
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **July 17, 2025**

DIAMEDICA THERAPEUTICS INC.

(Exact Name of Registrant as Specified in Charter)

British Columbia, Canada
(State or Other Jurisdiction
of Incorporation)

001-36291
(Commission File Number)

Not Applicable
(IRS Employer Identification No.)

**301 Carlson Parkway, Suite 210
Minneapolis, Minnesota 55305**
(Address of Principal Executive Offices)

(763) 496-5454
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of Class	Trading Symbol(s)	Exchange Name
Voting common shares, no par value per share	DMAC	The Nasdaq Stock Market LLC

- ☐ Written communications pursuant to Rule 425 under the Securities Act.
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
- ☐ Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On July 17, 2025, DiaMedica Therapeutics Inc. (the "Company") issued a press release announcing positive interim results from Part 1a of the Phase 2 study of DM199 for the treatment of preeclampsia. A copy of such press release is being furnished as Exhibit 99.1 to this report.

Additionally, on July 17, 2025, the Company posted on its website a presentation summarizing the interim results from Part 1a of the Phase 2 study of DM199 for the treatment of preeclampsia, a copy of which is attached hereto as Exhibit 99.2.

The information, including Exhibits 99.1 and 99.2, in this Form 8-K is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Form 8-K shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall otherwise be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are being furnished herewith:

Exhibit Number	Description
99.1	Press release issued by DiaMedica Therapeutics Inc., dated July 17, 2025.
99.2	Investor Presentation.
104	Cover Page Interactive Data File, formatted in Inline Extensible Business Reporting Language (iXBRL).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DiaMedica Therapeutics Inc.
(Registrant)

Date: July 17, 2025

By: /s/ Scott Kellen
Scott Kellen
Chief Financial Officer and Secretary



DiaMedica Therapeutics Reports Positive Interim Phase 2 Preeclampsia Results: Statistically Significant Reductions in Blood Pressure and No Placental Transfer

Conference Call Today July 17, 2025 at 4:30 PM Eastern Time / 3:30 PM Central Time

- **DM199 Demonstrated Highly Statistically Significant and Clinically Meaningful Reductions in Systolic and Diastolic Blood Pressure for Combined Cohorts 6-9**
- **DM199 Did Not Cross the Placental Barrier and was Generally Safe and Well Tolerated**
- **Highly Statistically Significant Reduction in Uterine Artery Pulsatility Index**
- **Robust Evidence Supports a Potential Best-In-Class Mechanism Enhancing Placental Perfusion, Protecting the Endothelium and Reducing Blood Pressure**

Minneapolis, Minnesota – July 17, 2025 – (BUSINESS WIRE) – DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company, today announced positive interim results from Part 1a of the Phase 2 study of DM199 for the treatment of preeclampsia. The study achieved pre-specified safety and efficacy endpoints for the Part 1a dose escalation phase, reinforcing the therapeutic potential of DM199. DM199, rinvecalinase alfa, is a recombinant form of the KLK1 protein expected to influence blood pressure regulation and vascular health in the treatment of preeclampsia (PE). Currently, there are no approved pharmacological treatments for the management of PE in the United States and Europe, representing a significant global unmet medical need.

“These interim results exceeded our expectations demonstrating DM199’s potential to be a first-in-class, disease modifying therapy for preeclampsia, coupled with a promising fetal exposure profile,” said Rick Pauls, President and CEO of DiaMedica Therapeutics. “We believe that the statistically significant reductions in blood pressure and pulsatility index represent on-target responses consistent with DM199’s mechanism of action signaling the potential of DM199 to greatly benefit this underserved patient population. These results are bolstered by data showing that DM199 did not cross the placental barrier, which historically has been a safety hurdle faced in developing treatments for PE. DM199 could potentially offer a significant safety advantage for both mothers and their babies.”

The Phase 2 study of DM199 for PE is an investigator-sponsored, open-label, single center, single-arm, safety and pharmacodynamic, proof-of-concept study of DM199 in treating preeclampsia. It is being 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 30 women with fetal growth restriction.

Blood Pressure Reduction

The study revealed a dose-dependent reduction in both systolic blood pressure (SBP) and diastolic blood pressure (DBP):

- Cohort 9 (n=3; highest dose) achieved the most substantial mean reductions at 5 minutes post-infusion:
 - SBP reductions: -35 mmHg ($p<0.05$)
 - DBP reductions: -15 mmHg ($p<0.05$)
- Pooled cohorts 6–9 (n=12), the potentially therapeutic dose range, exhibited statistically significant mean blood pressure reductions at 5 minutes, 30 minutes, and 24 hours post-infusion, showing a durable response over time:
 - SBP reductions: -25mmHg ($p=0.0003$), -15mmHg ($p=0.0018$) and -20 mmHg ($p=0.0031$)
 - DBP reductions: -13mmHg ($p=0.0007$), -13mmHg ($p=0.0002$) and -10 mmHg ($p=0.0294$)

Safety

DM199 demonstrated no placental transfer and no serious treatment emergent adverse events (TEAEs) were reported across all cohorts. TEAEs events were mild and limited to nausea (n=4)(14%), headache (n=3)(11%) and flushing (n=1)(4%). Additionally, there were no discontinuations of treatment and no inductions of early labor.

