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DiaMedica Therapeutics Announces Fast Track Designation Granted to 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 kidney diseases, today announced that the U.S. Food & Drug Administration (FDA) has granted Fast Track Designation to the Company's lead candidate DM199 for the treatment of acute ischemic stroke (AIS) where tissue plasminogen activator and/or mechanical thrombectomy are not indicated or medically appropriate.

Fast Track is a process intended to facilitate the development and expedite the review of investigational drugs for the treatment of serious or life-threatening conditions where there is an unmet medical need. Drugs that receive Fast Track designation may be eligible for more frequent communications and meetings with FDA to review the drug's development plan, including the design of the proposed clinical trials, use of biomarkers and the extent of data needed for approval. Drugs with Fast Track Designation may also qualify for accelerated and priority review of new drug applications if relevant criteria are met.

"Receipt of Fast Track designation from the FDA underscores the significant unmet medical need among patients suffering from acute ischemic stroke, an area where there hasn't been a new therapeutic that could meaningfully change outcomes for stroke patients in 25 years," said Rick Pauls, DiaMedica's Chief Executive Officer. "The FDA Fast Track Designation is an important milestone in the development of DM199, as it provides opportunities to engage collaboratively with the FDA to further the clinical development and future regulatory review of DM199 for the treatment of acute ischemic stroke. We look forward to working with the FDA to bring DM199 to market as quickly as possible."

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 and clinically studied 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 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 "may," "intend," "look forward," "estimate," "believe," "anticipate," "expect," "plan," "continue," "will," 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 benefits of Fast Track Designation for DM199 for the treatment of acute ischemic stroke. 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; risks associated with DiaMedica's plans to develop, obtain regulatory approval for and commercialize its DM199 product candidate for the treatment of acute ischemic stroke and chronic kidney disease 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 acute ischemic stroke and chronic kidney 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, 2020 2020 and subsequent filings with the U.S. Securities and Exchange Commission. 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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