Cardiol Therapeutics Announces Massachusetts General Hospital, Largest Teaching Hospital of Harvard Medical School, as the 8th Major Medical Centre Participating in MAvERIC-Pilot

written by Raj Shah | December 5, 2023

MAvERIC-Pilot is a Phase II Study in Recurrent Pericarditis and is Anticipated to Complete Patient Recruitment during Q1 2024

December 5, 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 Massachusetts General Hospital ("Mass General") has been initiated and is eligible to enroll patients in MAvERIC-Pilot, the Company's Phase II open-label pilot study, 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™ and to assess freedom from pericarditis recurrence.

“We are delighted to have the world-renowned Massachusetts General Hospital contributing to our MAvERIC-Pilot study enrollment,” commented Dr. Andrew Hamer, Cardiol Therapeutics’ Chief Medical Officer and Head of Research & Development. “Mass General has been consistently ranked as a top hospital in the United States and has the largest hospital-based research program in the country. We look forward to the support of Mass General’s clinicians and participating patients towards reaching full enrollment in this ground-breaking study.”

MAvERIC-Pilot is enrolling 25 patients at eight prominent medical research centers in the United States that specialize in pericarditis care. The study recently surpassed 50% of its enrollment objective and is anticipated to complete patient recruitment during Q1 2024. 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.

About Recurrent Pericarditis

Recurrent pericarditis refers to inflammation of the pericardium (the membrane or sac that surrounds the heart) that follows an initial episode (frequently resulting from a viral infection).

Patients may have multiple recurrences. Symptoms include debilitating chest pain, shortness of breath, and fatigue, resulting in physical limitations, reduced quality of life, emergency department visits, and hospitalizations. Significant accumulation of pericardial fluid and scarring can progress to life-threatening constriction of the heart. The only FDA-approved therapy for recurrent pericarditis, launched in 2021, is costly and is primarily used as a third-line intervention. The number of patients seeking and receiving treatment for recurrent pericarditis annually in the United States is estimated at 38,000. Hospitalization due to recurrent pericarditis is often associated with a 6-8-day length of stay and cost per stay is estimated to range between $20,000 and $30,000 in the United States.

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,

including forecast of full enrollment in MAvERIC-Pilot during Q1 2024, and the Company's plan to advance the development of a novel subcutaneous formulation of CardiolRx™ for use in heart failure. 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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