UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): **June 19, 2019**

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.)

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

(763) 496-5454
(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 19, 2019, DiaMedica Therapeutics Inc. (the "Company") announced interim results of the Phase 1b study from 28 evaluable participants with moderate and severe 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.

Also on June 19, 2019, the Company made available an investor presentation in connection with its announcement of the interim results of the Phase 1b study from 28 evaluable participants with moderate and severe CKD. A copy of the investor presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

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.

On June 19, 2019, the Company announced interim results of the Phase 1b study from 28 evaluable participants with moderate and severe CKD. DM199 (recombinant KLK1) was observed in the study to be safe and well tolerated with no drug-related serious adverse events, consistent with earlier DM199 studies in healthy volunteers. The study also demonstrated a dose range which the Company believes will restore normal KLK1 levels in CKD patients. It is noteworthy that the pharmacokinetic ("PK") profile in CKD subjects after dosing was similar to the PK profile in healthy volunteers. Encouraging early signals in estimated glomerular filtration rate, urinary albumin to creatinine ratio and other biomarkers were also observed in the study, which the Company believes show drug activity, consistent with the DM199 mechanism of action, and may represent initial proof-of-mechanism. The favorable interim safety, tolerability and PK data, complemented by pharmacodynamic observations, support the advancement of DM199 development to a Phase II clinical trial in patients with CKD.

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.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
99.1	Press Release dated June 19, 2019 announcing interim results of the Phase 1b trial of DM199 in chronic kidney disease participants (filed herewith)
99.2	Investor Presentation issued by DiaMedica Therapeutics Inc. on June 19, 2019 (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 19, 2019

Exhibit 99.1

DiaMedica Therapeutics Announces Interim Results from Phase 1b Trial of DM199 in Chronic Kidney Disease Participants

- *Favorable DM199 safety profile across tested doses*
- *Pharmacodynamic results helped identify dose range for Phase II studies*
- *Encouraging early signals in mechanism biomarkers (NO and PGE2), Kidney function (eGFR) and urine albumin (UACR)*
- *Phase II trial initiation expected 2H19 with interim analysis Q4 2019 – Q1 2020*
- *Company to host conference call and webcast on June 20, 2019 at 7:00 a.m. CT*

Minneapolis, Minnesota – (Globe Newswire – June 19, 2019) – DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biotechnology company, today announced interim results of the Phase 1b study from 28 evaluable participants with moderate and severe chronic kidney disease (CKD). DM199 (recombinant KLK1) was observed to be safe and well tolerated with no drug-related serious adverse events (SAEs), consistent with earlier DM199 studies in healthy volunteers. The study also demonstrated a dose range which the Company believes will restore normal KLK1 levels in CKD patients. It is noteworthy that the pharmacokinetic (PK) profile in CKD subjects after dosing was similar to the PK profile in healthy volunteers.

Encouraging early signals in estimated glomerular filtration rate (eGFR), urinary albumin to creatinine ratio (UACR) and other biomarkers were also observed in the study, which the Company believes show drug activity, consistent with the DM199 mechanism of action, and may represent initial proof-of-mechanism. The favorable interim safety, tolerability and PK data, complemented by pharmacodynamic (PD) observations, support the advancement of DM199 development to a Phase II clinical trial in patients with CKD.

Phase 1 Trial Design and Interim Results

Trial Design. The randomized, multi-center U.S., single dose open label trial enrolled CKD participants in two cohorts with moderate (Stage III) and severe renal function (Stage IV) impairment and Type 1 or Type 2 diabetes mellitus. The study was designed to evaluate the safety and tolerability of single subcutaneously administered DM199 - dose levels of 3, 5 and 8 µg/kg - assess PK, PD and guide the design of Phase II CKD studies over 11-days. The study has enrolled 31 adult CKD subjects from which 28 subjects are currently evaluable.

Safety and Tolerability Data. DM199 was observed to be well tolerated with no dose-limiting tolerability. There were no deaths, no discontinuations due to a treatment-related adverse event (AE), and no treatment-related SAEs. AEs were minor and consistent with standard treatment(s) in the CKD patient population. The most common AE was orthostatic hypotension that resolved without intervention.

Pharmacokinetic Data. PK was evaluated over 11 days. The Company believes that it has identified a dose range to normalize KLK1 levels in both moderate and severe CKD patients. DiaMedica is pleased to report that the PK profiles were similar between moderate and severe CKD patients, as well as previous healthy subjects, dosed at the 3µg/kg. Therefore, the Company does not believe dosing adjustments is warranted, based on severity of disease.

