Caladrius Biosciences' Prospective Merger Partner, Cend Therapeutics, Announces Collaboration Agreement with Roche to Evaluate CEND-1 in Combination with Immunotherapy to Treat Pancreatic Cancer

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Study to be part of Roche's Morpheus Platform designed to enable more rapid and efficient development of novel cancer immunotherapy combinations

Agreement accelerated by Caladrius' initial investment in Cend

BASKING RIDGE, N.J. and SAN DIEGO, Aug. 10, 2022 (GLOBE NEWSWIRE) -- Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company") and Cend Therapeutics, Inc. ("Cend"), today announced Cend's execution of a collaboration agreement with F. Hoffmann-La Roche Ltd. ("Roche") to evaluate Cend's lead investigational drug, CEND-1, in combination with atezolizumab (Tecentriq ®), Roche's PD-L1 checkpoint inhibitor, along with standard-of-care chemotherapy in patients with metastatic pancreatic ductal adenocarcinoma ("mPDAC"). Under the terms of the agreement, Roche will be responsible for operational management of the trial while Cend and Roche share equally in the costs of the CEND-1 treatment arms in the study.

"We are extremely pleased to work with Roche, a global leader in oncology, to explore the potential of CEND-1 in combination with chemotherapy and immunotherapy for the treatment of pancreatic cancer," stated David Slack, Chief Executive Officer of Cend. "We are committed to exploring applications of CEND-1 to improve clinical outcomes for patients with this deadly disease. This collaboration represents a desire to explore a novel combination that may enable immunotherapy to benefit pancreatic cancer patients, who, to date, have not benefited broadly from this important emerging class of anti-cancer treatments."

"We are truly delighted to report progress regarding the development of CEND-1 supported by our collaboration agreement with Cend. Caladrius' commitment of resources, including its investment in Cend, provide support for this collaboration. We are excited to work with Roche as Caladrius and Cend combine to form Lisata Therapeutics," stated David Mazzo, Ph.D., Chief Executive Officer of Caladrius. "We hope that this collaboration is the harbinger of many similar collaborations with other partners as we work to expand the application of CEND-1 across different tumor types and in combination with different anti-cancer agents."

Phase 1b clinical results with Cend's investigational drug, CEND-1, in combination with standard-of-care chemotherapy regimen of gemcitabine and nab-paclitaxel, have been previously reported and recently published in *Lancet Gastroenterology and Hepatology* (https://www.thelancet.com/journals/langas/article/PIIS2468-1253(22)00197-2/fulltext). Additionally, a controlled Phase 2b clinical trial of the CEND-1/gemcitabine/nab-paclitaxel regimen in first-line mPDAC recently has been initiated and plans for treatment combinations in Phase 1b/2 clinical trials in additional solid tumor indications are being actively planned.

About Morpheus Phase 1b/2 study of CEND-1 in combination with Atezolizumab in mPDAC

The co-funded evaluation of CEND-1 in combination with atezolizumab will be conducted as part of Roche's Morpheus Platform. The Morpheus Platform is a collection of Phase 1b/2 clinical trials in multiple high unmet need cancer indications including pancreatic cancer, designed to assess safety and early efficacy to enable more rapid and efficient development of novel cancer immunotherapy combinations.

The trial including CEND-1 will be a Phase 1b/2, open-label, randomized, multi-national study in patients with first-line mPDAC. It will add Roche's anti-PD-L1 (programmed death ligand-1) checkpoint inhibitor drug, atezolizumab, to the CEND-1/gemcitabine/nab-paclitaxel regimen. The study includes three arms to compare the atezolizumab/CEND-1/gemcitabine/nab-paclitaxel versus CEND-1/gemcitabine/nab-paclitaxel regimen or gemcitabine/nab-paclitaxel alone and will be conducted at sites across the United States as well as in Germany, Spain and South Korea.

About Pancreatic Cancer

Pancreatic cancer is the third leading cause of cancer-related death with very poor five-year survival. Globally, pancreatic cancer accounts for over 430,000 deaths each year, including over 48,000 in the United States. Pancreatic ductal adenocarcinoma (PDAC) is characterized by marked desmoplasia that creates a dense capsule or stroma around the tumor that contributes to drug resistance due, in part, to poor anti-cancer drug delivery to tumor tissue.

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 the tumor microenvironment to release a peptide fragment, called a CendR fragment, which binds to a second receptor, neuropilin-1, to activate a novel uptake pathway (the CendR pathway) that allows anti-cancer drugs to 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. CEND-1 has also been shown in animal models of pancreatic and other cancers to alter the tumor microenvironment to decrease immunosuppression selectively within the tumor, which may enable a patient's immune system and immunotherapies to fight cancer with greater effectiveness.

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. 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 development compounds 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' 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.

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 on Form S-4 (File No. 333-265638) containing a proxy statement, prospectus and information statement with the SEC, in connection with the proposed transaction, which was declared effective by the SEC on July 28, 2022 and mailed to stockholders of Caladrius on or about August 2, 2022. **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' directors and executive officers is included in Caladrius' 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 are included in the proxy

statement relating to the transaction. These documents can be obtained free of charge from the sources indicated below.

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