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DiaMedica Therapeutics Announces Interim Results from Phase 1b Trial of DM199 in Chronic Kidney Disease Participants

- *Favorable DM199 safety profile across tested doses*
- *Pharmacodynamic results helped identify dose range for Phase II studies*
- *Encouraging early signals in mechanism biomarkers (NO and PGE_2), Kidney function (eGFR) and urine albumin (UACR)*
- *Phase II trial initiation expected 2H19 with interim analysis Q4 2019 – Q1 2020*
- *Company to host conference call and webcast on June 20, 2019 at 7:00 a.m. CT*

MINNEAPOLIS, June 19, 2019 (GLOBE NEWSWIRE) -- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biotechnology company, today announced interim results of the Phase 1b study from 28 evaluable participants with moderate and severe chronic kidney disease (CKD). DM199 (recombinant KLK1) was observed to be safe and well tolerated with no drug-related serious adverse events (SAEs), consistent with earlier DM199 studies in healthy volunteers. The study also demonstrated a dose range which the Company believes will restore normal KLK1 levels in CKD patients. It is noteworthy that the pharmacokinetic (PK) profile in CKD subjects after dosing was similar to the PK profile in healthy volunteers.

Encouraging early signals in estimated glomerular filtration rate (eGFR), urinary albumin to creatinine ratio (UACR) and other biomarkers were also observed in the study, which the Company believes show drug activity, consistent with the DM199 mechanism of action, and may represent initial proof-of-mechanism. The favorable interim safety, tolerability and PK data, complemented by pharmacodynamic (PD) observations, support the advancement of DM199 development to a Phase II clinical trial in patients with CKD.

Phase 1 Trial Design and Interim Results

Trial Design. The randomized, multi-center U.S., single dose open label trial enrolled CKD participants in two cohorts with moderate (Stage III) and severe renal function (Stage IV) impairment and Type 1 or Type 2 diabetes mellitus. The study was designed to evaluate the safety and tolerability of single subcutaneously administered DM199 - dose levels of 3, 5 and 8 µg/kg - assess PK, PD and guide the design of Phase II CKD studies over 11-days. The study has enrolled 31 adult CKD subjects from which 28 subjects are currently evaluable.

Safety and Tolerability Data. DM199 was observed to be well tolerated with no dose-limiting tolerability. There were no deaths, no discontinuations due to a treatment-related adverse event (AE), and no treatment-related SAEs. AEs were minor and consistent with standard treatment(s) in the CKD patient population. The most common AE was orthostatic

hypotension that resolved without intervention.

Pharmacokinetic Data. PK was evaluated over 11 days. The Company believes that it has identified a dose range to normalize KLK1 levels in both moderate and severe CKD patients. DiaMedica is pleased to report that the PK profiles were similar between moderate and severe CKD patients, as well as previous healthy subjects, dosed at the 3µg/kg. Therefore, the Company does not believe dosing adjustments is warranted, based on severity of disease.

Pharmacodynamic Data. PD was evaluated through exploratory biomarkers as pre-defined secondary endpoints for this study. Although subjects only received a single dose in the study, favorable overall results were observed including short-term improvements at approximately 24 hours after DM199 administration including Nitric Oxide (NO), average increase of 35.2%, Prostaglandin E_2 (PGE_2), average increase of 41.2%, eGFR, average increase of 4.08 mL/min/173^2, and UACR, average decrease of 18.7%. No similar discernable changes in blood pressure (other than Orthostatic hypotension), glucose or MMP9 levels were observed in study participants.

DiaMedica expects to provide full results of the study in a peer-reviewed publication and/or poster presentation.

"We're pleased to report interim results from the Phase Ib study met expectations for the primary endpoints, PK, safety and tolerability. Moreover, although this study was not designed for efficacy testing, it was notable that overall secondary endpoints, including NO, PGE_2, eGFR and UACR, **showed encouraging early signals.** The initial clinical data supports the expected mechanism of action for DM199," said Dr. Harry Alcorn, Jr., Chief Medical Officer at DiaMedica. "Most importantly, we're encouraged about DM199's potential as a treatment option to improve the lives of patients with chronic kidney disease."

