November 1, 2021

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

– Dose dependent increase in DSG3-CAART persistence observed in the third dose cohort relative to the first two low dose cohorts throughout the 28 days following infusion –

– No dose-limiting toxicities (DLTs) or clinically relevant adverse events observed as of October 31, 2021, in the first three dose cohorts, dosing up to 500 million DSG3-CAART cells –

– Dosing initiated in fourth patient cohort at a dose of 2.5 billion DSG3-CAART cells with 28-day safety data anticipated in 1Q22 –

– Top-line biologic activity data for the first two low dose cohorts anticipated to be announced in 4Q21 –

PHILADELPHIA, Nov. 01, 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 clinical data from the third dose cohort using 500 million DSG3-CAART cells in the DesCAARTes™ Phase 1 clinical trial for the treatment of patients with mucosal-dominant pemphigus vulgaris (mPV).

As of October 31, 2021, three patient cohorts in the DesCAARTes™ Phase 1 trial have completed DSG3-CAART dosing. The Company observed a dose dependent increase in DSG3-CAART persistence in the third cohort relative to the first two low dose cohorts throughout the 28 days following infusion. In addition, no clinically relevant adverse events or DLTs were observed during the 28-day monitoring period post-infusion. These safety data were observed without preconditioning, and in the presence of circulating anti-DSG3 antibodies.

“We are highly encouraged by the observation of dose dependent increases in persistence as well as the continued absence of any DLTs or clinically relevant adverse events for DSG3-CAART across the first three cohorts, particularly in the presence of circulating anti-DSG3 antibodies and without lymphodepletion,” said David J. Chang, M.D., Chief Medical Officer of Cabaletta. “The rapid pace of the clinical trial has been possible due to the enthusiasm and engagement of patients, investigators and patient advocacy groups. With a 100% manufacturing success rate to date, we look forward to continuing to advance the trial until we identify a maximum tolerated dose and dosing regimen that has the potential to achieve a durable response while maintaining a favorable tolerability profile for patients suffering with mPV.”

As of October 31, 2021, three additional clinical sites have opened for recruitment, doubling the total number of activated DesCAARTes™ trial sites to six. Dosing of patients in the fourth

cohort at a treatment dose of 2.5 billion DSG3-CAART cells has been initiated. The Company anticipates announcing 28-day safety data for the fourth dose cohort in the first quarter of 2022. Top-line biologic activity data for the first two low dose cohorts are anticipated to be announced in the fourth quarter of 2021.

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 to determine the maximum tolerated dose, 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's ability to enroll the requisite number of patients and dose each dosing cohort in the intended manner and time; the expected timing and significance around the announcement of 28-day safety for the fourth dose cohort in the first quarter of 2022 and top-line data on biologic activity for the first two low dose cohorts in the fourth quarter of 2021; the expectation that Cabaletta 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 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; the impact of COVID-19 on the timing, progress, interpretability of data, and results of ongoing or planned clinical trials, including the 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'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, such as the COVID-19 pandemic, affecting countries or regions in which we have operations or do business; 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 pemphigus vulgaris or for improving healing of mucosal blisters in patients with mucosal pemphigus vulgaris, respectively; 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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