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Caladrius Biosciences and Cend Therapeutics Announce Publication of Pancreatic Cancer Trial Data in *The Lancet Gastroenterology and Hepatology*

Peer-reviewed study data suggest CEND-1, in combination with gemcitabine and nab-paclitaxel, demonstrates favorable safety and tolerability along with encouraging efficacy

BASKING RIDGE, NJ and SAN DIEGO, CA (July 6, 2022) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company developing innovative therapies designed to treat or reverse disease, and Cend Therapeutics, Inc. ("Cend"), a privately-held, clinical-stage drug discovery and development company developing a novel approach to enable more effective treatments for solid tumor cancers, pursuant to a collaboration agreement entered into by each company in connection with their recently announced and pending merger to form Lisata Therapeutics, today announced that *The Lancet Gastroenterology and Hepatology* has published data from the Phase 1b study of CEND-1, Cend's lead investigational drug, in combination with gemcitabine and nab-paclitaxel for the treatment of first-line, metastatic pancreatic ductal adenocarcinoma ("mPDAC"). The study was published online on June 5, 2022, and can be accessed by visiting https://www.thelancet.com/journals/langas/onlinefirst.

The publication details the results of an open-label, multi-center, Phase 1b trial conducted in 31 patients in the safety population and 29 patients in the efficacy population. The objectives of the study were to determine the safety, tolerability, pharmacokinetics, and preliminary efficacy of CEND-1 in combination with gemcitabine and nab-paclitaxel in patients with mPDAC.

"Pancreatic cancer has always been one of the most difficult tumors to treat. The protective meshwork, or tumor stroma, that surrounds the cancer cells has proved a difficult barrier for chemotherapy drugs to penetrate. In this first-in-human study using the new treatment modality, it appears that CEND-1 may overcome this barrier, and although the sample size was small, we were extremely excited to see such a significant response rate and prolonged progression-free survival with a number of long-term survivors," said Andrew Dean, M.D., lead investigator at the St. John of God Hospital, Subiaco, Australia. "I believe CEND-1 has the potential to provide a substantial benefit as part of a combination treatment and look forward to the results of the ongoing expansion studies."

"We are proud to have the very encouraging results of our Phase 1b study of CEND-1 in pancreatic cancer published in a prestigious peer-reviewed journal," stated Harri Järveläinen, Chief Operating Officer of Cend. "These results reinforce our belief that CEND-1 could become a transformative new medicine for the treatment of pancreatic cancer and other difficult-to-treat solid tumor cancers."

The data in the publication expand on the preliminary findings presented at the 2020 European Society for Medical Oncology (ESMO) Congress. Importantly, the new results suggest a potential for marked and durable improvement in treatment effectiveness in combination with standard-of-care ("SoC") drugs for mPDAC. Principal results include:

- CEND-1 was well tolerated; no dose-limiting toxicities were identified; safety of the combination was consistent with SoC alone
- Pharmacokinetic profile in the target range that is associated with optimal efficacy
- Median Progression-Free Survival 9.7 months
- Median Overall Survival 13.2 months (after extended follow-up of patients continuing treatment)
- Overall Response Rate (Partial Response (PR) + Complete Response (CR) = Objective Response Rate (ORR) 59%
- Disease Control Rate (Stable Disease + PR + CR = DCR) at 16 weeks 90%
- CA19-9 circulating tumor biomarker reductions of 50% or greater in 91% of patients

“We are very pleased to share the peer-reviewed Phase 1b clinical data for CEND-1, the same data that contributed heavily to our support for the proposed merger with Cend,” stated Kristen K. Buck, M.D., Executive Vice President of R&D and Chief Medical Officer of Caladrius, expected to hold the same position at Lisata Therapeutics after the merger closes. “I believe that the encouraging results indicate the benefit this potential new medicine can bring to patients with significant unmet medical needs and we look forward to continuing to maximally exploit the potential of CEND-1 as part of the treatment for an array of solid tumor cancers and in combination with a variety of therapies, including immunotherapies.”

About CEND-1

CEND-1 is an investigational drug that is intended to modify the tumor microenvironment. It is targeted to tumor vasculature by its affinity for *alpha*-v integrins that are selectively expressed in tumors, 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) 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) 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.

About Cend Therapeutics

Cend is a privately held, clinical-stage drug discovery and development 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.

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.

No Offer or Solicitation

This communication is not intended to and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities or the solicitation of any vote in any jurisdiction pursuant to the proposed transaction or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the United States Securities Act of 1933, as amended. Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained, the public offer will not be made directly or indirectly, in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including without limitation, facsimile transmission, telephone and the internet) of interstate or foreign commerce, or any facility of a national securities exchange, of any such jurisdiction.

Important Additional Information Will be Filed with the SEC

On June 15, 2022, Caladrius filed a registration statement containing a proxy statement, prospectus and information statement with the SEC, in connection with the proposed transaction. **CALADRIUS URGES INVESTORS AND STOCKHOLDERS TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT CALADRIUS, THE PROPOSED TRANSACTION AND RELATED MATTERS**. Investors and shareholders will be able to obtain free copies of the proxy statement, prospectus and other documents filed by Caladrius with the SEC through the website maintained by the SEC at www.sec.gov. In addition, investors and stockholders will be able to obtain free copies of the proxy statement, prospectus and other documents filed by Caladrius with the SEC by contacting Investor Relations by mail at Attn: Investor Relations, Caladrius Biosciences, Inc., 800 Westchester Avenue, Suite N341, Rye Brook, NY 10573. Investors and stockholders are urged to read the proxy statement, prospectus and the other relevant materials before making any voting or investment decision with respect to the proposed transaction.

Participants in the Solicitation

Caladrius and Cend, and each of their respective directors and executive officers and certain of their other members of management and employees, may be deemed to be participants in the solicitation of proxies in connection with the proposed transaction. Information about Caladrius's directors and executive officers is included in Caladrius's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 22, 2022 and amended on April 21, 2022. Additional information regarding these persons and their interests in the transaction will be included in the proxy statement relating to the transaction when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated below.

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