Caladrius Biosciences Reports Positive Full Results for CLBS16 from the ESCaPE-CMD Trial at SCAI 2020 Scientific Sessions

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Single administration of CLBS16 durably improves heart function and symptoms in patients with coronary microvascular dysfunction

BASKING RIDGE, N.J. (May 14, 2020) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse, not manage, disease, along with researchers from Cedars-Sinai (Los Angeles), Mayo Clinic (Rochester, Minn.) and The Christ Hospital (Cincinnati), today presented full data results from the ESCaPE-CMD trial of Caladrius's autologous CD34+ cell therapy, CLBS16, at the Society for Cardiovascular Angiography and Interventions ("SCAI") 2020 Scientific Sessions Virtual Conference. Data showed highly statistically significant improvement in coronary flow reserve ("CFR") correlating with symptom relief for patients with coronary microvascular dysfunction ("CMD") after a single intracoronary injection of CLBS16.

"We are extremely pleased, yet not surprised, that the full results for the ESCaPE-CMD corroborate the previously reported and very positive partial data from the study," said Douglas W. Losordo, M.D., FACC, FAHA, Chief Medical Officer at Caladrius. "The results show an encouraging ability to increase CFR and potentially reverse CMD, a disease that disproportionately afflicts more women than men, after a single administration. The outcome from this study brings us one step closer to realizing the promise of CD34+ cell therapy to augment microvasculature in the heart enabling the restoration of health rather than simply management of disease. We look forward to initiating the next trial for this program, a Phase 2b study, in the fall of 2020."

Trial investigators observed that patients experienced a highly statistically significant (p=0.0045) increase in coronary flow reserve at six months after a single intracoronary administration of CLBS16. The trial also evaluated changes from baseline to six months in chest pain frequency, Canadian Cardiovascular Society angina classification and Seattle Angina Questionnaire scores. A single administration of CLBS16 resulted in statistically significant improvements in all these measures of patient symptoms and function.

"As predicted, these data provided further evidence that CD34+ cell therapy can be a game changer resulting in long-term improvement in microvascular function, something that has not been shown with any other therapy to date," said Timothy D. Henry, M.D., Medical Director of the Carl and Edyth Lindner Center for Research at The Christ Hospital Health Network, who presented the data from the study at SCAI. "The CLBS16 program has demonstrated great promise and I am looking forward to seeing Caladrius further develop this new therapeutic option for CMD patients."

The ESCaPE-CMD[1] trial was an interventional, proof-of-concept study designed to evaluate the ability of Caladrius's autologous CD34+ cell therapy (CLBS16) to reverse the underlying pathology of CMD, the loss of microcirculation, and thereby alleviate symptoms. The key endpoint was change from baseline of coronary flow reserve, a direct measure of microvascular function, at six months following a single administration of CLBS16. The trial completed enrollment of the targeted 20 patients in May 2019 and the last patient completed the 6-month follow up in December 2019. The study's three principal investigators are Dr. C. Noel Bairey Merz, Cedars-Sinai Medical Center, Los Angeles, CA, Dr. Timothy D. Henry, The Christ Hospital, Cincinnati, OH and Dr. Amir Lerman, Mayo Clinic, Rochester, MN. All patients received a single infusion of their own GCSF-mobilized CD34+ cells formulated as CLBS16. For more information on the ESCaPE-CMD study, please visit https://clinicaltrials.gov/ct2/show/NCT03508609.

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[2,3] people in the U.S. 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 a misunderstanding 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.

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse, not manage, cardiovascular disease. We are developing a first- in-class cell therapy product that is based on the notion that our body contains finely tuned mechanisms for self-repair. 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 CLBS119, a CD34+ cell therapy product candidate for the repair of lung damage found in patients with severe COVID-19 infection who experienced respiratory failure, for which the Company plans to initiate a clinical trial in the coming months as well as three developmental treatments for ischemic diseases based on its CD34+ cell therapy platform: 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; CLBS16, the subject of a recently completed positive Phase 2 clinical trial in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); and 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"). For more information on the company, please visit www.caladrius.com.

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

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

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 the registered direct offering 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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