



## Caladrius Biosciences Announces Merger Partner, Cend Therapeutics, has Treated First Patient in Phase 2b Trial of CEND-1 in Collaboration with Australasian Gastro-Intestinal Cancer Trials Group

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BASKING RIDGE, N.J., June 09, 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, announces that its merger partner in the creation of Lisata Therapeutics ("Lisata"), Cend Therapeutics, Inc. ("Cend") today indicated that the first patient has been treated in the Phase 2b study of CEND-1 in combination with gemcitabine and nab-paclitaxel for the treatment of first-line, metastatic pancreatic ductal adenocarcinoma. The ASCEND trial is a 125-patient, double-blind, randomized, placebo-controlled clinical trial being conducted at up to 40 sites in Australia and New Zealand led by the Australasian Gastro-Intestinal Cancer Trials Group ("AGITG") in collaboration with the NHMRC Clinical Trial Centre at the University of Sydney. Cend will provide study drug and regulatory support. The continued development of CEND-1 is the subject of a collaboration agreement with and investment in Cend by Caladrius. It is expected that Cend-1 will become the centerpiece of the combined development pipelines of Cend and Caladrius under the Lisata banner.

"This is an exciting and important step in the advancement of CEND-1 and for patients with pancreatic cancer, which has an extremely high mortality rate and affects hundreds of thousands of patients globally each year. We know how hard the team at Cend has worked to get this study initiated," stated Kristen K. Buck, M.D., Executive Vice President of R&D and Chief Medical Officer of Caladrius. "We hope to report a number of further additional clinical advancements around Cend's pipeline in the coming months as we progress under our joint development agreement prior to the closing of the proposed merger."

### About CEND-1

CEND-1 is an investigational drug that modifies the tumor microenvironment. It is targeted to tumor vasculature by its affinity for *alpha-v* integrins that are selectively expressed in tumor, but not healthy tissue vasculature. CEND-1 is a cyclic peptide that, once bound to these integrins, is cleaved by proteases expressed in tumors to release a peptide fragment, called a CendR fragment, which binds to a second receptor, called neuropilin-1, to activate a novel uptake pathway that allows anticancer drugs to more selectively penetrate solid tumors. The ability of CEND-1 to modify the tumor microenvironment to enhance delivery and efficacy of co-administered drugs has been demonstrated in models of a range of solid tumors.

### 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).

The Company recently announced that it has signed a definitive merger agreement with Cend Therapeutics, Inc. ([www.cendrx.com](http://www.cendrx.com)). The merger is expected to close in the third quarter of 2022.

### About Cend Therapeutics

Cend is a clinical-stage biotech company focused on a novel approach to enable more effective treatments for solid tumor cancers. The CendR Platform™ provides a tumor-targeted tissue penetration capability to specifically enhance drug delivery to tumors. Cend is also applying its technology to alter immunosuppression selectively within the tumor microenvironment to enable a patient's immune system and immunotherapies to fight cancer with greater effectiveness. For more information on Cend, please visit [www.cendrx.com](http://www.cendrx.com)

### 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's 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's 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'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 included in Caladrius's 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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