# Cardiol Therapeutics Announces All Collaborating Clinical Research Centers Now Initiated and Eligible to Enroll Patients in ARCHER, a Phase II Trial of CardiolRx™ for the Treatment of Acute Myocarditis

## Recruitment Accelerating and Full Patient Enrollment Anticipated to be Completed During Q3 2024, up to Six Months Ahead of Schedule

## Multi-center, International, Double-blind, Placebo-controlled Trial Randomizing 100 Patients

**Toronto, ON – September 19, 2023** – 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, today announces that all collaborating research centers have been initiated and are eligible to enroll patients in ARCHER, the Company's Phase II, multi-center, international, double-blind, randomized, placebo-controlled trial designed to study the safety and tolerability of CardiolRx™, as well as its impact on myocardial recovery, in patients presenting with acute myocarditis. ARCHER is expected to enroll 100 patients at major cardiac centers in North America, Europe, Latin America, and Israel.

"Initiation of all clinical research centers coupled with the current rate of randomizations, as well as an expected increase in acute myocarditis cases as the northern hemisphere enters the viral infection seasons of autumn and winter, provide us a high degree of confidence to forecast that ARCHER will complete full patient enrollment ahead of schedule," commented Dr. Andrew Hamer, Cardiol Therapeutics' Chief Medical Officer and Head of Research & Development. "This is a significant milestone in expanding the reach of ARCHER worldwide and contributing to evaluating the clinical potential of CardiolRx™ in acute myocarditis, an inflammatory condition of the heart muscle characterized by chest pain, impaired heart function, arrhythmias, and conduction disturbances. The data generated from patients who enroll in ARCHER will provide important information in support of the use of CardiolRx™ as a novel small molecule therapeutic approach for this debilitating rare disease, which is an important cause of acute and fulminant heart failure and a leading cause of sudden cardiac death in people under 35 years of age, for which there are no approved therapies."

The ARCHER trial has been designed in collaboration with an independent steering committee comprising distinguished thought leaders in heart failure and myocarditis from international centers of excellence. The trial is now enrolling patients at over 35 pre-eminent cardiovascular research centers in North America, France, Brazil and Israel. The co-primary outcome measures of the trial, which will be evaluated after 12 weeks of double-blind therapy, consist of the following cardiac magnetic resonance imaging measures: left

ventricular function (longitudinal strain) and myocardial edema/fibrosis (extra-cellular volume), each of which has been shown to predict long-term prognosis of patients with acute myocarditis.

The Company believes there is a significant opportunity to develop an important new therapy for acute myocarditis that would also be eligible for designation as an orphan drug in the United States and the European Union. Orphan drug designation programs have been created to provide the sponsors of a drug significant incentives, including periods of prolonged marketing exclusivity and exemptions from certain fees, to develop treatments for rare diseases. Products with orphan drug designation also frequently qualify for accelerated regulatory review.

**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 ARCHER during Q3 2024, the data generated from patients who enroll in ARCHER will provide further information in support of the use of CardiolRx™ as a novel small molecule therapeutic approach for this debilitating rare disease, that ARCHER is expected to enroll 100 patients at major cardiac centers in North America, Europe, Latin America, and Israel, 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.*

**For further information, please contact:**

Trevor Burns, Investor Relations +1-289-910-0855
trevor.burns@cardiolrx.com