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DiaMedica Announces First Patients Dosed in Diabetic Kidney Disease Cohort in Phase II REDUX CKD Clinical Study

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company developing novel treatments for chronic kidney disease, today announced dosing of the first participants in the diabetic kidney disease (DKD) cohort of the REDUX Phase II Chronic Kidney Disease (CKD) study. In total, 16 additional participants have been enrolled in the REDUX study in the past six weeks, 11 of which were enrolled in the DKD cohort III, bringing the total enrolled participants to 34, including 11 African American subjects into cohort I and 12 subjects with IgA Nephropathy (IgAN) into cohort II of the REDUX study.

“We are very pleased with the recent uptick in enrollments in the REDUX trial and with the ability of our current study sites to identify, screen and enroll DKD participants,” commented Dr. Harry Alcon, Jr., Chief Medical Officer of DiaMedica Therapeutics, “we are further encouraged by these enrollments given that approximately half of our study sites remain unable to enroll new subjects as they continue to struggle with restrictions related to COVID-19. At this time, we are hopeful recruitment continues to improve; however, with the flu season approaching and COVID-19 still in play, we will continue to monitor and support our sites for enrollment.”

The Phase II REDUX clinical trial is a multi-center, open-label investigation targeting 90 participants with Stage II or III CKD, who will be enrolled in three equal cohorts. The study is being conducted in the United States at up to 13 sites. Cohort I is studying African Americans with hypertension but who are not diabetic. African Americans are at greater risk for CKD than Caucasians and those who have the APOL1 gene mutation are at an even higher risk. The study is designed to capture APOL1 gene mutation as an exploratory biomarker in this cohort. Cohort II is studying participants with IgA Nephropathy previously confirmed by biopsy. Cohort III is studying participants with Type II diabetes mellitus, hypertension and albuminuria.

The REDUX study is evaluating two dose levels of DM199 within each cohort. Study participants will receive DM199 by subcutaneous injection twice weekly for 95 days. The primary study endpoints include safety, tolerability, blood pressure, albuminuria and kidney function, which will be evaluated by changes from baseline in eGFR and albuminuria, as measured by the urinary albumin to creatinine ratio (UACR). Secondary endpoints are focused on evaluating the potential for DM199 to positively impact the underlying disease causing each participant’s kidney disease.

About DM199

DM199 is a recombinant (synthetic) form of human tissue kallikrein-1 (KLK1). KLK1 is a

serine protease (protein) that 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 prostaglandin. 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 chronic kidney disease and patients with acute ischemic stroke.

About DiaMedica Therapeutics Inc.

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

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 "may," "expects," "intends," "estimates", "believes", "anticipates", "plans", "continue," "will", 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, but not limited to, the anticipated clinical benefits and success of DM199 and plans with respect to enrollment in the REDUX study. 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 ability to conduct successful clinical testing of DM199 and within its anticipated parameters, costs and timeframes; the perceived benefits of DM199 over existing treatment options; the potential direct or indirect impact of the COVID-19 pandemic on enrollment in the REDUX study and DiaMedica's business; its reliance on collaboration with third parties to conduct clinical trials; its ability to continue to obtain funding for its operations, and the risks identified under the heading "Item 1.A. Risk Factors" in DiaMedica's annual report on Form 10-K for the fiscal year ended December 31, 2019 as filed with the SEC on March 23, 2020 and subsequent SEC filings by DiaMedica, including its quarterly report on Form 10-Q for the quarterly period ended June 30, 2020 as filed with the SEC on August 11, 2020. 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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