Dilation of Uterine Arteries

DM199 also produced a statistically significant reduction in pulsatility index (PI) measures, with a 13.2% ($p=0.0003$) mean reduction in blood flow resistance at the 2-hour mark, indicating a reduction in uterine artery resistance which suggests an improvement in uterine artery blood flow and placental perfusion. Improved perfusion may reduce placental hypoxia, supporting fetal growth and potential disease modification. The uterine artery pulsatility index is a doppler ultrasound measurement that reflects blood flow resistance in the uterine arteries.

Patient Demographics and Dosing:

- Participants were an average of 32.5 years old, had a mean gestation of 37 weeks at enrollment, and had a mean SBP of 165 mmHg and mean DBP of 102 mmHg at baseline.
- Following enrollment and baseline measurements, participants received DM199 IV infusion, followed by SBP and DBP measurements at 5 and 30 minutes post-IV. For cohorts 2 through 9, at 1 hour post-IV, participants received subcutaneous injection of DM199. SBP and DBP were measured again at/through 24 hours post-IV.
- Approximately 80% of deliveries occurred within 24 hours following enrollment, with a total of 9 vaginal deliveries and 16 cesarean sections.

“Mothers suffering with preeclampsia have no approved treatment options to address the root cause of the disease, ultimately putting their life and the health of the fetus, at risk,” said Professor Cathy Cluver, principal investigator of the Phase 2 preeclampsia trial and a maternal-fetal medicine specialist, founder and leader of the Preeclampsia Research Unit at Tygerberg Hospital, Stellenbosch University, South Africa. “With hypertension being the leading cause of delivery, often prematurely, in early onset preeclampsia, DM199’s ability to safely reduce blood pressure represents an exciting development in the search for an effective treatment for preeclampsia and I look forward to continuing our trial.”

The Company further notes that the DM199 investigator-sponsored Phase 2 trial will proceed with enrollment of the dose expansion cohort (Part 1b). Additionally, based upon the observation of PI reductions in Part 1a, enrollment in the fetal growth restriction (FGR) cohort (Part 3 of the study) will also be initiated.

Conference Call and Webcast Information

DiaMedica Management will host a conference call and webcast to discuss the interim Phase 2 preeclampsia study results later today on Thursday, July 17, 2025, at 4:30 PM Eastern Time / 3:30 PM Central Time:

Date:	Thursday, July 17, 2025
Time:	4:30 PM EDT / 3:30 PM CDT
Web access:	https://app.webinar.net/embnRNqXMqE
Dial In:	(800) 880-3330
Conference ID:	6198262

Interested parties may access the conference call by dialing in or listening to the simultaneous webcast. Listeners should log on to the website or dial in 15 minutes prior to the call. The webcast will remain available for play back on the Company's website, under [investor relations - events and presentations](#), following the earnings call and for 12 months thereafter. A telephonic replay of the conference call will be available until July 24, 2025, by dialing (800) 770-2030 (US Toll Free) and entering the replay passcode: 6198262#.

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. Preeclampsia occurs in two stages. First, in early pregnancy, the placenta fails to embed properly in the wall of the uterus, and the spiral arteries in the uterine wall that are supposed to dilate to promote healthy blood flow to the placenta do not widen. Stage 2 then occurs after 20 weeks of pregnancy as the placenta, which has been chronically starved of oxygen from the blood, begins to release noxious factors into the mother's circulation, inflicting widespread damage to her blood vessels and causing systemic endothelial dysfunction. 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.

About Fetal Growth Restriction

Fetal growth restriction (FGR) is a condition frequently associated with preeclampsia in which the fetus is not growing as expected due to a lack of adequate blood flow, oxygen, and nutrients reaching the placenta, and can often lead to premature birth, low birth weight, stillbirth, or potential long-term health problems for the baby after birth.

About DM199 (rinvecalinase alfa)

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 blood pressure, enhance endothelial health and improve perfusion to maternal organs and the placenta.

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," "seek," "might," "project," "target," "aim," 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 Company's expectations regarding anticipated clinical benefits and success of DM199 for the treatment of preeclampsia. 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 are subject to market and other conditions and include, among others, risks and uncertainties relating to the Phase 2 trial for preeclampsia and risks and uncertainties relating to the clinical expansion into preeclampsia; the possibility of unfavorable results from DiaMedica's ongoing or future clinical trials of DM199; 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 and its expectations regarding the benefits of DM199; 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 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, 2024 and quarterly report on Form 10-Q for the quarterly period ended March 31, 2025 filed with the U.S. Securities and Exchange Commission (SEC) and subsequent SEC reports. 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.

