

May 20, 2026



DiaMedica Therapeutics Announces 75% Enrollment Milestone in ReMEDy2 Phase 2/3 Acute Ischemic Stroke Trial

- ***ReMEDy2 Phase 2/3 AIS Trial of DM199 Surpasses 75% of Enrollment Required to Trigger Pre-Specified Interim Analysis***
- ***Interim Analysis by Independent DSMB Expected to Determine if a Sample Size Re-Estimation (Ranging Between 300 and 728 Patients) is Recommended***
- ***Interim Analysis Anticipated to be Completed Before Year-End 2026***

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for acute ischemic stroke, preeclampsia and fetal growth restriction, today announced that enrollment in its pivotal Phase 2/3 ReMEDy2 trial of DM199 (rinvecalinase alfa) in patients with acute ischemic stroke (AIS) has reached 75% of the 200-patient threshold required to trigger the planned interim analysis. The Company reiterates its guidance regarding completion of the interim analysis by the end of 2026.

The interim analysis will be conducted by the independent Data Safety Monitoring Board (DSMB) and is planned to determine if a sample size re-estimation is recommended for the ReMEDy2 trial. The interim analysis is intended to ensure the trial is adequately powered for success and preserves the trial's integrity. The Company will be blinded to the specific results of the interim analysis.

The ReMEDy2 trial (NCT05065216) is an adaptive, randomized, double-blind, placebo-controlled Phase 2/3 study evaluating DM199 in patients with AIS. The primary efficacy endpoint is stroke recovery as defined by the proportion of patients with a modified Rankin Score (mRS) of 0 or 1 (0-to-6-point scale) at Day 90 indicating an excellent clinical outcome. The trial protocol includes a pre-specified interim analysis on the first 200 enrolled participants, at which point the DSMB will assess whether to recommend a sample size re-estimation to optimize the trial's statistical power or stopping for futility. The final sample size, to be determined following the interim analysis, will range between 300 and 728 patients. Patient recruitment will continue at active clinical sites while the first 200 participants complete their follow-up and the interim analysis is conducted.

"Reaching 75% enrollment toward our interim analysis threshold is a meaningful milestone that reflects the dedication of our clinical sites and the urgency of finding new treatments for stroke patients," said Dr. Julie Krop, Chief Medical Officer of DiaMedica Therapeutics. "We now have approximately 70 sites activated. Based on projected enrollment rates across our network of centers in the United States, Canada, the United Kingdom and Europe, we anticipate completing the interim analysis before year-end. This analysis will be an important inflection point for the program, providing critical data to guide the path forward for DM199 in acute ischemic stroke."

About DM199

DM199 is a recombinant form of human tissue kallikrein-1 (KLK1), a serine protease involved in the regulation of local blood flow and inflammatory responses. DiaMedica believes DM199 has the potential to improve neurological outcomes in patients with acute ischemic stroke by promoting perfusion and neuroprotection in ischemic tissue.

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," "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 timing, nature and requirements for regulatory applications and approvals, including its application for an IND for the study of DM199 as a treatment for preeclampsia and fetal growth restriction and its conducting a Phase 2 trial in these indications; continued ReMEDy2 trial enrollment and timing of the interim analysis; anticipated clinical benefits and success of DM199 for the treatment of acute ischemic stroke; future R&D and G&A expenses and the Company's projected cash runway. 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; 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 our 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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