

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): May 13, 2020

DIAMEDICA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

British Columbia
(State or other jurisdiction
of incorporation)

001-36291
(Commission
File Number)

Not Applicable
(IRS Employer
Identification No.)

Two Carlson Parkway, Suite 260
Minneapolis, Minnesota
(Address of principal executive offices)

55447
(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 2.02. Results of Operations and Financial Condition.

On May 13, 2020, DiaMedica Therapeutics Inc. (the “Company”) announced its consolidated financial results for the three months ended March 31, 2020. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and the information set forth therein is incorporated herein by reference and constitutes a part of Item 2.02 of this report.

The information contained in Item 2.02 of this report and Exhibit 99.1 to this report shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and shall not be incorporated by reference into any filings made by the Company under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

Item 7.01. Regulation FD Disclosure.

On May 13, 2020, the Company announced top-line results of its Phase II ReMEDy trial assessing the safety, tolerability and therapeutic potential of DM199 in patients suffering from acute ischemic stroke. A copy of the press release is attached 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 Item 7.01 of this report.

On May 13, 2020, the Company made available an investor presentation in connection with the announcement of top-line results of its Phase II ReMEDy trial. A copy of the investor presentation is furnished as Exhibit 99.3 to this Current Report on Form 8-K and the information set forth therein is incorporated herein by reference and constitutes a part of Item 7.01 of this report.

The information contained in Item 7.01 of this report and Exhibit 99.2 and Exhibit 99.3 to this report shall not be deemed to be “filed” for purposes of Section 18 of the Exchange Act and shall not be incorporated by reference into any filings made by the Company under the Securities Act or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On May 13, 2020, the Company announced top-line results of its Phase II ReMEDy trial assessing the safety, tolerability and markers of therapeutic efficacy of DM199 in patients suffering from acute ischemic stroke. The Company announced that DM199, a drug intended to restore Kallikrein-1 protein (“KLK1”) levels and the body’s natural ability to regulate blood flow and reduce inflammation after an acute ischemic stroke, achieved primary safety and tolerability endpoints and no DM199-related serious adverse events were noted in the study. The Company also announced that there was also a demonstrated therapeutic effect in subjects who received tissue plasminogen activator (“tPA”) prior to enrollment, but not in participants receiving mechanical thrombectomy, according to top-line Phase II results.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | <u>Press Release dated May 13, 2020 providing a business update and reporting first quarter 2020 financial results (furnished herewith)</u> |
| 99.2 | <u>Press Release dated May 13, 2020 providing top-line results of DiaMedica Therapeutics, Inc.'s Phase II ReMEDy trial (furnished herewith)</u> |
| 99.3 | <u>Investor Presentation issued by DiaMedica Therapeutics, Inc. in connection with the release of its top-line results of its Phase II ReMEDy trial (furnished herewith)</u> |

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: May 13, 2020



**DiaMedica Announces Positive Results in Top-Line Data from the
Phase II ReMEDy Acute Ischemic Stroke Study and Provides a
Business Update and First Quarter 2020 Financial Results**

- *DM199 Met Primary Safety and Tolerability Endpoints in ReMEDy Study Top-Line Data*
- *Demonstrated Therapeutic Effect in Patients Not Pre-treated with Mechanical Thrombectomy*
- *DiaMedica Completes \$8.5M Public Offering of Common Shares*
- *Cash and Investments of \$12.6 Million; Runway Through 2021*
- *Conference Call with Management Tomorrow, May 14 at 7am CT*

Minneapolis, Minnesota – May 13, 2020 (Business Wire) – DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for kidney diseases and neurological disorders, today announced positive top-line results from ReMEDy, its Phase II study in acute ischemic stroke (AIS), as well as provided a business update and financial results for the three months ended March 31, 2020. DiaMedica will host a conference call with slides tomorrow, May 14, 2020, at 7:00 a.m. Central Time to discuss its ReMEDy top-line data, business update and first quarter financial results. In conjunction with this release, DiaMedica also issued today a separate more detailed release on the ReMEDy top-line data.

Clinical Developments

DM199 for the Treatment of Acute Ischemic Stroke

DM199 Acute Ischemic Stroke Phase II “ReMEDy” Trial – Positive Top-Line Data

DiaMedica today announced positive top-line results from its ReMEDy trial, a Phase II study assessing the safety, tolerability and therapeutic potential of DM199 in participants suffering from AIS. Final enrollment was 92 participants. The markers of therapeutic efficacy included the National Institutes of Health Stroke Scale, Modified Rankin Scale and the Barthel Index and multiple plasma-based biomarkers (e.g. C-reactive protein). These markers were assessed at multiple points throughout the study, including 90 days post-stroke.

DM199 met primary safety and tolerability endpoints and no DM199-related serious adverse events were noted in the study. According to top-line phase II results, there was also a demonstrated therapeutic effect in participants who received tissue plasminogen activator (tPA) prior to enrollment, but not in participants receiving mechanical thrombectomy.

"We are very excited about the positive top-line results which continue to demonstrate the excellent safety profile of DM199 and efficacy signals which are consistent with the approval study for Kailikang®, the urine-derived form of KLK1 which has been used to successfully treat stroke patients in China for years," stated Rick Pauls, DiaMedica's President and CEO. "These results strengthen our belief that DM199 can be a valuable treatment option for stroke victims, improving outcomes while providing a significantly longer, up to 24 hours, after onset of the stroke. We look forward to discussing a path to commercialization with the FDA."