Pharmacodynamic Data. PD was evaluated through exploratory biomarkers as pre-defined secondary endpoints for this study. Although subjects only received a single dose in the study, favorable overall results were observed including short-term improvements at approximately 24 hours after DM199 administration including Nitric Oxide (NO), average increase of 35.2%, Prostaglandin E2 (PGE2), average increase of 41.2%, eGFR, average increase of 4.08 mL/min/173^2, and UACR, average decrease of 18.7%. No similar discernable changes in blood pressure (other than Orthostatic hypotension), glucose or MMP9 levels were observed in study participants.

DiaMedica expects to provide full results of the study in a peer-reviewed publication and/or poster presentation.

"We're pleased to report interim results from the Phase Ib study met expectations for the primary endpoints, PK, safety and tolerability. Moreover, although this study was not designed for efficacy testing, it was notable that overall secondary endpoints, including NO, PGE2, eGFR and UACR, showed encouraging early signals. The initial clinical data supports the expected mechanism of action for DM199," said Dr. Harry Alcorn, Jr., Chief Medical Officer at DiaMedica. "Most importantly, we're encouraged about DM199's potential as a treatment option to improve the lives of patients with chronic kidney disease."

Conference Call & Webcast Information

DiaMedica will host a conference call and webcast to present the interim Phase 1b results and the proposed Phase II trial design on Thursday, June 20, 2019 at 7:00 am CT. Investors and analysts are invited to join the conference call (audio only) by phone by calling (866) 962-3583 (U.S.) or (630) 652-5857 (international) using the conference ID 1746669. A telephonic replay of the conference call will be available until June 27, 2019, by dialing 1(855) 859-2056 (US Toll Free Dial In), (404) 537-3406 (international), replay passcode 1746669.

A live webcast of the presentation may be accessed live at https://edge.media-server.com/m6/p/78quvxo3 or by visiting the Investors & Media section of the DiaMedica website at http://investors.diamedica.com. An archived replay of the webcast will be available on the Company's website for 90 days after the call.

About CKD

CKD occurs when kidneys are damaged and cannot filter blood the way they should. This damage can cause wastes to build up in the body. CKD is a progressive condition leading to the gradual loss of kidney function over time. Early stages of CKD may be present with few or no signs or symptoms and the majority of patients do not know they have kidney disease. Unfortunately, not until one has significant kidney impairment does one usually seek a physician for diagnosis and treatment. Slowing the progression of CKD, and/or normalization of kidney function is an unmet need in this population which if not treated appropriately can lead to cardiovascular events, hospitalizations, dialysis, kidney transplant or premature death.

About DM199

DM199 is a recombinant (synthetic) form of the human serine protease, KLK1. The KLK1 protein 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 prostacyclin and other anti-inflammatory mediators. 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 Korea for decades. DM199 is currently being studied in a Phase II clinical study for acute ischemic stroke and the Company is preparing to initiate Phase II clinical studies in patients with chronic kidney disease.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company focused on developing novel treatments for patients with chronic kidney diseases and acute ischemic stroke. DiaMedica's common shares are listed on The Nasdaq Capital Market under the trading symbol "DMAC."

For more information, please visit www.diamedica.com, or follow us on Twitter.

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", "will," "may" 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 success and benefits of DM199 as a potential treatment for CKD, the timing of the Company's clinical programs, including an anticipated Phase II study starting in the second half of 2019 in patients with CKD, and identification of a dose range which the Company believes will restore normal KLK1 levels in CKD patients. 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, DiaMedica's plans to develop, obtain regulatory approval for and commercialize its DM199 product candidate for the treatment of CKD and its expectations regarding the benefits of DM199; DiaMedica's ability to conduct successful clinical testing of DM199 for CKD; the perceived benefits of DM199 over existing treatment options for CKD; ability to obtain required regulatory approvals of DM199 for CKD; the potential size of the markets for DM199 and the Company's ability to serve those markets; the success, cost and timing of planned clinical trials, as well as reliance on collaboration with third parties to conduct clinical trials; its ability to obtain funding for its operations, including funding necessary to complete planned clinical trials and obtain regulatory approvals for DM199 for 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, 2018 filed with the U.S. Securities and Exchange Commission ("SEC") and subsequent SEC 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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Exhibit 99.2


DiaMedica
THERAPEUTICS
Nasdaq: DMAC
DM199 CKD Phase Ib
Interim Results and Phase II
Overview June 2019

