

# **DiaMedica Therapeutics Announces Enrollment of 200th Patient in ReMEDy2 Phase 2/3 Acute Ischemic Stroke Trial**

- ***Independent Data Safety Monitoring Board to Conduct a Pre-Specified Interim Analysis to Assess Need for Sample Size Re-Estimation***
- ***Interim Analysis Results Expected in Q1 2027***

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, today announced that the 200th patient has been enrolled in its pivotal Phase 2/3 ReMEDy2 trial of DM199 (rinvecalinase alfa) in participants with acute ischemic stroke (AIS), reaching the prespecified enrollment threshold for the trial's planned interim analysis.

Under the trial protocol, the interim analysis will be conducted by the independent Data Safety Monitoring Board (DSMB) after the first 200 participants complete their 90-day follow-up. The DSMB will assess the need for a sample size re-estimation to optimize the trial's statistical power or stopping for futility. If the trial continues, the final sample size will range between 300 and 728 participants according to a predetermined statistical plan. DiaMedica will remain blinded to the data at the interim analysis.

Patient recruitment will continue at clinical sites while the 200th participant completes their 90-day follow-up and the interim analysis is conducted. DiaMedica expects the interim analysis to be completed in the first quarter of 2027.

"Enrollment of the 200th participant brings ReMEDy2 to the prespecified threshold for the trial's interim analysis," said Julie Krop, MD, Chief Medical Officer of DiaMedica Therapeutics. "We are grateful to the entire DiaMedica team as well as the participants, investigators and clinical sites participating in ReMEDy2 across our global network. The independent DSMB analysis will determine the final size of the trial as we continue evaluating DM199 as a potential new treatment for patients suffering an acute ischemic stroke."

"ReMEDy2 was designed with the potential to support registration if successful," said Rick Pauls, President and Chief Executive Officer of DiaMedica Therapeutics. "The adaptive design provides a disciplined and efficient framework to determine the appropriate final sample size while preserving the opportunity to demonstrate a clinically meaningful treatment effect. We believe DM199 has the potential to address a substantial unmet need in acute ischemic stroke by improving blood flow to ischemic brain tissue supporting neuronal survival and enabling greater patient recoveries."

**About the Phase 2/3 ReMEDy2 Trial of DM199 for Acute Ischemic Stroke**

The ReMEDy2 trial is an adaptive design, randomized, double-blind, placebo-controlled trial studying of DM199, to treat acute ischemic stroke participants. The trial is intended to enroll approximately 300 participants at up to 100 sites globally. The primary efficacy endpoint is the proportion of subjects achieving a modified Rankin Score (mRS) of 0 or 1 points at Day 90 following treatment which represents an excellent outcome. The final sample size will be determined based upon the results of an interim analysis of 200 participants, and, if not stopped for futility, may range between 300 and 728 participants, according to a pre-determined statistical plan. Participants enrolled in the trial will be treated for three weeks with either DM199 or placebo, beginning within 24 hours of the onset of AIS symptoms, with the final follow-up at 90 days. The trial excludes participants who received mechanical thrombectomy (MT) or participants with large vessel occlusions in the intracranial carotid artery or the M1 segment for the middle cerebral, vertebral or basilar arteries or those that are otherwise eligible for MT. Participants treated with tissue plasminogen activator (tPA) or tenecteplase (TNK), (thrombolytic agents) intended to dissolve blood clots, are eligible for participation if they continue to experience a persistent neurological deficit after receiving thrombolytic treatment and meet all other trial criteria.

### **About Acute Ischemic Stroke**

Acute ischemic stroke (AIS) occurs when a blood clot blocks a vessel supplying blood in the brain, leading to a sudden loss of oxygen and nutrients and, if not corrected, ultimately neuronal cell death. According to the U.S. Centers for Disease Control and Prevention, stroke causes approximately one out of every 20 deaths in the United States each year, and nearly nine out of 10 strokes are ischemic. No new therapeutics have been approved for acute ischemic stroke in over 25 years.

When a blood vessel in the brain becomes blocked during a stroke, a core ischemic zone of affected brain tissue will typically suffer a nearly complete loss of blood flow (blood flow reduction of 75% to 90%), while the surrounding area, known as the ischemic penumbra, a rim of mildly to moderately ischemic tissue surrounding the core ischemic zone, may remain viable for several hours but is at risk of progressive damage, creating an opportunity for treatments designed to improve perfusion and protect ischemic brain tissue.

### **About DM199 (rinvecalinase alfa)**

DM199 is a recombinant form of human tissue kallikrein-1 (rhKLK1). KLK1 is a serine protease enzyme that plays an important role in vascular regulation through the kallikrein-kinin system, activating downstream pathways that increase the production and release of nitric oxide, prostacyclin and endothelium-derived hyperpolarizing factor. In AIS, 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 preeclampsia, fetal growth restriction and acute ischemic stroke. DiaMedica's lead candidate DM199 is the first pharmaceutically active recombinant 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](http://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," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "seek," "should," "target," "will," or "would," 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 timing, nature and requirements for clinical trials, regulatory applications and approvals; continued ReMEDy2 trial enrollment; the timing, conduct and potential outcomes of the planned interim analysis by the independent DSMB, including any recommendation regarding sample size re-estimation or stopping for futility, and the final sample size of the ReMEDy2 trial; the potential for the ReMEDy2 trial to support registration of DM199; the potential of DM199 to demonstrate a clinically meaningful treatment effect and to address unmet need in acute ischemic stroke; and anticipated clinical benefits and success of DM199 for the treatment of preeclampsia, fetal growth restriction and acute ischemic stroke. 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, including delays in participants completing their 90-day follow-up or in completion of the interim analysis; the risk that the DSMB may recommend stopping the ReMEDy2 trial for futility or may recommend an increase in the sample size, which could materially increase the cost and duration of the trial; the risk that the ReMEDy2 trial, even if completed, may not achieve its primary endpoint or be sufficient to support regulatory approval; 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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