Caladrius Biosciences Receives SAKIGAKE Expedited Review Designation in Japan for CLBS12 for Treating Critical Limb Ischemia

April 10, 2018

BASKING RIDGE, N.J. (April 10, 2018) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a development-stage biopharmaceutical company with multiple technology platforms targeting autoimmune and select cardiology indications, announces today that the Company has received SAKIGAKE designation from the Japan Ministry of Health, Labour and Welfare ("MHLW") for CLBS12 for the treatment of critical limb ischemia ("CLI"). CLBS12 is currently in a Phase 2 trial in Japan for the treatment of no-option CLI, a severe obstruction of arterial blood flow to the extremities in patients that results in severe pain at rest and/or non-healing ulcers, which carry a risk of amputation.

The SAKIGAKE designation is part of Japan's effort to accelerate the development and approval of regenerative medicines. The Pharmaceutical and Medical Devices Act ("PMDA") enables an expedited path to conditional approval for regenerative medicine products that show sufficient safety evidence and signals of efficacy in Phase 2 study and is similar to the Breakthrough Therapy Designation in the United States. The strategy of SAKIGAKE includes a system for designating products for which prominent effectiveness (i.e. radical improvement compared to existing therapy) can be expected. For more information on SAKIGAKE, please visit (http://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/dl/140729-01-02.pdf)

"We are very pleased to receive SAKIGAKE status for CLBS12 in Japan. As a designated medicine under the SAKIGAKE Designation system, CLBS12 will have prioritized consultation, a dedicated review system to support the development and review process, as well as reduced review time from the normal 12 to 6 months. This is great news not only in practical terms, but also because we believe that it reflects the recognition by MHLW and PMDA of the therapeutic potential of CLBS12 for the patient population in desperate need of therapeutic options," Douglas W. Losordo, MD, FACC, FAHA, Senior Vice President, Clinical, Medical and Regulatory Affairs and Chief Medical Officer of Caladrius. "CLBS12 has the potential to offer a non-surgical therapeutic option to reverse critical limb ischemia in patients who have exhausted all other treatment modalities. We look forward to continuing to work with regulatory authorities in Japan to efficiently and rapidly complete development of CLBS12 and to offering this treatment to patients in need if approved."

About the CLBS12 Phase 2 Clinical Trial in Japan

The CLBS12 Phase 2 trial is a 35-patient prospective, randomized, controlled, multicenter study in no-option CLI patients in Japan. No-option CLI means that pharmacotherapy is unable to provide satisfactory treatment and that amputation of a limb or limbs is the next step in treatment for these patients. Patients randomized to treatment will be dosed with autologous G-CSF-mobilized peripheral blood-derived CD34 cells (CLBS12) through intramuscular injection, in addition to receiving standard of care pharmacotherapy. Patients randomized to the control arm will receive standard of care pharmacotherapy alone. The primary endpoint is time to continuous CLI-free status.

About Critical Limb Ischemia

CLI is a result of severe obstruction of the arteries that markedly reduces blood flow to the extremities, principally the feet and legs. CLI can lead to pain, skin ulcers and dermal sores, and, if not successfully addressed, amputation. No-option CLI means that pharmacotherapy has been ineffective and options for bypass or angioplasty have been exhausted.

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a clinical stage biopharmaceutical company with multiple technology platforms targeting autoimmune and select cardiovascular indications. The Company is investigating its lead product candidate, CLBS03, an *ex vivo* expanded polyclonal T regulatory cell therapy for the treatment of recent-onset type 1 diabetes, in an ongoing Phase 2 trial. CLBS14, a CD34 cell therapy intended as a treatment for coronary microvascular dysfunction and refractory angina, 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. Its 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 being conducted in Japan, a successful outcome of which will qualify the program for consideration of early conditional approval based on discussions with the Japanese regulatory authorities as provided for under Japan's progressive regenerative medicine regulations. 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 materially differ 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.

Contacts:

Investors:

Caladrius Biosciences, Inc.
John Menditto
Executive Director, Investor Relations and Corporate Communications
Phone: +1-908-842-0084
Email: jmenditto@caladrius.com

LHA Investor Relations
Miriam Weber Miller
Senior Vice President
Phone: +1-212-838-3777
Email: mmiller@lhai.com

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