FORWARD LOOKING STATEMENT

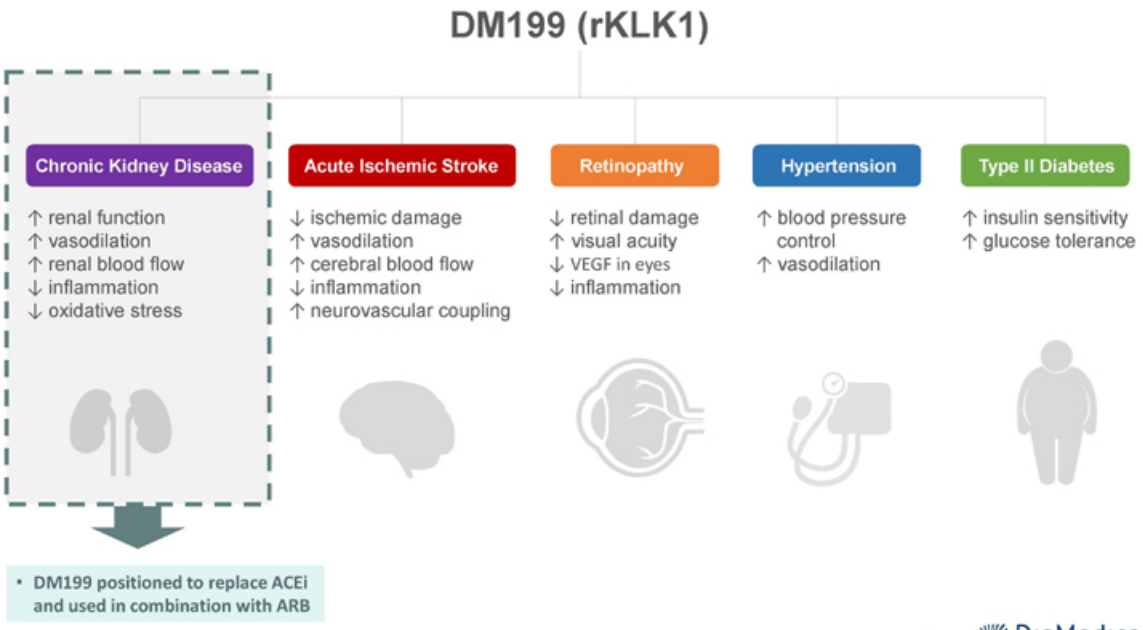
This presentation contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, which reflect the Company's current expectation regarding future events. The words "estimate", "believe", "anticipate", "intend", "expect", "future," "plan", "will," "may" 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 success and benefits of DM199 as a potential treatment for chronic kidney disease (CKD), the timing of the Company's clinical programs, including an anticipated Phase II study starting in the second half of 2019 in patients with CKD, and identification of a dose range which the Company believes will restore normal KLK1 levels in CKD patients. Forward-looking statements involve risks and uncertainties that may cause actual results, events, or developments to be materially different from any future results, events, or developments expressed or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, DiaMedica's plans to develop, obtain regulatory approval for and commercialize its DM199 product candidate for the treatment of CKD and its expectations regarding the benefits of DM199; DiaMedica's ability to conduct successful clinical testing of DM199 for CKD; the perceived benefits of DM199 over existing treatment options for CKD; ability to obtain required regulatory approvals of DM199 for CKD; the potential size of the markets for DM199 and the Company's ability to serve those markets; the success, cost and timing of planned clinical trials, as well as reliance on collaboration with third parties to conduct clinical trials; its ability to obtain funding for its operations, including funding necessary to complete planned clinical trials and obtain regulatory approvals for DM199 for 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, 2018 filed with the U.S. Securities and Exchange Commission (SEC) and subsequent SEC filings. Except as required by applicable securities laws, DiaMedica undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of existing or new information, future events, or otherwise.

AGENDA

1. **Introductory Remarks**
2. **Phase 1b Interim Results**
3. **Rationale for DM199 in CKD**
4. **Overview of Phase II Trial**
5. **Closing Remarks**

POTENTIAL THERAPEUTIC BENEFITS OF DM199: PROTEIN REPLACEMENT THERAPY

Promoting homeostasis: improving blood flow and reducing inflammation throughout the body



- DM199 positioned to replace ACEi and used in combination with ARB

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CHRONIC KIDNEY DISEASE (CKD)
SIGNIFICANT UNMET NEED

Chronic Kidney Disease (CKD)

- **The progressive loss of kidney function leading to dialysis, transplantation and ultimately death**
- **Current standard of care – managing blood pressure**
  - ACEi (i.e. Ramipril) and ARB (i.e. Valsartan, Losartan)
    - Less than 30% patients on required dose due to adverse side effect risks
- **KLK1 (DM199) treatment option to improve kidney function:**
  - Regulate/stabilize blood flow, reduce inflammation, reduce damage to small blood vessels to prevent structural damage
  - Kidney function improvement believed to be **independent of blood pressure control**
  - KLK1 (porcine) approved in Japan & China to treat CKD, retinopathy & hypertension

GROWING BODY OF DM199/KLK1 CLINICAL EVIDENCE

The Phase Ib in 28 evaluable participants builds on the body of knowledge of KLK1 and the use of approved crude forms (porcine and human urine) in Japan & China

