

# DiaMedica Therapeutics Announces Positive Interim Results from Phase 2 REDUX Study in CKD

- ***Results Affirm Biological Activity, Safety and Tolerability of DM199 Consistent with Porcine KLK1 Product in Asia***
- ***Early Data Indicate Statistically and Clinically Significant Reduction in UACR seen in IgA Nephropathy and Hypertensive African Americans – a Key Risk Factor in Predicting Kidney Disease Progression***
- ***Study Demonstrates Stable eGFR and Positive Effects on Blood Pressure Across All Cohorts***

**Company to discuss REDUX interim data on conference call and webcast today at 8:00 am Eastern Time / 7:00 am Central Time**

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for neurological disorders and cardio-renal diseases, today announced positive interim results from its Phase 2 REDUX trial of DM199 in chronic kidney disease (CKD). The REDUX trial is studying the treatment of CKD in three populations with rare or high unmet medical needs: African Americans (AA), non-diabetic and hypertensive (Cohort 1, n=12); IgA Nephropathy (IgAN) (Cohort 2, n=16); and diabetic kidney disease (DKD) (Cohort 3, n=28). All participants have proteinuria and an eGFR between 30-90 ml/min/1.73m<sup>2</sup>.

DM199 is demonstrating clinically meaningful improvements in kidney function in Cohorts 1 and 2, as measured by simultaneously stabilizing estimated glomerular filtration rate (eGFR) and decreasing urine albumin-to-creatinine ratio (UACR). In participants who were hypertensive (Cohorts 1 and 3), DM199 also reduced blood pressure by clinically significant levels. DiaMedica reported the following preliminary data:

- AA: Decrease in UACR -27% in moderate to severe albuminuria (baseline UACR >500) (n=6), Increase in eGFR +2 ml/min (n=12) and decrease in blood pressure -8/-3 mmHg;
- IgAN: UACR decreased by -33% (P=0.002) (baseline UACR>500) (n=11) and eGFR and blood pressure were stable (n=16);
- DKD: eGFR and UACR levels were stable and blood pressure decreased significantly by -5/1 mmHg (n=28)

DM199 was well tolerated across all cohorts, with no DM199 related severe adverse events (SAEs) or discontinuations due to drug-related adverse events (AEs). AEs were generally mild to moderate in severity, with the most common being local injection site irritation that resolved.

“This data provides further clinical validation of the meaningful biologic activity of the recombinant KLK1 (DM199) and support the potential of achieving clinical benefit equal to or better than the exogenous KLK1 product available in Asia,” said Rick Pauls, President and Chief Executive Officer of DiaMedica. “We are optimistic as we continue the trial of DM199 in IgAN and hypertensive African Americans with CKD and begin the pivotal Phase 2/3 study in acute ischemic stroke later this summer.”

Dr. Rajiv Agarwal, Professor of Medicine at Indiana University School of Medicine and member of the DiaMedica Scientific Advisory Board, noted that, “though these data are preliminary, they are encouraging signals of the role DM199 can play in treating kidney disease patients with significant unmet needs, particularly African Americans with uncontrolled hypertension. The observed improvements in eGFR, UACR and blood pressure all point to the important physiological effects of DM199 treatment and strongly support additional clinical study.”

### **Conference Call and Webcast Information:**

DiaMedica will host a live conference call and webcast on Tuesday June 29, 2021 at 7:00 am Central Time/8:00 am Eastern Time to discuss the interim REDUX CKD results.

Date: Tuesday, June 29, 2021  
Time: 7:00 AM CT / 8:00 AM ET  
Web access: <https://event.on24.com/wcc/r/3220309/67847BACCFE4F4EA5C4CC7DBF66259E0>  
Dial In: (866) 393-4306 (domestic)  
(734) 385-2616 (international)  
Conference ID: 2847537

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 DiaMedica’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 6, 2021, by dialing (855) 859-2056 (US Toll Free), (404) 537-3406 (International), and entering the replay passcode: 2847537.

### **About the CKD REDUX Study**

DiaMedica’s Phase 2 REDUX (Latin for restore) study is a multi-center, open-label, investigation to assess the safety and efficacy of two dose levels of DM199, administered over 95 days, in participants with CKD (Stage 2 or 3) targeting the enrollment of approximately 90 participants in three equal cohorts. Cohort 1 of the study is enrolling non-diabetic, African Americans with hypertension, a group that is at greater risk for CKD than Caucasians. Additionally, the study is designed to look specifically at the response of higher risk participants with the APOL1 gene mutation. Cohort 2 is enrolling participants with IgA Nephropathy (IgAN) and Cohort 3 has fully enrolled participants with diabetic kidney disease.

The primary efficacy endpoints are focused on evaluating the dose response effect of DM199, as compared to baseline, on overall kidney function as measured by the reduction in urinary albumin to creatinine ratio (UACR), and change in eGFR and blood pressure after 95 days of treatment.

## **About DM199**

DM199 is a recombinant (synthetic) form of human tissue kallikrein-1 (KLK1). KLK1 is a serine protease (protein) that plays an important role in the regulation of diverse physiological processes including blood flow, inflammation, fibrosis, oxidative stress and neurogenesis via a molecular mechanism that increases production of nitric oxide and prostaglandin. KLK1 deficiency may play a role in multiple vascular and fibrotic diseases such as chronic kidney disease, retinopathy, stroke, vascular dementia, and resistant hypertension where current treatment options are limited or ineffective. DiaMedica is the first company to have developed a recombinant form of the KLK1 protein. The KLK1 protein, produced from porcine pancreas and human urine, has been used to treat patients in Japan, China and South Korea for decades. DM199 is currently being studied in patients with acute ischemic stroke and chronic kidney disease.

## **About DiaMedica Therapeutics Inc.**

DiaMedica Therapeutics Inc. (Nasdaq: DMAC) is a clinical stage biopharmaceutical company focused on developing novel treatments to improve the lives of patients with neurological and chronic kidney diseases. To learn more about DiaMedica, visit [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 "estimate," "believe," "anticipate," "intend," "expect," "plan," "continue," "look forward," "will," "may," "potentially" 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 and information in this press release include statements regarding the anticipated clinical benefits and success of DM199, the safety and efficacy of DM199, the timing, requirements and anticipated outcomes of its clinical programs, including the ongoing REDUX study and its anticipated Phase 2/3 trial for DM199 in patients with acute ischemic stroke (AIS), which DiaMedica believes will commence in Summer 2021 and has the potential to serve as a pivotal registration study of DM199 in that patient population. 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, the possibility of unfavorable results from DiaMedica's ongoing or future clinical trials of DM199, including the fact that the interim REDUX study data release today is preliminary and interim and final results may differ materially from the data released today; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; the possibility of unfavorable results from subsequent analysis of existing or future data from the REDUX study or future studies of DM199; DiaMedica's plans to develop, obtain regulatory approval for and commercialize its DM199 product candidate for the treatment of AIS and chronic kidney disease (CKD) and its

expectations regarding the benefits of DM199; DiaMedica's ability to conduct successful clinical testing of DM199 and within its anticipated parameters, costs and timeframes; the perceived benefits of DM199 over existing treatment options; the potential direct or indirect impact of the COVID-19 pandemic on DiaMedica's business; 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 AIS and CKD, 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, 2020 and subsequent U.S. Securities and Exchange Commission filings by DiaMedica. 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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