Caladrius Biosciences Completes Enrollment in Phase 1b Study of CLBS201 for the Treatment of Diabetic Kidney Disease

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Top-line data from all subjects expected by the first quarter of 2023

BASKING RIDGE, N.J., Aug. 02, 2022 (GLOBE NEWSWIRE) -- Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company developing innovative therapies designed to treat or reverse disease, announced today the completion of enrollment and dosing in its Phase 1b, open-label, proof-of-concept study of CLBS201, a CD34+ regenerative cell therapy investigational product for intra-renal artery administration, for the treatment of diabetic kidney disease ("DKD"). The Company expects to announce top-line data from all subjects by the first quarter of 2023.

"We are pleased to announce that we have treated the last subject in our Phase 1b clinical trial evaluating CLBS201, which focuses on individuals who exhibit rapidly progressing stage 3b/4 DKD," stated Kristen K. Buck, M.D., Executive Vice President of R&D and Chief Medical Officer of Caladrius. "We look forward to sharing top-line data after all subjects have completed their six-month follow-up visit."

"Intra-renal artery infusion of CD34+ cells could be a breakthrough in the treatment of diabetic kidney disease; we are excited about our work with Caladrius on this program," stated Dr. Pablo Pergola, Research Director, Renal Associates, P.A., San Antonio, Texas, and principal investigator for the study. "We look forward to reviewing the results of this study and the potential development of a treatment for patients in need."

About the Phase 1b clinical trial of CLBS201 for the treatment of DKD

Progressive kidney failure is associated with attrition of the microcirculation of the kidney. Preclinical studies in kidney disease and injury models have demonstrated that protection or replenishment of the microcirculation results in improved kidney function. Based on these observations, the Company recently initiated a Phase 1, open-label, proof-of-concept trial evaluating CLBS201, a CD34+ regenerative cell therapy investigational product for intra-renal artery administration in patients with DKD. Patients selected for the study were in the pre-dialysis stage of kidney disease and exhibited rapidly progressing stage 3b disease. The objective of the protocol is to evaluate the tolerance of intra-renal cell therapy injection in DKD patients as well as the ability of CLBS201 to regenerate kidney function. For more information on this study, please visit clinicaltrials.gov (identifier: NCT04990427).

About Diabetic Kidney Disease

DKD, also called diabetic nephropathy, is a serious kidney-related complication of diabetes. Diabetes mellitus is the leading cause of kidney disease; approximately 40% of individuals with diabetes have DKD. Over time, high blood sugar from poorly controlled diabetes can damage the small blood vessels (microvasculature) in the kidneys, which can lead to kidney damage. This microvascular complication may eventually develop in approximately 30% of patients with type 1 diabetes and approximately 40% of patients with type 2 diabetes. All-cause mortality in patients with DKD is reported to be higher than in patients with diabetes without kidney disease.

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company dedicated to the development of innovative therapies designed to treat or reverse disease. We currently are developing first-in-class autologous 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: XOWNA® (CLBS16), the subject of both a recently completed positive Phase 2a study and an ongoing Phase 2b study (www.freedom-trial.com) in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); CLBS12 (HONEDRA® in Japan), recipient of a SAKIGAKE designation in Japan and eligible for early conditional approval for the treatment of critical limb ischemia ("CLI") and Buerger's disease based on the results of an ongoing clinical trial; and CLBS201, designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for DKD. For more information on the Company, please visit www.caladrius.com.

The Company recently announced that it has signed a definitive merger agreement with Cend Therapeutics, Inc. (www.cendrx.com) ("Cend") to form Lisata Therapeutics. Upon closing, Lisata will be a publicly traded company with an advanced clinical development pipeline and strong balance sheet, which is expected to fund product candidates to their next development milestone. The merger is expected to close in the third quarter of 2022.

Forward-Looking Statements

This communication contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this communication, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict," "see" and similar expressions and their variants, as they relate to Caladrius, Cend or the management of either company, before or after the aforementioned merger, may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements relating to the timing and completion of the proposed merger; Caladrius' continued listing on the Nasdaq Capital Market until closing of the proposed merger; the combined company's listing on the Nasdaq Capital Market after closing of the proposed merger; expectations

regarding the capitalization, resources and ownership structure of the combined company; the approach Cend is taking to discover and develop novel therapeutics; the adequacy of the combined company's capital to support its future operations and its ability to successfully initiate and complete clinical trials; the difficulty in predicting the time and cost of development of Cend's product candidates; the nature, strategy and focus of the combined company; the executive and board structure of the combined company; and expectations regarding voting by Caladrius' and Cend's stockholders. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the risk that the conditions to the closing of the transaction are not satisfied, including the failure to timely or at all obtain stockholder approval for the transaction; uncertainties as to the timing of the consummation of the transaction and the ability of each of Caladrius and Cend to consummate the transaction; risks related to Caladrius' ability to correctly estimate its operating expenses and its expenses associated with the transaction; the ability of Caladrius or Cend to protect their respective intellectual property rights; unexpected costs, charges or expenses resulting from the transaction; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the transaction; and legislative, regulatory, political and economic developments. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Caladrius' Annual Report on Form 10-K filed with the SEC on March 22, 2022. Caladrius can give no assurance that the conditions to the transaction will be satisfied. Except as required by applicable law, Caladrius undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

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