Caladrius Biosciences Doses First Patient with CLBS12 in Phase 2 Critical Limb Ischemia Trial in Japan

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BASKING RIDGE, N.J. (March 13, 2018) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a development-stage biopharmaceutical company with multiple technology platforms targeting autoimmune and select cardiovascular indications, announces today that the first patient has been dosed in the Company's Phase 2 clinical trial in Japan with its proprietary CD34 cell therapy (CLBS12) for the treatment of no-option critical limb ischemia ("CLI").

This trial is a 35-patient prospective, randomized, controlled, multicenter study. 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, defined as two consecutive monthly visits in which the patient is determined by an independent adjudication committee to be "CLI-free".

Based on discussions with the Japanese regulatory authorities and in accordance with the Japanese Pharmaceuticals and Medical Devices Law passed in November 2014, the Company believes that, with favorable results, the study will qualify for consideration of conditional approval for CLBS12 in Japan for the treatment of no-option CLI. The noted legislation expedites the development and commercialization of regenerative medicine therapies and grants conditional approval for regenerative medicines that demonstrate evidence for safety and the likelihood for efficacy.

"We are delighted to have dosed the first patient in this pivotal trial of CLBS12 in no-option CLI in Japan. As we previously reported, the study protocol and Chemistry, Manufacturing and Controls ("CMC") strategy for the trial both were constructed in consultation with the Japanese Pharmaceutical and Medical Devices Agency. Based on those discussions, it was agreed that, should this trial be successful, it will qualify CLBS12 for consideration of early conditional approval in Japan for this indication," said David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "The study has a clinically relevant yet practical endpoint, time-to-CLI-free status, that encompasses a broader spectrum of improvement than do time-to-amputation or amputation-free survival, which are the historical endpoints in CLI studies."

Commenting on the study, Douglas W. Losordo, M.D., FACC, FAHA, Senior Vice President of Clinical Medical and Regulatory Affairs and Chief Medical Officer of Caladrius, noted, "Our enthusiasm for this program is based on previous studies of autologous CD34 cell therapy for no-option CLI patients in both Japan and the U.S. suggesting that CD34 cell therapy was safe, led to improvement in CLI-free status and improved amputation-free survival." [1], [2], [3]

"With favorable data, we expect to pursue a commercial partnership for CLBS12 as a treatment for no-option CLI in Japan. We view CLI as the entry point to explore the broader applicability of CD34 therapy, which could potentially offer us significant opportunities across multiple underserved cardiovascular indications," added Dr. Mazzo.

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, 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 is enrolling 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 17, 2017, 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] Losordo DW, et al; Autologous CD34+ Cell Therapy for Critical Limb Ischemia Investigators. A randomized, controlled pilot study of autologous CD34+ cell therapy for critical limb ischemia. Circ Cardiovasc Interv. 2012 Dec;5(6):821-30.

[2] Kawamoto A, et al. Intramuscular transplantation of G-CSF-mobilized CD34(+) cells in patients with critical limb ischemia: a phase I/IIa, multicenter, single-blinded, dose-escalation clinical trial. Stem Cells. 2009 Nov;27(11):2857-64.

[3] Fujita Y, et al. Phase II clinical trial of CD34+ cell therapy to explore endpoint selection and timing in patients with critical limb ischemia. Circ J. 2014;78(2):490-501.

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