



Caladrius Biosciences Announces Orphan Drug Designation for CLBS12 for the Treatment of Buerger's Disease

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BASKING RIDGE, N.J., March 08, 2021 (GLOBE NEWSWIRE) -- Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse disease, today announced that the U.S. Food and Drug Administration ("FDA") has granted orphan drug designation to the Company's CD34+ cell therapy product, CLBS12, for the treatment of Buerger's disease – also known as thromboangiitis obliterans – a condition related to critical limb ischemia ("CLI") with no approved treatments to date in the U.S. .

"We are very pleased that the FDA has granted orphan drug designation to CLBS12 in Buerger's disease. Without a currently approved or effective treatment for this condition in the U.S., a significant unmet need remains for therapies that slow, stop or, ideally, reverse this debilitating disease," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "The Company's ongoing open-label, registration-eligible study of HONEDRA® (CLBS12) as a treatment for CLI and Buerger's Disease in Japan has shown strong results to date with approximately 60% of subjects in the completed Buerger's Disease cohort reaching a positive 'CLI-free' endpoint despite the natural history of continuous disease progression leading to amputation. With this designation we can now engage FDA in discussions to define the most efficient and rapid development pathway to registration in the U.S. Achieving orphan designation for CLBS12 takes us one step closer to realizing our goal of fulfilling the unmet medical need for Buerger's Disease patients around the world."

Orphan drug designation is granted by the FDA's Office of Orphan Products Development, which provides orphan status to drugs or biologics that are intended to treat rare diseases or disorders that affect fewer than 200,000 people in the United States. This designation provides the sponsor of the drug certain incentives, including tax credits, for qualified clinical trials and fee waivers. Orphan Drug designation confers eligibility for seven years of market exclusivity to an orphan drug post-approval, subject to a receipt by the FDA of marketing approval.

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse disease. We are developing first-in-class cell therapy products based on the finely tuned mechanisms for self-repair that exist in the human body. Our technology leverages and enables these mechanisms in the form of specific cells, using formulations and modes of delivery unique to each medical indication.

The Company's current product candidates include: CLBS16, the subject of both a recently completed positive Phase 2a study and a newly initiated Phase 2b study in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); HONEDRA® (CLBS12), recipient of orphan designation for Buerger's Disease in the U.S. as well as SAKIGAKE designation and eligible for early conditional approval in Japan for the treatment of critical limb ischemia ("CLI") and Buerger's Disease based on the results of an ongoing clinical trial; CLBS201, designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for chronic kidney disease ("CKD"); and OLOGO™ (CLBS14), a Regenerative Medicine Advanced Therapy ("RMAT") designated therapy for which the Company is in discussion with the FDA to finalize a Phase 3 protocol of reduced size and scope for a confirmatory trial in subjects with no-option refractory disabling angina ("NORDA"). For more information on the Company, please visit www.caladrius.com.

Contact:

Investors:

Caladrius Biosciences, Inc.

John Menditto

Vice President, Investor Relations and Corporate Communications

Phone: +1-908-842-0084

Email: jmenditto@caladrius.com

Media:

W2O Group

Christiana Pascale

Phone: +1-212-257-6722

Email: cpascale@w2ogroup.com



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