May 11, 2023

Cabaletta Bio Reports First Quarter 2023 Financial Results and Provides Business Update

– IND application cleared within 30 days for clinical trial of CABA-201 in patients with LN and SLE and Fast Track Designation granted by the FDA for CABA-201 to deplete CD19-positive B cells and improve disease activity in patients with LN and SLE –

– Phase 1/2 trial planned to evaluate CABA-201 in six patients with active LN and six patients with SLE without renal involvement in parallel cohorts at an initial dose of 1.0 x 10^6 cells/kg in each cohort –

– Invited, oral presentation on CD19-CAR T in SLE and poster presentations for CABA-201 and DSG3-CAART to be presented at the upcoming ASGCT 26th Annual Meeting –

PHILADELPHIA, May 11, 2023 (GLOBE NEWSWIRE) -- Cabaletta Bio, Inc. (Nasdaq: CABA), a clinical-stage biotechnology company focused on developing and launching the first curative targeted cell therapies for patients with autoimmune diseases, today reported financial results for the first quarter ended March 31, 2023, and provided a business update.

“The recent clearance of our first IND application to evaluate CABA-201 in patients with LN and SLE occurring within six months of in-licensing of the CABA-201 binder, as well as the subsequent Fast Track Designation to deplete CD19-positive B cells and improve disease activity in patients with LN and SLE granted by the FDA, underscore the continued ability of our team to rapidly and effectively execute. Since we announced CABA-201 in October 2022, our clinical team has been working with sites across the US, including many where we have existing clinical trials actively enrolling for our CAART programs, in preparation for the CABA-201 IND clearance to continue our efforts in ensuring a timely opening of sites for the initial CABA-201 clinical trial,” said Steven Nichtberger, M.D., Chief Executive Officer of Cabaletta. “We believe that we are competitively positioned to rapidly advance CABA-201 to patients because we have a product candidate specifically designed for autoimmune patients and engineered to potentially replicate the findings of recent academic studies coupled with an efficient clinical trial design. Clinical trial implementation is being facilitated by our uniquely experienced team with a track record of successful execution in logistically complicated, interdisciplinary cell therapy studies with the goal of bringing the potential of CABA-201 closer to patients with autoimmune disease.”

Recent Operational Highlights and Upcoming Anticipated Milestones

Chimeric Antigen Receptor T cells for Autoimmunity (CARTA) Strategy

CABA-201: Autologous, engineered T cells with a chimeric antigen receptor containing a fully human CD19 binder and a 4-1BB co-stimulatory domain as a potential treatment for a broad range of autoimmune diseases where B cells contribute to the initiation and/or

maintenance of disease.

- **IND application cleared. Company anticipates three-month clinical efficacy endpoint and tolerability data by the first half of 2024:** In March 2023, Cabaletta announced that the U.S. Food and Drug Administration (FDA) cleared the Company's first CARTA strategy Investigational New Drug (IND) application for CABA-201. Cabaletta has been cleared to initiate a Phase 1/2 clinical trial of CABA-201 for the treatment of six SLE patients with active LN, and in a separate parallel cohort, six patients with active SLE without renal involvement, with a selected dose of 1.0×10^6 cells/kg, which is equivalent to the dose used in the September 2022 *Nature Medicine* publication of a 4-1BB containing CD19-CAR T construct evaluated in patients with SLE. Subjects will be treated with a standard preconditioning regimen consisting of fludarabine and cyclophosphamide prior to CABA-201 infusion. The Company anticipates generating three-month clinical data on efficacy endpoints and tolerability for patients dosed with CABA-201 by the first half of 2024.

- **CABA-201 granted Fast Track Designation by FDA:** In April 2023, the FDA granted Fast Track Designation to CABA-201 to deplete CD19-positive B cells and improve disease activity in patients with LN and SLE. This designation may facilitate the potential for expedited review and development of CABA-201 by conferring potential benefits to the program, including the opportunity for more frequent meetings and interactions with the FDA during the clinical development period as well as eligibility for accelerated approval and/or priority review, if relevant criteria are met.

- **Preclinical data to be presented at ASGCT 26th Annual Meeting:** Cabaletta plans to present IND-enabling preclinical data which characterize the specificity and activity of CABA-201 in a poster presentation at the upcoming American Society of Gene and Cell Therapy (ASGCT) 26th Annual Meeting.

Chimeric AutoAntibody Receptor T (CAART) cells Strategy

DSG3-CAART: Desmoglein 3 chimeric autoantibody receptor T (DSG3-CAART) cells as a potential treatment for patients with mucosal pemphigus vulgaris (mPV).

- **Updated DesCAARTes™ trial data to be presented at ASGCT 26th Annual Meeting:** Cabaletta plans to present updated clinical and translational data from the ongoing DesCAARTes™ trial in a poster presentation at the ASGCT 26th Annual Meeting.

