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): **June 29, 2021**

DIAMEDICA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

British Columbia	**001-36291**	**Not Applicable**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Two Carlson Parkway, Suite 260 **Minneapolis, Minnesota** (Address of principal executive offices)	**55447** (Zip Code)

(763) 312-6755
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report.)

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:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Voting common shares, no par value per share	DMAC	The Nasdaq Stock Market LLC

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 June 29, 2021, DiaMedica Therapeutics Inc. (the "Company") announced interim results from its Phase 2 REDUX study of DM199 in participants with chronic kidney disease ("CKD"), as described in more detail under Item 8.01 of this Current Report on Form 8-K. A copy of the press release announcing the interim results is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference and constitutes a part of this report.

On June 29, 2021, the Company made available an investor presentation in connection with the announcement of the interim results of its Phase 2 REDUX study. A copy of the investor presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K, and the information set forth therein is incorporated herein by reference and constitutes a part of this Item 7.01.

The information furnished under this Item 7.01 shall not be deemed "filed" for the purposes of Section 18 of the United States Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any other filing by the Company under the Exchange Act or the United States Securities Act of 1933, as amended, except as otherwise expressly stated in such filing.

Item 8.01. Other Events.

As described under Item 7.01 above, on June 29, 2021, the Company announced interim results from its Phase 2 REDUX study of DM199 in participants with CKD. The REDUX study is investigating the treatment of CKD in three patient populations with rare or high unmet medical needs. Cohort 1 is enrolling and studying non-diabetic, hypertensive African Americans; Cohort 2 is enrolling and studying patients with IgA Nephropathy; and Cohort 3 is fully enrolled and studying patients with diabetic kidney disease. To date, DM199 is demonstrating clinically meaningful improvements in kidney function in Cohorts 1 and 2, as measured by simultaneously stabilizing estimated glomerular filtration rate and decreasing urine albumin-to-creatinine ratio. In participants who were hypertensive (Cohorts 1 and 3), DM199 also reduced blood pressure by clinically significant levels. A copy of the press release announcing the interim results is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference and constitutes a part of this report.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
99.1	Press Release dated June 29, 2021 announcing positive interim results from Phase 2 REDUX study in CKD (filed herewith)
99.2	Investor Presentation issued by DiaMedica Therapeutics, Inc. in connection with the release of its interim results of its Phase 2 REDUX study in CKD (furnished herewith)

SIGNATURE

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

DIAMEDICA THERAPEUTICS INC.

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

Dated: June 29, 2021

Exhibit 99.1

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, Minnesota – June 29, 2021 (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^2.

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 provide 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.

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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DM199 REDUX Phase 2 CKD Interim Results

June 29 2021

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 our current expectations. When used in this presentation, 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. The forward-looking statements in this presentation include statements regarding the anticipated clinical benefits and success of DM199, the safety and efficacy of DM199, the timing, requirements and anticipated outcomes of our clinical programs, including the ongoing REDUX study and our anticipated Phase 2/3 trial for DM199 in patients with acute ischemic stroke (AIS), which we believe will commence in Summer 2021 and has the potential to serve as a pivotal registration study of DM199 in that patient population. Such statements reflect management's current view and we undertake no obligation to update or revise any of these statements. 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 our ongoing or future clinical trials of DM199, including the fact that the interim REDUX study data is preliminary and interim and final results may differ materially from the data released; 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; our plans to develop, obtain regulatory approval for and commercialize our DM199 product candidate for the treatment of AIS and chronic kidney disease (CKD) and our expectations regarding the benefits of DM199; our ability to conduct successful clinical testing of DM199 and within 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 our business; our reliance on collaboration with third parties to conduct clinical trials; our ability to continue to obtain funding for our 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 our annual report on Form 10-K for the fiscal year ended December 31, 2020 and our subsequent U.S. Securities and Exchange Commission (SEC) filings. The forward-looking information contained in this presentation represents our expectations as of the date of this presentation and, accordingly, is subject to change after such date. Investors should not place undue importance on forward-looking information and should not rely upon this information as of any other date. While we may elect to, we do not undertake to update this information at any particular time except as required in accordance with applicable laws.