Contact:

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

Media Contact:

Madelin Hawtin
LifeSci Communications
mhawtin@lifescicomms.com

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Released July 17, 2025



Cautionary Note Regarding Forward-Looking Statements

This presentation 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 presentation, the words "estimate," "believe," "anticipate," "intend," "expect," "plan," "continue," "potential," "will," "may," "could," "seek," "might," "project," "target," "aim" or "should," 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 reflect management's current plans, expectations, intentions, objectives, market opportunity and other estimates, beliefs regarding the benefits and potential of DM199 and anticipated timing of future events, all of which involve assumptions that may never materialize or may prove to be incorrect and inherently involve significant risks and uncertainties, including factors beyond DiaMedica's control that could 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 are subject to market and other conditions and include, among others, risks and uncertainties relating to DiaMedica's clinical expansion into preeclampsia, the ability of its physician collaborators to successfully conduct a Phase 2, proof-of-concept trial of DM199 as a treatment for preeclampsia, DiaMedica's reliance on its physician collaborators and the ability of other investigators to repeat the interim top-line results; regulatory applications and related filings and approval timelines; the possibility of additional future adverse events associated with or unfavorable results from the preeclampsia or other trials; DiaMedica's plans to develop, obtain regulatory approval for its DM199 product candidate for the treatment of preeclampsia or other indications and its expectations regarding the benefits of DM199, including its ability to impact blood pressure and improve endothelial health, and the potential market size for DM199 in preeclampsia; DiaMedica's ability to conduct successful clinical testing of DM199 within its anticipated parameters, including targeted enrollment numbers, costs and timeframes; 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 planned clinical trials and obtain regulatory approvals for DM199 for preeclampsia or other indications 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, 2024, and subsequent U.S. Securities and Exchange Commission filings, including its most recent quarterly report on Form 10-Q for the quarterly period ended March 31, 2025.

Other risks and uncertainties of which DiaMedica is not currently aware may also affect the Company's forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. All forward-looking statements contained in this presentation speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. DiaMedica undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

Early-Onset PE and FGR: Severe Conditions with a \$5B+ U.S. Market



Disease Overview

- › **Preeclampsia (PE):** life-threatening high blood pressure disorder accompanied by multi-system organ damage that occurs only during pregnancy.
 - Early onset PE is a severe sub-type that occurs before 34 weeks of pregnancy where **50% of deliveries are driven by refractory hypertension despite maximal intervention⁶**.
 - There are currently **no disease modifying therapies** approved for PE.
- › **Fetal Growth Restriction (FGR):** A condition where a baby is not growing as expected, often due to **preeclampsia** or other complications.

Annual Incidence in U.S.

325,000+
FGR & PE^{1,2}

~200,000
PE²

~30,000
Early onset PE^{3,4}

+
~20,000
Early onset FGR^{5*}

INITIAL
TARGETS



1. Baschat et al. (2021). FIGO initiative on fetal growth: Best practice advice for screening, diagnosis, and management of fetal growth-restriction. *International Journal of Gynecology & Obstetrics*, 152(51), 5-12.
2. Chappell L. C., et al. (2021). Pre-eclampsia. *The Lancet*, 398(10267), 341-354.
3. Teta H., et al. (2023). Clinical presentation, maternal fetal, and neonatal outcomes of early-onset versus late onset pre-eclampsia syndrome in a teaching hospital in a low-resource setting: A retrospective cohort study. *PLoS One*, 18(2), e0281952.
4. E., G., Asanli, et al. (2023). Early onset and late onset pre-eclampsia: maternal and perinatal outcomes in a tertiary healthcare center. *International Journal of Reproduction, Contraception, Obstetrics and Gynecology*, 10(1), 2266-2269.
5. Dall'Asta, A., et al. (2017). Early onset fetal growth restriction: Maternal health, neonatology and perinatology. 3, 2.
6. Pardo, M. L., et al. (2020). Prospective, randomized, double-blind, placebo-controlled evaluation of the pharmacokinetics, safety, and efficacy of recombinant antithrombin versus placebo in preterm preeclampsia. *American Journal of Obstetrics & Gynecology*, 223(5), 738.e1-738.e13.

