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Cabaletta Bio Receives FDA Clearance of IND Application for CABA-201 for Treatment of Systemic Lupus Erythematosus

– IND application cleared within 6 months of in-licensing CABA-201 binder –

– CABA-201 data package and experience from prior autoimmune cell therapy INDs informed Phase 1/2 clinical trial design, including the initial dose to be evaluated and the patient dosing intervals –

PHILADELPHIA, March 31, 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 announced that the Company's Investigational New Drug (IND) application for CABA-201, a 4-1BB-containing fully human CD19-CAR T cell investigational therapy, has been cleared by the U.S. Food and Drug Administration (FDA). The Company plans to initiate a Phase 1/2 clinical trial of CABA-201 for the treatment of systemic lupus erythematosus (SLE) in patients with active lupus nephritis (LN) or active SLE without renal involvement.

"We believe the clearance of this IND application within 6 months of licensing the binder for CABA-201 is an important milestone for patients with autoimmune disease. The efficient clinical trial design was informed by the data package we submitted, including clinical safety data with the CABA-201 binder, our experience from prior autoimmune cell therapy IND applications and our exclusive translational research partnership with the senior author of the *Nature Medicine* paper, which demonstrated 5/5 durable remissions throughout the follow-up period up to 17 months in patients with refractory SLE," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. "The Phase 1/2 clinical trial will begin in patients with either active LN or SLE without renal involvement. Based on its similarity to the product used in the *Nature Medicine* paper, we believe CABA-201 has the potential to provide deep and durable responses for patients with SLE and possibly other autoimmune diseases where B cells play a role to initiate or sustain disease pathology. By achieving a timely IND clearance, we believe we are well positioned to generate 3-month clinical data on efficacy endpoints and tolerability for patients dosed with CABA-201 by the first half of 2024."

SLE is a chronic, potentially severe, autoimmune disease, most commonly impacting young women between the ages of 15 and 40 with higher frequency and more severity in people of color, where the immune system attacks healthy tissue throughout the body. It is characterized by abnormal B cell function and autoantibody production resulting in a range of clinical manifestations including end organ damage and an increased risk of death. It affects an estimated 160,000-320,000 patients in the U.S. in total. LN is the most common end-organ manifestation of SLE, affecting approximately 40% of SLE patients. Among these

patients, the risk of end-stage renal disease is approximately 17% and the risk of death is approximately 12%, each within 10 years of diagnosis.

CABA-201 is designed to be given as a one-time infusion, with the potential to transiently, but fully, eliminate B cells, thus enabling an “immune system reset” and durable remission in patients with SLE. The Phase 1/2 clinical trial is an open-label dose evaluation study designed to evaluate CABA-201 in SLE subjects with active LN or active SLE without renal involvement. Subjects will be treated with a standard preconditioning regimen consisting of fludarabine and cyclophosphamide prior to CABA-201 infusion. This represents the first trial that employs Cabaletta’s CARTA (Chimeric Antigen Receptor T cells for Autoimmunity) strategy.

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 fully human CD19-CAR T, as the lead product candidate being evaluated in lupus nephritis and systemic lupus erythematosus without renal involvement, 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 may offer potentially curative therapies for patients with a broad range of autoimmune diseases. Cabaletta Bio’s headquarters and labs 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 expectations regarding: Cabaletta’s ability to grow its autoimmune-focused pipeline; the ability to capitalize on and potential benefits resulting from the translational research partnership with Professor Georg Schett and the exclusive license agreement with IASO Bio; the Company’s business plans and objectives; Cabaletta Bio’s expectations around the potential success and therapeutic benefits of CABA-201, including its belief that CABA-201 may enable an “immune system reset” and provide deep and durable responses for patients with SLE and potentially for patients diagnosed with other autoimmune disease; the Company’s plans to initiate a Phase 1/2 clinical trial of CABA-201 in patients with SLE, including its anticipated progress, clinical trial design, ability to leverage its experience in autoimmune cell therapy and lupus product development; the Company’s planned initial clinical data read-out in the first half of 2024; Cabaletta’s ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner in its Phase 1/2 clinical trial of CABA-201; and 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.

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 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 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 and 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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