Cardiol Therapeutics Announces Phase II ARCHER Trial Presented at the World Congress on Acute Heart Failure 2024

Scope of presentation included trial design, rationale, and blinded baseline data on first 50 patients randomized into the Phase II study evaluating CardiolRx™ in patients with acute myocarditis

ARCHER trial rationale and design also accepted for publication in the journal *ESC Heart Failure*

ARCHER trial has now exceeded 85% of target patient enrollment

MAvERIC-Pilot Phase II study investigating CardiolRx™ for recurrent pericarditis expected to report topline results in early June 2024

Toronto, ON – May 14, 2024 – 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 announced its Phase II randomized, double-blind, placebo-controlled trial evaluating the impact of CardiolRx™ on myocardial recovery in patients with acute myocarditis ("ARCHER") was the subject of an oral presentation at the World Congress on Acute Heart Failure 2024, May 11 – 14 in Lisbon, Portugal – the annual congress of the Heart Failure Association of the European Society of Cardiology ("ESC"). The trial design, rationale, and blinded baseline data on the first 50 patients randomized into ARCHER was presented by Univ.-Prof. Dr. med. Carsten Tschöpe from the Berlin Institute of Health – Charité, on behalf of the ARCHER steering committee comprising distinguished thought leaders in heart failure and myocarditis from international centers of excellence who contributed to the design and execution of ARCHER. Concurrent with the presentation, the journal *ESC Heart Failure*, which is dedicated to advancing knowledge about heart failure worldwide, has accepted the manuscript describing the rationale and design of the ARCHER trial for publication.

"Acceptance to present the ARCHER trial design at such a prestigious scientific meeting and pending publication of the manuscript is testament to the high level of interest from the cardiology community in novel approaches to treat acute myocarditis for which there are currently no therapies approved by European and United States regulatory authorities. The baseline data from the first 50 ARCHER patients reveal demographics expected in acute myocarditis. Importantly, the initial baseline values of the primary and secondary outcome measures assessing myocardial function reveal low variability and reflect patients with acute myocarditis which is consistent with the patient segment expected to benefit from CardiolRx™ therapy," commented David Elsley, President and Chief Executive Officer of Cardiol Therapeutics. "Patient recruitment has been accelerating due in large part to the growing global awareness of myocarditis and the interest and commitment demonstrated by our clinical collaborators and participating patients. We are pleased to report ARCHER has now exceeded 85% of target enrollment. We anticipate that results from the ARCHER trial will assist in furthering our understanding of the therapeutic potential of CardiolRx™ and will

complement our more advanced MAvERIC-Pilot Phase II study in patients presenting with recurrent pericarditis, expected to report topline results in early June 2024."

The ARCHER trial is expected to enroll 100 patients at pre-eminent cardiovascular research centers in the United States, Canada, France, Brazil, and Israel. The primary outcome measures of the trial, which will be evaluated following 12 weeks of double-blind therapy, consist of two 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. Additional efficacy outcome measurements include left ventricular ejection fraction, survival, freedom from major cardiovascular events, resolution of clinical symptoms, and change in biomarkers associated with cardiac function and inflammation.

Acute myocarditis is an inflammatory condition of the heart muscle (myocardium) characterized by chest pain, shortness of breath at rest or during activity, fatigue, rapid or irregular heartbeat (arrhythmias), and light-headedness or the feeling one might faint. The disease is 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. Viral infection is the most common cause of myocarditis; however, it can also result from bacterial infection and commonly used drugs and mRNA vaccines, as well as therapies used to treat several common cancers, including chemo-therapeutic agents and immune checkpoint inhibitors. Patients hospitalized with the condition experience an average seven-day length of stay and a 4 – 6% risk of in-hospital mortality, with average hospital charge per stay estimated at $110,000 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 ("US FDA") 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. 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 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 studies and trial activities and timelines associated with such activities, including for primary efficacy endpoint and secondary endpoints, the Company's plan to advance the development of CRD-38, a novel subcutaneous formulation of cannabidiol intended for use in heart failure, the ARCHER initial baseline values of the primary and secondary outcome measures assessing myocardial function are consistent with the patient segment expected to benefit from CardiolRx™ therapy, that results from the ARCHER trial will assist in furthering our understanding of the therapeutic potential of CardiolRx™ and will complement the MAvERIC-Pilot, and the Company's expectation to report topline results from MAvERIC-Pilot in early June 2024 and that these results will inform the design of a pivotal Phase III clinical trial in recurrent pericarditis to underpin the potential regulatory approval of CardiolRx™, and the Company's expectation to enroll 100 patients at pre-eminent cardiovascular research centers in North America, France, Brazil and Israel. 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 April 1, 2024, 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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