*FGR Only

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Interim Phase 2 (Part 1a) Results



Interim Phase 2 (Part 1a) Results of DM199 for Preeclampsia are a **Clear Success**

- › **Safety:** No placental transfer of DM199. Well tolerated with no serious TEAEs reported.
- › **Blood Pressure (BP):** Dose-dependent reductions in both systolic (SBP) and diastolic (DBP)
 - **Cohort 9 (n=3; highest dose):** Achieved the largest mean BP reduction of all cohorts at predefined 5-minute post-infusion timepoint: SBP ↓ 35 mmHg ($p<0.05$), DBP ↓ 15 mmHg ($p<0.05$)
 - **Pooled cohorts 6-9 (n=12):** Statistically significant mean reductions in SBP and DBP across all predefined post-infusion timepoints—5 minutes, 30 minutes, and 24 hours
 - SBP: ↓ 25, ↓ 15, ↓ 20 mmHg at 5 min, 30 min, and 24 hours ($p=0.0003$, $p=0.0018$, $p=0.0031$)
 - DBP: ↓ 13, ↓ 13, ↓ 10 mmHg at 5 min, 30 min, and 24 hours ($p=0.0007$, $p=0.0002$, $p=0.0294$)
- › **Dilation of intrauterine arteries:** Statistically significant improvement in pulsatility index at the 2-hour timepoint¹, signaling potential for enhanced placental perfusion and disease modification
 - ↓ 13.2% reduction in blood flow resistance ($p=0.0003$)



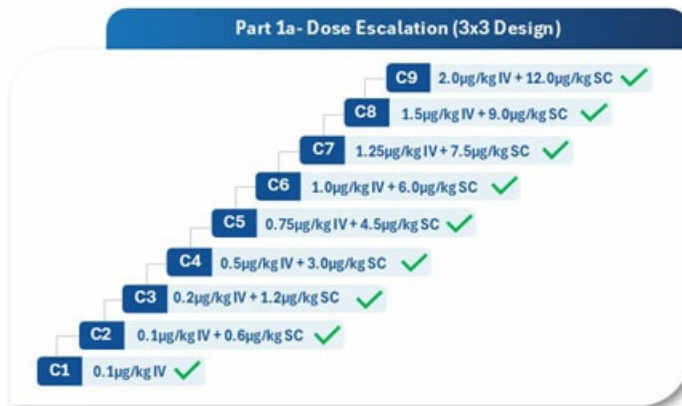
TEAE: Treatment Emergent Adverse Event

1. Uterine Doppler measurements were performed on participants at baseline, 2 hours, and 24 hours; however, as most participants delivered within 24 hours, measurements at the 24-hour timepoint were available for only 5 patients.

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DM199 Preeclampsia Phase 2 IST Trial – Part 1a

Women planned for delivery within 72 hours



- › Study designed to assess DM199 placental transfer with minimal fetal exposure and to evaluate early blood pressure effects. Repeated dosing avoided to prevent prolonged fetal exposure if transfer occurred. Limited dosing (one each IV & SC) minimized fetal exposure risk during this assessment.



Part 1 Overview

- › 27-42 weeks gestation (singleton)
- › >150 systolic blood pressure
 - › Receiving standard of care
- › <72 hours scheduled for delivery

Study Groups

- › **1a.** Up to 30 preeclampsia participants
 - › Ascending dose study identifying the optimal, medically relevant dose based on BP reductions
- › **1b.** 30 preeclampsia participants. Expansion cohort at dose identified in 1A

Primary Endpoints:

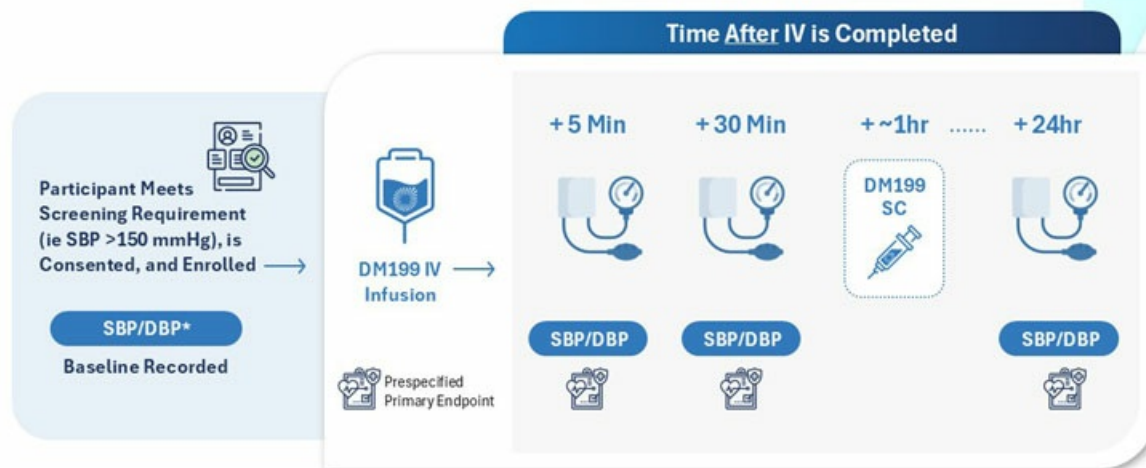
- › Safety and tolerability
 - › Includes results of placental crossing analysis/assay
- › Lower blood pressure

Key Exploratory Endpoint

- › Dilation of uterine arteries (Doppler)

