



## Caladrius Biosciences Treats First Patient in the Phase 1b Trial of CLBS201 for the Treatment of Diabetic Kidney Disease

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BASKING RIDGE, N.J., April 12, 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 first patient has been treated in its Phase 1b open-label, proof-of-concept study of CLBS201 for the treatment of diabetic kidney disease ("DKD") at the Clinical Advancement Center in San Antonio, Texas. CLBS201 is an investigational autologous CD34+ cell therapy product for administration directly into the renal artery(ies) to reverse or slow the decline of renal function in diabetic patients with rapidly progressive chronic kidney disease ("CKD").

"With this trial, we hope to bring much improved patient outcomes to diabetic patients with reduced kidney function. Specifically, we are targeting patients with later stage CKD. Based on a wealth of published preclinical and early clinical data, we believe that the innate ability of CD34+ cells to promote the growth of new microvasculature could be a means to attenuate the progression or, potentially, reverse the course of DKD," said David J. Mazzo, PhD, President and Chief Executive Officer of Caladrius. "The treatment of the first patient in this Phase 1b study of CLBS201 is another important milestone for our Company and we anticipate top-line data by the first quarter of 2023."

"Regenerative medicine is a new, but rapidly evolving strategy for treating diabetic kidney disease and shows much promise as a potential breakthrough," stated Dr. Pablo Pergola, Research Director, Renal Associates, P.A., San Antonio, Texas, and principal investigator for the study. "My practice is proud and excited to be at the forefront of this effort."

For more information on this study, please visit [clinicaltrials.gov](https://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.<sup>1</sup> 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.<sup>2,3</sup>

[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](http://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](http://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, 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; 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 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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