



## Caladrius Biosciences Completes Enrollment in Phase 2 ESCaPE-CMD Trial for Coronary Microvascular Dysfunction

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*Topline results expected by the end of 2019*

**BASKING RIDGE, N.J. (June 4, 2019)** – Caladrius Biosciences, Inc. (Nasdaq: CLBS) (“Caladrius” or the “Company”), a late-stage therapeutics development biopharmaceutical company pioneering advancements of cell therapies in select cardiovascular and autoimmune diseases, announced today the completion of enrollment and dosing in the Phase 2 ESCaPE-CMD study for CLBS16 (formerly known as CLBS14-CMD) in patients with coronary microvascular dysfunction (“CMD”). The Company expects to announce topline results shortly after the last patient completes follow up at the end of 2019.

“The completion of enrollment and dosing for this important study marks the first of several clinical milestones Caladrius expects to announce during the next 12-18 months and we look forward to sharing the results of the ESCaPE-CMD study after the last patient completes the 6 month follow up at the end of this year,” said Douglas W. Losordo, MD, FACC, FAHA, Executive Vice President, Global Head of Research and Development, Chief Medical Officer at Caladrius. “A preponderance of patients with CMD are reported to be females, many of whom have not been diagnosed or treated, making this condition that has no targeted therapy currently available an emerging and important women’s health issue.”

This Phase 2 interventional, open label, proof-of-concept study was conducted at two centers in the United States, Cedars-Sinai in Los Angeles, CA and the Mayo Clinic in Rochester, MN. In the study, 20 patients with diagnosed CMD received CLBS16 via a routine intracoronary infusion. The safety and efficacy endpoints include changes from baseline to six months for coronary flow reserve, or CFR (a direct measure of microvascular function), endothelial-dependent microvascular function, time to angina and other cardiovascular metrics. For more information on the ESCaPE-CMD study, please visit <https://clinicaltrials.gov/ct2/show/NCT03508609?term=clbs14&rank=1>. Preliminary results from the first 30% of the patients to complete the 6-month follow-up are highly promising with evidence that improved CFR is associated with symptomatic improvement (as reported by the Company during its recent quarter conference call and as described in the corporate presentation posted on the Company’s website). The results from this study are particularly important because they may provide information as to the impact of CLBS16 on patients with CMD while also providing potential corroboration of the mechanism of action of CD34+ cells in humans of promoting the growth of new microvasculature in response to myocardial ischemia. We will also look to these results for further support for the proposed mechanism of action of CLBS14 in no option refractory disabling angina, an indication for which Caladrius is preparing to commence a registration Phase 3 study.

Funding for the Phase 2 ESCaPE-CMD study came, in part, from a \$1.9 million grant from the National Institutes of Health under award number R44 HL135889. The content of this press release is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

#### About CLBS16 (formerly CLBS14-CMD)

CLBS16 is a proprietary formulation of autologous G-CSF mobilized peripheral blood derived CD34+ cells – endothelial progenitor cells that reside naturally in the bone marrow. Among the functions of these cells is the preprogrammed ability to induce capillary growth to regenerate microcirculation in damaged tissue experiencing microvascular insufficiency. CLBS16, administered via infusion into a coronary artery, is formulated specifically to enhance the potency of the natural process whereby CD34+ cells repair and regenerate microvasculature.

#### About Coronary Microvascular Dysfunction (CMD)

CMD, previously known as syndrome X, is a heart disease that occurs in the presence or absence of obstructions in the large arteries and involves damage to the inner lining of the tiny arterial blood vessels in the heart. It has been reported that a significant number of patients with coronary artery disease have CMD with a preponderance of those patients reported to be female. As many as half of patients with chest pain due to a lack of blood supply to the heart muscle have been shown to have non-obstructive coronary arteries, and studies indicate that the majority of those patients have CMD<sup>1</sup> and could be eligible for CLBS16. There is currently no available targeted therapy for CMD.

#### About Caladrius Biosciences

Caladrius is a late-stage therapeutics development biopharmaceutical company pioneering advancements of cell therapies for select cardiovascular and autoimmune diseases. Our leadership team collectively has decades of biopharmaceutical development experience and world-recognized scientific achievement in the fields of cardiovascular and autoimmune disease, among other areas. Our current product candidates include three developmental treatments for cardiovascular diseases based on our CD34+ cell therapy platform: CLBS12, recipient of a SAKIGAKE designation, in Phase 2 testing in Japan and eligible for early conditional approval for the treatment of critical limb ischemia; CLBS16 (formerly known as CLBS14-CMD), subject of the proof-of-concept ESCaPE-CMD clinical trial in the U.S.A. for the treatment of coronary microvascular dysfunction; and CLBS14 (formerly known as CLBS14-NORDA), recipient of a RMAT designation in the U.S.A. and for which we are in preparations to commence a Phase 3 clinical trial in no option refractory disabling angina. For more information on the company, please visit [www.caladrius.com](http://www.caladrius.com).

#### Safe Harbor for Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking

statements reflect management's current expectations, as of the date of this press release, and involve certain risks and uncertainties. All statements other than statements of historical fact contained in this press release are forward-looking statements including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. Without limiting the foregoing, the words "plan," "project," "forecast," "outlook," "intend," "may," "will," "expect," "likely," "believe," "could," "anticipate," "estimate," "continue" or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements, although some forward-looking statements are expressed differently. Factors that could cause future results to differ materially from the recent results or those projected in forward-looking statements include the "Risk Factors" described in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 14, 2019 and in the Company's other periodic filings with the SEC. The Company's further development is highly dependent on, among other things, future medical and research developments and market acceptance, which are outside of its control. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Press Release. Caladrius does not intend, and disclaims any obligation, to update or revise any forward-looking information contained in this Press Release or with respect to the matters described herein.

**<sup>1</sup>Coronary Microvascular Dysfunction— Epidemiology, Pathogenesis, Prognosis, Diagnosis, Risk Factors and Therapy —Circulation Journal 2017**

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