March 5, 2026

DiaMedica Therapeutics Receives Health Canada Clearance to Initiate Phase 2 Study of DM199 in Preeclampsia

- ***"No Objection Letter" from Health Canada enables initiation of Phase 2 DM199 study in early-onset preeclampsia***
- ***DM199 Preeclampsia program featured in recent National Public Radio (NPR) coverage***

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for preeclampsia, fetal growth restriction and acute ischemic stroke (AIS), today announced that it has received a No Objection Letter (NOL) from Health Canada for its Clinical Trial Application to evaluate DM199 in a Phase 2 trial in patients with early-onset preeclampsia (PE). This regulatory clearance enables DiaMedica to initiate its Phase 2 study of DM199 in early-onset preeclampsia. The Company plans to initiate the trial in 2026 and expand into the United States and United Kingdom as regulatory clearances are obtained.

"Health Canada's authorization to initiate our Phase 2 clinical trial of DM199 in preeclampsia represents an important regulatory milestone for DiaMedica," said Rick Pauls, President and Chief Executive Officer of DiaMedica Therapeutics. "This clearance allows us to launch our planned Phase 2 PE study to build upon the encouraging results observed in the investigator-sponsored trial in South Africa. We look forward to continuing our work to bring a clinically meaningful therapeutic option for women suffering from early-onset preeclampsia, a patient population with significant unmet medical need and no currently approved treatment options."

The Phase 2 trial is an open-label, dose-ranging study evaluating DM199 as a treatment for pregnant women diagnosed with early-onset preeclampsia between 24 and 32 weeks of gestation. The study will evaluate safety, tolerability and, on an exploratory basis, early markers of efficacy after treatment with DM199, including changes in uterine artery pulsatility index, sFlt-1, placental growth factor (PGIF) and other biomarkers associated with preeclampsia, maternal and fetal complications and gestational age at delivery. The study will initially evaluate three dose levels of DM199 administered subcutaneously every three days until delivery. The study is expected to begin later this year, with expansion into the United States and United Kingdom planned following regulatory clearances.

Recent NPR coverage highlights the urgent need for new treatments for preeclampsia and underscores the promise of DM199 as a potential therapeutic approach to improve maternal outcomes, if successfully developed and approved. Read the full story here: https://www.npr.org/2026/02/14/nx-s1-5708744/preeclampsia-pregnancy-complication-treatment

The foregoing hyperlink link to a third-party news article is provided solely for informational purposes. The linked content was prepared and is maintained by an independent third party and is not part of this press release or any related filing with the U.S. Securities and Exchange Commission. DiaMedica does not control or endorse the linked content and makes no representation or warranty as to the accuracy, completeness, timeliness or fairness of any information or opinions contained therein.

About DM199 (rinvecalinase alfa) for Preeclampsia

DM199 is a recombinant form of the human tissue kallikrein-1 protein (rhKLK1), currently in clinical development for preeclampsia, fetal growth restriction and acute ischemic stroke. KLK1 is a serine protease enzyme that plays an important role in the regulation of diverse physiological processes via a molecular mechanism that increases production of nitric oxide, prostacyclin and endothelium-derived hyperpolarizing factor. Collectively, in preeclampsia, these processes are believed to improve arterial health, including the uterine arteries, reduce blood pressure and enhance microcirculatory blood flow and tissue perfusion.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company committed to improving the lives of people suffering from serious ischemic diseases with a focus on preeclampsia, fetal growth restriction and acute ischemic stroke. DiaMedica's lead candidate DM199 is the first pharmaceutically active recombinant (synthetic) form of the KLK1 protein, an established therapeutic modality in Asia for the treatment of acute ischemic stroke, preeclampsia and other vascular diseases. For more information visit the Company's 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 "anticipates," "believes," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "should," or "will," 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 Company's expectations regarding the receipt of regulatory approvals and the timing and participating of other regions in its a Phase 2 study of DM199 in early-onset preeclampsia; and anticipated clinical benefits and success of DM199 for the treatment of preeclampsia and fetal growth restriction. 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, risks and uncertainties relating to; the risk that existing preclinical and clinical data from DM199 as a treatment for preeclampsia may not be predictive of the results of ongoing or later clinical trials; DiaMedica's plans to develop, obtain an IND for the clinical study of DM199 for PE and fetal

growth restriction and ultimately regulatory approval for and commercialize its DM199 product candidate for the treatment of preeclampsia, fetal growth restriction and acute ischemic stroke, the timing of trial enrollments, regulatory applications and related filing and approval timelines; the possible occurrence of future adverse events associated with or unfavorable results from DiaMedica's current and planned trials and their potential to adversely affect current of future trials; the possibility of unfavorable results from DiaMedica's ongoing or future clinical trials of DM199; and its expectations regarding the benefits of DM199; DiaMedica's ability to conduct successful clinical testing of DM199 and within its anticipated parameters, site activations, enrollment numbers, costs and timeframes; the perceived benefits of DM199 over existing treatment options; the potential direct or indirect impact of hospital and medical facility staffing shortages, increased tariffs and worldwide global supply chain shortages on DiaMedica's business and clinical trials, including its ability to meet its site activation and enrollment goals; 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 current and planned clinical trials and obtain regulatory approvals for DM199 for preeclampsia and acute ischemic stroke 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, 2024 filed with the U.S. Securities and Exchange Commission (SEC) and subsequent SEC reports, including the most recent quarterly report on Form 10-Q for the quarterly period ended September 30, 2025. 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.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20260305855442/en/

Scott Kellen
Chief Financial Officer
Phone: (763) 496-5118
skellen@diamedica.com

For Investor Inquiries:
Mike Moyer
Managing Director, LifeSci Advisors, LLC
Phone: (617) 308-4306
mmoyer@lifesciadvisors.com

Media Contact:
Madelin Hawtin
LifeSci Communications
mhawtin@lifescicomms.com

Source: DiaMedica Therapeutics Inc