DiaMedica Therapeutics Announces Publication of Positive Clinical Results for DM199 in the International Journal of Clinical Trials

MINNEAPOLIS, Nov. 07, 2017 (GLOBE NEWSWIRE) -- DiaMedica Therapeutics Inc. (the “Company”) (TSX Venture:DMA) (OTCQB:DMCAF), a clinical stage biopharmaceutical company focused on improving the lives of patients with neurological and kidney diseases associated with low KLK1 levels, announced the publication of positive results from its Phase Ib bridging trial. The study was designed to compare the profile of DM199 to that of the approved urinary KLK1 product (trade name Kailikang®) on the market in Asia for acute ischemic stroke. The reference drug is administered intravenously and has a very short pharmacokinetic profile. The DiaMedica study identified an intravenous dose of DM199 having a similar pharmacokinetic profile to urinary KLK1 along with a superior subcutaneous dosing strategy.

The paper, entitled “Safety, tolerability, and pharmacokinetic profile of recombinant human tissue kallikrein, DM199, after intravenous and subcutaneous administration in healthy volunteers”, established the pharmacokinetic profile of DM199 when administered intravenously or subcutaneously in 36 healthy volunteers. A 30-minute infusion delivered intravenously showed rapid exposure of plasma DM199 with a short exposure window. A single subcutaneous injection provided sustained exposure of plasma DM199. The sustained plasma level of DM199 is superior to Kailikang®. DM199 was safe and well tolerated following both routes of administration with no treatment limiting adverse events. The Company plans to use the results of this study to guide Phase II dosing in upcoming clinical trials.

“We are happy to have the results of our recent trial published in an important peer-reviewed journal. This publication provides significant validation for the ongoing clinical development of DM199,” said Dr. Todd Verdoorn, Chief Scientific Officer of DiaMedica. “The results of the study fully support our Phase II REMEDY trial that is designed to test the action of DM199 in ischemic stroke patients.”

DM199 has the same amino acid sequence as the reference drug, identical biochemical activity, and similar physiological effects. The results from the Phase Ib study show that the dosing of DM199 will be significantly more convenient and potentially provide improved efficacy compared to the limited exposure of the reference drug. 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 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®) manufactured by Genentech. 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 kidney diseases. DiaMedica has completed five clinical trials with DM199, including single ascending and multiple ascending doses, studies in diabetic patients, and a Phase I pharmacokinetic study to confirm dosing strategies. In addition to a good safety and tolerability profile, DM199 modestly reduced blood pressure in multiple studies as expected based on its biochemical activity. DM199 also significantly increased cerebral blood flow in a preclinical rat study.

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.

For further information:
Paul Papi
Vice President of Business Development
2 Carlson Parkway, Suite 260
Minneapolis, MN 55447
(617) 899-5941
info@diamedica.com

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 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.

Neither the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of the contents of this press release.

Source: DiaMedica Therapeutics Inc.