Caladrius Biosciences to Assess its CLBS201 CD34+ Cell Therapy in Diabetic Kidney Disease

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FDA authorizes new IND for the study of CLBS201 in patients with reduced kidney function

BASKING RIDGE, N.J., June 22, 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 authorized its investigational new drug ("IND") application for the study of CLBS201, a CD34+ cell therapy for the treatment of diabetic kidney disease ("DKD").

"Our latest development program, CLBS201, is designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for diabetic patients with reduced kidney function. Specifically, we will be targeting patients with later stage chronic kidney disease. Based on a wealth of published preclinical and early clinical data, it appears that the innate ability of CD34+ cells to promote the growth of new microvasculature could be a means to attenuate the progression, or even reverse the course, of DKD," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "We plan to initiate a phase 1/2 proof-of-concept study of CLBS201 within the next several months. Kidney disease remains a largely unmet medical need, especially as the general population ages and the incidence of diabetes and hypertension increases."

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 (www.freedom-trial.com) 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 diabetic kidney disease ("DKD"); 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.

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 the completion of the private placement, the satisfaction of customary closing conditions related to the private placement and the intended use of net proceeds from the private placement as well as 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; market and other conditions; 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 February 25, 2021 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, except as required by law.

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