KLK1 Endogenous Protein

- Naturally produced in the body
- KLK1 believed to play vital role in kidney health
- Link between lower KLK1 levels and CKD progression

Crude Forms of KLK1 Used in Asia

- Millions of patients treated in Japan and China for kidney diseases and related disorders with KLK1 derived from porcine (pig) pancreas and human urine

DM199 Strong Safety & Activity Profile

- Safe & well-tolerated in 200+ subjects to date
- Comparable enzymatic activity to crude KLK1
- Kidney improvement anticipated to be independent of blood pressure control

DM199 Positive Phase 1b Data

- Safety & tolerability consistent with past studies
- Identified Phase II CKD dosing levels
- PK consistent with non-CKD patients
- Encouraging signals in NO, PGE_2, eGFR & UACR
- Reinforces understanding of MOA

DM199: CKD phase Ib interim results

Note: The Company expects to publish full results in peer reviewed journal and/or upcoming conference presentation

DM199 CKD PHASE Ib TRIAL DESIGN

Key objectives of Phase 1b:

Evaluate the safety, tolerability, PK and PD of DM199 in CKD participants

Phase Ib, Multi-Center US, Randomized, multi Dose
- 32 CKD participants (Cohort 1 N=24, Cohort 2 N=8)
- 3 dose levels – single dose
- 2 Cohorts (moderate & severe CKD subjects)

Primary and secondary endpoints over 11 days:
- Safety & Tolerability
- Pharmacokinetics (PK)
- Pharmacodynamics (PD) and biomarkers:
  - Nitric oxide, prostaglandin, urine albumin to creatinine ratio (UACR), eGFR, blood pressure & others

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DM199 CKD PHASE Ib SAFETY AND TOLERABILITY RESULTS SUPPORT ADVANCING TO PHASE II

Safety & tolerability profile consistent with prior studies

Safety and tolerability:

- DM199 was safe and well-tolerated with no drug related SAE's
- No discontinuations due to treatment related AEs
- AE reported were very typical for this type of study, patient population, and drug route
- AE observed in 31 participants:
  - Orthostatic hypotensive (n=9)
  - Injection site reaction (n=4)
  - Headache (n=3)
  - Diarrhea (n=3)
  - Misc. heartburn, dry mouth, nausea (n=5)

All AE's were minor, resolved without intervention and consistent with anticipated AEs in this patient population

Study Supports advancing to Phase II study in 2H 2019

DM199: CKD PHASE Ib PK SUPPORT INFREQUENT DOSING

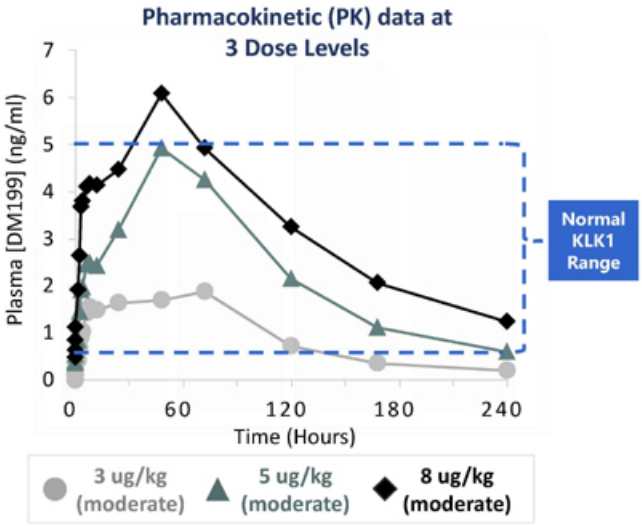
Identified dose level and frequency for Phase II CKD studies

Displayed well-behaved PK profile

- Dose-proportional serum drug exposure levels
- Consistent with previous non-CKD participants

Half-life supports infrequent dosing

- Serum half-life supports dosing 2x per week without change to formulation
- Opportunity for future long-acting formulation to further reduce dosing frequency



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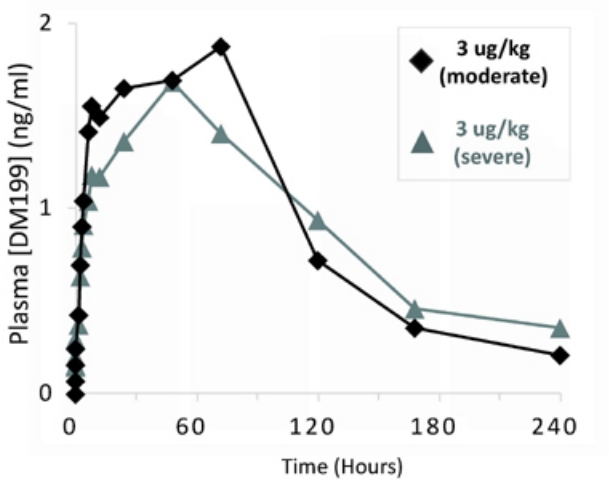
DM199 CKD PHASE 1B PK IN MODERATE & SEVERE PARTICIPANTS

