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DiaMedica Therapeutics Announces First Patients Dosed in Phase 2 Trial of DM199 for the Treatment of Fetal Growth Restriction

- ***First clinical evaluation of DM199 (rinvecalinase alfa) in fetal growth restriction, a leading cause of stillbirth with no approved pharmacologic treatment***
- ***DM199 is intended to improve maternal uterine artery blood flow to the placenta without crossing into fetal circulation***
- ***Fetal Growth Restriction white paper authored by leading maternal-fetal medicine experts released***

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company developing novel treatments for preeclampsia, fetal growth restriction and acute ischemic stroke, today announced the dosing of the first two patients in an investigator-sponsored Phase 2 trial evaluating DM199 (rinvecalinase alfa) for the treatment of fetal growth restriction (FGR). This is the first clinical evaluation of DM199 in FGR. The open-label, single-arm study is designed to evaluate three dose levels of DM199 in up to 30 patients with early-onset FGR.

Fetal growth restriction is a serious pregnancy complication in which the fetus fails to reach its expected growth potential, most commonly due to inadequate placental function and reduced maternal uterine blood flow. Globally, FGR affects approximately 10% of pregnancies and is a leading cause of stillbirth, preterm delivery, neonatal complications and long-term health consequences. Severe early-onset FGR, affecting approximately 1 in 500 pregnancies, carries a 15-20% risk of neonatal mortality as well as long-term neurodevelopmental complications. There are currently no approved pharmacologic therapies for FGR.

“Fetal growth restriction remains one of the most urgent unmet needs in maternal-fetal medicine. It can be monitored, but there is no therapy that can modify the disease course,” said Rick Pauls, President and Chief Executive Officer of DiaMedica Therapeutics. “The early signals we have observed in our ongoing preeclampsia study support the scientific rationale for evaluating DM199 in FGR and we are committed to advancing this program as rapidly as possible for patients who currently have no other options.”

DM199 is a recombinant form of human tissue kallikrein-1 (KLK1), an enzyme that activates natural vasodilatory pathways, including bradykinin-mediated production of nitric oxide, prostacyclin and endothelium-derived hyperpolarizing factor. These molecules relax and dilate blood vessels, increasing blood flow. In FGR, impaired maternal uterine blood flow limits delivery of oxygen and nutrients to the placenta and fetus. By dilating maternal vessels that supply the placenta, DM199 has the potential to improve placental perfusion, support

fetal growth and prolong pregnancy. Additionally, as a large recombinant protein therapeutic, DM199 has been shown not to cross the placental barrier into fetal circulation, a potentially important safety advantage in treating pregnancy-related disorders.

“Fetal growth restriction is one of the most heartbreaking conditions we manage, because today we can only monitor the baby and decide when to deliver, often far too early. The pathology underlying fetal growth restriction is directly linked to impaired placental perfusion and abnormal maternal uterine vascular function,” said Catherine Cluver, MD, PhD, lead investigator of this investigator-initiated trial and Professor of Maternal-Fetal Medicine at Stellenbosch University, Cape Town, South Africa. “A therapy that could restore blood flow to the placenta would represent a fundamental shift in how we approach this condition.”

DiaMedica also announced the release of a new white paper, *The Potential of DM199 to Treat Fetal Growth Restriction*, authored by Professors Stephen Tong, Susan Walker and Catherine Cluver, and now available on the Company’s website at Preeclampsia & Fetal Growth Restriction: DiaMedica Therapeutics, Inc. (DMAC). The paper reviews the scientific basis for DM199 in treating FGR and the evidence supporting its potential as the first therapy to address this unmet medical need.

About the Phase 2 Fetal Growth Restriction Trial

The open-label Phase 2 investigator-sponsored trial is expected to enroll up to 30 women with early-onset FGR between 27 and 32 weeks of gestation. The primary objective is to assess safety and tolerability. Exploratory efficacy endpoints include uterine artery vascular resistance, umbilical artery Doppler findings, fetal growth trajectory, birthweight centile, pregnancy prolongation and DM199 levels in umbilical cord blood at birth.

About Fetal Growth Restriction

Fetal growth restriction occurs when a fetus fails to reach its genetic growth potential in the womb, most commonly because of placental insufficiency. FGR affects approximately 10% of pregnancies globally and is associated with increased risk of stillbirth, preterm birth, neonatal morbidity and long-term neurodevelopmental, cardiovascular and metabolic complications. Severe early-onset FGR often requires delivery before 32 weeks of gestation. Current management is limited to monitoring and determining the optimal timing of delivery. Additional detail on the scientific rationale for evaluating DM199 in FGR is available in a white paper in the Clinical Trials: Preeclampsia and Fetal Growth Restriction section of the Company’s website at Preeclampsia & Fetal Growth Restriction: DiaMedica Therapeutics, Inc. (DMAC).

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," "committed," "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 regarding the design, conduct, timing, progress and potential results of the investigator-sponsored Phase 2 trial of DM199 in fetal growth restriction, including the evaluation of three dose levels and the enrollment of up to 30 patients; the timing and potential results of the Company's trial; the potential for DM199 to be the first therapy to address the unmet medical need in FGR; the potential for DM199 to increase blood flow to the placenta and to treat fetal growth restriction; and the potential safety, tolerability, efficacy and therapeutic benefit of DM199. 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 fetal growth restriction 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, including investigator-sponsored trials; the risk that DM199 may not demonstrate the anticipated mechanism of action, safety profile or therapeutic benefits in FGR; 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 reliance 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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