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DiaMedica Therapeutics Initiates Pivotal Trial of DM199 for the Treatment of Acute Ischemic Stroke

- ***The ReMEDy2 Trial Will Assess the Potential of DM199 to Both Improve Recovery After a Stroke and Prevent Stroke Recurrence***
- ***Opportunity to Expand Therapeutic Treatment Window and Eligible Patient Population for Acute Ischemic Stroke for the First Time in Decades***

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for neurological disorders and kidney diseases, today announced the initiation of the first site for its pivotal ReMEDy2 Trial, a Phase 2/3 clinical study of DM199 for the treatment of acute ischemic stroke (AIS).

The ReMEDy2 Trial is a randomized, double-blind, placebo-controlled Phase 2/3 adaptive trial designed to enroll 350 patients at 75 sites in the United States. Patients enrolled in the study will be treated with either DM199 or placebo within 24 hours of the onset of AIS symptoms. The study excludes patients treated with tissue plasminogen activator (tPA) and those with large vessel occlusions. The study population is representative of the 80% of AIS patients who do not have treatment options today, primarily due to the short treatment window of 4.5 hours required for administration of tPA.

The ReMEDy2 trial has two primary endpoints and is powered for success with either endpoint: 1) recovery from stroke as measured by the well-established modified Rankin Scale (mRS) at day 90, and 2) the rate of ischemic stroke recurrence at day 30. Recurrent strokes represent 25% of all ischemic strokes, often occur in the first few weeks after an initial stroke and are typically more disabling, costly, and fatal than initial strokes. Secondary endpoints for the study will evaluate participant deaths, mRS shift (which shows the treatment effect on participants across the full spectrum of stroke severity) and additional standard stroke scores (NIHSS and Barthel Index scores).

“Our investigators are enthusiastic to study a promising new therapy for their patients with the flexibility of a 24-hour treatment window, particularly given the challenges in emergency medicine today,” said Rick Pauls, DiaMedica’s Chief Executive Officer. “By either or both improving overall recovery and reducing the risk of a recurrent stroke, DM199 could be the first new therapeutic in 25 years that could meaningfully change outcomes for stroke patients. Stroke represents a significant, unmet medical need for approximately 700,000 patients annually in the U.S. and millions more globally.”

“KLK1 has been shown to stabilize plaque and reduce blood pressure, both important factors in stroke patient recovery and prevention of additional strokes,” said Scott Kasner, M.D., ReMEDy2 National Principal Investigator and Professor of Neurology and Director of the

Comprehensive Stroke Center, University of Pennsylvania. “KLK1’s mechanistic activity, clinical data from Asia using the endogenous form of KLK1 in stroke patients and the results from the ReMEDy Phase 2 AIS study provide overwhelming support for our community to study whether a recombinant KLK1 such as DM199 can significantly improve and prolong the lives of our patients.”

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, among other things, increases production of nitric oxide and prostaglandin. KLK1 deficiency may play a role in multiple vascular and fibrotic diseases such as stroke, chronic kidney disease, retinopathy, vascular dementia and resistant hypertension where current treatment options are limited or ineffective. DiaMedica is the first company to have developed a pharmaceutically active recombinant form of the KLK1 protein. The KLK1 protein, in forms 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 acute ischemic stroke and chronic kidney disease.

About Acute Ischemic Stroke and Stroke Recurrence

Stroke is characterized by the rapidly developing loss of brain function due to a blockage of blood flow in the brain. As a result, the affected tissues of the brain becomes inactive and may eventually die. AIS is characterized by interruption of the blood supply by a blood clot (ischemia). Risk factors for stroke include, among other things, advanced age, hypertension (high blood pressure), previous stroke or transient ischemic attack (TIA), diabetes, high cholesterol, cigarette smoking, atrial fibrillation, physical inactivity and obesity.

According to the U.S. Centers for Disease Control:

- Every year in the United States, approximately 795,000 people experience a stroke (ischemic or hemorrhagic). Approximately 610,000 of these are first events and approximately 25%, or 185,000, are recurrent stroke events.
- Approximately one of every 20 deaths in the United States is caused by stroke and is the fifth leading cause of death. On average, someone in the United States has a stroke every 40 seconds and someone dies from a stroke every four minutes.
- Stroke is the leading cause of serious long-term disability and reduces mobility in more than half of stroke survivors aged 65 and over.
- Risk of having a first stroke is nearly twice as high for African Americans as for Caucasians, and African Americans have the highest rate of death due to stroke.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company committed to improving the lives of people suffering from serious diseases. DiaMedica’s lead candidate DM199 is the first pharmaceutically active recombinant (synthetic) form of the KLK1 protein, an established therapeutic modality for the treatment of acute ischemic stroke and chronic kidney disease. For more information visit our website at www.diamedica.com.

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," "look forward," "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 benefits and success of DM199, the timing and requirements of its clinical programs, including its anticipated Phase 2/3 trial for DM199 in patients with AIS, which DiaMedica believes will commence in Summer 2021 after an FDA review completion in mid-May and has the potential to serve as a pivotal registration study of DM199 in that patient population, and enrollment, clinical results and ability to achieve clinical milestones, including the timing of completion of enrollment and readout of results in its REDUX trial, and cash runway timing. 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, the possibility of unfavorable results from DiaMedica's ongoing or future clinical trials of DM199; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; DiaMedica's plans to develop, obtain regulatory approval for and commercialize its DM199 product candidate for the treatment of AIS and CKD and its expectations regarding the benefits of DM199; 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 DiaMedica's business; DiaMedica's reliance on collaboration with third parties to conduct clinical trials; DiaMedica's ability to continue to obtain funding for its operations, including funding necessary to complete planned clinical trials and obtain regulatory approvals for DM199 for AIS and 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, 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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