Similar PK profile between severe and moderate participants

Moderate & severe CKD patients similar PK profile

- No dosing adjustments needed based on kidney function
- Do not anticipate full renal study will be be required based on results



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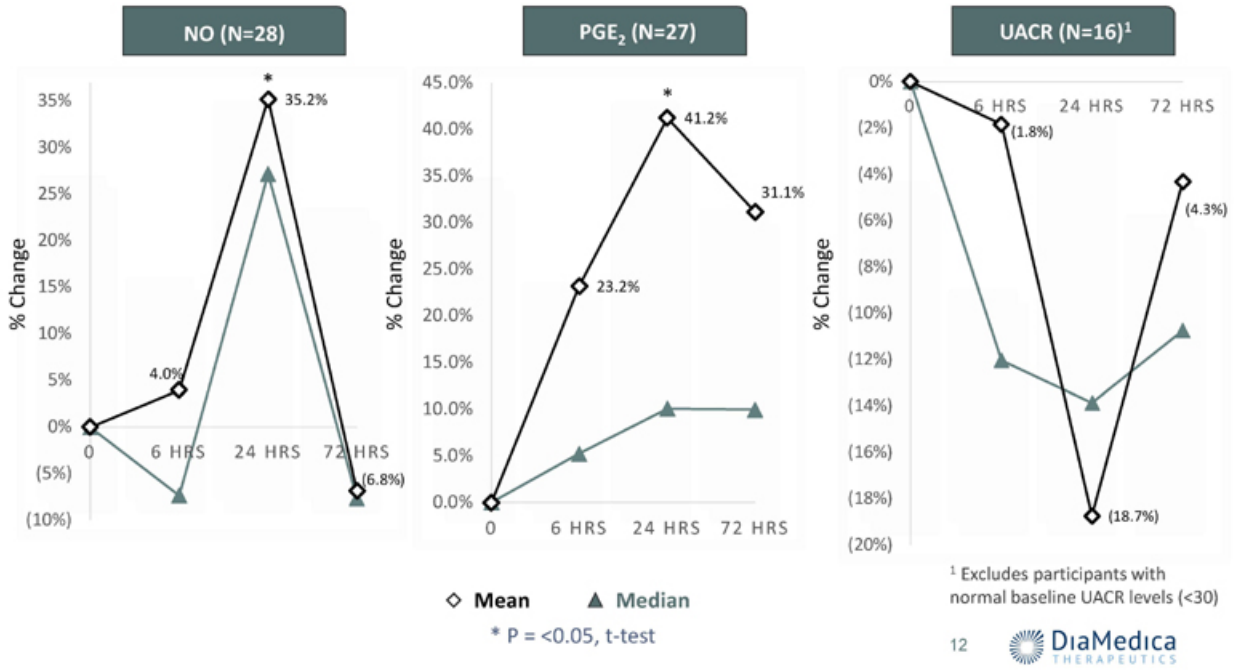
DM199 CKD PHASE 1B OVERALL TREND ANALYSIS FOR NO, PGE_2 AND UACR

Observed trends in NO, PGE_2 and UACR with peak values at 24 hours

Trends correspond with greatest eGFR improvement



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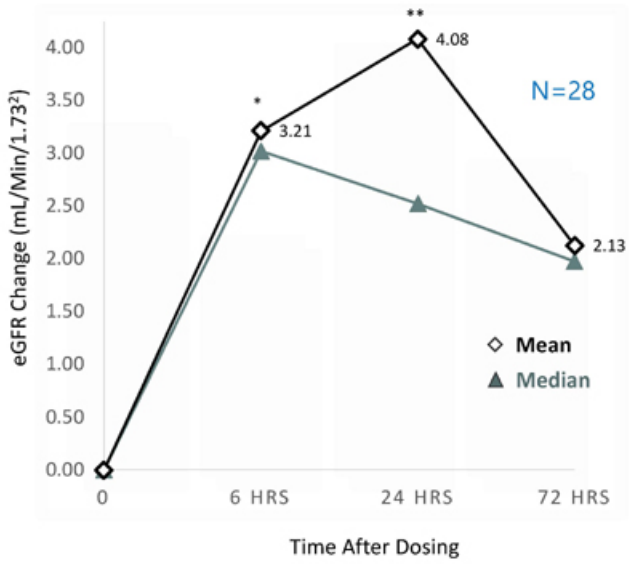
DM199 CKD PHASE 1B OVERALL eGFR DATA – EARLY SIGNAL

