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DiaMedica Receives FDA Feedback on DM199 Preeclampsia Nonclinical Program

- ***DiaMedica planning to conduct a rat pharmacokinetic and activity study, which it believes will address FDA-requested data for a preeclampsia IND***

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company, today announced that it has received a written response from the U.S. Food and Drug Administration (FDA) regarding the need for additional nonclinical reproductive toxicity data to support continued development of DM199 (rinvecalinase alfa) for the treatment of preeclampsia (PE). DiaMedica believes, based on the FDA's feedback, that the previously completed rat reproductive toxicity study may be acceptable to support a U.S. investigational new drug (IND) application, provided that DiaMedica can demonstrate sufficient evidence of DM199 exposure and enzymatic activity throughout the previous completed rat study, as well as adequate pharmacologic effect in rats to support their use as an appropriate toxicology species.

To address the FDA's request, DiaMedica is initiating a pharmacokinetic (PK) (drug exposure) and pharmacologic activity study of DM199 in rats and is summarizing the recently completed study data intended to support the pharmacodynamic activity of DM199 in this species. Upon completion of the rat PK study, DiaMedica plans to submit the requested information to FDA for review.

"We appreciate the FDA's feedback and we look forward to completing these non-clinical studies to ultimately support filing of a U.S. IND filing, while we initiate our PE study in Canada and the United Kingdom later this year," said Dr. Julie Krop, DiaMedica's Chief Medical Officer.

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 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 "anticipate," "believe," "continue," "could," "expect," "intend," "may," "plan," "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 DiaMedica's belief that, based upon the FDA's feedback, the previously completed rat reproductive toxicity study may be acceptable to support a U.S. IND application; that it can demonstrate sufficient evidence of DM199 exposure and enzymatic activity throughout the previously completed rat study, as well as provide evidence of adequate pharmacologic effect in rats, which in its totality, support the use of rats as an appropriate toxicology species; and that the anticipated scope and design of the planned PK study may be sufficient to address the FDA's request for additional data. 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 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, fetal growth restriction, 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, fetal growth restriction, 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, 2025 filed with the U.S. Securities and Exchange Commission (SEC) and subsequent SEC reports, including DiaMedica's most recent quarterly report on Form 10-Q. 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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