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## Cardiol Therapeutics Initiates Health Canada Approved Phase 1 Clinical Study of CardiolRx™

Study Designed to Support Cardiol Therapeutics' Phase 2 International Trial in Acute Myocarditis

Oakville, ON – August 26, 2020 – Cardiol Therapeutics Inc. (TSX: CRDL)(OTCQX: CRTPF) ("Cardiol" or the "Company"), a leader in the development of pharmaceutical cannabidiol formulations for the treatment of cardiovascular diseases, including heart failure and acute myocarditis, is pleased to announce the initiation of its Health Canada approved Phase 1 clinical study of CardiolRx™. CardiolRx is an extra strength formulation of pharmaceutical cannabidiol that has been formulated to set the highest industry standard for purity, consistency, and stability.

Cardiol's Phase 1 clinical trial is a double-blind, placebo-controlled, randomized study to assess safety, tolerability, and pharmacokinetics of single followed by multiple day ascending doses of CardiolRx administered orally in up to 55 healthy adult subjects, both in the fasting and fed states. The study is expected to be completed during Q4, 2020, and is believed to represent the first Health Canada approved study of a high concentration (100 mg/mL) cannabidiol formulation that contains virtually no THC (<5 ppm). This level of purity is extremely important for patient populations who should not take THC, particularly children, where THC can impact brain development, and older individuals who wish to avoid intoxication and who may be more susceptible to adverse drug effects.

By measuring standard safety parameters and the pharmacokinetics of CardiolRx, including the degree of drug absorption and resulting blood levels at escalating doses, the Phase 1 study will provide important information to optimize dosing levels for the Company's planned Phase 2 international trial in acute myocarditis. Cardiol's acute myocarditis trial has been designed by an independent steering committee comprising highly distinguished thought leaders in heart failure and myocarditis from international centers of excellence, including: the Cleveland Clinic, the Mayo Clinic, the Houston Methodist DeBakey Heart and Vascular Center, the University of Ottawa Heart Institute, McGill University Health Centre, University of Pittsburgh Medical Center, and Charité Hospital Berlin.

Acute myocarditis is an inflammatory condition of the heart that represents a leading cause of sudden cardiac death in children and otherwise healthy young adults. The most common cause of acute myocarditis is a viral infection of the heart tissue which is initially responsible for the inflammation. Based on the large body of experimental evidence of the anti-inflammatory and

cardioprotective properties of cannabidiol in models of cardiovascular disease, the Company believes there is an opportunity to develop a potential breakthrough therapy for acute myocarditis that would be eligible for designation as an orphan drug. The U.S. orphan drug program was created to offer companies significant incentives, including multi-year marketing exclusivity, to develop treatments for diseases that affect fewer than 200,000 people in the U.S. The program was successfully utilized to accelerate the first FDA approval of cannabidiol for the treatment of two pediatric epilepsy syndromes as orphan diseases. Cardiol believes there is a similar opportunity to fast track the development of its CardiolRx formulation as an orphan drug for the treatment of acute myocarditis, for which there is currently no accepted standard of care.

"There is now increasing evidence that the SARS-CoV-2 virus (responsible for COVID-19) is causing a disturbing number of new cases of myocarditis in young adults, perhaps most notably Red Sox pitcher Eduardo Rodriguez and several U.S. college football players. As global awareness of the devastating consequences of acute myocarditis increases in the wake of the COVID-19 pandemic, we see an opportunity to accelerate the development of CardiolRx as an important new cardioprotective therapy," said David Elsley President and CEO of Cardiol Therapeutics Inc. "The initiation of our Phase 1 clinical study represents another significant milestone for Cardiol, as we aim to position the Company at the forefront of heart failure research."

## **About Cardiol Therapeutics**

Cardiol Therapeutics Inc. (TSX: CRDL) (OTCQX: CRTPF) is a leader in the development of pharmaceutical cannabidiol formulations for the treatment of cardiovascular diseases, including heart failure and acute myocarditis. The Company's lead product, CardiolRx™, is pharmaceutically produced, manufactured under cGMP, and is THC free (<5 ppm). The Company plans to commercialize CardiolRx in the billion-dollar market for medicinal cannabinoids in Canada.

Cardiol is planning a Phase 2 international trial of CardiolRx in acute myocarditis, a condition caused by inflammation in heart tissue, which remains the most common cause of sudden cardiac death in people less than 35 years of age. The Company is also developing proprietary cannabidiol formulations for the treatment of inflammation in the heart that is associated with the development and progression of heart failure. Heart failure is the leading cause of death and hospitalization in North America, with associated annual healthcare costs in the U.S. alone exceeding \$30 billion. For further information about Cardiol Therapeutics, please visit cardiolrx.com.

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## Cautionary statement regarding forward-looking information:

This news release contains "forward-looking information" within the meaning of applicable Canadian securities laws. All statements, other than statements of historical fact, that address activities, events, or developments that Cardiol Therapeutics Inc. ("Cardiol" or the "Company") believes, expects, or anticipates will, may, could or might occur in the future are "forwardlooking information". Forward-looking information contained herein may include, but is not limited to, statements with respect to the expected completion of the Phase 1 clinical study in Q4. 2020 and the Company's plans to commercialize CardiolRx and for an international clinical study of CardiolRx. Forward-looking information contained herein reflects the current expectations or beliefs of Cardiol based on information currently available to it and is 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. These risks and uncertainties and other factors include that the risks and uncertainties associated with product commercialization and clinical studies referred to in the Company's Annual Information Form dated March 30, 2020. These 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. Although Cardiol believes that the expectations reflected in the forward-looking information are reasonable, they do involve certain assumptions, risks, and uncertainties and are not (and should not be considered to be) quarantees of future performance. It is important that each person reviewing this news release understands the significant risks attendant to the operations of Cardiol.