Estimated glomerular filtration rate (eGFR) – measure of kidney function



Time After Dosing	% of Patients With An Increase in eGFR
6 Hours	75.0%
24 Hours	82.1%
72 Hours	71.4%

* P = <0.05, t-test

** P = <0.01, t-test

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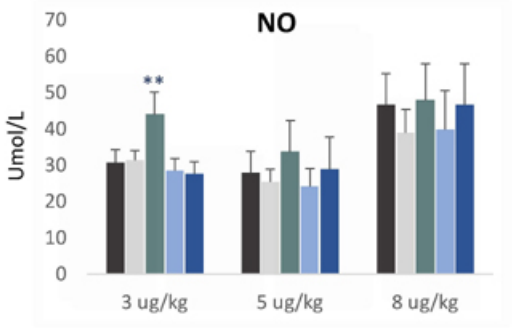
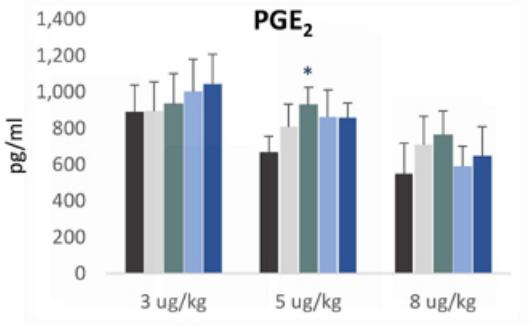
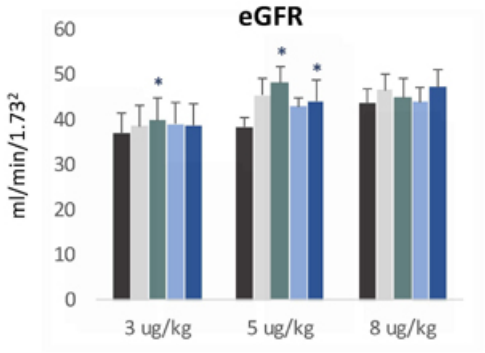
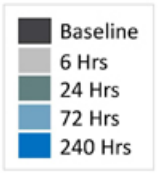
DM199 CKD PHASE 1b PD AND BIOMARKERS BY DOSE LEVELS FOR NO, PGE_2, eGFR AND UACR

DM199 by dose @ 3, 5 and 8 µg/kg









* P = <0.05, t-test
** P = <0.01, t-test

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DM199 POSITIVE CKD PHASE 1B INTERIM RESULTS

Achieved primary endpoints and secondary objectives

Well-tolerated with no apparent safety signals

- No dose-limiting toxicities identified
- No discontinuations or serious adverse events (SAE)

Identified Phase II CKD dosing

- PK profile unaffected by stage of kidney disease (moderate/severe/T1D)
- PK profile consistent with prior studies in non-CKD participants
  - Consistent PK profile indicates kidney function does not impact clearance of DM199
  - Full renal characterization studies may not be required
- Dosing levels for Phase II studies identified

Encouraging early overall signals of mechanism of action, changes at 24 hours

- Nitric oxide (NO) ↑ 35.2% ($p<0.05$)
- Prostaglandin E_2 (PGE_2) ↑ 41.2% ($p<0.05$)
- eGFR mL/min/1.73^2 ↑ 4.08 ($p<0.01$)
- UACR ↓ 18.7%
- No changes in MMP9, blood pressure or blood glucose during study

Supports advancing to Phase II study in 2H 2019

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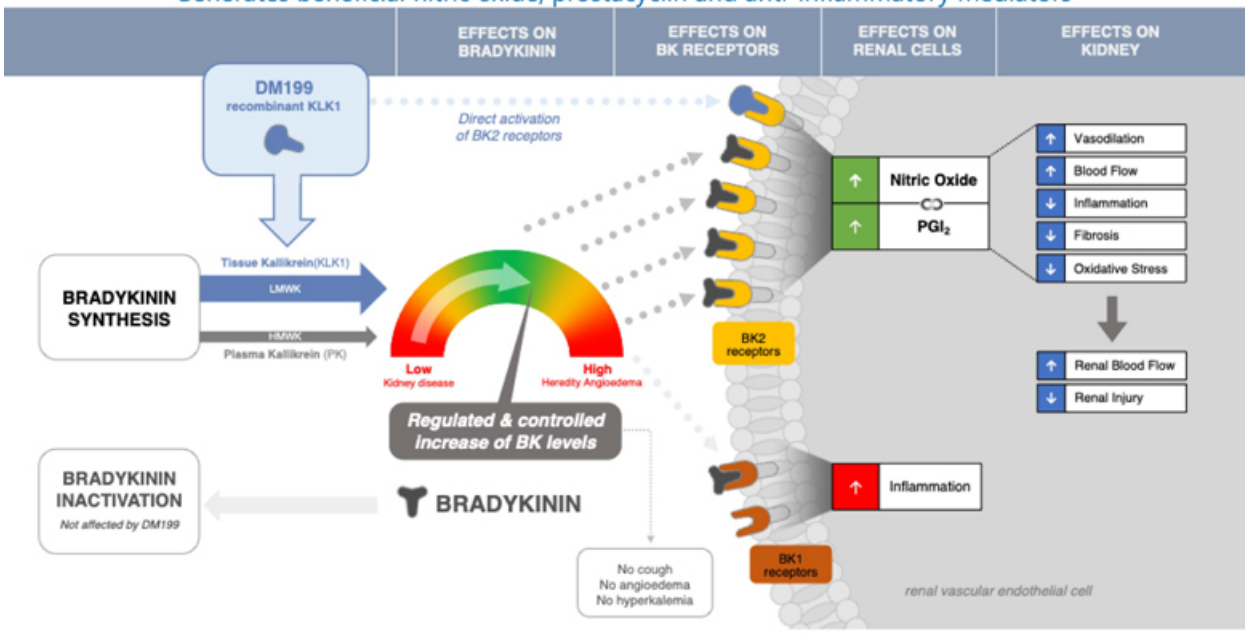
Rationale for investigating DM199 for CKD