DM199 for the Treatment of Chronic Kidney Disease

Phase II Clinical Study in CKD Caused by IgA Nephropathy and in African Americans with Hypertension – Enrollment Continues

The Phase II REDUX (latin for restore) trial is a multi-center, open-label investigation of approximately 60 participants with chronic kidney disease (CKD), who are being enrolled in two cohorts (30 per cohort). The study is ongoing in the United States at 12 sites and targets participants with CKD: Cohort I is enrolling non-diabetic, hypertensive African Americans with Stage II or III CKD, a group which is at greater risk for CKD than Caucasians. African Americans who have the APOL1 gene mutation are at an even higher risk. The study is designed to capture the APOL1 gene mutation as an exploratory biomarker in this cohort. Cohort II is enrolling participants with IgA Nephropathy (IgAN). The overall study evaluates two dose levels of DM199. Study participants in each cohort will receive DM199 by subcutaneous injection twice weekly for 95 days. The primary study endpoints include safety, tolerability, blood pressure, proteinuria and kidney function, which will be evaluated by changes from baseline in estimated glomerular filtration rate (eGFR) and albuminuria, as measured by the urinary albumin to creatinine ratio (UACR).

Due to actions implemented to combat the novel strain of the coronavirus (COVID-19) pandemic, the Company is experiencing slower than expected enrollment in the REDUX clinical study as activities are reduced or suspended at the clinical study sites as they address staff and patient safety concerns. The Company currently expects a delay in the timing of costs incurred as a result of the COVID-19 pandemic, but not a significant overall increase. The Company will continue to assess the effect of the pandemic on its REDUX trial by monitoring the spread of the COVID-19 virus and the actions implemented to combat the virus.

“Our highest priority right now is to protect the safety of subjects and clinical staff participating in the REDUX trial, and we believe that we have accomplished that” commented Dr. Harry Alcorn, DiaMedica’s Chief Medical Officer. “While enrollment has significantly slowed, we believe that the measures taken will allow our study to resume more normal rates of enrollment as COVID-19 related restrictions are eased.”

Public Offering of Common Shares

On February 13, 2020, the Company issued and sold an aggregate of 2,125,000 common shares in a public, underwritten offering at a public offering price of \$4.00 per share. As a result of the offering, the Company received gross proceeds of \$8.5 million and net proceeds of \$7.7 million, after deducting the underwriting discount and offering expenses.

Financial Results

Research and development (R&D) expenses were \$1.4 million for the three months ended March 31, 2020, compared with \$2.6 million for the three months ended March 31, 2019, a decrease of \$1.2 million. The decrease was due to costs incurred during the first quarter of 2019 which did not reoccur during the first quarter of 2020, primarily the costs for a production run of the DM199 drug substance and the Phase Ib study in CKD patients. Declining costs for the ReMEDy study in the current year period also contributed to the decrease. These decreases were partially offset by costs incurred for the REDUX study, which began enrollment in December 2019, and increased non-cash share-based compensation costs.

General and administrative (G&A) expenses were \$1.0 million for the three months ended March 31, 2020, up from \$814,000 for the three months ended March 31, 2019. The increase in G&A expenses resulted primarily from increased non-cash share-based compensation costs.

Total other (income) expense, net, for the three months ended March 31, 2020 was a net expense of \$12,000, compared with net income of \$178,000 for the three months ended March 31, 2019. The change was primarily caused by the foreign currency transaction losses associated with funds held in non-functional currency (US dollar) accounts, principally Australian dollars. A decrease in R&D incentives, associated with decreased ReMEDy costs and reductions in interest income earned on marketable securities during the three months ended March 31, 2020, also contribute to this change.

Balance Sheet and Cash Flow

The Company had cash, cash equivalents and marketable securities of \$12.6 million, current liabilities of \$0.9 million and working capital of \$13.2 million as of March 31, 2020, compared to \$7.9 million in cash, cash equivalents and marketable securities, \$1.3 million in current liabilities and \$7.5 million in working capital as of December 31, 2019. The increases in the Company's combined cash, cash equivalents and marketable securities and in its working capital are due primarily to the February 2020 public offering of common shares.

Net cash used in operating activities was \$3.0 million for the three months ended March 31, 2020, compared to \$3.1 million for the three months ended March 31, 2019. The net cash used in each of these periods primarily reflects the net loss for these periods, offset by non-cash charges for stock-based compensation and adjusted for the net effects of changes in operating assets and liabilities.

Conference Call Information

DiaMedica Management will host a conference call to discuss both its first quarter 2020 financial results and the top-line results from its ReMEDy study on Thursday, May 14, 2020, at 7:00 a.m. Central Time:

Date: Thursday, May 14, 2020
Time: 7:00 AM CT / 8:00 AM ET
Web access: <https://event.on24.com/wcc/r/2158468/5BAA62D375A1F892573859D379BAF858>
Dial In: (833) 502-0492 (domestic)
(778) 560-2558 (international)
Conference ID: 8757888

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 events and presentations, following the earnings call and for 12 months thereafter. A telephonic replay of the conference call will be available until May 21, 2020, by dialing (800) 585-8367 (US Toll Free), (416) 621-4642 (International), replay passcode 8757888.

