Caladrius Biosciences Reports Positive Results for CLBS16 from the ESCaPE-CMD Trial at American Heart Association Scientific Sessions 2019

November 16, 2019

Single administration of CLBS16 durably improves heart function and symptoms with no cell-related adverse events

CLBS16 cell therapy shows promise as a significant advancement in treatment of Coronary Microvascular Dysfunction (CMD), a condition that disproportionately afflicts women

PHILADELPHIA (November 16, 2019) – Caladrius Biosciences, Inc. (Nasdaq: CLBS), a late-stage biopharmaceutical company focused on developing treatments for select cardiovascular diseases, along with researchers from Cedars-Sinai (Los Angeles), Mayo Clinic (Rochester, Minn.) and The Christ Hospital (Cincinnati), today presented results from the ESCaPE-CMD trial of Caladrius's autologous CD34+ cell therapy, CLBS16, at the American Heart Association Scientific Sessions 2019. Data showed highly statistically significant improvement in coronary flow reserve correlating with symptom relief for patients with coronary microvascular dysfunction after a single intracoronary injection of CLBS16. The results for patients who have completed the six-month follow-up to date (17 of 20) were presented, with the results from the remaining patients expected by the end of 2019.

"CLB16 represents a potential breakthrough for the treatment of CMD, a condition that affects millions in the U.S. and that disproportionately afflicts women. This is the first time that a therapy has shown the ability to durably increase coronary flow reserve and potentially reverse CMD after a single dose. These reported results clearly support the premise that manageable cell-based tissue regeneration is possible in patients with CMD," said David J. Mazzo, Ph.D., President and CEO of Caladrius. "The reported results from the ESCaPE-CMD trial bring 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."

Trial investigators observed that patients experienced a highly statistically significant (p=0.0087) increase in coronary flow reserve 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.

"Coronary microvascular dysfunction is becoming increasingly recognized as a major health problem that disproportionately affects women. Unfortunately, there are no currently available therapies that directly target this condition. The reported data from this study provide objective evidence that CD34+ cell therapy results in long-lasting 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. "The CLBS16 program has demonstrated real promise and I am looking forward to seeing Caladrius further develop this new therapeutic option for CMD patients."

The ESCaPE-CMD[1] trial is an interventional, proof-of-concept study designed to evaluate the effect of Caladrius's autologous CD34+ cell therapy (CLBS16) on CMD symptoms and indicators while also evaluating treatment tolerance. The key endpoint was measurement of the change from baseline of coronary flow reserve, a direct measure of microvascular function, at six months following a single injection of CLBS16. The trial completed enrollment of the targeted 20 patients in May of 2019. The study's three principal investigators are Dr. C. Noel Bairey Merz, Cedars-Sinai, Dr. Timothy D. Henry, The Christ Hospital, and Dr. Amir Lerman, Mayo Clinic. All patients received a single infusion of their own GCSF-mobilized CD34+ cells formulated as CLBS16.

"CMD patients often are frustrated and in despair due to unresolved symptoms even after exhausting all other available therapies. These data indicate that the naturally-occurring CD34+ repair cell could provide a durable improvement in symptoms and reduced risk of adverse cardiovascular outcomes," said Douglas W. Losordo, M.D., FACC, FAHA, Chief Medical Officer at Caladrius. "We are extremely encouraged by these results from the trial and look forward to advancing the development of CLBS16 expeditiously with the goal of one day soon helping the large and underserved population of patients suffering from CMD."

Results from the six-month follow-up of the remaining treated patients will be available by year-end 2019.

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 such as 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 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 Japan and advanced therapy medicinal product classification (ATMP) in Europe, eligible for early conditional approval for the treatment of critical limb ischemia in Japan based on an ongoing clinical trial; CLBS16, subject of the proof-of-concept ESCaPE-CMD clinical trial in the U.S.A. for the

treatment of coronary microvascular dysfunction; and CLBS14, a Phase 3 ready clinical program in no option refractory disabling angina and recipient of a RMAT designation in the U.S.A. For more information on the company, please visit www.caladrius.com

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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.

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[1] 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.

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

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

Source: Caladrius Biosciences, Inc.