



## **Caladrius Biosciences Treats First Patient in the Phase 2b FREEDOM Trial of CLBS16 for the Treatment of Coronary Microvascular Dysfunction**

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*Initiation of the Phase 2b FREEDOM trial represents the next step in development of CLBS16 as a potential breakthrough treatment for the millions of sufferers of CMD in the U.S., most of whom are women*

*Patient enrollment underway at The Christ Hospital Health Network in Cincinnati (OH) and Mayo Clinic in Rochester (MN) with additional sites across the United States targeted to open soon*

*Strong investigator and subject interest driven by the positive results of the Phase 2a ESCaPE-CMD trial reported in spring of 2020*

BASKING RIDGE, N.J., Jan. 19, 2021 (GLOBE NEWSWIRE) -- Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse disease, announced that it has treated the first patient in its Phase 2b FREEDOM trial of CLBS16 as a therapy for coronary microvascular dysfunction ("CMD") at The Christ Hospital Health Network in Cincinnati, Ohio. The 105-patient double-blind and placebo-controlled clinical trial is designed to further evaluate the efficacy and safety of intracoronary delivery of autologous CD34+ cells (CLBS16) in subjects with CMD and without obstructive coronary artery disease.

"We are very excited about our CLBS16 program as it represents a potential breakthrough in the treatment of CMD, a condition which afflicts millions of patients in the US alone, many of whom are women. As a result, CMD is a women's health issue of emerging importance as currently there are no products with approved labeling for coronary microvascular dysfunction," said David J. Mazzo, PhD, President and Chief Executive Officer of Caladrius. "The treatment of the first patient in the FREEDOM trial is an important milestone for our Company and the program and we look forward to completing enrollment by the target of year-end 2021. It is especially noteworthy that even during the COVID-19 pandemic, physicians and patients are active in our trial, denoting the seriousness of the disease and underscoring the lack of available effective treatment for CMD."

"Following the outstanding full data results from the ESCaPE-CMD study that I presented at SCAI 2020, we are very excited to participate in the FREEDOM trial," said Timothy D. Henry, M.D., Medical Director of the Carl and Edyth Lindner Center for Research at The Christ Hospital Health Network. "Caladrius' CLBS16 program has demonstrated great promise and I am looking forward to seeing how this new therapeutic option can benefit patients with CMD."

For more information on this study, please visit [clinicaltrials.gov](https://clinicaltrials.gov) (identifier: NCT04614467).

If you are a patient or a physician and have questions about eligibility for this study, please visit [www.freedom-trial.com](http://www.freedom-trial.com).

### **About Coronary Microvascular Dysfunction**

Coronary microvascular dysfunction is a type of non-obstructive coronary artery disease that causes decreased blood flow to the heart muscle that affects approximately 8.3 million people in the U.S.<sup>1,2</sup> With common symptoms that include recurring, debilitating chest pain, tiredness, and shortness of breath, many CMD patients are undiagnosed because of the absence of large vessel obstruction. Due to an under appreciation of the disease, patients, the majority of whom are women, often go years without proper treatment. When a diagnosis of CMD is missed, patients are untreated and remain at high risk of heart attack and/or cardiovascular-related death.

[1] Mittal, S.R.; Indian Heart Journal, Volume 66, 2014, Pages 678–681

[2] Cleveland Clinic/AHA (American Heart Association)

### **About Caladrius Biosciences**

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse disease. We are developing first-in-class cell therapy products based on the finely tuned mechanisms for self-repair that exist in the human body. Our technology leverages and enables these mechanisms in the form of specific cells, using formulations and modes of delivery unique to each medical indication.

The Company's current product candidates include: HONEDRA<sup>®</sup> (formerly CLBS12), recipient of SAKIGAKE designation and eligible for early conditional approval in Japan for the treatment of critical limb ischemia ("CLI") based on the results of an ongoing clinical trial; OLOGO<sup>™</sup> (formerly CLBS14), a Regenerative Medicine Advanced Therapy ("RMAT") designated therapy for which the Company has finalized with the U.S. Food and Drug Administration (the "FDA") a protocol for a Phase 3 confirmatory trial in subjects with no-option refractory disabling angina ("NORDA"); CLBS16, the subject of both a recently completed positive Phase 2a study and a newly initiated Phase 2b study in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); CLBS119, an emergent CD34+ stem cell therapy responding to the COVID-19 pandemic and the potentially permanent damage the virus inflicts on the lungs of many patients; and CLBS201, designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for chronic kidney disease ("CKD"). 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 the intended use of net proceeds from financings as well as 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 5, 2020 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, except as required by law.

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