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 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 Korea for decades. DM199 is currently being studied in patients with chronic kidney disease and patients with acute ischemic stroke.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company focused on developing novel treatments for chronic kidney diseases and neurological disorders. DiaMedica shares are listed on The Nasdaq Capital Market under the trading symbol "DMAC."

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" 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 assessment of the data from the ReMEDy study and the future publication and sharing of the full study results, and regulatory path forward, the timing and requirements of its clinical programs, including enrollment and clinical results and ability to achieve clinical milestones. 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 additional clinical trials of DM199 or from subsequent analysis of existing data from the ReMEDy study or existing or new data received from additional ongoing and future studies 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 CKD and AIS 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; its reliance on collaboration with third parties to conduct clinical trials; its ability to continue to obtain funding for its operations, including funding necessary to complete planned clinical trials and obtain regulatory approvals for DM199 for CKD and AIS, 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, 2019, 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.

Contact:

Scott Kellen
Chief Financial Officer
Phone: (763) 496-5118
skellen@diamedica.com

DiaMedica Therapeutics Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

| | Three Months Ended March 31, | |
|---|---------------------------------|------------|
| | 2020 | 2019 |
| Operating expenses: | | |
| Research and development | \$ 1,381 | \$ 2,607 |
| General and administrative | 1,023 | 814 |
| Operating loss | (2,404) | (3,421) |
| Other (income) expense: | | |
| Governmental assistance - research incentives | (115) | (174) |
| Other (income) expense, net | 127 | (4) |
| Total other (income) expense | 12 | (178) |
| Loss before income tax expense | (2,416) | (3,243) |
| Income tax expense | 9 | 9 |
| Net loss | (2,425) | (3,252) |
| Other comprehensive income | | |
| Unrealized gain on marketable securities | 40 | 3 |
| Net loss and comprehensive loss | \$ (2,385) | \$ (3,249) |
| Basic and diluted net loss per share | \$ (0.19) | \$ (0.27) |
| Weighted average shares outstanding – basic and diluted | 13,107,725 | 11,956,874 |

DiaMedica Therapeutics Inc.
Consolidated Balance Sheets
(In thousands, except share amounts)

| | <u>March 31, 2020</u> | <u>December 31, 2019</u> |
|--|-----------------------|--------------------------|
| | (unaudited) | |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 3,300 | \$ 3,883 |
| Marketable securities | 9,348 | 3,995 |
| Amounts receivable | 985 | 823 |
| Prepaid expenses and other assets | 337 | 47 |
| Deposits | 195 | 88 |
| Total current assets | <u>14,165</u> | <u>8,836</u> |
| Non-current assets: | | |
| Operating lease right-of-use asset | 140 | 153 |
| Property and equipment, net | 60 | 64 |
| Total non-current assets | <u>200</u> | <u>217</u> |
| Total assets | <u>\$ 14,365</u> | <u>\$ 9,053</u> |
| LIABILITIES AND EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 444 | \$ 182 |
| Accrued liabilities | 435 | 1,076 |
| Finance lease obligation | 6 | 6 |
| Operating lease obligation | 50 | 54 |
| Total current liabilities | <u>935</u> | <u>1,318</u> |
| Non-current liabilities: | | |
| Finance lease obligation, non-current | 11 | 13 |
| Operating lease obligation, non-current | 96 | 105 |
| Total non-current liabilities | <u>107</u> | <u>118</u> |
| Shareholders' equity: | | |
| Common shares, no par value; unlimited authorized; 12,006,874 and 11,956,874 shares issued and outstanding, as of September 30, 2019 and December 31, 2018, respectively | — | — |
| Additional paid-in capital | 72,323 | 64,232 |
| Accumulated other comprehensive income | 42 | 2 |
| Accumulated deficit | (59,042) | (56,617) |
| Total shareholders' equity | <u>13,323</u> | <u>7,617</u> |
| Total liabilities and shareholders' equity | <u>\$ 14,365</u> | <u>\$ 9,053</u> |

DiaMedica Therapeutics Inc.
Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

| | Three Months Ended March 31, | |
|---|-------------------------------------|-----------------|
| | 2020 | 2019 |
| Cash flows from operating activities: | | |
| Net loss | \$ (2,425) | \$ (3,252) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based compensation | 393 | 130 |
| Amortization of discount on marketable securities | (14) | (26) |
| Non-cash lease expense | 13 | 12 |
| Depreciation | 6 | 6 |
| Changes in operating assets and liabilities: | | |
| Amounts receivable | (162) | (150) |
| Prepaid expenses | (290) | 72 |
| Deposits | (107) | — |
| Accounts payable | 262 | 201 |
| Accrued liabilities | (654) | (127) |
| Net cash used in operating activities | <u>(2,978)</u> | <u>(3,134)</u> |
| Cash flows from investing activities: | | |
| Purchase of marketable securities | (8,799) | (10,928) |
| Maturities of marketable securities | 3,500 | — |
| Purchase of property and equipment | (2) | — |
| Net cash used in investing activities | <u>(5,301)</u> | <u>(10,928)</u> |
| Cash flows from financing activities: | | |
| Proceeds from issuance of common shares, net of offering costs | 7,682 | — |
| Proceeds from the exercise of stock options | 16 | — |
| Principal payments on finance lease obligations | (2) | (2) |
| Net cash provided by financing activities | <u>7,696</u> | <u>(2)</u> |
| Net increase (decrease) in cash and cash equivalents | (583) | (14,064) |
| Cash and cash equivalents at beginning of period | <u>3,883</u> | <u>16,823</u> |
| Cash and cash equivalents at end of period | <u>\$ 3,300</u> | <u>\$ 2,759</u> |



