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DiaMedica Therapeutics Announces First Patient Dosed in REDUX Phase II Clinical Trial of DM199 for the Treatment of Chronic Kidney Disease

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biotechnology company, today announced dosing of the first patient in its REDUX Phase II study of DM199 for the treatment of Chronic Kidney Disease (CKD). This study is designed to investigate the safety, tolerability and efficacy of DM199 for the treatment of CKD in African Americans with hypertension and CKD in individuals with IgA Nephropathy.

“We are thrilled to announce dosing of the first patient in our Phase II CKD study, a significant milestone in the development of DM199,” said Dr. Harry Alcorn, Chief Medical Officer of DiaMedica Therapeutics. “We believe that DM199 protein replacement therapy could have a meaningful impact on the lives of patients with chronic kidney disease.”

About the REDUX Phase II Trial of DM199 for Chronic Kidney Disease
The Phase II REDUX clinical trial is a multi-center, open-label investigation of 60 participants with Stage II or III CKD, who will be enrolled in two cohorts (30 participants per cohort). The study will be conducted in the United States at up to 10 sites. Cohort I is in African Americans with hypertension but 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 in participants with IgA Nephropathy (IgAN) previously confirmed by biopsy.

The study will evaluate 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 the estimated glomerular flow rate (eGFR) and albuminuria, as measured by the urinary albumin to creatinine ratio (UACR).

For more information regarding this study, please visit **www.clinicaltrials.gov** (NCT04123613).

DM199 for Chronic Kidney Disease
Currently, there is no cure for CKD and treatment involves management of symptoms and efforts to reduce complications and slow progression of the disease. Blood pressure medications, such as angiotensin converting enzyme inhibitors (ACEi) or angiotensin receptor blockers (ARB), are often prescribed to control hypertension, and hopefully, slow the progression of CKD. The Company’s product candidate, DM199, offers a potentially

novel approach for the treatment of CKD. The human kallikrein (KLK1) protein plays a vital role in normal kidney function. Studies suggest that patients with moderate to severe CKD have low levels of KLK1. DiaMedica believes that DM199 may prevent or reduce further kidney damage by replenishing KLK1 levels and restoring a natural physiologic system that may prevent ongoing kidney damage. KLK1 can facilitate the production of protective nitric oxide, prostacyclin and anti-inflammatory mediators. In this way DM199 has the potential to:

- Improve blood flow to the kidney by restoring proper regulation of blood flow through arteries, veins and especially the capillaries (vasoregulation);
- Support the structural integrity of the kidney by reducing scar tissue formation (fibrosis), oxidative stress, and inflammation; and
- Activate mechanisms that upregulate T-regs, improve insulin sensitization, glucose uptake and glycogen synthesis.

About IgA Nephropathy
IgAN is a serious, progressive, autoimmune disease that occurs when an antibody called immunoglobulin A (IgA) builds up in the kidneys. This results in local inflammation that, over time, can impair the kidneys' ability to filter waste from blood. Up to 50% of those patients diagnosed with IgAN will progress to end-stage renal disease (ESRD), where the kidneys have ceased to function and the individual requires regular dialysis or kidney transplantation. IgAN affects approximately 140,000 people in the United States and 200,000 people in Europe. IgAN is considered a rare disease in the United States and in Europe.

About Hypertensive African Americans
CKD affects approximately 6 million African Americans and, according to the National Kidney Foundation, hypertension is the second leading cause of kidney failure among African Americans. The prevalence of hypertension in African Americans in the United States is among the highest in the world. Onset of hypertension in African Americans generally occurs at an earlier age than Caucasians. Contributing to this condition is the tendency for hypertensive African Americans to be particularly sensitive to high salt diets, referred to "salt sensitive." Current treatment options for hypertensive African Americans with CKD are limited to managing their hypertension.

About DM199
DM199 is a recombinant (synthetic) form of the human protein kallikrein referred to as KLK1. The KLK1 protein plays an important role in the regulation of a variety of physiological processes in the kidneys, including blood flow, inflammation, fibrosis and oxidative stress. The Company believes that DM199 may restore KLK1 levels, enabling the natural physiologic process of the body to selectively release bradykinin-mediated nitric oxide, prostaglandins (PGE2 and PGI2-cAMP) and other anti-inflammatory mediators in the kidneys, which in turn may work synergistically to improve renal blood flow (dilating both afferent & efferent arterioles) and reduce inflammation, oxidative stress and fibrosis. The Company also believes that DM199 may play a role in restoring the body's ability to naturally regulate the function of the epithelial sodium channel (ENaC), which controls sodium levels in the body.

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

“DMAC.”

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

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”, “continue,” “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 benefits and clinical success of DM199 and the timing, parameters and requirements of DiaMedica’s clinical programs, including anticipated enrollment, number of study sites and clinical results. 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 ability to conduct successful clinical testing of DM199 and within its anticipated parameters and timeframes; the perceived benefits of DM199 over existing treatment options; DiaMedica’s plans to develop, obtain regulatory approval for and commercialize its DM199 product candidate for the treatment of CKD and acute ischemic stroke (AIS) and its expectations regarding the benefits of DM199; ability to obtain required regulatory approvals; the potential size of the markets for DM199 and its 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 AIS, 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, 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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Scott Kellen
Chief Financial Officer
Phone: (763) 496-5118
skellen@diamedica.com

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