DM199 Administration Timepoints and Prespecified BP Measurements

Timepoints of BP Measurements Approximate Tmax of IV and SC Doses



Baseline Demographics

IQR: Interquartile Range
SD: Standard Deviation



Characteristics	DM199 (n=28)
Median (IQR) gestation at enrollment (weeks + days)	37+0 (35+6 - 38+1)
Median (IQR) maternal age (years)	32.5 (28.8 - 36.3)
Mean (SD), birth weight in grams	2591.3 (553.4)
BMI, median (IQR)	36.8 (33.4 - 43.4)
Race, n(%)	
Black	22 (79)
Mixed	6 (21)
Mean (SD) systolic blood pressure (mmHg)	165.9 (11.7)
Mean (SD) diastolic blood pressure (mmHg)	103.3 (9.8)
Received antihypertensives 24 hours prior to enrollment, n(%)	
1	10 (36)
2	14 (50)
3	4 (14)
Received short-acting antihypertensives after randomization, n(%)	8 (29)
Received magnesium sulphate, n(%)	27 (96)
Received corticosteroids after randomization, n(%)	1 (4)

Delivery Characteristics

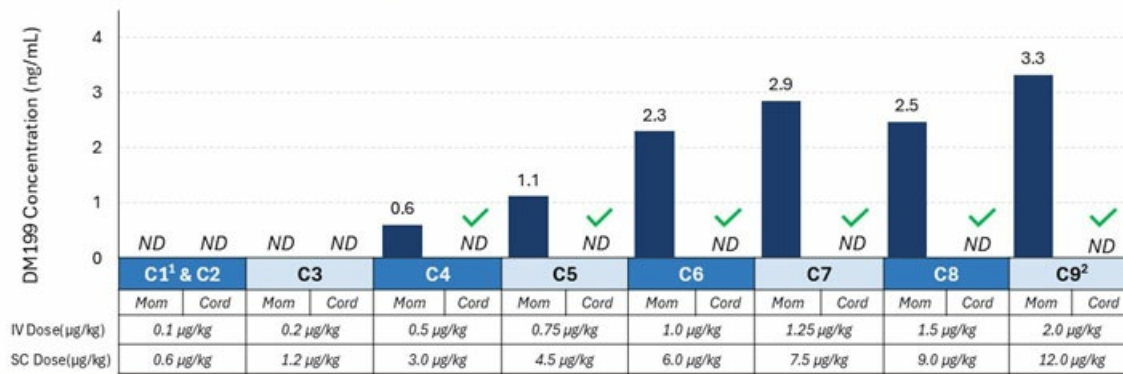
> ~80% of deliveries occurred within 24 hours

Characteristics	DM199 n(%)
Vaginal delivery	9 (32)
Cesarean section	19 (68)
Time to delivery	
<2 hours	1 (4)
<4 hours	3 (11)
<8 hours	9 (32)
<12 hours	16 (57)
<24 hours	22 (79)
≥24 hours	6 (21)
Received balloon catheter	14 (50)
Received prostaglandins	9 (32)
Received oxytocin	11 (39)

DM199 Was NOT Detected in Umbilical Cord Blood in Any Dose Cohort

- At delivery, DM199 was not detected in any cord blood samples, while a clear dose-dependent increase in DM199 was observed in maternal plasma.
- Data suggests DM199 does **not cross the placental barrier**, a potentially unique safety advantage.

Average Plasma DM199 Concentrations (Maternal and Cord Blood Samples At Delivery)



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ND: Non-detectable concentrations – lower limit of quantification is <0.5 ng/mL IV= Intravenous SC=Subcutaneous

1. Did not receive SC dose
2. Data cut for placental transfer was 6/27/25 to allow for sample shipment and analysis. Results for the final C9 patient, enrolled on 7/1/25, are not available

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DM199 Was Generally Safe and Well Tolerated

- › No serious TEAEs were reported in response to any dose

Maternal Treatment-Emergent Adverse Events

TEAE	N=28 [n(%)]	Dose Cohorts
Nausea	4 (14%)	C8 (n=2), C9 (n=2)
Headache	3 (11%)	C3 (n=1), C6 (n=2)
Flushing	1 (4%)	C9

