

Cardiol Therapeutics Announces Plans for Orphan Drug Program in Acute Myocarditis with CardiolRx CBD Formulation

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Cardiol Therapeutics Inc. (TSX: CRDL; OTCQX: CRTPF) (“Cardiol” or the “Company”), a leader in the research and commercial development of pharmaceutical cannabidiol (CBD) and targeted therapies for heart disease, is pleased to announce that the Company is planning an international clinical trial in acute myocarditis utilizing its CardiolRx CBD formulation.

CardiolRx is Cardiol’s pure pharmaceutically-produced CBD. Designed to be the safest and most consistent formulation on the market, CardiolRx is cGMP certified and does not contain any THC. The Company plans to commercialize CardiolRx pharmaceutical CBD during 2019 in the billion-dollar market for medicinal cannabinoids in Canada and is pursuing market introduction opportunities in Europe and Latin America. Cardiol’s acute myocarditis program provides a unique opportunity to build brand awareness in support of this commercial launch and is being designed by an independent Steering Committee comprised of thought leaders in cardiology from North America and Europe.

Acute myocarditis is characterized by inflammation of the heart muscle (myocardium). The most common cause is viral infection of the heart tissue which is initially responsible for the inflammation. In most cases, the virus clears, and inflammation subsides, but in a significant number of cases the inflammation persists with ongoing myocardial damage and depressed heart function. Although the symptoms are often mild, myocarditis remains an important cause of acute and fulminant heart failure and is the most common cause of sudden cardiac death in people less than 35 years old. In addition, some patients proceed to develop chronic dilated cardiomyopathy which continues to be the leading indication for cardiac transplantation. Although viral causes of myocarditis are the most common, myocarditis can result from a broad range of infections and can be caused by drugs including chemo-therapeutic agents used to treat several common cancers. Symptoms include chest pain, fatigue, shortness of breath, and arrhythmias. Myocarditis damages heart cells, reducing overall heart function as measured by left ventricular ejection fraction such that the heart does not pump sufficient blood to meet the needs of the body.

Based on the large body of experimental evidence of the powerful anti-inflammatory activity of CBD in models of cardiovascular disease, Cardiol believes there is a significant 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.

“The U.S. orphan drug program was successfully utilized to accelerate the first FDA approval of CBD for the treatment of rare forms of pediatric epilepsy and significant shareholder value was created in the process,” stated David Elsley, President and CEO of Cardiol Therapeutics. “Given the mortality and the significant morbidity risk associated with acute myocarditis, we believe there is a similar opportunity in pursuing an expedited development program of our CardiolRx pharmaceutical CBD formulation for this serious orphan disease which has no accepted standard of care.”

About Cardiol Therapeutics

Cardiol Therapeutics Inc. (TSX: CRDL; OTCQX: CRTPF) is a leader in producing 100% pure pharmaceutical CBD and developing groundbreaking therapies for heart disease. The Company is focused on commercially launching the safest and most consistent CBD products for consumers and healthcare providers in the multi-billion-dollar medicinal cannabinoid markets. Cardiol is utilizing nanotechnologies designed to deliver CBD and other anti-inflammatory drugs for the treatment of heart failure. Heart failure is a leading cause of death and hospitalization in North America, with associated healthcare costs exceeding US\$30 billion annually in the U.S. alone. For further information about Cardiol, please visit the Company’s website at www.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 which may include, but is not limited to, statements with respect to: future events; the future performance or the intended business strategy of Cardiol Therapeutics Inc. ("Cardiol"); 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, including, but not limited to, the proposed timeline of Cardiol's product candidate pipeline for commercial introduction; 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. 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 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 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 these forward-looking statements 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.