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Cardiol Therapeutics Announces First Patient Enrolled in *ARCHER*, a Phase II Clinical Trial of CardiolRx™ for Treatment of Acute Myocarditis

Multi-center, international, double-blind, randomized, placebo-controlled trial to enroll 100 patients

Oakville, ON – August 3, 2022 – 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 cannabidiol as an anti-inflammatory and anti-fibrotic therapy for the treatment of cardiovascular diseases ("CVD"), announced today that the first patient has been enrolled 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. CardiolRx is a pharmaceutically produced oral cannabidiol formulation being developed for the treatment of acute and chronic inflammation associated with heart disease.

Dennis McNamara, MD, MS, Professor of Medicine at the University of Pittsburgh, Director of the Center for Heart Failure Research at the University of Pittsburgh Medical Center, and Chair of the study steering committee commented, "We have long suspected that it is the response to injury that needs to be addressed to improve outcomes in myocarditis. Given its impact limiting these inflammatory mechanisms, we believe cannabidiol has the potential to truly benefit patients with this condition. I am pleased this important milestone has now been achieved and the *ARCHER* study, designed to investigate CardiolRx's therapeutic potential in myocarditis, is formally underway."

ARCHER has received regulatory clearance in multiple jurisdictions, including IND authorization from the FDA, and is expected to enroll 100 patients at major cardiac centers in North America, Europe, Latin America, and Israel. The primary endpoints 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 (ejection fraction and 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.

Myocarditis is an acute inflammatory condition of the heart muscle (myocardium) characterized by chest pain, impaired cardiac function, atrial and ventricular arrhythmias, and conduction disturbances. Although the symptoms are often mild, myocarditis remains an important cause of acute and fulminant heart failure and is a leading cause of sudden cardiac death in people under 35 years of age. In addition, some patients proceed to develop chronic dilated cardiomyopathy which continues to be the leading indication for cardiac transplantation.

Although viral infection is the most common cause of myocarditis, the condition can also result from administration of therapies used to treat several common cancers, including chemo-therapeutic agents and immune checkpoint inhibitors. Myocarditis has also been described as a complication of COVID-19 and, more recently, has been reported as a rare complication associated with certain vaccines for COVID-19. Acute myocarditis should be managed with guideline directed therapies for heart failure, arrhythmia and conduction disturbances; however, there is no uniformly accepted treatment for the underlying inflammatory processes associated with this condition.

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. The U.S. Orphan Drug Designation program was created to provide the sponsor of a drug significant incentives, including seven-year marketing exclusivity and exemptions from certain FDA fees, to develop treatments for diseases that affect fewer than 200,000 people in the U.S. (73,000 myocarditis cases are estimated in the U.S. annually). Products with Orphan Drug Designation also frequently qualify for accelerated regulatory review. The program was successfully utilized to support the first FDA approval of cannabidiol for the treatment of seizures associated with rare pediatric epilepsy syndromes. Cardiol believes there is a similar opportunity to develop its CardiolRx formulation as an orphan drug for the treatment of acute myocarditis.

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 cannabidiol as an anti-inflammatory and anti-fibrotic therapy for the treatment of CVD. The Company's lead product candidate, CardiolRx™, is a pharmaceutically produced oral cannabidiol formulation that is being clinically developed for use in cardiovascular medicine. CardiolRx is currently being evaluated in a Phase II/III multi-national, randomized, double-blind, placebo-controlled study (the "*LANCER"* trial). *LANCER* is designed to evaluate the efficacy and safety of CardiolRx as a cardioprotective therapy to reduce major cardiovascular and respiratory events in patients hospitalized with COVID-19 who have a prior history of, or risk factors for, CVD, and to investigate the influence CardiolRx has on key biomarkers associated with heart disease.

Cardiol has also received IND authorization from the FDA to conduct clinical studies to evaluate the efficacy and safety of CardiolRx in two orphan drug indications: (i) the *ARCHER* trial, a Phase II multi-national, randomized, double-blind, placebo-controlled trial in acute myocarditis, an important cause of acute and fulminant heart failure in young adults and the leading cause of sudden cardiac death in people less than 35 years of age; and (ii) a Phase II multi-center open-label pilot study in recurrent pericarditis (inflammation 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.

In addition, Cardiol is developing a subcutaneous formulation of cannabidiol for the treatment of inflammation and fibrosis associated with the development and progression of heart failure – a leading cause of death and hospitalization in the developed world, with associated healthcare costs in the U.S. 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 cardiovascular disease; the belief that cannabidiol has the potential to truly benefit patients with myocarditis; the Company's expectation of enrolling 100 patients at major cardiac centers in North America, Europe, Latin America, and Israel pursuant to the ARCHER study; the Company's belief that 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; the Company's belief that there is an opportunity to develop its CardiolRx™ formulation as an orphan drug for the treatment of acute myocarditis. 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 dated March 23, 2022, 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. Any forward-looking information speaks only as of the date on which it is made 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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