

August 22, 2023

Cabaletta Bio®

# Cabaletta Bio and WuXi Advanced Therapies Announce Expansion of GMP Manufacturing Agreement to Include CABA-201

*– Agreement expansion facilitates preparation for commercial readiness for CABA-201, enabling treatment of patients in multiple planned clinical trials with separate parallel cohorts*

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*– Partnership for CABA-201 builds on existing manufacturing agreement for clinical trial supply of MuSK-CAART for MusCAARTes™ trial –*

PHILADELPHIA, Aug. 22, 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 it has entered into certain work orders relating to Good Manufacturing Practice (GMP) manufacturing under its existing master services agreement with WuXi Advanced Therapies (WuXi ATU), a global Contract Testing, Development and Manufacturing Organization (CTDMO). As part of the agreement, WuXi ATU will serve as a cell processing manufacturing partner for the planned global clinical development of CABA-201 in multiple indications, including potential late-stage clinical trials and commercial readiness activities for CABA-201.

“We have had a successful collaboration with WuXi ATU over the past two years for the GMP compliant production of novel cell therapies. Based on this initial collaboration, we chose to expand our partnership to include WuXi ATU as a manufacturer for our CABA-201 clinical programs,” said Gwendolyn Binder, Ph.D., President of Science and Technology of Cabaletta. “WuXi ATU’s dedicated production capacity for CABA-201 supports our planned global expansion and commercial preparedness efforts and will enable us to dose patients in multiple clinical trials with separate parallel cohorts, while maintaining a capital-efficient manufacturing strategy.”

Under the terms of the agreement, WuXi ATU will provide GMP manufacturing of CABA-201, a 4-1BB-containing fully human CD19-CAR T cell investigational therapy, to support any of Cabaletta’s planned clinical trials, including the previously announced separate Phase 1/2 clinical trials of CABA-201 for the treatment of patients with systemic lupus erythematosus and idiopathic inflammatory myopathies, or myositis. In addition, WuXi ATU will continue to serve as the Company’s cell processing manufacturing partner for the MusCAARTes™ Phase 1 clinical trial of MuSK-CAART.

“We are delighted to expand our partnership with Cabaletta to advance the development of CABA-201 for patients with autoimmune diseases,” said David Y. H. Chang, Ph.D., President and Chief Technology Officer of WuXi ATU. “We look forward to applying our

expertise in cell and gene therapy manufacturing to better support our customers to bring potentially life-saving treatments faster to patients in need.”

### **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 systemic lupus erythematosus and myositis, 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 that offer deep and durable responses for patients with a broad range of autoimmune diseases. Cabaletta Bio’s headquarters and labs are located in Philadelphia, PA.

### **About WuXi Advanced Therapies (WuXi ATU)**

As the advanced therapies business unit of WuXi AppTec, WuXi Advanced Therapies is a Contract Testing, Development and Manufacturing Organization (CTDMO) that offers integrated platforms to transform the discovery, development, testing, manufacturing, and commercialization of cell and gene therapies. Our services and solutions accelerate time to market and support customer programs around the world. For more information, please visit [www.advancedtherapies.com](http://www.advancedtherapies.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 its expectations regarding: Cabaletta’s ability to capitalize on and the potential benefits of the expanded scope of its collaboration with WuXi ATU; 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 separate Phase 1/2 clinical trials of CABA-201 in each indication; the Company’s business plans and objectives; the progress and results of its 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; the expectation that Cabaletta Bio may improve outcomes for patients suffering from systemic lupus erythematosus, myositis, MuSK-associated myasthenia gravis, or other autoimmune diseases as well as its expected therapeutic benefits; 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: 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 and public health crises; 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.

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Source: Cabaletta Bio