May 3, 2021

Cabaletta Bio Reports First Quarter 2021 Financial Results and Provides New Pipeline Updates

– Acute safety data from the first cohort in the DesCAARTes™ trial announced today; no dose limiting toxicities (DLTs) or clinically relevant adverse events observed in the first dose cohort as of April 30, 2021 –

– PLA2R-CAART announced as a new development program for patients with PLA2R-associated membranous nephropathy; pre-IND meeting with FDA planned in the second half of 2021 –

– MuSK-CAART Investigational New Drug (IND) application submission planned for the second half of 2021 –

PHILADELPHIA, May 03, 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 reported financial results for the first quarter ended March 31, 2021, and provided new pipeline updates.

“The initial safety data from the first low dose cohort of three patients in the DesCAARTes™ clinical trial for DSG3-CAART, our lead clinical candidate, support the acute safety profile of DSG3-CAART at the administered dose in mucosal-dominant pemphigus vulgaris patients, and are an encouraging indicator for the safety of the CAAR T platform overall. We look forward to reporting additional topline data on safety and potential target engagement on completed dose cohorts throughout the second half of 2021,” said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. “On the heels of this important milestone, which we believe begins to de-risk our CABA™ platform, we are pleased to announce a new development program, PLA2R-CAART, for the treatment of patients with PLA2R-associated membranous nephropathy with a pre-IND meeting planned for the second half of 2021. In addition, we look forward to submitting our second IND application for MuSK-CAART, our lead preclinical candidate, in the second half of 2021."

Acute Safety Data from First Dose Cohort of DesCAARTes™ Trial

Today, the Company reported results from the first cohort of three patients dosed with DSG3-CAART. There were no clinically relevant adverse events, including cytokine release syndrome or neurotoxicity, during the 8-day acute safety window, which the Company expects is the period with highest probability of observing treatment-related toxicities. In addition, no dose-limiting toxicities (DLTs) were observed in the first two subjects who have completed the 28-day DLT monitoring period post-infusion. The third patient has completed the 8-day acute safety window, and is in the DLT follow-up period. These safety data were observed with an administered dose of 20 million DSG3-CAART cells, without

preconditioning and in the presence of circulating anti-DSG3 antibodies; DSG3-CAART was detected at low levels via quantitative polymerase chain reaction in both patients who have completed the 28-day DLT period and been evaluated. The third patient is scheduled to be evaluated for presence of DSG3-CAART after completion of the 28-day DLT monitoring period.

The DesCAARTes™ trial is currently enrolling patients in the second cohort at a treatment dose of 100 million DSG3-CAART cells. Infusions are planned to initiate following the third patient in the first cohort completing the 28-day monitoring period without any DLTs. Cabaletta expects to announce acute safety data for the second and third cohorts in the third and fourth quarters of 2021, respectively. Topline data on target engagement from the first cohort are anticipated during the second half of 2021. Cabaletta will continue to provide additional topline safety and target engagement data from the DesCAARTes™ trial once available on a cohort-by-cohort basis.

Other Pipeline Highlights

MuSK-CAART: Muscle Specific Kinase (MuSK) chimeric autoantibody receptor T (MuSK-CAART) cells as potential treatment for patients with MuSK-associated myasthenia gravis.

- IND-enabling studies consistent with U.S. Food and Drug Administration (FDA) guidance received during the Pre-IND meeting are ongoing and the Company plans to submit an IND to the FDA in the second half of 2021, which will incorporate clinical trial design insights from the DesCAARTes™ trial with DSG3-CAART.

PLA2R-CAART: Phospholipase A2 receptor (PLA2R) chimeric autoantibody receptor T (PLA2R-CAART) cells as a potential treatment for patients with PLA2R-associated membranous nephropathy.

- Cabaletta plans to advance PLA2R-CAART discovery candidates for the treatment of patients with PLA2R-associated membranous nephropathy.