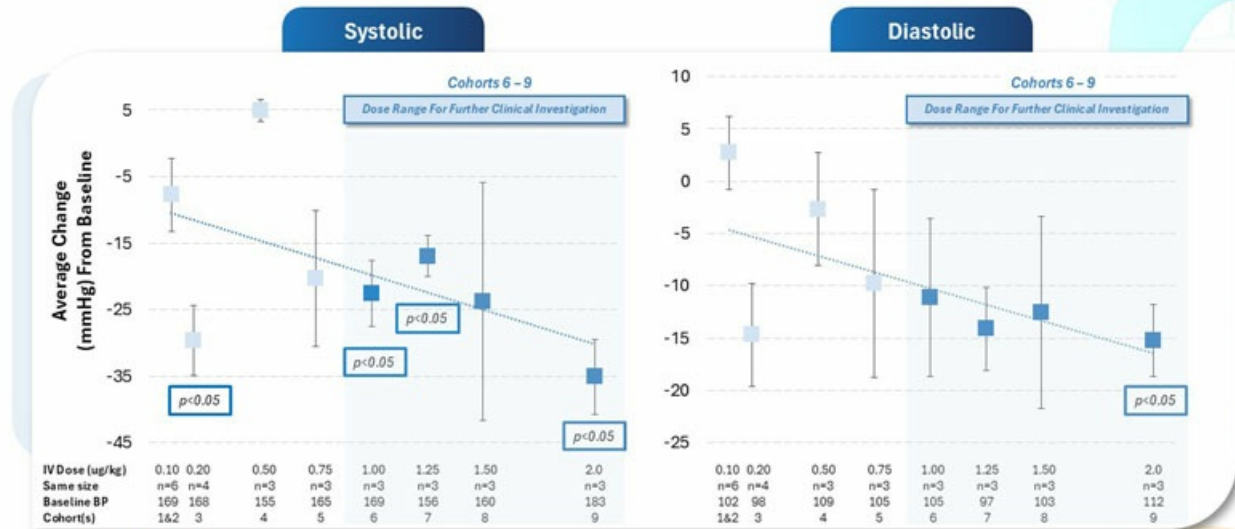
Expected Events Of Preeclampsia (per protocol definition)

Expected Event	N=28 [n(%)]	Dose Cohorts
Postpartum Hemorrhage	4 (14%)	C3 (n=2), C4 (n=1), C8 (n=1)
Eclampsia	1 (4%)	C1
HELLP Syndrome	1 (4%)	C4
Pulmonary Edema	1 (4%)	C9

- › No events of hypotension;
- › No patient paused or discontinued treatment;
- › No induction of early labor

Blood Pressure Was Reduced at Prespecified 5-Minute Post-Infusion Endpoint

Pooled Cohorts C6–C9 achieved statistically significant reductions in SBP (-25 mmHg) and DBP (-15 mmHg)



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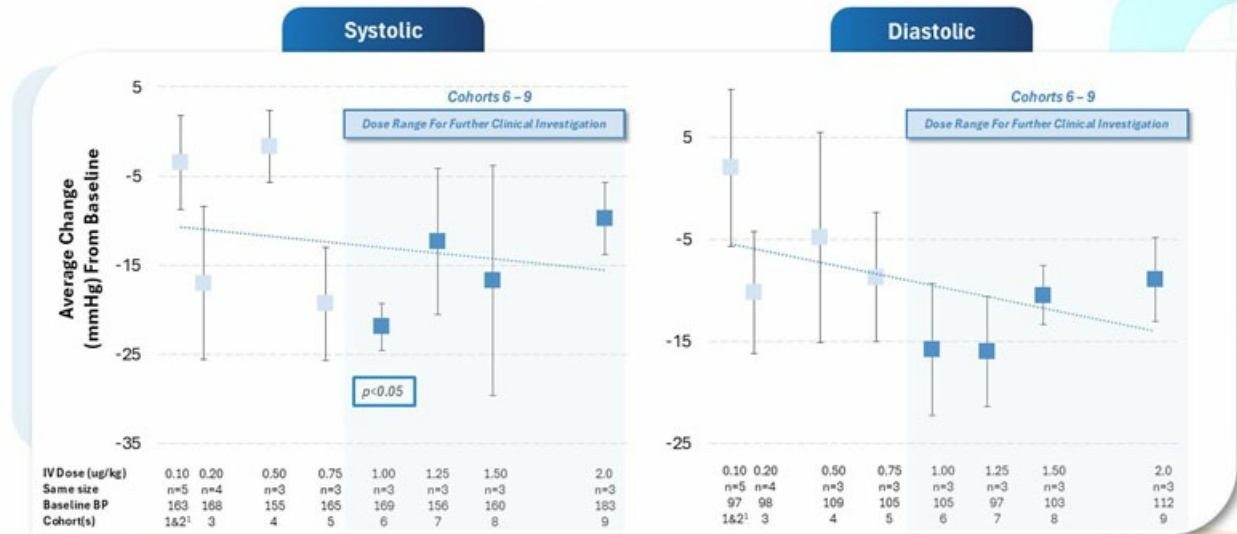
Mean ± SEM presented | Paired T-test vs. baseline | best-fit line based on mean values
No patients received short-acting BP meds during these time points

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Blood Pressure Was Reduced at Prespecified 30-Minute Post-Infusion Endpoint

Pooled Cohorts C6–C9 achieved statistically significant reductions in SBP (-15 mmHg) and DBP (-13 mmHg)



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Mean ± SEM presented | Paired T-test vs. baseline | best-fit line based on mean values
No patients received short-acting BP meds during these time points

