DiaMedica Announces the Initiation of Phase 2 Trial Evaluating DM199 (Recombinant Human KLK1) in Patients with Acute Ischemic Stroke

- DM199 may offer substantial benefits to stroke patients with a drug treatment window of 24 hours post-stroke
- The REMEDY trial is designed to assess the clinical effect of DM199 for acute ischemic stroke with the endorsement from the Australasian Stroke Clinical Trials Network (“ASTN”)
- Dr. Bruce Campbell, a prominent neurologist, has been named Principal Investigator

MINNEAPOLIS, Sept. 11, 2017 (GLOBE NEWSWIRE) -- DiaMedica Therapeutics Inc. ("DiaMedica") (TSX-V:DMA) (OTCQB:DMCAF), a clinical stage biopharmaceutical company focused on improving lives of patients with neurological and kidney diseases associated with low KLK1 levels, announces its Phase 2 REMEDY clinical trial assessing the safety, tolerability, and markers of therapeutic activity of DM199 (recombinant human KLK1) in patients suffering from acute ischemic stroke.

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 Principal Investigator of the study is Bruce Campbell, a neurologist and Head of Hyperacute Stroke in the Department of Neurology, Royal Melbourne Hospital (“RMH”). Campbell is a principal research fellow in the Melbourne Brain Centre at RMH, Department of Medicine, University of Melbourne.

About ASTN:
DiaMedica is also pleased to announce that the Australasian Stroke Trials Network
The ASTN has endorsed the REMEDY trial. The ASTN is the key organization that promotes, facilitates, and coordinates stroke clinical trials in Australia and New Zealand. The ASTN endorses clinical trials based on protocol quality and feasibility, assists with study site identification, facilitates study logistics, and supports patient enrollment efforts.

“We look forward to working with the ASTN, Dr. Bruce Campbell and the clinical stroke community as we conduct the REMEDY trial,” stated Mr. Rick Pauls, President and CEO of DiaMedica. “The design of the REMEDY trial will benefit from the recently completed bridging clinical trial that identified a DM199 dosing strategy that restores deficient KLK1 levels and has a superior pharmacokinetic profile than the approved Kailikang® product. We estimate that over 50,000 stroke patients annually are prescribed Kailikang® in China despite its known deficiencies in formulation and human urine sourcing.”

**About KLK1:**

“DM199 (recombinant KLK1 protein) activates molecular pathways that improve vasodilation, angiogenesis, and blood flow. KLK1 also reduces fibrosis, inflammation, and oxidative stress to protect brain tissue from damage caused by stroke and foster faster, more complete recovery of function,” stated Dr. Todd Verdoorn, Chief Scientific Officer of DiaMedica. “DM199 represents a novel, breakthrough treatment strategy for acute ischemic stroke. Together with an excellent safety profile, the long and short-term actions of DM199 on blood flow and neuronal health could significantly improve the outcome for stroke patients.”

**About 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 Clinical Progress:**

DM199 is a recombinant (synthetic) human tissue kallikrein (“KLK1”) protein to treat neurological and kidney diseases. DiaMedica has completed five clinical trials with DM199, including single ascending and multiple ascending doses, studies in diabetic patients, and a Phase 1 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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