DiaMedica Announces Positive Results in Top-Line Data from the Phase II ReMEDy Acute Ischemic Stroke Study

- *DM199 Met Primary Safety and Tolerability Endpoints in ReMEDy study Top-Line Data*
- *Demonstrated therapeutic Effect in Participants Not Pre-Treated With Mechanical Thrombectomy*
- *Reduced Risk of Recurrent Stroke*
- *Results Consistent with Clinical Studies of Approved Urinary Derived KLK1 in China*
- *Improvement in eGFR for pre-defined chronic kidney disease sub-group*

Company to discuss top-line data during its scheduled first quarter financial results conference call tomorrow at 8:00 am Eastern Time

Minneapolis, Minnesota, May 13, 2020 (Business Wire) – DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company developing novel treatments for neurological disorders and chronic kidney disease, announced today that DM199, a drug intended to restore KLK1 levels and the body's natural ability to regulate blood flow and reduce inflammation after an acute ischemic stroke (AIS), met primary safety and tolerability endpoints in the ReMEDy phase II study. Further, no DM199-related serious adverse events were noted in the study. According to top-line phase II results, there was also a demonstrated therapeutic effect in participants who received tissue plasminogen activator (tPA) prior to enrollment, but not in participants receiving mechanical thrombectomy.

The ReMEDy study enrolled 92 participants to assess DM199, a recombinant form of human tissue Kalikrein-1 (KLK1), a serine protease, or protein, which plays a critical role in local blood flow regulation and in reducing inflammation, in the treatment of participants who experienced an AIS. AIS occurs when a clot blocks blood flow through a brain artery and represents approximately 85% of all strokes in the United States. According to the U.S. Centers for Disease Control and Prevention (CDC), there are approximately 690,000 acute ischemic strokes in the United States annually, one quarter of which are recurrent strokes, or strokes occurring in people who have had a previous stroke.

Ninety-one (91) of the 92 ReMEDy study enrolled participants were evaluable for safety in this multi-center, double-blind, randomized, placebo-controlled study. Participants were enrolled within 24 hours of stroke symptom onset and received an initial administration of DM199 or placebo as an intravenous infusion, followed by subcutaneous injections every three days over the following three weeks.

Prior to enrollment, 44 of the 91 evaluable patients (48%) received a mechanical thrombectomy, a treatment indicated for those who have a large vessel occlusion and can be treated within six to 24 hours of the onset of stroke symptoms. While approximately 20% of AIS patients are believed to be eligible for a mechanical thrombectomy, currently only about 5 to 10% receive the treatment due to elapsed time post stroke or unavailability of the therapy at the hospital where they present. DM199 is intended to treat the approximately 90% of AIS patients who do not receive either mechanical thrombectomy or tPA. Treatment for these patients is limited to palliative therapies.

Due to the large volume of participants receiving mechanical thrombectomy prior to enrollment in the study (48%) and a disproportionate distribution between the active treatment and placebo groups, DM199 did not produce a therapeutic effect in the overall study analysis.

When participants treated with mechanical thrombectomy are excluded from the study data set, representing the group of participants most closely aligned with the target treatment population for DM199 noted above, a positive therapeutic effect was demonstrated. As shown in the table below, when evaluating the participants treated with DM199 (n=25) vs. palliative therapies and/or tPA (n=21), the results showed that 36% of participants receiving DM199 progressed to a full or nearly full recovery at 90 days (NIHSS: 0-1), compared to 14% of participants in the placebo group. This represents a 22% increase in the proportion of participants achieving a full or nearly full recovery. Additionally, subject deaths decreased from 24% in the placebo group to 12% in the active therapy group, a 50% reduction.

DM199 vs. Palliative Therapies and/or tPA

| | NIHSS Outcomes at 90 Days | | | |
|----------------|---------------------------|-----|-----|-------|
| | 0-1 | 2-8 | ≥ 9 | Death |
| Placebo (n=21) | 14% | 57% | 5% | 24% |
| DM199 (n=25) | 36% | 36% | 16% | 12% |

In addition, in the evaluable participants (n=91), a significant reduction in the number of participants with severe recurrent stroke was noted in the active treatment group: 1 (2%) patient treated with DM199 vs. 7 (16%) on placebo (p=0.028), with 4 of the 7 on placebo resulting in participant death.

