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DiaMedica Therapeutics Announces Ethics Committee Clearance at First Site to Initiate REMEDY Phase 2 Trial for Acute Ischemic Stroke

MINNEAPOLIS, Nov. 22, 2017 (GLOBE NEWSWIRE) -- DiaMedica Therapeutics Inc. (the "**Company**") (TSX Venture:DMA) (OTCQB:DMCAF), announced it has received ethics committee approval to initiate the first clinical site for its Phase 2 REMEDY clinical trial with DM199 (recombinant human KLK1).

REMEDY is a multi-center, double-blind, randomized, placebo-controlled Phase 2 clinical trial investigating DM199 treatment in patients who have suffered a moderate to moderately severe acute ischemic stroke. The trial is scheduled to enroll approximately 60 patients with acute ischemic stroke who will be randomized to receive either DM199 or placebo. The study drug (DM199 or placebo) will be administered as an intravenous infusion (within 24 hours of stroke symptom onset) followed by subcutaneous injections for 21 days. The primary end points will be safety and tolerability. Secondary endpoints will consist of monitoring drug exposure, along with multiple tests designed to investigate DM199's therapeutic potential including plasma-based biomarkers and standard functional stroke measures assessed at 90 days post-stroke.

"The Australian Human Research Ethics Committee approval represents a significant milestone for DiaMedica," stated Todd Verdoorn, DiaMedica's Chief Scientific Officer. "Ethics Committee approval is based on DiaMedica's deep understanding of DM199's therapeutic mechanism in acute ischemic stroke and our substantial body of work showing the safety and tolerability of DM199. We are looking forward to working with our clinical partner, The Royal Melbourne Hospital, and the study's Principal Investigator, Dr. Bruce Campbell, Head of Hyperacute Stroke in the Department of Neurology."

"This clinical trial will build upon our previous clinical studies and the published efficacy of a human urine version of the KLK1 protein that has been administered to over 400,000 stroke patients in Asia," said Rick Pauls, President and CEO of DiaMedica.

About Acute Ischemic Stroke

An acute ischemic stroke is characterized by rapid loss of brain function due to an interruption of blood supply to the brain due to a blood clot. Affected areas of the brain become inactive and cells eventually die causing neurological impairment. Each year over 12 million people worldwide suffer an acute ischemic stroke and it is the leading cause of death and disability globally. The only approved U.S. Food and Drug Administration ("FDA") or European Medicines Agency ("EMA") drug treatment is tPA (Activase®). However, only 5-7% of acute ischemic stroke patients are actually treated with tPA due to eligibility and other

issues.

About DM199

DM199 is a recombinant (synthetic) human tissue kallikrein ("KLK1") protein to treat neurological and chronic kidney diseases. KLK1 is a naturally occurring enzyme with a pivotal role in the kallikrein-kinin system (KKS) that regulates blood pressure and local blood flow which has important role for the treatment of diseases including acute ischemic stroke and chronic kidney disease. DiaMedica has completed five clinical trials with DM199, including single ascending and multiple ascending doses, studies in diabetic patients, and a Phase 1b pharmacokinetic study to confirm dosing strategies. In addition to a good safety and tolerability profile, DM199 showed the anticipated activity, lowering blood pressure, over the course of treatment in multiple clinical studies. DM199 also significantly increased cerebral blood flow in a preclinical rat study.

In the recently completed Phase Ib pharmacokinetic study, DiaMedica identified intravenous and subcutaneous dose levels of DM199 that produces sustained plasma levels known to be therapeutic in stroke patients. This profile should allow DM199 to be safely and conveniently administered to stroke patients during their initial hospitalization and after they are sent home. The sustained plasma exposure of DM199 should provide continuous enzyme replacement therapy to optimally benefit patients and is potentially superior to the urinary form of KLK1, Kailikang®, a prescription drug approved in China for acute ischemic stroke.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics is a clinical stage biopharmaceutical company focused on developing novel treatments for neurological and kidney diseases. DiaMedica's shares are listed on the TSX Venture Exchange under the trading symbol "DMA" and on the OTCQB under the trading symbol "DMCAF". For more information, please visit **www.diamedica.com**. Follow us on social media -**Twitter**, **LinkedIn**.

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The statements made in this press release that are not historical facts contain forward-looking information that involves risk and uncertainties. All statements, other than statements of historical facts, which address DiaMedica's expectations, should be considered forward-looking statements. Such statements are based on management's exercise of business judgment as well as assumptions made by and information currently available to management. When used in this document, the words "may", "will", "anticipate", "believe", "estimate", "expect", "intend" and words of similar import, are intended to identify

any forward-looking statements. You should not place undue reliance on these forward-looking statements. These statements reflect a current view of future events and are subject to certain risks and uncertainties as contained in the DiaMedica's filings with the Canadian securities regulators, all of which are available on SEDAR (***www.sedar.com***). Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results could differ materially from those anticipated in these forward-looking statements. DiaMedica undertakes no obligation, and does not intend to update, revise or otherwise publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of any unanticipated events, unless required by law. Although management believes that expectations are based on reasonable assumptions, no assurance can be given that these expectations will materialize.

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Source: DiaMedica Therapeutics Inc.