Caladrius Biosciences Announces IDMC Recommendation to Advance CLBS201 Trial for the Treatment of Diabetic Kidney Disease

May 19, 2022

Independent Data Monitoring Committee advises continuation of trial without modification

No safety or tolerability concerns observed in the first two patients dosed

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

BASKING RIDGE, N.J., May 19, 2022 (GLOBE NEWSWIRE) -- Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company dedicated to the development of innovative therapies designed to treat or reverse disease, today announced that the Independent Data Monitoring Committee ("IDMC") overseeing the Phase 1b, open-label, proof-of-concept study of CLBS201 for the treatment of diabetic kidney disease ("DKD") has reviewed the initial safety and tolerability data from the first two, sequentially treated, patients. Based on their assessment of the data, the IDMC approved proceeding with the enrollment of the remaining four patients in the study without further review.

"We are very pleased with the progress of the study and with the recommendations of the IDMC," stated Kristen K. Buck, M.D., Executive Vice President of R&D and Chief Medical Officer of Caladrius. "We find it encouraging that CLBS201 appeared to be well-tolerated based on the initial assessment of data. We look forward to continuing this study and hope to rapidly enroll the remaining patients, leading to top-line data by the first quarter of 2023."

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 will be in the pre-dialysis stage of kidney disease and will exhibit rapidly progressing stage 3b disease. The protocol provides for a staggered, sequentially dosed cohort of six patients overseen by an IDMC with the objective of determining 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.[1] 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.[2,3]

[1] Radica Z. Alicic, et al. (2017) Diabetic Kidney Disease. CJASN, 12 (12) 2032-2045
[2] Maltese G, et al. (2015) Preventing diabetic renal disease: the potential reno-protective effects of SGLT2 inhibitors. Br J Diabetes Vasc. Dis. 15:114-118
[3] Karalliedde J, et al. (2010) Proteinuria in diabetes: bystander or pathway to cardiorenal disease? JASN. 21:2020-2027

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 diabetic kidney disease ("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). The merger is expected to close in the third quarter of 2022.

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, 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 plans or expectations to complete strategic transactions to diversify the Company's pipeline of development product candidates; statements relating to the timing and completion 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's and Cend's stockholders; and 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. 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's 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" described in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 22, 2022, 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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