Cardiol Therapeutics Enrolls First Patient in Pivotal Phase III MAVERIC Trial in Recurrent Pericarditis

- *Designed to assess the impact of CardiolRx™ on preventing episodes of recurrent pericarditis, the first patient has been randomized by Northwestern University in Chicago.*
- *Based on a successful end-of-Phase II meeting with the US FDA and subject to MAVERIC outcomes, Cardiol believes the results from MAVERIC will support a New Drug Application.*
- *Data from Cardiol's Phase II MAvERIC-Pilot study presented at the American Heart Association Scientific Sessions 2024 showed that pericarditis patients treated with CardiolRx™ experienced marked and rapid reductions in pericarditis pain and inflammation, and a substantial reduction in the number of pericarditis recurrences per year.*
- *Recurrent pericarditis is a debilitating heart condition that results in chest pain, shortness of breath and fatigue, physical limitations, reduced quality of life, and hospitalizations.*
- *CardiolRx™, which has been granted US FDA Orphan Drug Designation for this indication, is a small molecule oral drug targeting inflammasome pathway activation that is central to the development and progression of pericarditis.*

TORONTO, ON – April 16, 2025 – Cardiol Therapeutics Inc. (**NASDAQ: CRDL**) (**TSX: CRDL**) ("**Cardiol**" or the "**Company**"), a clinical-stage life sciences company focused on developing anti-inflammatory and anti-fibrotic therapies for the treatment of heart disease, announced today that Northwestern University has enrolled the first patient in the pivotal Phase III MAVERIC trial ("MAVERIC") evaluating Cardiol's lead drug candidate CardiolRx™ for the prevention of recurrent pericarditis. This multi-center, randomized, double-blind, placebo-controlled trial is designed to definitively assess the impact of CardiolRx™ on preventing recurrent pericarditis in patients at high risk for disease relapse and to support regulatory approval.

MAVERIC is currently being initiated at pre-eminent cardiovascular clinical research sites throughout the United States under an Investigational New Drug application authorized by the United States Food and Drug Administration ("US FDA"). The MAVERIC Program and Phase III leadership comprises an independent committee of international thought leaders in pericardial disease and clinical trial design: Allan Klein, MD, CM from Cleveland Clinic (MAVERIC Program Chair); Massimo Imazio, MD, FESC from University of Udine, Italy (MAVERIC Program Co-Chair); Paul Cremer, MD from Northwestern University (MAVERIC Trial Principal Investigator); Allen Luis, MBBS, PhD from Mayo Clinic Rochester (MAvERIC-Pilot Principal Investigator); Antonio Abbate, MD, PhD from University of Virginia; and, Stephen Nicholls, MBBS, PhD from Monash University, Melbourne, Australia.

"Recurrent pericarditis remains a challenging condition to manage and can significantly impact patients' quality of life. There is a pressing need for new treatment options earlier in the care pathway, before resorting to second- and third-line therapies such as corticosteroids or IL-1 blockers," commented Paul C. Cremer, MD, MAVERIC Trial Principal Investigator. "In collaboration with research centers across the United States, Canada, and Europe, we look forward to completing this important study of a new oral therapy with the potential to improve the treatment paradigm for this underserved patient population."

"Initiation of the MAVERIC Phase III trial is an important milestone in our Company's efforts to provide a more accessible, non-immunosuppressive therapeutic option for thousands of pericarditis patients. We congratulate Dr. Cremer and his colleagues at Northwestern for recruiting MAVERIC's first patient and we are grateful for the interest shown by our collaborators from other leading pericardial disease centers who will be participating in the study," said David Elsley, President and CEO of Cardiol Therapeutics. "Based on the strength and consistency of the data from our Phase II MAvERIC-Pilot study, we believe that CardiolRx™ can make a meaningful difference in the lives of pericarditis patients."

MAVERIC is a Phase III, multi-center, randomized, double-blind, placebo-controlled trial designed to enroll 110 patients with recurrent pericarditis at approximately 20 clinical sites across the United States, Canada, and Europe. Patients who have been treated with an interleukin-1 ("IL-1") blocker for at least 12 months and are scheduled to have this treatment discontinued, will be randomly assigned to receive either CardiolRx™ or placebo following cessation of the IL-1 blocker. Discontinuation of IL-1 blocker therapy is associated with a high risk for recurrence and has been reported to occur within 12 weeks in up to 75% of patients. The primary clinical objective of the trial will be to assess the impact of CardiolRx™ versus placebo on freedom from a new episode of recurrent pericarditis at 24 weeks. Other clinical endpoints include time to a new episode of pericarditis recurrence, and changes in patient-reported pericarditis chest pain score and changes to the inflammatory marker C-reactive protein.

MAVERIC, formerly referred to as MAVERIC-2, follows positive results from Cardiol's Phase II MAvERIC-Pilot study. Data from MAvERIC-Pilot were previously reported on November 18 at the American Heart Association Scientific Sessions 2024 and showed that patients experienced marked and rapid reductions in both pericarditis pain and inflammation that were maintained throughout the study. In addition, the results demonstrated a substantial reduction in pericarditis episodes per year. Treatment with CardiolRx™ was shown to be safe and well tolerated in a patient population who presented with a high degree of disease burden.

About Pericarditis

Pericarditis refers to inflammation of the pericardium (the membrane or sac that surrounds the heart), which frequently results from a viral infection. Patients may have multiple recurrences following that initial episode, and the primary goal of treatment is recurrence prevention. 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. On an annual basis, the number of patients in the United States experiencing at least one recurrence is estimated at 38,000. Approximately 60% of patients with more than one recurrence suffer for more than two years, and one third remain impacted at five years. Hospitalization due to recurrent pericarditis is typically associated with a 6-8-day 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 developing 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 ("US FDA") to conduct clinical studies to evaluate the efficacy and safety of CardiolRx™ in two diseases affecting the heart: recurrent pericarditis and acute myocarditis. The MAVERIC Program in recurrent pericarditis, 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, comprises the completed Phase II MAvERIC-Pilot study (NCT05494788) and the ongoing Phase III MAVERIC trial (NCT06708299). The ongoing ARCHER trial (NCT05180240) is a Phase II study 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. The US FDA has granted Orphan Drug Designation to CardiolRx™ for the treatment of pericarditis, which includes recurrent pericarditis.

Cardiol is also developing CRD-38, a novel subcutaneously administered drug formulation 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 regarding 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 studies and trial activities, timelines associated with such activities, and potential success of such activities, including the Company's plan to complete the Phase III study in recurrent pericarditis with CardiolRx, the Company's plan to advance the development of CRD-38, a novel subcutaneous formulation of cannabidiol intended for use in heart failure, the newly published data providing additional important rationale for the development of CRD-38 as a new approach to the treatment of heart failure, and the JACBTS publication provides fascinating new data that suggest a key mode of action of CRD-38 to potentially treat heart failure is through its ability to sustain cardiomyocytes and preserve mitochondrial function. 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 Information Form filed with the Canadian securities administrators and U.S. Securities and Exchange Commission on March 31, 2025 , available on SEDAR+ at sedarplus.ca and EDGAR at sec.gov, as well as the risks and uncertainties associated with product commercialization, regulatory approvals, clinical studies and uncertainties in predicting treatment outcomes. 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. Investors are cautioned not to rely on these forward-looking statements and are encouraged to read the Company's Annual Information Form filed on March 31, 2025.

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