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# DiaMedica Announces First Enrollment in its PHASE 2 “REMEDY” TRIAL for Acute Ischemic Stroke

- **DM199 may offer an effective and safe treatment with a significantly longer treatment window (24 hours) compared to the current standard of care**
- **REMEDY trial lead by prominent neurologist Dr. Bruce Campbell, its Principal Investigator**

MINNEAPOLIS, Feb. 22, 2018 (GLOBE NEWSWIRE) -- DiaMedica Therapeutics Inc. (“*DiaMedica*”) (TSX VENTURE: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 the first patient enrollment in its Phase 2 REMEDY trial assessing the safety, tolerability and markers of therapeutic efficacy of DM199 (recombinant human KLK1) in patients suffering from acute ischemic stroke at the Royal Melbourne Hospital, Melbourne Australia.

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 will enroll approximately 60 patients who will be randomized to receive either DM199 or placebo. The study drug (DM199 or placebo) is administered as an intravenous infusion within 24 hours of stroke symptom onset followed by subcutaneous injections every three days for a period of three weeks. Primary endpoints include safety and tolerability. Secondary endpoints consist of the standard functional stroke scales (NIHSS, Modified Rankin Scale and Barthel Index), the plasma concentration of DM199 and multiple tests designed to investigate DM199’s therapeutic potential based upon standard plasma-based biomarkers, such as inflammation.

The Principal Investigator of the study is Bruce Campbell, MD, MBBS(Hons) BMedSc PhD, FRACP, a neurologist and Head of Hyperacute Stroke in the Department of Neurology, Royal Melbourne Hospital. Dr. Campbell commented, “I look forward to the outcome of the trial in the potential advancement of treatment options for patients with ischemic stroke.”

Mr. Rick Pauls, President and CEO of DiaMedica, stated, “We look forward to working with Dr. Campbell and all site investigators as we enter the enrollment phase of the REMEDY trial.” Mr. Pauls further commented, “In addition to the Royal Melbourne site we expect to have additional centers enrolling patients in the very near future.”

The design of the REMEDY trial builds upon the recently completed Phase 1b pharmacokinetic study in which DiaMedica identified a DM199 dosing strategy that restored deficient KLK1 levels and demonstrated a pharmacokinetic profile superior to the Chinese approved Kailikang<sup>®</sup> product. DiaMedica estimates that over 50,000 stroke patients annually

are prescribed Kailikang despite its known deficiencies in formulation and the challenges of its human urine sourcing.

### **About KLK1:**

DM199 is a recombinant (synthetic) form of human tissue kallikrein ("KLK1"), a protein currently used to treat neurological and kidney diseases. Dr. Todd Verdoorn, Chief Scientific Officer of DiaMedica stated, "DM199 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 is expected to promote faster, more complete recovery of function for stroke patients." Dr. Verdoorn further commented, "DM199 represents a novel, breakthrough treatment strategy for acute ischemic stroke. Together with an excellent safety profile, the short and long-term actions of DM199 on blood flow and neuronal health could markedly enhance recovery and improve the quality of life for patients suffering from stroke."

### **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. Currently, the only approved drug treatment in the United States and Europe is tPA (Activase<sup>®</sup>). However, only 5-7% of acute ischemic stroke patients are actually treated with tPA due to eligibility, its short treatment window and other issues.

### **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](http://www.diamedica.com). Follow us on social media - [Twitter](#), [LinkedIn](#).

### **FORWARD-LOOKING STATEMENTS**

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 fact, 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](http://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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DiaMedica Therapeutics Inc.

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