Caladrius Biosciences Receives Advanced Therapy Medicinal Product Classification for CLBS12, its CD34+ Cell Therapy for Critical Limb Ischemia

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BASKING RIDGE, N.J. (July 15, 2019) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a late-stage therapeutics development biopharmaceutical company pioneering advancements of cell therapies in select cardiovascular and autoimmune diseases, announced today that the European Medicines Agency ("EMA") has granted Advanced Therapy Medicinal Product ("ATMP") classification to the Company's CD34+ cell therapy product, CLBS12, for the treatment of critical limb ischemia ("CLI"). Advanced therapy medicinal products are defined as medical treatments that are based on genes or cells and are intended as long-term or permanent therapeutic solutions to acute or chronic human diseases at a genetic, cellular or tissue level. CLBS12 has previously been awarded a SAKIGAKE designation in Japan, a status which makes the product eligible for early conditional approval based on the on-going clinical trial in that country.

"We are delighted and encouraged that the EMA has recognized our CD34+ cell therapy product, CLBS12, with an ATMP classification. This classification sets the stage for us to work closely with European regulators to define the most expeditious development and regulatory plan to registration for CLBS12 for the treatment of critical limb ischemia," said Douglas W. Losordo, M.D., FACC, FAHA, Executive Vice President, Global Head of Research and Development, Chief Medical Officer at Caladrius. "Critical limb ischemia is a serious unmet medical need in which there exists a severe obstruction of arterial blood flow to the extremities resulting in severe pain, eventual amputation and potential mortality. Obtaining the ATMP classification takes us one step closer to realizing our objective of making CLBS12 available to patients as an innovative new treatment for CLI."

ATMP classifications are granted for new therapeutics which fulfill the definitions for medicinal products that are gene therapy, somatic cell therapy and/or tissue engineered products. The ATMP program at EMA provides specific regulatory guidelines for preclinical development, manufacturing and product quality testing of ATMPs and also offers incentives including fee reductions for regulatory advice, recommendations and evaluation and certification of quality and non-clinical data. For additional information on ATMP classifications, please visit www.ema.europa.eu/ema.

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 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 a registration-eligible trial in Japan and eligible for early conditional approval for the treatment of critical limb ischemia; CLBS16 (formerly known as CLBS14-CMD), subject of the proof-of-concept ESCaPE-CMD clinical trial in the U.S.A. for the treatment of coronary microvascular dysfunction; and CLBS14 (formerly known as CLBS14-NORDA), recipient of a RMAT designation in the U.S.A. and for which we are in preparation to commence a Phase 3 clinical trial in no option refractory disabling angina. For more information on the company, 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 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.

Contacts:

Investors:
Caladrius Biosciences, Inc.
John Menditto

Vice President, Investor Relations and Corporate Communications
Phone: +1-908-842-0084
Email: jmenditto@caladrius.com

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