DM199 MECHANISM OF ACTION

DM199 boosts KLK1 levels enabling release of physiological levels of BK when and where needed.
Generates beneficial nitric oxide, prostacyclin and anti-inflammatory mediators



DM199 to increase low levels of KLK1, BK, BK2 receptors, NO, PGI_2, cGMP and cAMP in patients with CKD

LMWK - low molecular weight kininogen
HMWK - high molecular weight kininogen

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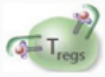
DM199 MULTIFUNCTIONAL SERINE PROTEASE

Promoting homeostasis: improving blood flow and reducing inflammation throughout the body

Increases **Tregs**		**Suppresses autoimmune response via increased regulatory T cells (Tregs)** • Potential Indications: Type 1 diabetes[1], lupus[2], IgAN & other autoimmune • DM199 increases CD4+, CD25+, Fox3+, Tregs, TGF-b1 & suppresses CD8+
Cleaves **VEGF**	↓ VEGF	**Reduces inflammation & angiogenesis in retina by cleaving VEGF in eyes[3]** • Improved visual acuity & maintained chorioretinal blood flow, anti-VEGF & inflammation effects in diabetic macular edema patients • Administered via systemic delivery, instead of eye injections
Activates **ENaC**		**Regulates sodium (Na) and potassium (K)[4]** • Maintains electrolyte balance • Avoiding hyperkalemia, sudden cardiac death

[1] *PlosOne, September 2014, Volume 9, Issue 9.*
[2] *PlosOne* July 2013,Volume 8, Issue 7.
[3] Clinical Ophthalmology 2018:12 1845–1852
[4] Am J Physiol Renal Physiol 303: F540–F550, 2012.

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KLK1 (PORCINE) DATA IN PATIENTS HIGHLIGHTS THE POTENTIAL FOR IMPROVING CKD

20+ clinical studies with KLK1 (porcine) demonstrated improvement in albuminuria, renal function and compliments ARB

Meta analysis – KLK1 (porcine) for CKD[1]

"... clinical efficacy of pancreatic KLK1 in treating kidney disease is significant and worthy of wide application."

Clinical Efficacy of Pancreatic Kininogenase in the Treatment of Diabetic Nephropathy: A Systematic Evaluation

By: Xiaozheng Chen, Xi Chen, Jianmin He
(Internal Medicine Dept., Shaoguan Railawy Hospital, Shaoguan city, Guangdong 512023, China)

ABSTRACT

Objective: To evaluate the clinical efficacy of pancreatic kininogenase in the treatment of diabetic nephropathy.

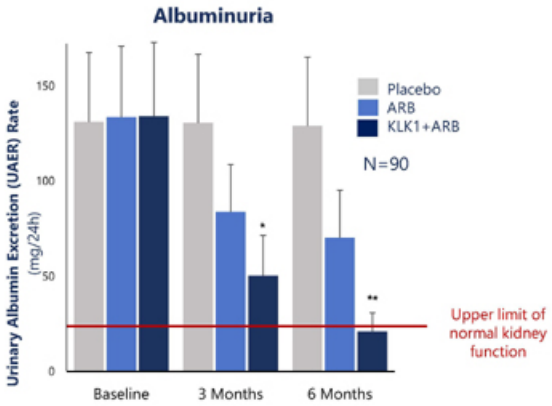
Methods: The methodology were evaluated based on references in the recent 20 years from PubMed, Science Direct, EBSCO host, EMBASE, the Cochrane Library, CNKI, CECDB CQVIP. The researchers performed rigorous evaluation on the quality of the included studies and extracted data. Review Manager 5.0 Software was applied to evaluated the qualified randomized controlled tirals (RCTs).