Further, in reviewing evaluable participants (n=91), improvements in the following biomarkers were observed in participants treated with DM199, which the Company believes are consistent with the DM199 mechanism of action:

- Increased nitric oxide (+105%) and prostaglandin E2 (+54%) were observed at day 22 vs baseline (p<0.05). Placebo group was not statistically significant vs baseline (p>0.05). These changes noted in the active treatment group did not reach statistical significance compared to placebo.
 - Reduction in C-reactive protein (CRP) of (-70%), a blood marker of inflammation, at 90 days. CRP decreased significantly vs. baseline (p<0.05), but was not statistically significant vs. placebo. The change in the placebo group was not statistically significant vs. baseline (p>0.05).
 - Reduction in elevated glucose levels in participants with type 2 diabetes, as defined by a blood glucose level >7 mmol/L (n=14), an average decrease of 1.9 mmol/L (p=0.06) in blood glucose levels of participants on active therapy was observed at day 22. In comparison, participants in the placebo group (n=16) showed an average increase of 0.08 mmol/L (p=0.94) at day 22.
-

DiaMedica is also developing DM199 for the treatment of chronic kidney disease (CKD). Accordingly, changes in the estimated glomerular filtration rate (eGFR), a measure of kidney function, were analyzed in participants with eGFR <70 mL/Min/1.73² at baseline, which indicates the presence of CKD. Participants receiving DM199 exhibited a marked increase in eGFR at days 22 (last dose) and 56 (34 days post-treatment), as shown in the table below. Further the Company noted that eGFR at day 22 increased by at least 2 mL/Min in 77% of DM199 participants compared to 20% in placebo (p=0.007). DM199 is currently being evaluated in the REDUX phase II study for CKD.

| | eGFR Mean Δ from Baseline (mL/Min/1.73 ²) | |
|-------------------------|---|----------------------------------|
| | Day 22 (Last Dose) | Day 56 (Off Treatment) |
| Placebo | +0.84 (n=15) | -0.24 (n=12) |
| DM199 | +7.5 (n=13) | +5.8 (n=12) |
| Group Difference | +6.6 | +6.1 |

“These findings are consistent with Chinese data on the urine-derived form of KLK1 and provide a signal that recombinant human KLK1 appears safe and may have promise as a new tool for physicians who have limited options for the treatment of patients suffering acute ischemic stroke,” said Professor Bruce Campbell, BMedSc, PhD, FRACP, FAHMS Neurologist, Head of Stroke Department of Neurology at the Royal Melbourne Hospital.

DiaMedica’s President and CEO, Rick Pauls, said: “Very few patients have a treatment option for AIS today. Approximately 10% of patients receive tPA or mechanical thrombectomy and we are developing DM199, with a 24 hour therapeutic treatment window, to significantly expand the proportion of patients who have access to effective and safe treatment.” Mr. Pauls continued, “It’s also very encouraging to see data suggesting that DM199 treatment may mitigate the adverse impact of ischemic stroke on kidney function, a significant but poorly understood comorbidity in many stroke victims.”

The detailed results of the ReMEDy trial has been accepted for E-Poster discussion at the joint European Stroke Organisation and World Stroke Organization Conference (ESO-WSO 2020), to be held in Vienna, Austria on November 7, 2020 and will also be submitted for publication.

DiaMedica intends to request a meeting with the FDA to define the development program leading to a path to commercialization for acute ischemic stroke.

Conference call and webcast information

DiaMedica will host a live conference call and webcast on Thursday May 14, 2020 at 7:00 am Central Time to discuss the top-line phase II data.

Conference Call details:

Date: Thursday, May 14, 2020
Time: 7:00 AM CT / 8:00 AM ET
Web access: <https://event.on24.com/wcc/r/2158468/5BAA62D375A1F892573859D379BAF858>
Dial In: (833) 502-0492 (domestic)
(778) 560-2558 (international)
Conference ID: 8757888

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 events and presentations, following the earnings call and for 12 months thereafter. A telephonic replay of the conference call will be available until May 21, 2020, by dialing (800) 585-8367 (US Toll Free), (416) 621-4642 (International), replay passcode 8757888.

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 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 Korea for decades. DM199 is currently being studied in patients with chronic kidney disease and patients with acute ischemic stroke.

About DiaMedica Therapeutics Inc.

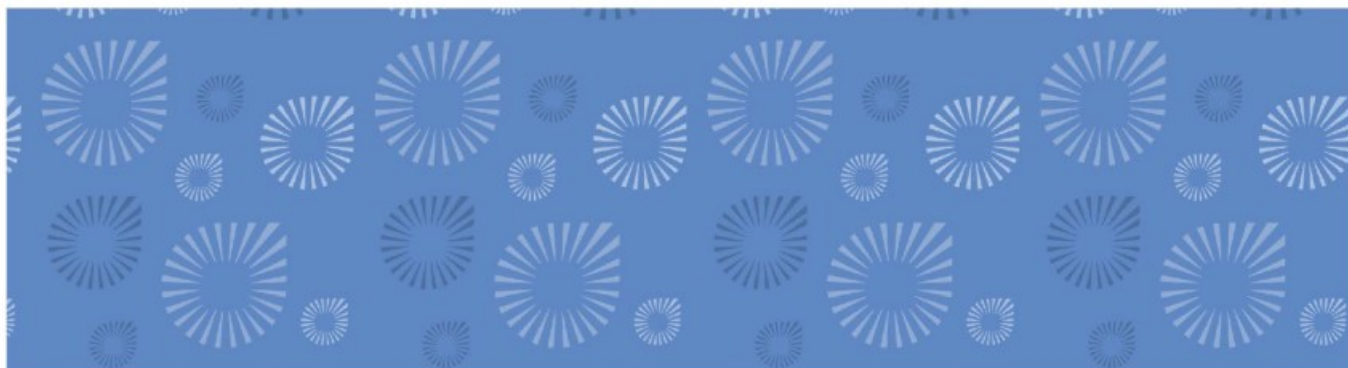
DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company focused on developing novel treatments for neurological and kidney diseases. DiaMedica's common shares are listed on The Nasdaq Capital Market under the trading symbol "DMAC."

