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DiaMedica Therapeutics Doses First Patient in Phase 1b Clinical Study of DM199 in Patients with Chronic Kidney Disease

Minneapolis, Minnesota – (Globe Newswire – February 14, 2019)– DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biotechnology company, today announced that it has initiated dosing patients with chronic kidney disease (“CKD”) in a Phase 1b clinical study evaluating DM199. The Phase 1b study, conducted in the US, is a multi-center, open label clinical trial to evaluate the safety, tolerability and pharmacokinetics of three dose levels of DM199 in 32 patients with moderate and severe CKD.

“This study will assist in determining dose levels required to restore normal KLK1 protein levels in patients with CKD and provide additional insights about the specific CKD patient populations that may benefit most from DM199 treatment and to guide the design of upcoming Phase II studies,” said Dr. Harry Alcorn, Chief Medical Officer at DiaMedica Therapeutics. “We are excited about the potential for DM199 to provide a positive benefit to patients with CKD as we commence our US clinical studies.”

Chronic kidney disease is a widespread health problem that generates significant economic burden throughout the world, including 30 million people in the US who suffer from this debilitating and potentially life-threatening condition according to the National Kidney Foundation. The primary causes of CKD are diabetes (Type 1 and Type 2) and hypertension. CKD is also caused by several other health conditions that can damage your kidneys and lead to CKD and end stage renal disease including lupus nephritis, polycystic kidney disease, interstitial nephritis, glomerulonephritis, acute kidney injury and focal segmental glomerulosclerosis.

DM199 for Chronic Kidney Disease

Currently, there is no cure for CKD and treatment involves management 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, a recombinant (synthetic) form of the KLK1 protein, offers a potentially novel approach for the treatment of CKD since the KLK1 protein plays a vital role in normal kidney function. Studies suggest that patients with moderate to severe CKD may excrete abnormally low levels of KLK1 in their urine. DiaMedica believes that DM199 may prevent or reduce further kidney damage by replenishing KLK1 levels and restoring systems that 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 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 DM199

DM199 is a recombinant form of human tissue kallikrein-1 (“KLK1”). KLK1 is an endogenous serine protease (protein) produced in the kidneys, pancreas and salivary glands, which plays a critical role in the regulation of local blood flow and vasodilation (the widening of blood vessels which decreases blood pressure) in the body, as well as an important role in managing inflammation and oxidative stress (an imbalance between potentially damaging reactive oxygen species, or free radicals, and antioxidants in your body). Scientific reports suggest that 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 pharmacologically active recombinant form of the KLK1 protein. The KLK1 proteins, produced from porcine (pig) pancreas and human urine, have been used to treat patients in Japan, China and Korea.

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.”

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 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”, “potential”, 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. The forward-looking statements in this press release include statements regarding the expectation that KLK1 may improve outcomes in patients suffering from CKD. 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 our 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 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 the risks identified under the heading “Risk Factors” in DiaMedica’s final prospectus filed with the U.S. Securities and Exchange Commission (“SEC”) pursuant to Rule 424(b) promulgated under the U.S. Securities Act of 1933, as amended, on December 10, 2018, in connection with DiaMedica’s Registration Statement on Form S-1, as amended, and subsequent SEC filings by DiaMedica. The forward-looking statements in this press release represent 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 statements and should not rely upon them as of any other date. While DiaMedica may elect to, it does not undertake to update these statements at any particular time except as required in accordance with applicable laws.

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