- Given the role of autoantibodies and proteinuria in risk stratification for patients with membranous nephropathy and as biomarkers disease progression and resolution, Cabaletta believes it can advance a product candidate to address the existing unmet need.

- The Company plans to request a Pre-IND submission meeting with the FDA during the second half of 2021 to gain clarity on the future development path and potential IND submission timing for the program.

Upcoming Events

- Cabaletta will participate in a fireside chat at the virtual Jefferies Healthcare Conference from June 1-4, 2021.

First Quarter 2021 Financial Results

The Company expects that its cash, cash equivalents and investments as of March 31, 2021, along with proceeds from sales under the Company's at-the-market offering

program in April 2021, will enable it to fund its operating plan through at least the fourth quarter of 2022.

- Research and development expenses for the three months ended March 31, 2021 were $6.6 million, compared to $4.6 million for the same period in 2020.

- General and administrative expenses for the three months ended March 31, 2021 were $3.2 million, compared to $3.3 million for the same period in 2020.

- As of March 31, 2021, cash, cash equivalents and investments totaled $102.0 million, compared to $108.7 million as of December 31, 2020.

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 Chimeric AutoAntibody Receptor (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 see www.clinicaltrials.gov. 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 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, progress of the trial, results and expected timing to report additional acute safety data for the second and third cohorts in the third and fourth quarters of 2021, respectively, and topline data on any completed dosing cohorts in the second half 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; MuSK-CAART program, including the completion and expected results of its ongoing IND-enabling studies and plans to submit an IND application or equivalent regulatory filing for MuSK-CAART in the second half of 2021; presentation of additional data at upcoming scientific conferences, and other preclinical data; expectations regarding the design, implementation, timing and success of its current and planned clinical trials and the successful completion of nonclinical studies; planned potential timing and advancement of its preclinical studies and clinical trials and related regulatory submissions; ability and the potential to successfully maintain or secure the necessary cell processing capacity and supply for its product candidates for clinical trials, including Cabaletta's planned

development and timing of next generation T cell engineering tools and process advancement; ability to replicate results achieved in preclinical studies or clinical trials in any future studies or trials; ability to continue its growth and realize the anticipated contribution of the members of its board of directors and executives to its operations and progress; expectations of the potential impact of COVID-19 on strategy, future operations, and the timing of its clinical trials, including the potential impacts on enrollment and initiation of its DesCAARTes™ Phase 1 trial; statements regarding regulatory filings regarding its development programs; use of capital, expenses, future accumulated deficit and other financial results in the future; and ability to fund operations through the fourth quarter of 2022.

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 the impact of COVID-19 affecting countries or regions in which we have operations or do business, including potential negative impacts on our employees, customers, supply chain and production as well as global economies and financial markets; risks related to Cabaletta's ability to protect and maintain its intellectual property position; Cabaletta's ability to demonstrate sufficient evidence of safety, efficacy and tolerability in its 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 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 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.

CABALETTA BIO, INC.
SELECTED FINANCIAL DATA
(unaudited; in thousands, except share and per share data)

Statements of Operations

	Three Months Ended March 31,	
	2021	2020
	Unaudited	
Operating expenses:		
Research and development	$ 6,556	$ 4,620
General and administrative	3,156	3,275

Total operating expenses	9,712	7,895
Loss from operations	(9,712)	(7,895)
Other income:		
Interest income	10	410
Net loss	(9,702)	(7,485)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.41)	$ (0.33)

Selected Balance Sheet Data

	March 31, 2021	December 31, 2020
	(unaudited)	
Cash, cash equivalents and investments	$ 102,028	$ 108,662
Total assets	107,283	114,724
Total liabilities	3,969	5,180
Total stockholders' equity	103,314	109,544

Contacts:
Anup Marda
Chief Financial Officer
investors@cabalettabio.com

Sarah McCabe
Stern Investor Relations, Inc.
212-362-1200
sarah.mccabe@sternir.com

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