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 "may," "expects," "intends," "estimates," "believes," "anticipates," "plans," "continue," "will", 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, but not limited to, the anticipated clinical benefits and success of DM199; the safety and efficacy of DM199; the assessment of the data from the ReMEDy study and the future publication and sharing of the full study results, and regulatory path forward. 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 additional clinical trials of DM199 or from subsequent analysis of existing data from the ReMEDy study or existing or new data received from additional ongoing and future studies 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 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; its reliance on collaboration with third parties to conduct clinical trials; its ability to continue to obtain funding for its operations, and the risks identified under the heading "Item 1.A. Risk Factors" in DiaMedica's annual report on Form 10-K for the fiscal year ended December 31, 2019 as filed with the SEC on March 23, 2020 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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Nasdaq: DMAC

**ReMEDy PII Trial
Acute Ischemic Stroke
Top-Line Results**

May 14 2020



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, 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 acute ischemic stroke (AIS); the timing of the Company's clinical programs; the safety and efficacy of DM199; the assessment of the data from the ReMEDy study and the future publication and sharing of the full study results, and regulatory path forward. 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, the possibility of unfavorable results from additional clinical trials of DM199 or from subsequent analysis of existing data from the ReMEDy study or existing or new data received from additional ongoing and future studies 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 ability to conduct successful clinical testing of DM199 and within its anticipated parameters, costs and timeframes; DiaMedica's plans to develop, obtain regulatory approval for and commercialize its DM199 product candidate for the treatment of AIS and its expectations regarding the benefits of DM199; the potential size of the markets for DM199 and the Company's ability to serve those markets; the reliance on collaboration with third parties to conduct clinical trials; its ability to obtain funding for its operations, 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, 2019 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.

KEY TAKEAWAYS FROM REMEDY PHASE II STUDY

- 1 **DM199 was safe and well tolerated** – Administered to over 200 participants; positive safety profile which de-risks regulatory pathway
-

- 2 **DM199 outperformed placebo in AIS patients** who did not receive mechanical thrombectomy (MT) prior to enrollment (N=46)
 - Results compare favorably to Alteplase® (recombinant tPA) Phase III approval study & comparable to Kailikang® (urinary KLK1)
 - Represents DM199 target patient population (the ~90%)
 - 24-hour therapeutic window (vs. less than 4.5-hours with tPA)
-

- 3 **Reductions in recurrent stroke and the inflammatory biomarker C-Reactive Protein**
 - Key benefits over and above near-term recovery of ability to function independently
-

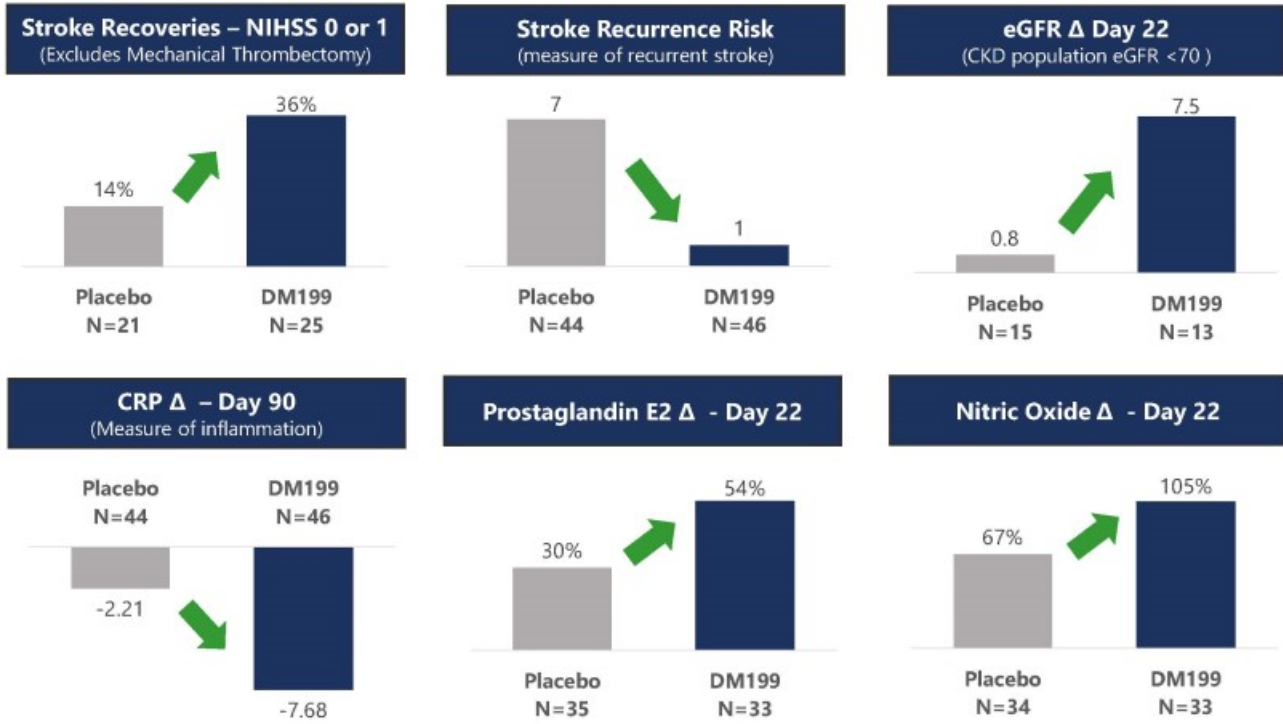
- 4 **Improvement in kidney function (eGFR)** for subjects with Chronic Kidney Disease* (N=28)
-

