October 14, 2019

DiaMedica Therapeutics Announces Clearance to Initiate Phase II Clinical Trial of DM199 for Chronic Kidney Disease

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC) announced today that the U.S. Food and Drug Administration (FDA) has accepted the Company's Phase II clinical trial protocol for the treatment of Chronic Kidney Disease (CKD). The Phase II trial is designed to assess the safety and efficacy of DM199 in the treatment of CKD in two cohorts: patients with CKD caused by IgA nephropathy (IgAN) and hypertensive African American patients with CKD. DiaMedica intends to initiate participant enrollment in the next few weeks.

"Based upon the Company's previously announced Phase Ib results demonstrating early signals in both estimated glomerular filtration rate (eGFR) and albuminuria improvement, which were consistent with published clinical data using porcine-derived KLK1 in Asia for CKD, we are cautiously optimistic about the potential for DM199 to provide a safe and effective new treatment option for individuals suffering from CKD," said Rick Pauls, DiaMedica's President and CEO. "We are looking forward to working with patients and physicians to evaluate the potential of DM199."

DM199 is a recombinant (synthetic) form of the human serine protease kallikrein (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.

This Phase II study is a multi-center, open-label investigation of approximately 60 participants with CKD, who will be enrolled in two cohorts, and will be conducted in the United States at up to 10 sites. The study will be focused on participants with CKD caused by IgAN and non-diabetic, hypertensive African American participants with CKD. African Americans are at greater risk for CKD than Caucasians, and African Americans 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. 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 and kidney function, which will be evaluated by changes from base line in eGFR and albuminuria, as measured by the urinary albumin to creatinine ratio (UACR).

About IgA Nephropathy

IgAN is a serious, progressive autoimmune disease that results in chronic inflammation of the kidneys. Up to 50% of those 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 Non-Diabetic Hypertensive African Americans with CKD

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, and the 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 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.”

CAUTIONARY STATEMENT 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 and requirements of DiaMedica’s clinical programs, including enrollment 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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