- **Progressing combination sub-study of DesCAARTes™ trial:** In late 2022, Cabaletta presented updated DSG3-CAART data which provided a rationale to prioritize the enrollment of the combination sub-study cohort (2.5 billion cells in combination with cyclophosphamide and intravenous immunoglobulin [IVIg]), with the goal of addressing possible cytokine and autoantibody effects on CAART activity. Cabaletta anticipates reporting one-month safety and persistence data for the combination sub-study in the second quarter of 2023 and six-month data for the combination sub-study in the second half of 2023.

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

- **Enrolling in first-in-human MusCAARTes™ trial:** The MusCAARTes™ trial for MuSK-CAART in patients with MuSK autoantibody-positive MG is a Phase 1, open-label study that consists of an accelerated dose escalation phase and is followed by a cohort expansion phase at the final selected dose. With insights generated from the DesCAARTes™ trial, the MusCAARTes™ study design has been accelerated through (i) initiation at a dose of 500 million cells (versus 20 million cells in DesCAARTes™), (ii) use of a "2+4" dosing scheme, and (iii) early implementation of a combination approach. Patient enrollment for the MusCAARTes™ trial is ongoing and the Company expects to report six-month data for the combination cohort of the MusCAARTes™ trial in the first half of 2024.

Upcoming Events

- Cabaletta will present an invited, oral presentation on the CD19-CAR T approach in SLE in addition to preclinical data from its CABA-201 program and updated clinical and translational data from its DSG3-CAART product candidate in poster presentations at the ASGCT 26th Annual Meeting, which is being held at the Los Angeles Convention Center in Los Angeles, CA from May 16-20, 2023.

First Quarter 2023 Financial Results

- Research and development expenses were $12.4 million for the three months ended March 31, 2023, compared to $9.2 million for the same period in 2022.

- General and administrative expenses were $4.5 million for the three months ended March 31, 2023, compared to $3.8 million for the same period in 2022.

- As of March 31, 2023, Cabaletta had cash and cash equivalents of $93.8 million, compared to $106.5 million as of December 31, 2022.

The Company expects that its cash and cash equivalents as of March 31, 2023, will enable it to fund its operating plan into the first quarter of 2025.

About Cabaletta Bio
Cabaletta Bio (Nasdaq: CABA) is a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies that have the potential to provide a deep and durable, perhaps curative, treatment for patients with autoimmune diseases. The CABA™ platform encompasses two strategies: the CARTA (chimeric antigen receptor T cells for autoimmunity) strategy, with CABA-201, a 4-1BB-containing CD19-CAR T, as the lead product candidate, and the CAART (chimeric autoantibody receptor T cells) strategy, with multiple clinical-stage candidates, including DSG3-CAART for mucosal pemphigus vulgaris and MuSK-CAART for MuSK myasthenia gravis. The expanding CABA™ platform is designed to develop potentially curative therapies for patients with a broad range of autoimmune diseases. Cabaletta Bio's headquarters are located in Philadelphia, PA.

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 its expectations regarding: Cabaletta's ability to grow its autoimmune-focused pipeline; its plans around CABA-201,

including its ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner and advance the trial is planned in its Phase 1/2 clinical trial of CABA-201 as well as leverage the potential benefits from using the initial dose used in the September 2022 *Nature Medicine* publication; Cabaletta's ability to retain and recognize the intended incentives conferred from the Fast Track Designation for CABA-201; the company's business plans and objectives; the progress and results of its DesCAARTes™ Phase 1 trial and MusCAARTes™ Phase 1 trial, including Cabaletta's ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner, and progress the trial; statements regarding anticipated significance of, and timing of release of, efficacy endpoints and tolerability data for CABA-201 and its safety and persistence data and combination sub-study cohort data for its DesCAARTes trial; statements regarding regulatory filings for its development programs, including the planned timing of such regulatory filings and potential review by such regulatory authorities; the expectation that Cabaletta Bio may improve outcomes for patients suffering from SLE, mPV, MG, or other autoimmune diseases as well as its expected therapeutic benefits; the ability to accelerate Cabaletta's pipeline and develop meaningful therapies for patients, including in collaboration with academic and industry partners and the ability to optimize such collaborations on its development programs; use of capital, expenses, future accumulated deficit and other financial results in the future; availability of funding for existing programs; and ability to fund operations into the first quarter of 2025.

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 DSG3-CAART, MuSK-CAART and CABA-201; the risk that the results observed with the similarly-designed construct employed in the recent *Nature Medicine* publication, including due to the dosing regimen, are not indicative of the results we seek to achieve with CABA-201; 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 volatile market and economic conditions; risks related to the impact of public health epidemics affecting countries or regions in which Cabaletta has operations or does 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 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

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,	
	2023	**2022**
	Unaudited	
Operating expenses:		
Research and development	$ 12,435	$ 9,170
General and administrative	4,521	3,829
Total operating expenses	16,956	12,999
Loss from operations	(16,956)	(12,999)
Other income:		
Interest income	1,102	53
Net loss	(15,854)	(12,946)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.45)	$ (0.45)

Selected Balance Sheet Data

	March 31, 2023	**December 31, 2022**
	(unaudited)	
Cash, cash equivalents and investments	$ 93,845	$ 106,547
Total assets	103,447	116,968
Total liabilities	11,796	12,448
Total stockholders' equity	91,651	104,520

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