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## Cardiol Therapeutics Receives Health Canada Approval for Phase 1 Study of its Pharmaceutically Produced Cannabidiol (CBD) Formulation

Study represents the first Canadian clinical trial of an oral pharmaceutical cannabidiol product specifically formulated for patients who should not be exposed to THC

**Oakville, ON – March 5, 2020 – Cardiol Therapeutics Inc. (TSX: CRDL; OTCQX: CRTPF)** (“Cardiol” or the “Company”), a leader in the production of pharmaceutical cannabidiol (CBD) and the development of innovative cannabidiol medicines for heart diseases, has received a No Objection Letter from Health Canada to conduct a Phase 1 study of the Company’s pharmaceutically produced (cGMP), high concentration, pure cannabidiol formulation that is THC free (<5ppm). The Company plans to initiate the study in Q2, 2020.

Cardiol’s Phase 1 study is designed to measure the pharmacokinetics (blood levels of drug) following single and multiple doses of the Company’s extra strength 100mg/mL concentration pharmaceutical cannabidiol formulation in up to up to 55 healthy subjects, both in the fasting and fed states. The study will also measure standard safety parameters at escalating doses to help select the optimal dosing levels for the Company’s planned international Phase 2 study in acute myocarditis, an inflammatory form of heart failure that represents a leading cause of sudden cardiac death in children and young adults.

“Receiving Health Canada’s No Objection Letter to conduct a Phase 1 study is an important development for Cardiol, as this will be the first study designed to investigate safety and dosing levels of our high concentration cannabidiol formulation developed for patients who should not be exposed to THC,” said David Elsley, President and CEO of Cardiol Therapeutics. “The study is expected to provide important data to support the commercial and clinical development of this unique THC free (<5ppm) product which contains the same cannabidiol concentration as the medicine approved by the FDA for rare forms of paediatric epilepsy.”

There is a growing demand for a cannabidiol formulation that does not contain THC. Both the College of Physicians and Surgeons of Ontario and the Canadian Paediatric Society recommend that physicians do not expose young people under the age of 25 to THC, as its effects on brain development are unknown. For elderly patients, THC exposure can lead to unfavourable drug interactions and adverse effects of intoxication. Cardiol plans to enter the Canadian medicinal cannabinoid market (estimated at \$1.2 billion annually) imminently and to address the market’s largest segments – people under 25 and adults over 65 years of age – by offering what the Company believes to be the purest form of cannabidiol in the world.

Cardiol’s ultra-pure cannabidiol formulation is pharmaceutically produced specifically for medical purposes and is manufactured under the most stringent quality standards set by the pharmaceutical industry. It is free from the psychotropic effects of THC and is produced using

controlled processes in a cGMP, Health Canada approved, FDA registered and inspected pharmaceutical facility. This allows for consistent quality and purity from batch to batch, resulting in a THC free (<5 ppm) cannabidiol oil – ideal for patients who should not be exposed to THC.

### **About Cardiol Therapeutics**

Cardiol Therapeutics Inc. (TSX: CRDL; OTCQX: CRTPF) is focused on producing pharmaceutical cannabidiol (CBD) products and developing innovative therapies for heart diseases, including acute myocarditis and other causes of heart failure. The Company's lead product, CardiolRx™, is formulated to be the most consistent cannabidiol formulation on the market. CardiolRx is pharmaceutically produced, manufactured under cGMP, and is THC free (<5 ppm). The Company also plans to commercialize CardiolRx in the billion-dollar market for medicinal cannabinoids in Canada and is pursuing distribution opportunities in Europe and Latin America.

In heart failure, Cardiol is planning an international clinical study 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 nanotechnology to uniquely deliver pharmaceutical cannabidiol and other anti-inflammatory drugs directly to sites of inflammation in the heart associated with 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](http://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") believes, expects or anticipates will, may, could or might occur in the future are "forward-looking information". Forward-looking information is frequently identified by the use of words such as "plans", "expects", "projects", "intends", "believes", "anticipates", "forecasts", and other similar words and phrases, including variations (and negative variations) of such words and phrases, or may be identified by statements to the effect that certain actions, events or conditions "may", "could", "should", "would", or "will" be taken, occur or be achieved. Forward-looking information contained herein may include, but is not limited to, statements with respect to: future events; the future performance or the intended business strategy of Cardiol, including, but not limited to, the plan to commercialize CardiolRx™ 100 and the planning of an international clinical study of CardiolRx in acute myocarditis; the potential for Cardiol's licensed drug encapsulation and delivery technologies to enhance the bioavailability of pharmaceuticals; management's*

*expectations regarding estimated future pharmaceutical research and development opportunities, collaborations and prospects; the success and proposed timing of Cardiol's product development activities; the ability of Cardiol to develop its product candidates; Cardiol's plans to research, discover, evaluate and develop additional products; Cardiol's proposed future collaborations to advance Cardiol's lead nanoformulations into clinical development; and the potential for Cardiol's cannabinoid-based products to provide sources of future revenue. 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 success of Cardiol's product candidates will require significant capital resources and years of clinical development efforts; the results of clinical testing and trial activities of Cardiol's products; Cardiol's ability to obtain regulatory approval and market acceptance of its products; Cardiol's ability to raise capital and the availability of future financing; Cardiol's lack of operating history; unforeseeable deficiencies in the development of Cardiol's product candidates; uncertainties relating to the availability and costs of financing needed in the future for Cardiol's research and development initiatives; Cardiol's ability to manage its research, development, growth and operating expenses; the potential failure of clinical trials to demonstrate acceptable levels of safety and efficacy of Cardiol's product candidates; Cardiol's ability to retain key management and other personnel; risks related to fluctuations in medicinal cannabinoid markets in Canada and worldwide; uncertainties regarding Cardiol's ongoing collaborative and manufacturing partnerships; uncertainties regarding results of researching and developing products for human use; Cardiol competes in a highly competitive and evolving industry; Cardiol's ability to obtain and maintain current and future intellectual property protection; and other risks and uncertainties and factors. 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.*