

# Cardiol Therapeutics Announces Completion of Phase I Clinical Study of CardiolRx(TM)

## Study results are expected to support the Company's plans to file an IND application with the FDA for a Phase II clinical trial in acute myocarditis

Oakville, Ontario--(Newsfile Corp. - December 22, 2020) - **Cardiol Therapeutics Inc. (TSX: CRDL) (OTCQX: CRTPF)** ("**Cardiol**" or the "**Company**"), a clinical-stage biotechnology company focused on developing innovative therapies for inflammatory heart disease, is pleased to announce completion of the Company's Health Canada approved Phase I clinical study of CardiolRx™. CardiolRx is an ultra-pure, extra strength cannabidiol oral formulation that is pharmaceutically produced, manufactured under cGMP, and THC-free (<10 ppm).

Cardiol's Phase I double-blind, placebo-controlled, randomized study was designed to assess safety, tolerability, and pharmacokinetics of single, followed by multiple day ascending doses of CardiolRx administered orally to 52 healthy adult subjects, both in the fasting and fed states. The therapy was shown to be generally well tolerated with no serious adverse events reported in the study and 51 subjects completed all requirements of the study protocol. 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.

The results of the study are expected in early Q1, 2021, and will form an integral part of the Company's planned IND application with the FDA for an international Phase II clinical trial in acute myocarditis. 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.

In the United States, an orphan drug designation is granted for pharmaceuticals being developed to treat medical conditions affecting fewer than 200,000 people. These conditions are referred to as orphan diseases. The assignment of orphan status to a disease and to drugs developed to treat it is a matter of public policy in many countries and has yielded medical breakthroughs that might not otherwise have been achieved. In the U.S. and the European Union, orphan drugs are eligible for accelerated marketing approvals and companies developing orphan drugs typically receive other incentives, including a prolonged period of market exclusivity that can extend over seven years, during which the drug developer has sole rights to market the drug.

### **About Cardiol Therapeutics.**

Cardiol Therapeutics Inc. (TSX: CRDL) (OTCQX: CRTPF) is a clinical-stage biotechnology company focused on the research and clinical development of anti-inflammatory therapies for the treatment of cardiovascular disease ("CVD"). The Company's lead product, CardiolRx™, is a pharmaceutically produced oral cannabidiol formulation that is currently entering a Phase II/III outcomes study in patients hospitalized for COVID-19. This trial, potentially leading to registration, is designed to evaluate the efficacy and safety of CardiolRx as a cardioprotective therapy to reduce mortality and major cardiovascular events in COVID-19 patients who have a prior history of, or risk factors for, CVD, and to investigate the effect of CardiolRx on key markers of inflammatory heart disease.

Cardiol is also planning to file an IND for a Phase II international trial to investigate the anti-inflammatory and anti-fibrotic properties of CardiolRx in patients with acute myocarditis, which remains the most common cause of sudden cardiac death in people under 35 years of age. In addition, Cardiol is developing a subcutaneous formulation of CardiolRx and other anti-inflammatory therapies for the treatment of chronic heart failure - a leading cause of death and hospitalization in North America, with associated annual healthcare costs in the U.S. alone exceeding \$30 billion.

Cardiol recently commercialized Cortalex™ ([cortalex.com](http://cortalex.com)) in the Canadian market. Cortalex is a pharmaceutically produced cannabidiol formulation, developed for patients who wish to avoid THC or for whom THC exposure is not recommended. For more information about Cardiol Therapeutics, please visit [cardiolrx.com](http://cardiolrx.com).

**For further information, please contact:**

David Elsley, President & CEO +1-289-910-0850  
[david.elsley@cardiolrx.com](mailto:david.elsley@cardiolrx.com)

Trevor Burns, Investor Relations +1-289-910-0855  
[trevor.burns@cardiolrx.com](mailto:trevor.burns@cardiolrx.com)

**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 "forward-looking information". Forward-looking information contained herein may include, but is not limited to, statements with respect to the Phase I results expected in early Q1, 2021 and that will form an integral part of the Company's planned IND application with the FDA for an international Phase II clinical trial in acute myocarditis, the Company's belief that there is an opportunity to develop a potential breakthrough therapy for acute myocarditis that would be eligible for designation as an orphan drug, the Company's plans for a potentially registrational Phase II/III, double-blind, placebo-controlled clinical trial investigating the efficacy and safety of CardiolRx™, in hospitalized COVID-19 patients with a prior history of, or risk factors for, cardiovascular disease, and for developing a subcutaneous formulation of CardiolRx and other anti-inflammatory therapies for the treatment of chronic heart failure. 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 the risks and uncertainties referred to in the Company's Annual Information Form dated March 30, 2020, including the risks and uncertainties associated with product commercialization and clinical studies, and uncertainties in predicting treatment outcomes. 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) guarantees of future performance. It is important that each person reviewing this news release understands the significant risks attendant to the operations of Cardiol.*



To view the source version of this press release, please visit  
<https://www.newsfilecorp.com/release/70795>