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# **DiaMedica Therapeutics Announces Formation of Scientific Advisor Board to Support the Development of DM199 for the Treatment of Preeclampsia**

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for severe ischemic diseases, is excited to announce the formation of its Scientific Advisory Board (SAB) to support the development of DM199, its proprietary recombinant serine protease, for the treatment of preeclampsia (PE). The members of the newly formed SAB are renowned experts in PE and maternal-fetal health and will collaborate closely with the company's leadership to accelerate the development of DM199, for the treatment of preeclampsia.

"We are thrilled to welcome these distinguished doctors to our Scientific Advisory Board," said Rick Pauls, President and Chief Executive Officer of DiaMedica Therapeutics. "Their expertise and guidance will be invaluable as we work to advance treatment options for this potentially fatal and life-threatening condition."

Lorianne Masuoka, DiaMedica Therapeutics' Chief Medical Officer added, "The insights from these experts will be instrumental in guiding our research and clinical strategy to improve care for women affected by preeclampsia. We are confident that their contributions will play a crucial role in accelerating our progress toward meaningful solutions for mothers and their babies."

The members of DiaMedica Therapeutics' Preeclampsia Scientific Advisory Board include:

## **Professor Vincenzo Berghella**

Professor Vincenzo Berghella serves as the Director of Maternal-Fetal Medicine and the Director of the Maternal-Fetal Medicine Fellowship Program at Thomas Jefferson University, as well as a member of the Society for Maternal-Fetal Medicine. Dr. Berghella received his residency at New York Downtown Hospital and completed his fellowship at Thomas Jefferson University Hospital. He is board certified in Obstetrics and Gynecology with a subspecialty in Maternal-Fetal Medicine and holds an impressive portfolio of approximately 700 peer-reviewed publications in renowned journals such as *The Lancet*, *AJOG-MFM*, and *The Journal of Maternal-Fetal & Neonatal Medicine*.

## **Professor Cathy Cluver**

Professor Cathy Cluver, a maternal-fetal medicine specialist, founded and leads the Preeclampsia Research Unit at Tygerberg Hospital, Stellenbosch University, South Africa.

Dr. Cluver was awarded the Daubenton Medal for outstanding results for the Fellowship of Obstetrics and Gynaecology. Dr. Cluver then completed her subspecialist training in 2016 after a year's fellowship at Mercy Hospital for Women in Melbourne, Australia. Dr. Cluver was awarded her PhD in 2019 and has completed multiple preeclampsia treatment trials assessing novel therapies to treat preeclampsia and curates one of the largest preeclampsia biobanks. Dr. Cluver has over 80 publications, including works in the *Lancet* and *BMJ*.

### **Professor Bob Silver**

Professor Bob Silver, MD is a distinguished faculty member in the Department of Obstetrics and Gynecology at the University of Utah Health Sciences Center. He holds the prestigious John A. Dixon Presidential Endowed Chair and serves as the Chairman of the department, as well as Co-Director of Labor and Delivery. Dr. Silver is fellowship-trained in maternal-fetal medicine and has a clinical focus on stillbirth, pregnancy loss, and placental complications, including preeclampsia and fetal growth restriction.

He is actively engaged in several ongoing National Institutes of Health-sponsored networks, clinical trials, and cohort studies. Dr. Silver is a prominent member of professional organizations such as the Society for Maternal-Fetal Medicine, the American Gynecological and Obstetric Society, and the International Stillbirth Alliance. His research has garnered significant funding from the NICHD and NHLBI, resulting in over 400 peer-reviewed publications in esteemed journals, including the *New England Journal of Medicine* and the *Journal of the American Medical Association*.

### **Professor Stephen Tong**

Professor Stephen Tong is listed in Expertscape as one of the top 10 preeclamptic experts in the world. He is a key opinion leader in preeclampsia, having penned invited reviews or commentaries about the disease in the world's most prestigious scientific journals.

Dr. Tong is jointly trained as an OB (Mercy Hospital for Women) and laboratory scientist (Professorial Fellow, University of Melbourne). Dr. Tong has a strong interest in translational research - developing therapeutics to tackle major pregnancy complications and has had a lead role in taking four therapeutic concepts identified in his laboratory to phase I-III clinical trials run across the globe – UK, New Zealand and South Africa.

Dr. Tong has authored 250 papers, 100+ on preeclampsia, and published original research as the first or senior author in the world's premier journals – *Nature*, *The Lancet*, *British Medical Journal*, *Nature Communications*, *JAMA Pediatrics*, *JAMA Psychiatry* and others. Dr. Tong is chair of the advisory board of the Robinson Research Institute in Adelaide, Australia; Co-Director of Mercy Perinatal; Research Director at Mercy Hospital for Women; awarded three prestigious National Health and Medical Research Council national awards for his research and has received over \$10 million in competitive grant funding.

### **Professor Susan Walker**

Professor Sue Walker is the inaugural Sheila Handbury Chair of Maternal Fetal Medicine, Head of the Department of Obstetrics, Gynaecology and Newborn Health at University of Melbourne and Divisional Chair, Perinatal Medicine at Mercy Hospital for Women, Australia. Dr. Walker's research program is focused on improving detection and treatment of

preeclampsia and fetal growth restriction, where she has authored over 240 publications. She is on the Board of the Perinatal Society of Australia and New Zealand and serves on the Executive of the Stillbirth Centre for Research Excellence. In recognition of her roles in clinical care, research, professional leadership and education, Dr. Walker was made an Officer, Order of Australia in 2018, and Fellow of the Academy of Health and Medical Science in 2023.

## **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 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 potentially 30 subjects with fetal growth restriction. Part 1A top line study results are anticipated in the first half of 2025 and are intended to demonstrate whether DM199 is safe and lowers maternal blood pressure. Additionally, patients with early onset PE will be evaluated for improvements in uterine artery dilation, a sign that DM199 is a potentially disease modifying therapy.

## **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](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 "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 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 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 September 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](mailto:skellen@diamedica.com)

**For Investor Inquiries:**

Mike Moyer  
Managing Director, LifeSci Advisors, LLC  
[mmoyer@lifesciadvisors.com](mailto:mmoyer@lifesciadvisors.com)

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