REDUX Interim Analysis

Encouraging data to support further study of DM199 in kidney disease and stroke

DM199 has been safe and well tolerated in the REDUX study

- No safety or tolerability concerns after 3 months of dosing with 62 patients and over 1,500 injections
- Data consistent with data from the approved porcine version of KLK1 in Asia

DM199 potentially driving clinically relevant changes in patients with chronic kidney disease

- Biologically active drug with clinical changes seen across all patient cohorts
- Most significant impacts on patients with moderate to severe albuminuria

Complete data and analysis will be required for conclusions and next steps

- Small sample sizes - enrollment continuing in two of the three cohorts
- Full data set not available across all patients and across all metrics for all patients dosed
- PK and biomarker analysis to be included in Late-Breaking presentation anticipated during ASN Kidney Week in November 2021

Phase 2 REDUX Study - Safety and Signal Seeking for DM199 in CKD

Key Objectives:

1. **Safety and tolerability**
   - Repeat injections over three months
   - Benchmark to approved porcine KLK1 from Asia
2. **Signals of clinically relevant activity**
   - Measured by UACR, eGFR and BP
3. **Analysis of Clinical Data, PK and Biomarkers**
   - Utilize PK for dose selection for future studies in CKD and stroke
   - Biomarkers to assess activity

Chronic Kidney Disease (CKD) Populations Studied with DM199
Patients with High Unmet Medical Needs

IgA Nephropathy (IgAN)

- Serious and progressive autoimmune disease of kidneys
- Up to 50% at risk of developing ESRD within 10-20 years
- Orphan disease indication in US (~140K) and Europe (~200K); ~2M in China
- No approved treatment

Hypertensive African Americans with CKD

- ~6 million African Americans with CKD
- 3x – 4x more kidney failure than Caucasians
- Exhibit lower KLK1 levels and lower renal blood flow
- APOL1 gene mutation = higher risk of ESRD
  - Potential rare disease

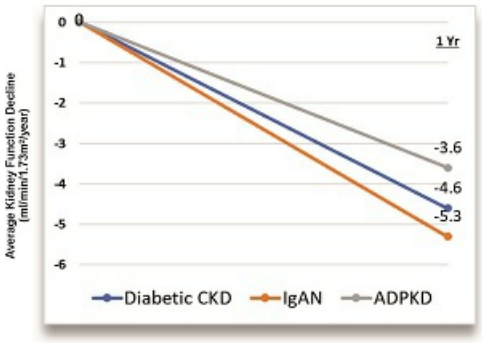
Diabetic Kidney Disease (DKD)

- ~12 million in US3
- Most frequent cause of ESRD worldwide
- Anti-hypertensives & SGLT2's only slow disease progression

1. Centers for Disease Control, 2019 Kidney Disease Fact Sheet
2. National Institute of Health Fact Sheet, 2010
3. USRD, CKD and ESRD (https://www.usrds.org/2018/view/v1_07.aspx)

CKD Patients - Kidney Function Worsens Over Time

Average Annual eGFR Decline
Standard of care only reduces slope of decline



- Slowing eGFR decline an important endpoint in kidney disease
- Reducing UACR is a surrogate endpoint for predicting kidney disease progression and allows for earlier measurement of a therapeutic impact on kidney disease

1. N Engl J Med 2019 Jun 13;380(24):2295-2306
2. https://www.evaluate.com/vantage/articles/news/snippets/amed-data-calliditas-heads-us
3. Torres NEJM (2017)

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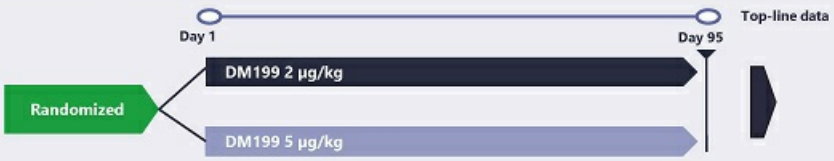
DM199 REDUX Phase 2 CKD Study Design

