or discontinuation of immunosuppressive therapies and systemic corticosteroids, and absence of systemic rescue medication, as well as other biologic activity measures, including a persistent decline in anti-DSG3 antibody titers, indicating target engagement. “The persistence of DSG3-CAART post-infusion is also being evaluated as it may be an important indicator. We look forward to generating data on potential biologic activity, with the goal of providing a targeted and highly effective, and perhaps curative, therapy without generalized immunosuppression,” continued Dr. Chang.

The DesCAARTes™ trial has initiated dosing of patients in the third cohort at a treatment dose of 500 million DSG3-CAART cells. Cabaletta expects to announce top-line data on biologic activity from the first two cohorts as well as safety data from the 500 million dose cohort in the fourth quarter of 2021. Absent DLTs in the third cohort, a fourth dose cohort

using 2.5 billion cells is also anticipated to initiate dosing this year. Cabaletta will continue to provide additional data on a cohort-by-cohort basis for the DesCAARTes™ trial as they become available.

About the DesCAARTes™ Clinical Trial
Cabaletta's DesCAARTes™ Phase 1 trial is an open-label, multi-center study of DSG3-CAART in adults with mucosal-dominant pemphigus vulgaris (mPV). The trial is designed to evaluate the safety and tolerability of DSG3-CAART as well as to identify evidence of target engagement and early signs of efficacy. The study consists of three parts: 1) dose escalation, 2) dose consolidation, and 3) expansion at the final selected dose and schedule. The trial is expected to enroll approximately 30 patients across multiple clinical sites throughout the United States. Visit our website (DesCAARTes™ Phase 1 Trial) for more information.

About Pemphigus Vulgaris
mPV is a rare autoimmune blistering disease that is characterized by the loss of adhesion between cells of the skin or mucous membranes. mPV is caused by the production of autoantibodies that disrupt structural proteins within the skin and/or mucosa that connect with other proteins to enable the skin and/or mucosal cells to connect with each other. The autoantibodies can target DSG3 and/or desmoglein 1 (DSG1), which are primarily expressed in the mucosal membranes and skin, respectively. mPV is characterized by autoantibodies against DSG3 only whereas mucocutaneous PV (mcPV) is characterized by autoantibodies against DSG3 and DSG1.

About CAAR T Cell Therapy
Chimeric AutoAntibody Receptor (CAAR) T cells are designed to selectively bind and eliminate only disease-causing B cells, while sparing the normal B cells that are essential for human health. CAAR T cells are based on the chimeric antigen receptor (CAR) T cell technology. While CAR T cells typically contain a CD19-targeting molecule, CAAR T cells express an autoantibody-targeted antigen on their surface. The co-stimulatory domain and the signaling domain of both a CAR T cell and a CAAR T cell carry out the same activation and cytotoxic functions. Thus, Cabaletta's CAARs are designed to direct the patient's T cells to kill only the pathogenic cells that express disease-causing autoantibodies on their surface, potentially leading to complete and durable remission of disease while sparing all other B cell populations that provide beneficial immunity from infection.

About Cabaletta Bio
Cabaletta Bio is a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies, and exploring their potential to provide a deep and durable, perhaps curative, treatment, for patients with B cell-mediated autoimmune diseases. The Cabaletta Approach to selective B cell Ablation (CABA™) platform, in combination with Cabaletta's proprietary technology, utilizes CAAR T cells that are designed to selectively bind and eliminate only specific autoantibody-producing B cells while sparing normal antibody-producing B cells, which are essential for human health. The Company's lead product candidate, DSG3-CAART, is being evaluated in the DesCAARTes™ phase 1 clinical trial as a potential treatment for patients with mucosal pemphigus vulgaris, a prototypical B cell-mediated autoimmune disease. The FDA granted Fast Track Designation for DSG3-CAART in May 2020. For more information about the DesCAARTes™ Phase 1 clinical trial, please visit our website (DesCAARTes™ Phase 1 Trial). The Company's lead

preclinical product candidate, MuSK-CAART, is in IND-enabling studies and is designed as a potential treatment for patients with MuSK-associated myasthenia gravis. For more information, visit www.cabalettabio.com.

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 expectations regarding the progress and results of its DesCAARTes™ Phase 1 trial, including Cabaletta Bio's ability to enroll the requisite number of patients and dose each dosing cohort in the intended manner; the expectation that Cabaletta Bio may improve outcomes for patients suffering from mPV; the effectiveness and timing of product candidates that Cabaletta may develop, including in collaboration with academic partners; the safety, efficacy and tolerability of DSG3-CAART for the treatment of mPV; the impact of COVID-19 on the timing, progress, interpretability of data, and results of ongoing or planned clinical trials; the significance of data Cabaletta may announce regarding certain efficacy outcomes assessed in the DesCAARTes™ trial; the impact of preclinical data on the future development of CAAR T therapies in our pipeline portfolio expectations of the potential impact of COVID-19 on strategy, future operations, and the timing of its clinical trials, including the potential impacts on conduct of its DesCAARTes™ Phase 1 trial; and statements regarding regulatory filings regarding its development programs.

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: the risk that signs of biologic activity may not inform long-term results; Cabaletta Bio's ability to demonstrate sufficient evidence of safety, efficacy and tolerability in its preclinical and clinical trials of DSG3-CAART; risks related to clinical trial site activation or enrollment rates that are lower than expected; risks related to unexpected safety or efficacy data observed during clinical studies; risks related to the impact of public health epidemics affecting countries or regions in which we have operations or do business, such as COVID-19; Cabaletta's ability to retain and recognize the intended incentives conferred by Orphan Drug Designation and Fast Track Designation for DSG3-CAART for the treatment of PV; risks related to Cabaletta's ability to protect and maintain its intellectual property position; uncertainties related to the initiation and conduct of studies and other development requirements for its product candidates; 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 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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