

Cardiol Therapeutics Announces It Has Exceeded 50% Enrollment in Its Phase II MAVERIC-Pilot Study in Recurrent Pericarditis

written by Raj Shah | November 1, 2023

November 1, 2023 ([Source](#)) – Cardiol Therapeutics Inc. (NASDAQ: CRDL) (TSX: CRDL) (“Cardiol” or the “Company”), a clinical-stage life sciences company focused on the research and clinical development of anti-inflammatory and anti-fibrotic therapies for the treatment of heart disease, is pleased to announce that it has exceeded 50% of the patient enrollment target for its Phase II open-label pilot study (“MAVERIC-Pilot”), investigating the safety, tolerability, and efficacy of CardiolRx™ in patients with recurrent pericarditis. In addition to standard safety assessments, the study is designed to evaluate improvement in objective measures of this rare disease, and during an extension period, assess the feasibility of weaning concomitant background therapy including corticosteroids, while taking CardiolRx™.

“Achieving this milestone reflects the commitment and interest demonstrated by our clinical collaborators and participating patients, and we thank them for their contribution to the progress being made in this important study,” said David Elsley, Cardiol Therapeutics’ President and Chief Executive Officer. “Recurrent pericarditis is a debilitating inflammatory heart disease associated with symptoms that adversely affect quality of life and physical activity. Results of the MAVERIC-Pilot study will assist in further understanding the therapeutic

profile of our lead investigational drug in this condition and inform the design of a pivotal Phase III clinical trial to underpin the potential regulatory approval of CardiolRx™, which is also being evaluated in the global ARCHER Phase II trial in patients presenting with acute myocarditis.”

MAVERIC-Pilot is enrolling 25 patients at medical research centers in the United States that specialize in pericarditis care. The study Chairman is Allan L. Klein, MD, Director of the Center of Pericardial Diseases and Professor of Medicine, Heart and Vascular Institute, at the Cleveland Clinic. The primary efficacy endpoint is the change, from baseline to 8 weeks, in patient-reported pericarditis pain using an 11-point numeric rating scale (“NRS”). The NRS is a validated clinical tool employed across multiple conditions with acute and chronic pain, including previous studies of recurrent pericarditis. Secondary endpoints include the NRS score after 26 weeks of treatment, and changes in circulating levels of C-reactive protein, a commonly used clinical marker of inflammation. Importantly, the study will assess freedom from pericarditis recurrence.

Pre-clinical data adding to the strong scientific basis for investigating CardiolRx™ clinically in recurrent pericarditis were presented at the American Heart Association Scientific Sessions 2022. Cardiol’s research collaborators from Virginia Commonwealth University presented results demonstrating the protective effects of CardiolRx™ in a model of pericarditis, which included a significant reduction in imaging signs of pericardial effusion and thickening, and significant suppression of key pro-inflammatory markers interleukin-1 β (“IL-1 β ”) and interleukin-6 (“IL-6”). The release of these cytokines IL-1 β and IL-6 is responsible for the cycle of inflammation in recurrent pericarditis leading to the pericardial effusion and thickening, and associated chest pain, characteristic of the disease.

About Cardiol Therapeutics

Cardiol Therapeutics Inc. (**NASDAQ: CRDL**) (**TSX: CRDL**) is a clinical-stage life sciences company focused on the research and clinical development of anti-inflammatory and anti-fibrotic therapies for the treatment of heart disease. The Company's lead small molecule drug candidate, CardiolRx™ (cannabidiol) oral solution, is pharmaceutically manufactured and in clinical development for use in the treatment of heart disease. It is recognized that cannabidiol inhibits activation of the inflammasome pathway, an intracellular process known to play an important role in the development and progression of inflammation and fibrosis associated with myocarditis, pericarditis, and heart failure.

Cardiol has received Investigational New Drug Application authorization from the United States Food and Drug Administration to conduct clinical studies to evaluate the efficacy and safety of CardiolRx™ in two diseases affecting the heart: (i) a Phase II multi-center open-label pilot study in recurrent pericarditis (the MAVERIC-Pilot study; NCT05494788), an inflammatory disease of the pericardium which is associated with symptoms including debilitating chest pain, shortness of breath, and fatigue, and results in physical limitations, reduced quality of life, emergency department visits, and hospitalizations; and (ii) a Phase II multi-national, randomized, double-blind, placebo-controlled trial (the ARCHER trial; NCT05180240) in acute myocarditis, an important cause of acute and fulminant heart failure in young adults and a leading cause of sudden cardiac death in people less than 35 years of age.

Cardiol is also developing a novel subcutaneously administered drug formulation of cannabidiol intended for use in heart failure – a leading cause of death and hospitalization in the

developed world, with associated healthcare costs in the United States exceeding \$30 billion annually.

For more information about Cardiol Therapeutics, please visit cardiolrx.com.

Cautionary statement regarding forward-looking information:

This news release contains “forward-looking information” within the meaning of applicable securities laws. All statements, other than statements of historical fact, that address activities, events, or developments that Cardiol believes, expects, or anticipates will, may, could, or might occur in the future are “forward-looking information”. Forward-Looking information contained herein may include, but is not limited to, statements relating to the Company’s focus on developing anti-inflammatory and anti-fibrotic therapies for the treatment of heart disease, the molecular targets and mechanism of action of the Company’s product candidates, the Company’s intended clinical study and trial activities and timelines associated with such activities, the Company’s plan to advance the development of a novel subcutaneous formulation of CardiolRx™ for use in heart failure, and details as to how the results of the MAVERIC Pilot Study will be used going forward. Forward-Looking information contained herein reflects the current expectations or beliefs of Cardiol based on information currently available to it and is based on certain assumptions and is also subject to a variety of known and unknown risks and uncertainties and other factors that could cause the actual events or results to differ materially from any future results, performance or achievements expressed or implied by the forward-looking information, and are not (and should not be considered to be) guarantees of future performance. These risks and uncertainties and other factors include the risks and uncertainties referred to in the Company’s Annual Report on Form 20-F dated March 28, 2023, as well as the

risks and uncertainties associated with product commercialization and clinical studies. These assumptions, risks, uncertainties, and other factors should be considered carefully, and investors should not place undue reliance on the forward-looking information, and such information may not be appropriate for other purposes. Any forward-looking information speaks only as of the date of this press release and, except as may be required by applicable securities laws, Cardiol disclaims any intent or obligation to update or revise such forward-looking information, whether as a result of new information, future events, or results, or otherwise.

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