Study Includes 3 Distinct Causes of CKD

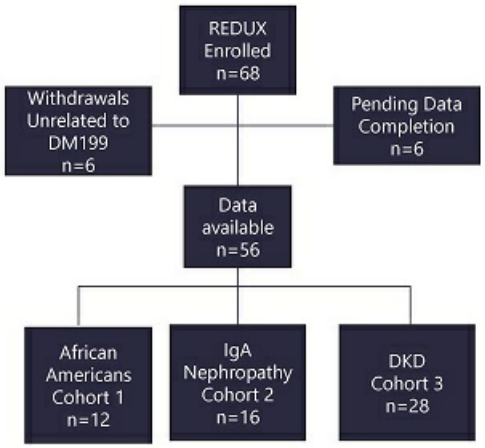
Design	Phase 2, Open Label, Multi-Center (14 US Sites), Randomized Study of 2 Dose Levels		
		Target	Interim Analysis
Sample Size (3 Cohorts)	African Americans, hypertensive with CKD	n=~30	n=12
	IgA Nephropathy	n=~30	n=16
	Diabetic Kidney Disease	n=~30	n=28
Eligibility Criteria	eGFR 30-90 mL/min Albuminuria: 150 – 5,000		
Treatment	95 days of treatment SC dosing, 2x week		



Study endpoints after dosing at 2 or 5 µg/kg

- Albuminuria (UACR) and eGFR
- Safety, tolerability, blood pressure and pharmacodynamics

Analysis Population: Patient Disposition and Baseline Demographics



Baseline Demographics – Analysis Population

	AA/CKD n=12	IgAN n=16	DKD n=28
M:F	7:5	12:4	17:11
Mean age	57	51	68
Race AA:Caucasian:Other	12:0:0	1:15:0	8:13:7
eGFR	43.3 ml/min	39.8 ml/min	45.8 ml/min
UACR	809 mg/g	988 mg/g	1,273 mg/g
Blood Pressure SBP/DBP	146/91	128/83	144/80

Excellent Safety and Tolerability of DM199 - Consistent with Earlier Studies

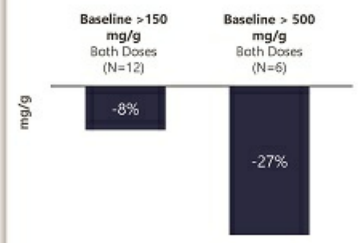
62 patients completed study and over 1,500 injections – June 2021

- No discontinuations due to drug-related adverse events
- No drug-related SAEs
  - No drug-related hypotension, angioedema or fluid overload-events
- AEs were been generally mild-to-moderate
  - Most common reported drug-related AE is local site irritation/injection site reactions

Hypertensive African Americans with CKD – Interim Analysis

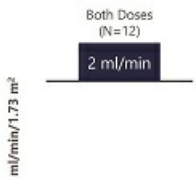
Positive Signals in Reducing UACR, Increasing eGFR and Reducing BP,

Albuminuria (UACR)



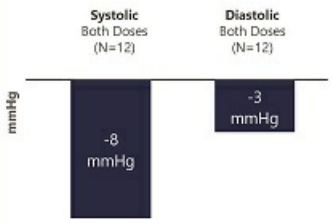
- Reductions most significant in moderate to severe patients (UACR>500)
- Reductions more significant at the lower dose level (-52%) in moderate to severe patients (n=3)

eGFR



- Encouraging eGFR – stable to increase from baseline

Blood Pressure



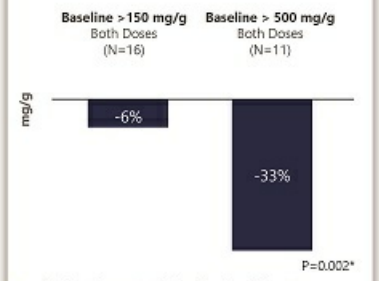
- BP reductions (-14/-7) in low dose cohort (n=7)
- Statistically significant reduction in systolic BP overall at 2 ug/kg dose level (-8/-3) (n=31) (p=0.037)^

* Paired T-test

IgA Nephropathy – Interim Analysis

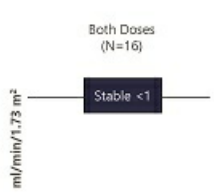
Positive Signals in Decreasing UACR and Stabilizing eGFR