Conference Call & Webcast Information

DiaMedica will host a conference call and webcast to present the interim Phase 1b results and the proposed Phase II trial design on Thursday, June 20, 2019 at 7:00 am CT. Investors and analysts are invited to join the conference call (audio only) by phone by calling (866) 962-3583 (U.S.) or (630) 652-5857 (international) using the conference ID 1746669. A telephonic replay of the conference call will be available until June 27, 2019, by dialing 1(855) 859-2056 (US Toll Free Dial In), (404) 537-3406 (international), replay passcode 1746669.

A live webcast of the presentation may be accessed live athttps://edge.media-server.com/m6/p/78quvxo3 or by visiting the Investors & Media section of the DiaMedica website at http://ir.diamedica.com. An archived replay of the webcast will be available on the Company's website for 90 days after the call.

About CKD

CKD occurs when kidneys are damaged and cannot filter blood the way they should. This damage can cause wastes to build up in the body. CKD is a progressive condition leading to the gradual loss of kidney function over time. Early stages of CKD may be present with few or no signs or symptoms and the majority of patients do not know they have kidney disease.

Unfortunately, not until one has significant kidney impairment does one usually seek a physician for diagnosis and treatment. Slowing the progression of CKD, and/or normalization of kidney function is an unmet need in this population which if not treated appropriately can lead to cardiovascular events, hospitalizations, dialysis, kidney transplant or premature death.

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 and other anti-inflammatory mediators. 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 a Phase II clinical study for acute ischemic stroke and the Company is preparing to initiate Phase II clinical studies in patients with chronic kidney disease.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company focused on developing novel treatments for patients with chronic kidney diseases and acute ischemic stroke. DiaMedica's common shares are listed on The Nasdaq Capital Market under the trading symbol "DMAC."

For more information, please visit www.diamedica.com, or follow us onTwitter.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and forward-looking information that are based on the beliefs of management and reflect management's current expectations. When used in this press release, the words "estimate", "believe", "anticipate", "intend", "expect", "plan", "will," "may" or "should", the negative of these words or such variations thereon or comparable terminology and the use of future dates are intended to identify forward-looking statements and information. The forward-looking statements and information in this press release include statements regarding the anticipated clinical success and benefits of DM199 as a potential treatment for CKD, the timing of the Company's clinical programs, including an anticipated Phase II study starting in the second half of 2019 in patients with CKD, and identification of a dose range which the Company believes will restore normal KLK1 levels in CKD patients. Such statements and information reflect management's current view and DiaMedica undertakes no obligation to update or revise any of these statements or information. By their nature, forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements, or other future events, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Applicable risks and uncertainties include, among others, DiaMedica's plans to develop,

obtain regulatory approval for and commercialize its DM199 product candidate for the treatment of CKD and its expectations regarding the benefits of DM199; DiaMedica's ability to conduct successful clinical testing of DM199 for CKD; the perceived benefits of DM199 over existing treatment options for CKD; ability to obtain required regulatory approvals of DM199 for CKD; the potential size of the markets for DM199 and the Company's ability to serve those markets; the success, cost and timing of planned clinical trials, as well as reliance on collaboration with third parties to conduct clinical trials; its ability to obtain funding for its operations, including funding necessary to complete planned clinical trials and obtain regulatory approvals for DM199 for CKD, and the risks identified under the heading "Risk Factors" in DiaMedica's annual report on Form 10-K for the fiscal year ended December 31, 2018 filed with the U.S. Securities and Exchange Commission ("SEC") and subsequent SEC filings by DiaMedica. The forward-looking information contained in this press release represents the expectations of DiaMedica as of the date of this press release and, accordingly, is subject to change after such date. Readers should not place undue importance on forward-looking information and should not rely upon this information as of any other date. While DiaMedica may elect to, it does not undertake to update this information at any particular time except as required in accordance with applicable laws.

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