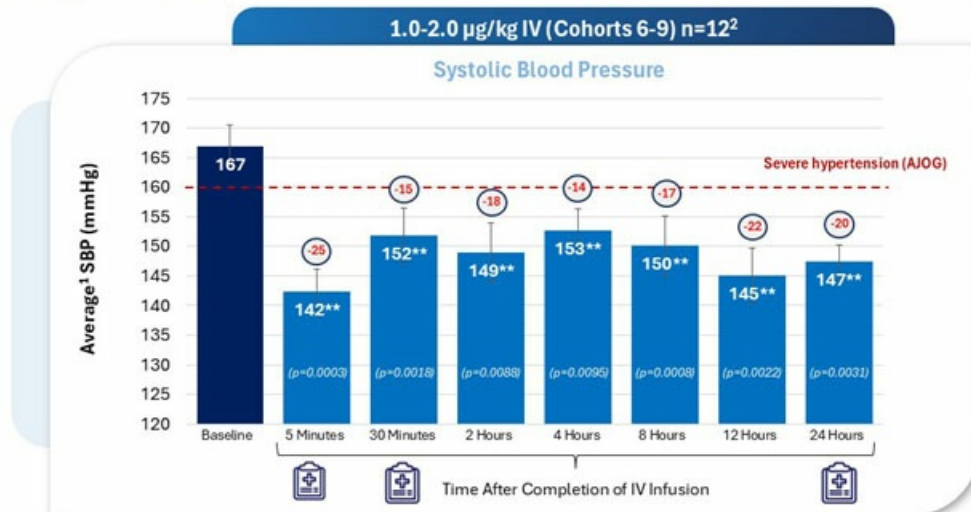
1. Excludes Patient 1 due to delivery occurring 15 minutes after infusion completion (emergency c-section)

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DM199 Drove Statistically Significant Systolic Blood Pressure Reduction

Pooled Analysis of Cohorts 6 to 9



Mean ± SEM presented | Paired T-test vs. baseline: *p<0.05 | **p<0.01

1. Average of three consecutive readings per timepoint

2. Patients in cohorts 6-8 (n=9) did not receive any short-acting antihypertensive medications after DM199 administration. Patients in cohort 9 (n=3) received short-acting BP medications at various time points after the 30-minute measurement but prior to the 24-hour assessment.

Note: measurement timepoints presented as scheduled. Actual measurement times varied

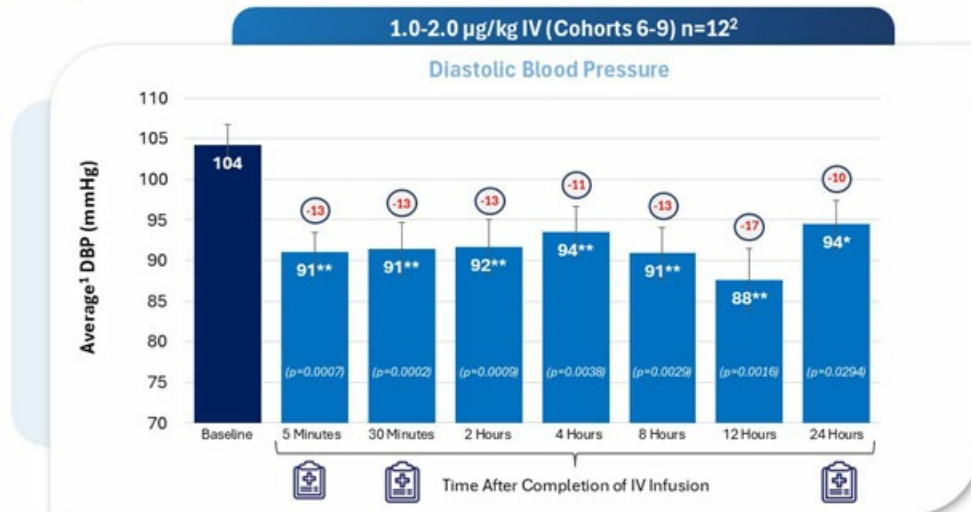


Prespecified Primary Endpoint

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DM199 Drove Statistically Significant Diastolic Blood Pressure Reduction

Pooled Analysis of Cohorts 6 to 9



Mean ± SEM presented | Paired T-tests vs. baseline: *p<0.05 | **p<0.01

1. Average of three consecutive readings per timepoint

2. Patients in cohorts 6-8 (n=9) did not receive any short-acting antihypertensive medications after DM199 administration. Patients in cohort 9 (n=3) received short-acting BP medications at various time points after the 30-minute measurement but prior to the 24-hour assessment.

