Cardiol Therapeutics Announces Database Lock for Phase II ARCHER Trial of CardiolRx™ in Acute Myocarditis

- *ARCHER is designed to assess the impact of CardiolRx™ on cardiac magnetic resonance imaging parameters that measure heart dysfunction and edema/fibrosis—key measurements used to predict prognosis in myocarditis patients.*
- *Acute myocarditis is a potentially life-threatening condition affecting the heart muscle (myocardium) and is characterized by chest pain, shortness of breath, fatigue, rapid or irregular heartbeat (arrhythmias), and light-headedness, and can lead to heart failure or sudden cardiac death.*
- *There are no FDA-approved drug therapies indicated for the treatment of acute myocarditis.*
- *Topline results are expected within the next two weeks.*

Toronto, ON – July 22, 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, today announced database lock for ARCHER, the Company's Phase II multi-national, randomized, double-blind, placebo-controlled trial investigating its lead asset, CardiolRx™, on myocardial recovery in patients with acute myocarditis.

"Database lock marks another important milestone in the ARCHER program, enabling statistical analysis, unblinding, and the reporting of topline results, which are now expected within the next two weeks," said David Elsley, President and Chief Executive Officer of Cardiol Therapeutics. "As we advance our lead program—the pivotal Phase III MAVERIC trial of CardiolRx™ in recurrent pericarditis—we believe results from ARCHER will further guide our broader development strategy in forms of heart disease where fibrosis plays a key role."

Dr. Andrew Hamer, Cardiol Therapeutics' Chief Medical Officer and Head of Research & Development, added, "Acute myocarditis remains a serious and underserved cardiovascular condition with no approved pharmacological therapy, underscoring the significance of ARCHER. On behalf of the ARCHER Steering Committee and Cardiol Therapeutics, I would like to thank our clinical investigators and the patients and their families for their essential contributions. We look forward to receiving the results of the statistical analysis, which we believe will provide important insights into the effects of CardiolRx™ on MRI-based measures of cardiac fibrosis and function in patients with myocarditis."

ARCHER is a Phase II multi-national, randomized, double-blind, placebo-controlled trial investigating the safety, tolerability, and impact of CardiolRx™ on myocardial recovery in patients presenting with acute myocarditis. The design and rationale for ARCHER were published on June 27, 2024, in the journal *ESC Heart Failure*. The study enrolled over 100 patients from leading cardiovascular research centers in the United States, France, Brazil, and Israel. The two primary outcome measures of the trial, which were evaluated following 12 weeks of double-blind therapy, consist of cardiac magnetic resonance imaging parameters:

global longitudinal strain and extra-cellular volume, which assess myocardial function and tissue characteristics associated with fibrosis and inflammation. Both parameters are recognized prognostic markers in patients with acute myocarditis.

Acute Myocarditis

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, commonly used drugs, and mRNA vaccines, as well as therapies used to treat several common cancers, including chemo-therapeutic agents and immune checkpoint inhibitors. There are no FDA-approved drug therapies for acute myocarditis. 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 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 Company's intended clinical studies and trial activities and timelines associated with 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 Company's preparation for statistical analysis, unblinding, and reporting of top-line results from its Phase II ARCHER trial of CardiolRx™ in acute myocarditis, and the Company's belief that results from the ARCHER trial will provide insights to help guide its broader development strategy in forms of heart disease where fibrosis plays a key role, and into the effects of CardiolRx™ on MRI-based measures of cardiac fibrosis and function in patients with 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 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 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. Investors are cautioned not to rely on these forward-looking statements.

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