Caladrius Receives FDA Regenerative Medicine Advanced Therapy Designation for CD34+ Cell Therapy for Treating Refractory Angina

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BASKING RIDGE, N.J. (June 19, 2018) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company with multiple technology platforms targeting select cardiovascular indications and autoimmune diseases, announces today that the U.S. Food and Drug Administration ("FDA") has granted regenerative medicine advanced therapy ("RMAT") designation to the Company's late-stage CD34+ cell therapy program for the treatment of refractory angina.

The FDA grants the RMAT designation to regenerative medicine therapies intended to treat a serious condition for which preliminary clinical evidence indicates a potential to address unmet medical needs for that condition. The RMAT designation affords regenerative therapies the advantages of expedited development and review of marketing applications as are available to drugs that receive breakthrough therapy designation, including increased meeting opportunities, early interactions to discuss potential surrogate or intermediate endpoints, shortened biologics license application ("BLA") review times and the potential of accelerated approval.

"We are delighted and encouraged that the FDA has recognized our CD34+ cell therapy program with an RMAT designation. Refractory angina is a serious condition with high morbidity and no known effective treatments. We look forward to working with the FDA to define a path to registration for our therapy with the aim of providing expeditious treatment to patients suffering from this condition," said David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius.

Caldadrius acquired an exclusive worldwide license to the late-stage CD34+ program from Shire plc in March of this year. The acquisition included the data set and regulatory filings for the CD34+ cell therapy program for the treatment of refractory angina. This includes manufacturing procedures, preclinical (*in vivo* and *in vitro)* and Phase 1, Phase 2 and Phase 3 clinical study data of CD34 cell therapy as a treatment for no-option refractory angina, along with the corresponding regulatory filings.

About Refractory Angina

It is estimated that as many as one million people in the United States have chronic symptomatic coronary artery disease (often referred to as refractory angina) that is recalcitrant to medical therapy and not amenable to conventional revascularization procedures. Patients have reproducible lifestyle-limiting symptoms such as chest pain and shortness of breath, and are easily fatigued. These symptoms are often due to totally occluded coronary arteries or to diffuse coronary atherosclerosis that makes revascularization problematic. As the population ages and the incidence of diabetes mellitus increases, this clinical condition is expected to become more prevalent. Patients with this condition have significant morbidity and experience a lower quality of life.[1]

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company with multiple technology platforms targeting select cardiovascular indications and autoimmune diseases. The Company is developing CLBS14, a CD34 cell therapy intended as a treatment for coronary microvascular dysfunction (CLBS14-CMD) and refractory angina (CLBS14-RfA). CLBS14 is Caladrius' proprietary and patent protected formulation of CD34 cells designed specifically to enhance the potency of the CD34 cells for repair and regeneration of cardiovascular tissue. CLBS14-CMD is the subject of an ongoing Phase 2 proof-of-principal study being conducted in the USA at Cedars-Sinai (Los Angeles) and the Mayo Clinic (Minneapolis). A companion product, CLBS12, is formulated specifically for intramuscular administration for the treatment of lower extremity ischemia. A Phase 2 study of CLBS12 as a treatment for critical limb ischemia is being conducted in Japan, a successful outcome of which will, based on discussions with the Japanese regulatory authorities, qualify the program for consideration of early conditional approval as provided for under Japan's progressive regenerative medicine regulations. CLBS12 has been granted SAKIGAKE designation in Japan for the CLI indication, a designation similar to "Breakthrough Therapy Designation" granted by the FDA in the USA. Additionally, the Company is investigating its CLBS03 product candidate, an ex vivo expanded polyclonal T regulatory cell therapy for the treatment of recent-onset type 1 diabetes, in an ongoing Phase 2 trial for which top-line data is expected in early 2019. CLBS03 has been granted Fast Track and orphan drug designations from the FDA as well as Advanced Therapeutic Medicinal Product ("ATMP") classification from the European Medicines Agency ("EMA"). For more information about Caladrius, please visit 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. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors. 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 22, 2018, as subsequently amended on April 2, 2018, 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.

[1]Grise MA and Verma A. Ochsner J. 2009 Winter; 9(4): 220–226.

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