Results: 12 RCTs were included, involving 762 patients (389 cases in the treatment group and 373 cases in the control group)/ Compared to angiotensin II receptor antagonist (ARB), angiotensin converting enzyme inhibitors (ACEI), alprostadil, pancreatic kininogenase can significantly reduce the urinary albumin excretion rate in the treatment of diabetic nephropathy, thus postponing the pathological process of diabetic nephropathy.

Conclusion: Kininogenase has significant curative effect in the treatment of diabetic nephropathy and is worthy of promotion.

KLK1 (porcine) + ARB treatment for 6 months[2]

UAER improved at 3 and 6 months (84%)



*P<0.05
**P<0.01

[1] Hainan Medical Journal, 2014-01
[2] Chin J Diabetes, August 2011, Vol 19, No 8.

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DM199 Phase II CKD Trial Overview

DM199 PROTEIN REPLACEMENT THERAPY PIPELINE

Could address a diverse pipeline of indications

PROGRAM	THERAPEUTIC INDICATIONS	DEVELOPMENT STAGE AND ANTICIPATED MILESTONES				
		PRE-	PHASE I	PHASE II	PHASE III	ANTICIPATED MILESTONES
DM199 Kidney Disease	**Phase Ib Dose Ranging**					Enrollment complete June 2019
	IgA Nephropathy (IgAN)					Phase 2 initiation 2H 2019
	CKD and Hypertension in African Americans (APOL1)					Phase 2 initiation 2H 2019
	Type 1 Diabetes or Lupus Nephritis					Planning
DM199 Stroke	**Acute Ischemic Stroke**	*Remedy Study*				Q4 2019 – Q1 2020

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DM199 FOR IGA NEPHROPATHY (IgAN)

IGA Nephropathy (IgAN)

Overview
- Cause: IgA, a protein meant to defend the body against foreign invaders, accumulates in the kidneys, attacking glomeruli
- Diagnosis: Hematuria, albuminuria, hypertension
- Prognosis: up to 50% at risk for ESRD within 10-20 years

Prevalence
- ~130,000 to 150,000 in US
- Considered rare disease (NORD)

Rationale
- DM199 increases Tregs and improves autoimmunity in T1D model, could potentially address the underlying autoimmune problems of IgAN and improving kidney function[1]
- No approved treatment for IgAN; only symptoms

[1] Eur Rev Med Pharmacol Sci 2015; 19 (2): 284-288

DM199 FOR AFRICAN AMERICANS WITH CKD (APOL1)

CKD in African Americans & APOL1

Overview

- African Americans 3-4x more likely to suffer kidney failure than Caucasians
  - APOL1 gene variations are 2x more likely to progress to ESRD
- APOL1 is a gene that affects arterial blood flow in kidneys
- CKD shortens life expectancy by 5-11 years

Prevalence

- ~7M African Americans with CKD in US
- ~15% African Americans with APOL1 gene variations

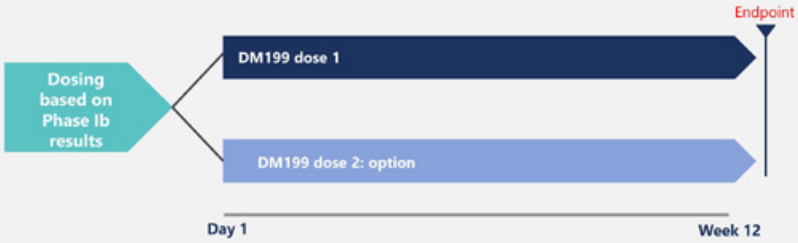
Rationale

- African Americans are more highly salt sensitive
- KLK1 more effective in salt-sensitive *in vivo* models
- African Americans exhibit lower KLK1 levels and renal blood flow
- No approved therapies

DM199 PHASE II CKD DRAFT STUDY DESIGN

Targeting multiple rare / unmet forms of chronic kidney diseases

Phase II, Multi-Center US, Randomized Study
- IgAN & African Americans-APOL1 gene with Kidney Disease cohorts
- ~30 participants per cohort
- Participants to act as their own control



Study endpoints at week 12:
- Safety, Tolerability, PK and PD
- Albumin to creatinine ratio (UACR), eGFR, blood pressure and others

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Nasdaq: DMAC

- **DM199 Protein replacement therapy - KLK1**
- **Low KLK1 levels associated with kidney disease**
- **Crude form of KLK1 approved and treated millions successfully in Asia**
- **Early DM199 signals in mechanism biomarkers, kidney function & urine albumin**
- **DM199 (recombinant KLK1) as a safe treatment option for CKD patients**