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DiaMedica Therapeutics Announces Successful Type B Meeting with FDA for the Study of DM199 in Patients with Acute Ischemic Stroke

DiaMedica Plans to Submit an Investigational New Drug (IND) Application with to FDA for a Phase 2/3 Study in the First Quarter of 2021

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC) announced that it recently received written responses from the FDA following a Type B Pre-IND meeting request that the Company submitted in October 2020 regarding the Company's development plan for its product candidate, DM199, in the treatment of acute ischemic stroke (AIS). DiaMedica believes that the feedback received from the FDA provides a well-defined regulatory pathway and plans to immediately proceed with preparing an IND submission to initiate a Phase 2/3 adaptive trial for the treatment of AIS in the coming months with the objective of commencing participant enrollment in the summer of 2021.

In written responses to the questions provided by DiaMedica, the FDA agreed with DiaMedica's proposals regarding key elements of a Phase 2/3 trial for DM199 in patients with AIS, including plans for an adaptive trial design with a primary endpoint based upon the modified Rankin Scale (mRS) at day 90 and acknowledged that, provided the study results qualify, a single trial may support a Biologics License Application (BLA) submission. Additionally, based upon the clinical and preclinical testing performed to date and currently in process, the FDA did not recommend any additional studies in preparation for an IND submission and initiation of the Company's planned Phase 2/3 trial.

"We appreciate the thoughtful feedback and guidance from the FDA and acceptance of our proposed design for the Phase 2/3 trial of DM199 in patients with acute ischemic stroke," said Rick Pauls, President and CEO of DiaMedica. "Following the guidance the FDA provided in the Type B Pre-IND meeting**,** we are focused on advancing DM199 as a novel treatment for acute ischemic stroke patients who do not have a treatment option available today, with the added advantage of DM199 having a 24-hour treatment window, extending beyond the current 4.5 hour treatment window of tissue plasminogen activator (tPA). We look forward to initiating the Phase 2/3 study."

DiaMedica is preparing a Phase 2/3 randomized, double-blind, placebo-controlled study. This study is intended to assess the efficacy, safety and tolerability of DM199 in patients with mild to moderate AIS. The study is expected to enroll approximately 300 to 350 male and female subjects age 18 and over. Enrolled participants must have a diagnosis of mild to moderate acute ischemic stroke (NIHSS scores between 5 and 20), and present within 24 hours of symptom onset. Current plans for the study are to exclude patients with large vessel occlusions, which are eligible for treatment with mechanical thrombectomy, and/or

patients eligible for tPA. The Company believes that its targeted study population represents approximately 80% of all AIS patients. Study participants will be dosed with either DM199 or placebo over 21 days with the primary endpoint measured at day 90. In order to increase the probability of a successful outcome, the Company also intends to propose conducting an interim analysis with the potential to adjust the study sample size to ensure proper statistical powering, if necessary. The primary endpoint for the Phase 2/3 trial will be the mRS. Secondary endpoints are anticipated to include stroke recurrence and standard stroke measures, including National Institutes of Health Stroke Scale (NIHSS) and Barthel Index.

About DM199 for Acute Ischemic Stroke

On average, someone in the United States has a stroke every 40 seconds and someone dies from a stroke every four minutes. AIS is the leading cause of adult disability in the United States and costs the United States an estimated $34 billion annually, including the cost of health care services, medications and lost productivity.

The Company's recently completed ReMEDy Phase 2 study in AIS (N=91), in addition to meeting its primary safety and tolerability endpoints, a statistically significant 86% (P=0.028) reduction in the number of participants with severe recurrent strokes was observed in the active treatment group (N=1) compared to placebo (N=7), a potentially transformative outcome given that approximately 25% of the 795,000 strokes occurring each year in the United States are recurrent strokes.

Additionally, in a subset of participants in the ReMEDy study that most closely represents the proposed targeted study population for DM199 (N=46), 36% of participants receiving DM199 (N=25) achieved a full or nearly full recovery at 90 days, an NIHSS score of 0-1, compared to 14% in the placebo group (N=21), an absolute difference of 22%. This subset was comprised of those participants not receiving a mechanical thrombectomy, indicative of a large vessel occlusion, prior to enrollment. Additionally, deaths in the DM199 group (N=25) were 12% compared to 24% in the placebo group (N=21), an absolute reduction of 50%. The combination of improvement in recoveries and reduction in recurrent strokes creates an encouraging signal for the potential benefit of DM199 to AIS patients and supports the further investigation of DM199 in AIS.

About DM199

DM199 is a recombinant (synthetic) form of the 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 increases production of nitric oxide and prostaglandin. KLK1 deficiency may play a role in multiple vascular and fibrotic diseases including stroke, stroke recurrences, kidney diseases, vascular dementia and resistant hypertension where current treatment options are limited or ineffective. DiaMedica is the first company to have developed a recombinant form of the KLK1 protein for clinical use. The KLK1 protein, produced from human urine and porcine pancreas, 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 diseases.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company focused on developing novel treatments for neurological and chronic kidney diseases. DiaMedica's shares are listed on The Nasdaq Capital Market under the trading symbol "DMAC." For more information, please visit 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 "plans," "believes," "anticipates," "intends," "expects," "proposed," "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 timing for the submission of an IND application with the FDA for a Phase 2/3 trial and the anticipated clinical benefits and success of DM199. 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 additional clinical trials of DM199 or from existing or new data received from additional ongoing and future studies 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 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 and its clinical trials in particular; 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 the risks identified under the heading "Item. 1A. Risk Factors" in DiaMedica's annual report on Form 10-K for the fiscal year ended December 31, 2019, and subsequent SEC filings by DiaMedica, including its quarterly report on Form 10-Q for the quarterly period ended September 30, 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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