Albuminuria (UACR)



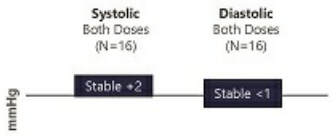
- Reductions statistically significant compared to baseline in moderate to severe patients (UACR>500)

eGFR



- eGFR stable from baseline

Blood Pressure



- Stable/did not decrease BP in normotensive participants
- Not surprising given KLK1 role in selectively reducing hypertension and not causing hypotension

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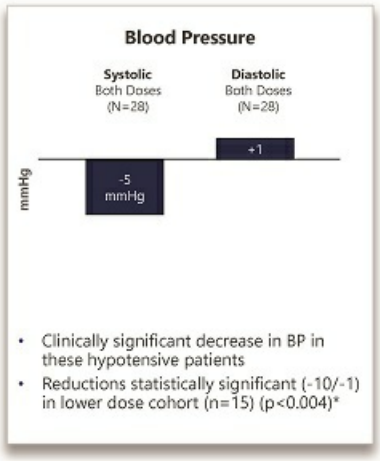
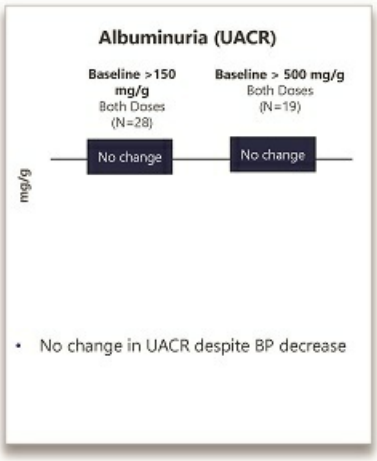
* Paired T-test

Diabetic Kidney Disease – Interim Analysis

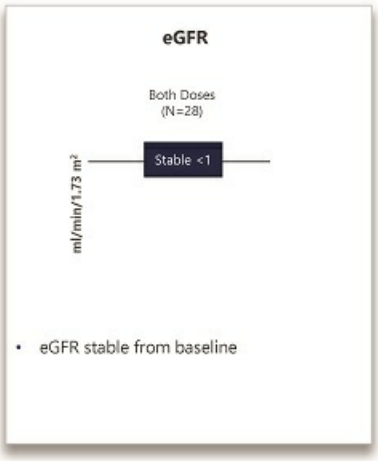
Positive Signals - Reducing Blood Pressure No Change in UACR and Stabilizing eGFR



- Clinically significant decrease in BP in these hypotensive patients
- Reductions statistically significant (-10/-1) in lower dose cohort (n=15) ($p<0.004$)*



- No change in UACR despite BP decrease



- eGFR stable from baseline

DiaMedica THERAPEUTICS

* Paired T-test

Interim Results Affirm Biological Activity and Safety of DM199

Consistent with MOA and Approved KLK1 Product in Asia

- ✓ **Clinically relevant signals in patients with CKD**
  - **UACR**
  - **eGFR**
  - **Hypertension**
- ✓ **Safe and Well Tolerated – No SAE or AE concerns related to DM199 (1,500+ injections)**
- ✓ **Data consistent with the documented safety and tolerability observed in the approved human urine and porcine derived KLK1 in Asia**
- ✓ **Data further supports initiation of pivotal study in acute ischemic stroke**

Priorities and Next Steps for DiaMedica

Continue Phase 2 CKD Study and Initiate Pivotal Study for Acute Ischemic Stroke (AIS)

Complete Phase 2 Enrollment for IgAN and Hypertensive African Americans with CKD

Analyze full CKD data set before initiating additional studies in CKD

- Larger sample size by dose, PK and biomarker data needed to inform future
- Submit Late-Breaking presentation to ASN Kidney Week in November 2021 with available data

Acute Ischemic Stroke - Initiate enrollment in study

- REDUX Safety, tolerability and biologic activity of DM199 in patients with CKD and consistency with the porcine KLK1 from Asia provides further support for the stroke program

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Thank you!

NASDAQ: DMAC