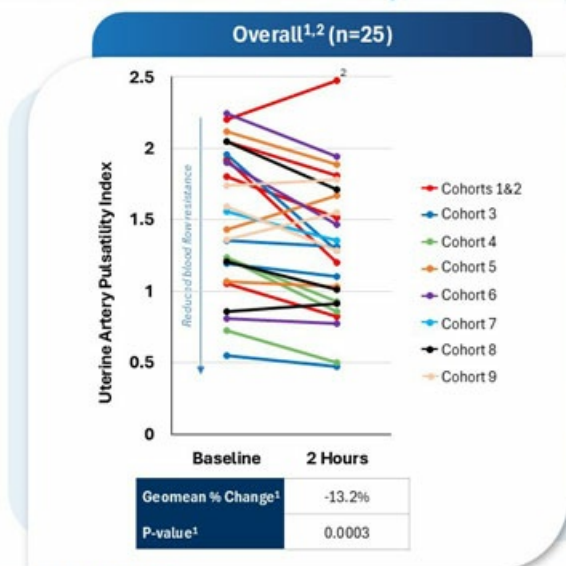
Note: measurement timepoints presented as scheduled. Actual measurement times varied



Prespecified Primary Endpoint

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DM199 Reduced Uterine Artery Resistance, Suggesting Enhanced Placental Perfusion



› Dilation of the uterine arteries was assessed by Doppler ultrasound at baseline and two hours after IV infusion

› 13.2% average reduction in blood flow resistance was observed across cohorts ($p=0.0003$), suggesting DM199 increased perfusion to the placenta

Improved perfusion may reduce placental hypoxia, supporting fetal growth and disease modification



1. Measurements not available for one patient in Cohort 1, and two patients in Cohort 7
2. One patient in Cohort 2 (baseline: 2.2, 2hr: 2.5) was crowning (baby's head visible at the vaginal opening) at the time of the 2-hour measurement, potentially impact the 2-hour measurement

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Summary Remarks

- ✓ DM199 is emerging as an exciting potential therapeutic option for **both preeclampsia and fetal growth restriction**
- ✓ DM199 appears to be **generally well tolerated** across broad exposure levels, and **does not cross the placental barrier**
- ✓ Early signals of **improved placental perfusion** suggest the potential for true **disease modification**
- ✓ **Robust, durable blood pressure reductions** provide broader clinical relevance, **indicating endothelial protection**—the key driver of maternal disease
- ✓ Ongoing **dose optimization** is expected to **further strengthen** DM199's profile as it advances into U.S. clinical trials next year

Next Steps for the Phase 2 Trial



Next Phases of Preeclampsia IST Following Part 1A Completion

All parts can enroll concurrently

Part 1b (n=30) Planned Delivery in 72 Hrs.

- Recruiting the same population as Part 1A: women with planned delivery within 72 hours and SBP >150 mmHg (27 – 42 weeks GA)
- Participants will receive a single IV/SC dose on Day 1, using the dose identified in Part 1A (no additional doses)
- Primary endpoints: Safety* and lowering blood pressure

Part 2 (n=30) Expectant Management

- Recruiting women with early onset preeclampsia (GA 27+0 to 32+6) who are candidates for expectant mgmt. (prolongation)
- Participants will receive an initial IV/SC dose on Day 1, followed by repeated SC doses until delivery
- Primary endpoints: Safety*, prolongation, change in UACR, need to increase/decrease antihypertensive agents

Part 3 (n=30) Fetal Growth Restriction

- Recruiting women with early onset FGR (GA 27+0 to 32+6), defined as fetal growth <3rd centile, who do not have preeclampsia
- Participants will receive an initial IV/SC dose on Day 1, followed by repeated SC doses until delivery
- Primary endpoints: Safety*, changes in uterine, ophthalmic, and fetal Dopplers, and birthweight centile



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GA* Gestational Age
*including placental transfer of DM199 (umbilical cord levels after birth)

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Fetal Growth Restriction: DM199's Indication Expansion

Strong mechanistic rationale based on Interim Part 1a PE data

> Fetal Growth Restriction is a Major Unmet Medical Challenge

- Placental insufficiency—particularly impaired uteroplacental blood flow—is a core pathophysiologic driver of FGR
- **No approved therapies** to directly treat FGR; current management is limited to monitoring and early delivery
- The Pulsatility Index (PI) in uterine and umbilical arteries is a core diagnostic and prognostic biomarker and is directly correlated with fetal oxygen/nutrient delivery



> DM199 Offers the Potential to Improve Uteroplacental Blood Flow

- Like preeclampsia, FGR is often marked by abnormal uterine artery Doppler waveforms:
 - Elevated PI
 - Absent or reversed end-diastolic flow
- DM199 has been shown to dilate intrauterine arteries, resulting in:
 - Improved uteroplacental perfusion
 - Reduced vascular resistance, as quantified by the Pulsatility Index



DM199's efficacy in lowering PI in preeclampsia patients supports its potential in FGR—especially early-onset forms



Thank You!

Nasdaq: dmac
www.diamedica.com