Potential Treatment Option Up to 24 Hours Post Acute Ischemic Stroke (AIS)

* CKD definition based on eGFR at baseline of <70 ml/min, a pre-defined study endpoint

ENCOURAGING TRENDS OBSERVED IN REMEDY

Multiple Measurements Reinforce Therapeutic Potential of DM199 and its Mechanism of Action



**REMEDY PHASE II
AIS RESULTS**



SIGNIFICANT UNMET NEED IN STROKE

Stroke is a Devastating Condition in Great Need of Treatment Options

Acute Ischemic Stroke (AIS)

Blockage of blood flow in brain

- 15 million strokes worldwide
- Prevalence in US: ~690,000 per year
 - Stroke occurs every 40 seconds
 - Stroke death occurs every 4 minutes
- 25% of strokes are recurrent strokes
- 2nd leading cause of death in developed countries
- ~10% of AIS patients receive Alteplase® (tPA) or mechanical thrombectomy
 - tPA must be administered within 4.5 hours of AIS



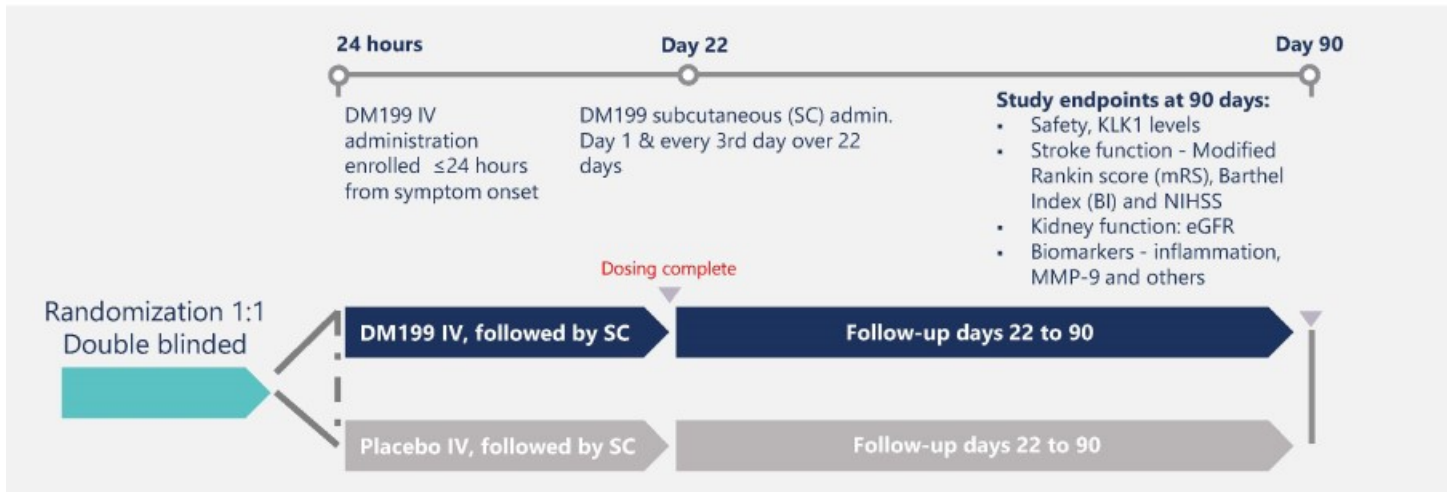
Approximately 90% of AIS Patients Only Receive Palliative Therapy

Note: throughout this presentation, unless otherwise noted, any references to "stroke" shall refer to acute ischemic stroke and not hemorrhagic stroke.

