Caladrius Biosciences Provides Update on Phase 2b FREEDOM Trial of XOWNA® in Coronary Microvascular Dysfunction

May 23, 2022

Interim analysis to be conducted following enrollment suspension in the double-blind, randomized, placebo-controlled clinical trial

Next development steps for XOWNA® to be announced by year-end 2022 following regulatory and business review

Caladrius Management will host a conference call tomorrow, May 24th at 8:15 a.m. EDT

BASKING RIDGE, N.J., May 23, 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 Company has suspended patient enrollment in its Phase 2b study of XOWNA®, known as the FREEDOM Trial, for the treatment of coronary microvascular dysfunction ("CMD"). The Company intends to conduct an interim analysis of the data from not less than the first 20 patients enrolled using the 6-month follow-up data to evaluate the efficacy and safety of XOWNA® in subjects with CMD and corroborate the ESCaPE-CMD study results. Additionally, the data from the analysis is expected to provide an indication of the magnitude of the XOWNA® effect size on the clinical endpoints likely to be required by the FDA in a future pivotal study. Per good clinical practice, Caladrius will continue to assess and follow all treated subjects according to protocol through completion of follow-up. The interim analysis is expected to be completed in August 2022 and the next steps in development of XOWNA® will subsequently be determined after appropriate regulatory and business review, expected to be announced prior to year-end 2022.

The FREEDOM Trial was originally designed as a 105-patient double-blind, randomized, placebo-controlled trial to further evaluate the efficacy and safety of intracoronary delivery of autologous CD34+ cells (XOWNA®) in subjects with CMD and without obstructive coronary artery disease and was expected to complete enrollment in approximately 12 months. The primary objectives of the FREEDOM Trial were to corroborate, in a controlled trial, the results of the ESCaPE-CMD trial, a Phase 2a open-label, proof-of-concept study in CMD patients, to get a better estimation of the treatment effect size of XOWNA® on clinical endpoints likely to be required by the FDA in a pivotal trial, and to assess the impact of XOWNA® on a patient population more broadly representative of the intended commercial population. As previously communicated, enrollment in the FREEDOM Trial initially proceeded as planned with the first patient treated in January 2021; however, the impact of the COVID-19 pandemic in the U.S., coupled with supply chain issues associated with the catheters used for diagnosis of CMD and/or administration of XOWNA® as well as with a contrast agent typically used in many catheter laboratories, have made and continue to make enrollment much slower than originally predicted and challenging to accelerate. Despite the multiple protocol amendments to address these obstacles, along with an increased number of sites in the study, the FREEDOM Trial has only enrolled approximately one third of the targeted 105 patients, and at this rate, more than four years would likely be required to reach the primary endpoint follow-up at 6 months post-treatment for all subjects. The Company believes that this revised timeline is not viable for financial and commercial reasons and an alternative development plan must be considered. As a result, the Company has suspended further enrollment activities and will conduct an interim analysis of the data to determine the next steps for the program.

"We have concluded that it is in the Company's best interest to suspend enrollment in the FREEDOM Trial and complete an interim analysis of the data from the subjects enrolled to date, which we expect will provide meaningful insight on the best future clinical development pathway of the program," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. "Since the inception of the FREEDOM Trial, new technology has been introduced and validated for the diagnosis of CMD, yet these new techniques are not widely available nor are the associated diagnostic parameters widely accepted. Further compounding the situation is the discontinuation by the manufacturer of the diagnostic equipment that was originally specified in the trial to qualify patients for the study, discontinuation and/or supply shortages of catheters qualified for XOWNA® administration and supply shortages of a contrast agent commonly employed in many catheter laboratories. These complications, coupled with the impact of the COVID-19 pandemic in the U.S., have made incremental enrollment exceedingly challenging, despite our efforts to accelerate enrollment by expanding the number of participating investigational sites as well as modifying the study protocol to make study inclusion criteria more flexible. Consequently, we have halted enrollment in the study to alleviate the operational and financial burden due to enrollment delays and the lack of visibility on the time to completion. We will consider additional protocol and/or executional changes based on the results of the interim analysis, which are expected in August 2022."

For more information on this study, please visit clinicaltrials.gov (identifier: NCT04614467).

About Coronary Microvascular Dysfunction

CMD is a type of non-obstructive coronary artery disease that causes decreased blood flow to the heart muscle that affects approximately 8.3 million people in the U.S.[1,2] With common symptoms that include recurring, debilitating chest pain, tiredness, and shortness of breath, many CMD patients are undiagnosed because of the absence of large vessel obstruction. Due to an under appreciation of the disease, patients, the majority of whom are women, often go years without proper treatment. When a diagnosis of CMD is missed, patients are untreated and remain at high risk of heart attack and/or cardiovascular-related death.

[1] Mittal, S.R.; Indian Heart Journal, Volume 66, 2014, Pages 678–681
[2] Cleveland Clinic/AHA (American Heart Association)

Conference Call Details:

Date: Tuesday, May 24, 2022
Time: 8:15 a.m. Eastern time
Toll-free Dial-in Number: (866) 595-8403
International Dial-in Number: (706) 758-9979
Conference ID: 7729348

A live webcast will be available on the Events & Presentations page (https://ir.caladrius.com/news-events/events-presentations) under the Investors & News section of the Caladrius website.

A telephone replay will also be available through May 27, 2022. To access replay, please dial (855) 859-2056 (Domestic) or (404) 537-3406 (International). At the system prompt, please enter the code 7729348 followed by the # sign.

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, our expectations with respect to the interim analysis of the data from the FREEDOM trial, 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 with Cend; the combined company's listing on the Nasdaq Capital Market after closing of the proposed merger; 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 merger with Cend 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; the uncertainties inherent in the clinical and preclinical development process; the ability of Caladrius to protect its intellectual property rights; 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 the Company's Quarterly Report on Form 10-Q filed with the SEC on May 5, 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.

Contact:

Investors:
Caladrius Biosciences, Inc.
John Menditto
Vice President, Investor Relations and Corporate Communications
Phone: 908-842-0084
Email: jmenditto@caladrius.com