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DiaMedica Therapeutics Announces Regulatory Approval to Begin Phase 2 Trial of DM199 in the Treatment of Preeclampsia

- **Dosing first participant expected in the fourth quarter of 2024 with preliminary proof-of-concept results targeted for the first half of 2025**

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for severe ischemic diseases, today announced regulatory approval has been received to initiate a Phase 2 clinical trial with DM199, its proprietary recombinant serine protease, for the treatment of preeclampsia. The South African Health Products Regulatory Authority (SAHPRA) has issued approval to proceed with the planned two-part Phase 2 study, which will be conducted as an investigator-sponsored trial at Tygerberg Hospital in Cape Town, South Africa, under the leadership of Prof. Catherine Cluver, MD, PhD as the principal investigator. DiaMedica previously received approval from the Health Research Ethics Committee at Stellenbosch University on June 26, 2024. The Company anticipates dosing will commence in the fourth quarter of 2024. Top-line results for Part 1a of the study are expected in the first half of 2025.

“We are excited to receive regulatory approval and are eager to advance our Phase 2 clinical trial of DM199 for preeclampsia.” said Rick Pauls, President and Chief Executive Officer of DiaMedica. “This trial marks a significant milestone in our efforts to develop the first therapeutic option for this serious unmet medical need.”

Dr. Lorianne Masuoka, Chief Medical Officer of DiaMedica, added, “We believe that DM199 has the potential to be a disease-modifying therapy for preeclampsia, based on its mechanism of action. Specifically, we believe that DM199 targets and has the potential to improve placental perfusion and enhance fetal growth, while also lowering maternal blood pressure and improving endothelial health. The data anticipated from Part 1a of the study should provide strong proof of concept for DM199's potential as a disease-modifying therapy, thereby increasing the likelihood of prolongation of gestational days and a healthier baby and mother.”

About Preeclampsia

Preeclampsia is a serious pregnancy disorder that typically develops after the 20th week of gestation, characterized by high blood pressure and damage to organ systems, often the kidneys and liver. Affecting up to 8% of pregnancies worldwide, preeclampsia can pose significant risks to both the mother and baby, including risk of stroke, placental abruption, progression to eclampsia, premature delivery and death. Symptoms may include severe

headaches, vision changes, upper abdominal pain and swelling in the hands and face. Delivery of the baby, often very prematurely, is the only available option for stopping the progression of preeclampsia. Women who have had preeclampsia have three to four times the risk of high blood pressure and double the risk for heart disease and stroke. There are currently no approved therapeutics for preeclampsia in the United States or Europe.

About the Preeclampsia Phase 2 Trial

This Phase 2 open-label, single center, single-arm, safety and pharmacodynamic, proof-of-concept, investigator-sponsored study of DM199 in treating preeclampsia will be conducted at the Tygerberg Hospital, Cape Town, South Africa (SA), under the direction of Catherine Cluver, MD, PhD, Professor of Maternal/Fetal Medicine, Stellenbosch University, Stellenbosch, SA, in collaboration with DiaMedica. This trial will enroll up to 90 women with preeclampsia and potentially 30 subjects with fetal growth restriction. Dosing is expected to commence in the fourth quarter of 2024 and Part 1a topline study results are anticipated in the first half of 2025 and are intended to demonstrate whether DM199 is safe, lowers maternal blood pressure and dilates intrauterine arteries to increase placental blood flow.

About DM199

DM199 (rinvecalinase alfa) is a recombinant form of human tissue kallikrein-1 (rhKLK1) in clinical development for acute ischemic stroke and preeclampsia. 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. In preeclampsia, DM199 is intended to lower maternal blood pressure, enhance endothelial health and improve perfusion to maternal organs and the placenta. In the case of acute ischemic stroke, in which DiaMedica is also studying the use of DM199, DM199 is intended to enhance blood flow and boost neuronal survival in the ischemic penumbra by dilating arterioles surrounding the site of the vascular occlusion and inhibition of apoptosis (neuronal cell death) while also facilitating neuronal remodeling through the promotion of angiogenesis.

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 acute ischemic stroke and preeclampsia. 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 DiaMedica's expectations regarding the timing for commencement of dosing, number of enrollees and top-line results for Part 1a of the preeclampsia Phase 2 investigator-sponsored trial and anticipated clinical benefits and success of DM199 for the treatment of preeclampsia and acute ischemic stroke. 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 DM199 Phase 2 investigator-sponsored trial for preeclampsia and the timing thereof, including for dosing and top-line results for Part 1a of the study, and the number of patients to be enrolled; the Company's ReMEDy2 trial for acute ischemic stroke and the timing thereof, including site activations and enrollment; and regulatory applications and related filing and approval timelines; the possibility of adverse events associated with or unfavorable results from the trials; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; the ability to conduct successful clinical testing of DM199 and within anticipated parameters, enrollment numbers, costs and timeframes; the adaptive design of the ReMEDy2 trial and the possibility that the targeted enrollment and other aspects of the trial could change depending upon certain factors, including the statistical plan, additional input from the FDA and the blinded interim analysis; the perceived benefits of DM199 over any existing treatment options; the potential direct or indirect impact of COVID-19, hospital and medical facility staffing shortages, and worldwide global supply chain shortages on DiaMedica's business and clinical trials, including the preeclampsia Phase 2 investigator-sponsored trial and the ReMEDy2 trial, and in particular site activation and enrollment goals and timing; 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 acute ischemic stroke and preeclampsia, 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, 2023 and subsequent reports filed with the U.S. Securities and Exchange Commission, including its most recent quarterly report on Form 10-Q for the quarterly period ended June 30, 2024. 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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Scott Kellen
Chief Financial Officer
Phone: (763) 496-5118
skellen@diamedica.com

For Investor Inquiries:
Mike Moyer
Managing Director, LifeSci Advisors, LLC
mmoyer@lifesciadvisors.com

Source: DiaMedica Therapeutics Inc.