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DiaMedica Therapeutics Provides DM199 Preeclampsia Program Update Following Pre-IND Meeting with FDA

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company developing novel treatments for preeclampsia (PE), fetal growth restriction (FGR) and acute ischemic stroke (AIS), today announced completion of a productive in-person pre-IND meeting with the United States Food and Drug Administration (FDA) for a planned study evaluating DM199 in preeclampsia. Minutes from the meeting affirmed the FDA's request for one additional non-clinical, 10-day modified embryo-fetal development (EFD) and pre- and postnatal development (PPND) study in a rabbit model. Preparations for this study have commenced, and results are expected to be available by the second quarter of 2026.

"We believe the meeting minutes provide important regulatory clarity on our non-clinical package as we prepare to submit an IND for the study of DM199 in patients with early-onset preeclampsia," said Rick Pauls, President and CEO of DiaMedica. "We look forward to ongoing engagement with the FDA as we advance efforts to develop a novel treatment for women suffering from this devastating condition, which is one of the leading causes of maternal and neonatal morbidity and mortality worldwide."

"The ongoing Phase 2 investigator-sponsored trial of DM199 in South Africa has now dosed over 30 women with late-stage PE. Interim data show encouraging safety and efficacy signals, including statistically significant reductions in blood pressure and dilation of intrauterine arteries, and importantly, with no placental transfer of DM199, thereby minimizing unforeseen fetal exposure," said Dr. Julie Krop, Chief Medical Officer of DiaMedica.

About DM199 (rinvecalinase alfa)

DM199 (rinvecalinase alfa) is a recombinant form of human tissue kallikrein-1 (rhKLK1) 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.

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 DiaMedica'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 expectations regarding the timing for a rabbit treatment study and the preeclampsia Phase 2 investigator-sponsored trial; anticipated clinical benefits and success of DM199 for the treatment of preeclampsia and acute ischemic stroke; and future regulatory requirements. 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 related to the timing and outcomes of non-clinical studies; risks and uncertainties relating to the timing of studies and trials; risks and uncertainties relating to the clinical expansion into preeclampsia and associated trials; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; DiaMedica's plans to develop, obtain regulatory approval for and commercialize its DM199 product candidate for the treatment of preeclampsia and acute ischemic stroke 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. 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.

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