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# DiaMedica Announces Positive Results From FDA Meeting on Planned Clinical Trial in Patients with Chronic Kidney Disease

- **DiaMedica has received final minutes from Type B meeting with the US FDA**
- **DiaMedica preparing to submit an IND to initiate DM199 clinical study in patients with chronic kidney disease in the US**

MINNEAPOLIS, May 03, 2018 (GLOBE NEWSWIRE) -- DiaMedica Therapeutics Inc. ("**DiaMedica**") (TSX VENTURE:DMA) (OTCQB:DMCAF), a clinical stage biopharmaceutical company focused on improving lives of patients with neurological and kidney diseases associated with low KLK1 levels, announced receipt of the final minutes from an in-person Type B meeting, with the Office of Drug Evaluation, Cardiovascular and Renal Division, of the U.S. Food and Drug Administration (FDA).

The objective of the meeting was to gain feedback and recommendations from the FDA on DiaMedica's planned clinical study of DM199 in patients with chronic kidney disease (CKD). The study endpoints will include 1) identifying dose(s) of DM199 that may normalize plasma concentrations of KLK1; 2) demonstrating the safety and tolerability; and 3) evaluating standard measures of kidney function and treatment biomarkers.

Type B meetings between the FDA and study sponsors (in this case DiaMedica) are held at predefined points during the clinical development process for novel drug treatments. Meetings typically take place right before submission of an investigational new drug application ("IND") or before or after the submission of clinical data or a new drug filing. Based on the FDA guidance, DiaMedica expects the study to include patients suffering from mild to moderate CKD (stage 3) due to Type 1 and Type 2 Diabetes and is designed to test multiple dosing strategies. Standard measures of safety, DM199 plasma levels and kidney function will be collected before, during and after DM199 treatment. DiaMedica intends to file an IND application and expects to initiate a trial in the 2<sup>nd</sup> half of 2018.

"This FDA meeting was an important milestone for us as we advance the development of DM199 for patients suffering from chronic kidney disease," said Todd Verdoorn, Chief Science Officer of DiaMedica. "We are pleased with the results of the discussion and the guidance provided on our trial design, and believe we now have a path forward to advance the development of DM199 for CKD. We look forward to initiating a phase 2a study in the second half of 2018, and potentially providing CKD patients an alternative drug therapy that is safer and more effective than what is currently available."

"We are very excited by the prospect of studying DM199 in patients suffering from chronic

kidney disease,” stated Rick Pauls, President and CEO of DiaMedica, “DM199 represents a novel treatment for patients with a mechanism that is upstream from ACEi, the only approved treatment today for CKD. In Japan and China, the KLK1 protein is extracted from pig pancreas for the treatment of CKD and retinopathy. We plan to leverage the existing use in the design of our upcoming studies.”

#### **About DM199:**

DM199 is a recombinant (synthetic) form of the human serine protease, KLK1. The KLK1 protein plays an important role in the regulation of diverse physiological processes including blood flow, inflammation, fibrosis, oxidative stress and neurogenesis via a molecular mechanism that increases production of nitric oxide and prostacyclin. KLK1 deficiency may play a role in multiple vascular and fibrotic diseases such as chronic kidney disease, retinopathy, stroke, vascular dementia, and resistant hypertension where current treatment options are limited or ineffective. DiaMedica is the first company to have developed a recombinant form of the KLK1 protein. The KLK1 protein, produced from porcine pancreas and human urine, has been used to treat patients in Japan, China and Korea for decades. DM199 is currently being studied in patients with acute ischemic stroke and DiaMedica is preparing to initiate a clinical study in patients with chronic kidney disease.

#### **About CKD:**

CKD is characterized by progressive loss of kidney function that can eventually lead to long-term kidney dialysis, kidney transplantation, and death. In the US it is estimated that over 30 million people suffer from CKD. Current treatments include management of blood pressure and blood glucose levels with drug treatments such as angiotensin receptor blockers and angiotensin converting enzyme inhibitors. Drug therapies can be associated with side effects that may limit optimal treatment and sometimes cause life-threatening events. Additional effective drug therapies are clearly needed.

CKD is a widespread health problem that generates significant economic burden throughout the world. The increasing incidence of CKD results in over 30 million Americans suffering from this debilitating and potentially life-threatening condition. Primary causes of CKD are diabetes (Type 1 and Type 2) and hypertension. Approximately 200,000 people in the US have CKD caused by Type 1 diabetes, a potential rare disease. Over 40% of all diabetics will eventually develop CKD making it one of the more common risks for diabetics. Clinically, CKD is characterized by persistent protein in the urine (proteinuria) and a progressive loss of the kidney’s normal ability to filter out waste products. This loss of kidney function increases the risk for hypertension and life-threatening heart disease.

#### **About DiaMedica Therapeutics Inc.**

DiaMedica Therapeutics is a clinical stage biopharmaceutical company focused on developing novel treatments for neurological and kidney diseases. DiaMedica's shares are listed on the TSX Venture Exchange under the trading symbol "DMA" and on the OTCQB under the trading symbol "DMCAF". For more information, please visit [www.diamedica.com](http://www.diamedica.com). Follow us on social media - [Twitter](#), [LinkedIn](#).

#### **FORWARD-LOOKING STATEMENTS**

The statements made in this press release that are not historical facts contain forward-looking information that involves risk and uncertainties. All statements, other than statements of historical facts, which address DiaMedica's expectations, should be considered forward-looking statements. Such statements are based on management's exercise of business judgment as well as assumptions made by and information currently available to management. When used in this document, the words "may", "will", "anticipate", "believe", "estimate", "expect", "intend" and words of similar import, are intended to identify any forward-looking statements. You should not place undue reliance on these forward-looking statements. Forward looking statements in this news release include, but are not limited to, the Company's expectations related to the filing, timing and ultimate acceptance of an IND, potential benefits of DM199 in the treatment of CKD patients, goals and other future plans. Factors that could cause actual results to differ materially from such forward-looking information described in detail in the DiaMedica's filings with the Canadian securities regulators, all of which are available on SEDAR ([www.sedar.com](http://www.sedar.com)). Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results could differ materially from those anticipated in these forward-looking statements. DiaMedica undertakes no obligation, and does not intend, to update, revise or otherwise publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of any unanticipated events, unless required by law. Although management believes that expectations are based on reasonable assumptions, no assurance can be given that these expectations will materialize.

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