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DiaMedica Therapeutics Announces First Patient Dosed in Relaunch of its Pivotal Phase 2/3 ReMEDy2 Trial of DM199 for the Treatment of Acute Ischemic Stroke

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for neurological disorders and cardio-renal disease, today announced the first patient being dosed in DiaMedica's relaunch of its pivotal Phase 2/3 ReMEDy2 Trial of DM199 for the treatment of acute ischemic stroke.

The company continues to work closely with its contract research organization (CRO), on re-engaging with study sites for the ReMEDy2 Trial. The trial is intended to enroll approximately 350 patients at up to 100 sites globally. The majority of the U.S. sites are expected to be activated by the end of the third quarter of 2024. With the support of the Canadian Stroke Consortium, the activation of study sites in Canada is expected to begin in the third quarter of 2024. In Australia, the Company has received provisional endorsement from the Australian Stroke Trials Network (ASTN) and Australian site activation is expected to commence in the fourth quarter of 2024. Initial steps are also being taken to expand ReMEDy2 into the United Kingdom, Spain, and select other European countries.

"We are thrilled to resume enrollment as this marks a major milestone towards continuing our study of DM199 as a potential treatment for ischemic stroke patients," commented Rick Pauls, DiaMedica's President and Chief Executive Officer.

"Site activation momentum continues to build, and we anticipate a significant ramp-up in the United States over the next six months," commented Lorianne Masuoka, DiaMedica's Chief Medical Officer. "Furthermore, we are highly encouraged by the quality of the sites we have already activated and those planned for activation in the coming months. These sites have historically been high enrollers in stroke studies."

About ReMEDy2 Trial

The ReMEDy2 trial is an adaptive design, randomized, double-blind, placebo-controlled trial studying the use of the Company's product candidate, DM199, to treat acute ischemic stroke (AIS) patients. Patients enrolled in the trial will be treated for three weeks with either DM199 or placebo, beginning within 24 hours of the onset of AIS symptoms, with the final follow-up at 90 days. The trial excludes patients treated with tissue plasminogen activator (tPA) and/or mechanical thrombectomy. DiaMedica believes that the proposed trial has the potential to serve as a pivotal registration study of DM199 in this patient population.

About DM199

DM199 is a recombinant (synthetic) form of human tissue kallikrein-1 (rKLK1; rinvecalinase alpha). rKLK1 is identical to naturally produced KLK1, a serine protease enzyme that plays an important role in the regulation of diverse physiological processes via a molecular mechanism that increases production of nitric oxide and prostacyclin. In the case of ischemic stroke, the administration of DM199 is intended to enhance blood flow to the infarction site and boost neuronal survival in the ischemic penumbra by dilating arterioles surrounding the site of the infarction and inhibition of apoptosis (neuronal cell death) while also facilitating neuronal remodeling through the promotion of angiogenesis. 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 and clinically studied rKLK1. Non-recombinant, tissue extracted KLK1, produced from the pancreas of pigs and human urine, has been approved for decades for patients in Japan, China and South Korea with a variety of ischemic conditions such as AIS, chronic renal disease, retinopathy and hypertension. DM199/rKLK1 is currently being studied in patients with AIS. In September 2021, the FDA granted Fast Track Designation to DM199 for the treatment of AIS.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company committed to improving the lives of people suffering from serious diseases with a focus on acute ischemic stroke. DiaMedica's lead candidate DM199 is the first pharmaceutically active recombinant (synthetic) form of the KLK1 protein, an established therapeutic modality in Asia for the treatment of acute ischemic stroke and other vascular diseases. For more information visit the Company's 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 "anticipates," "believes," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "should," or "will," 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 site selection and activation, timing for site activations and geographic locations thereof and enrollment in the ReMEDy2 trial and anticipated clinical benefits and success of DM199. 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, uncertainties relating to the timing of site activations and enrollment, regulatory applications and related filing and approval timelines; the possibility of additional future adverse events associated with or unfavorable results from the ReMEDy2 trial; 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 acute ischemic stroke and cardio-renal disease and its expectations regarding the benefits of DM199; DiaMedica's ability to conduct successful clinical testing of DM199 and within its anticipated parameters, enrollment numbers, costs and timeframes; the adaptive design of the ReMEDy2 trial and the possibility that the targeted enrollment and other aspects of the trial could change depending upon certain factors, including additional input from the FDA and the blinded interim analysis; the perceived benefits of DM199 over existing treatment options; the potential direct or indirect impact of COVID-19, hospital and medical facility staffing shortages, and worldwide global supply chain shortages on DiaMedica's business and clinical trials, including its ability to meet its site activation and enrollment goals; 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 acute ischemic stroke and cardio-renal disease, 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, 2023. 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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