DM199 REMEDY TRIAL DESIGN: PHASE 2 ACUTE ISCHEMIC STROKE STUDY

Phase II – first dose IV within 24 hours of stroke followed by 21-days subcutaneous (SC) treatment

- 92 participants enrolled; 91 evaluable participants
- Mild-moderate stroke severity (NIHSS score 6 to 25) at treatment
 - Patients who received mechanical thrombectomy, tPA or both, with eligible NIHSS score measured up to the 24 hours post stroke event, were allowed into the study



SUMMARY OF DM199 BASELINE CHARACTERISTICS

| <i>Safety N=91</i> | Placebo (N=45) | DM199 (N=46) |
|-----------------------------|-------------------|-----------------|
| Age (Years) | | |
| Mean | 71.7 | 69.9 |
| Range | 31-95 | 38-95 |
| Sex n (%) | | |
| Male | 28 (62.2%) | 25 (54.3%) |
| Female | 17 (37.8%) | 21 (45.7%) |
| NIHSS Baseline Score | | |
| Mean | 12.2 | 11.3 |
| Median | 10 | 10 |
| Administered | | |
| tPA | 18% | 28% |
| Mechanical Thrombectomy | 27% | 35% |
| tPA + MT | 27% | 11% |

DM199 SAFE & WELL-TOLERATED

DM199 Has Now Been Administered to Over 200 patients

- DM199 was safe and well-tolerated (primary end points)
- No DM199-related serious adverse events (SAEs)
 - All evaluations confirmed by independent data safety monitoring board
- The most commonly reported adverse events were:
 - Constipation (28 DM199 / 14 in Placebo)
 - Nausea (9 DM199 / 4 with Placebo)
 - Headache (7 DM199 / 5 Placebo)

**Strong Safety Profile - Should Simplify Approval Decisions by Regulatory Authorities.
"De-risking Regulatory Path"**

STROKE PHASE SHIFT ANALYSIS

- The NIH Stroke Scale Score (NIHSS) is a tool used to quantify patient impairment caused by a stroke:
 - Grades various cognitive, motor, speech and sensory tests
 - The NIHSS stroke score can range from 0 (full recovery) to 42 (death)
- The phase shift analysis compares subject improvement (“the shift”) in outcomes across the entire range of scores between the active treatment and placebo groups
 - NIHSS phase shift analysis was used as a primary endpoint in the Phase III approval study of Alteplase® (tPA), the only FDA approved drug for stroke
- The bookends (0-1 and death) of the NIHSS scoring have the least subjectivity & most importance to regulatory authorities

NIHSS Phase Shift Categories



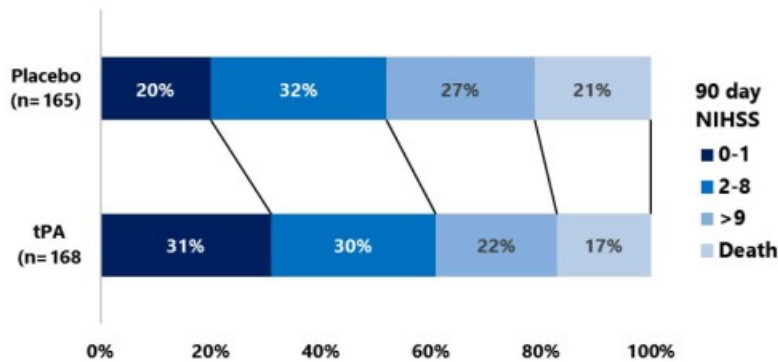
tPA (ALTEPLASE®) PHASE III STROKE IMPROVEMENT - NIHSS

REFERENCE

tPA is the Only FDA-Approved Drug Therapy for AIS

- Original approval of tPA was for use within 3 hours of stroke onset
- Approval study :
 - 11% absolute increase in full recovery (+55%), NIHSS 0-1
 - 4% absolute reduction in deaths (-19%)

tPA Phase III Trial (Treatment Within 3 Hours)¹

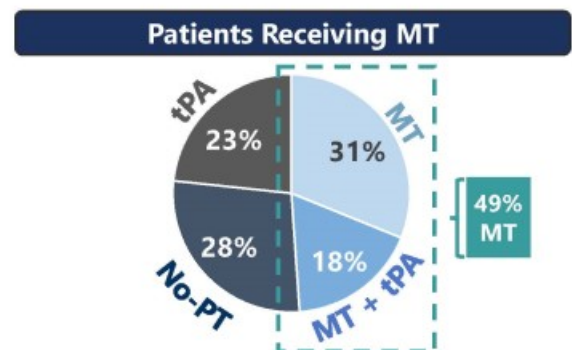
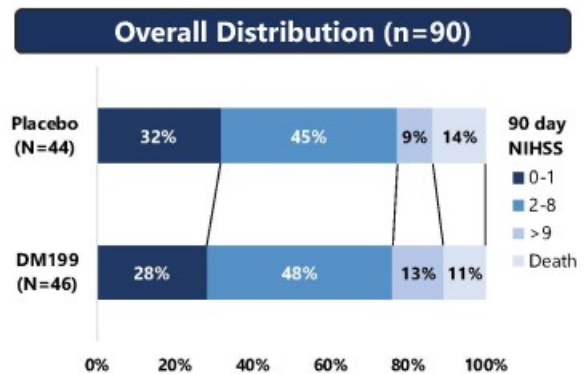


1. New England Journal of Medicine, Volume 333, Number 24, December 14, 1995
(Treatment window expanded to up to 4.5 hours with decreased efficacy)

DISPROPORTIONATE WEIGHTING OF MECHANICAL THROMBECTOMY IMPACTS OVERALL STUDY RESULTS

Future Efficacy Trials Focus on Targeted Patient Population (Excluding MT)

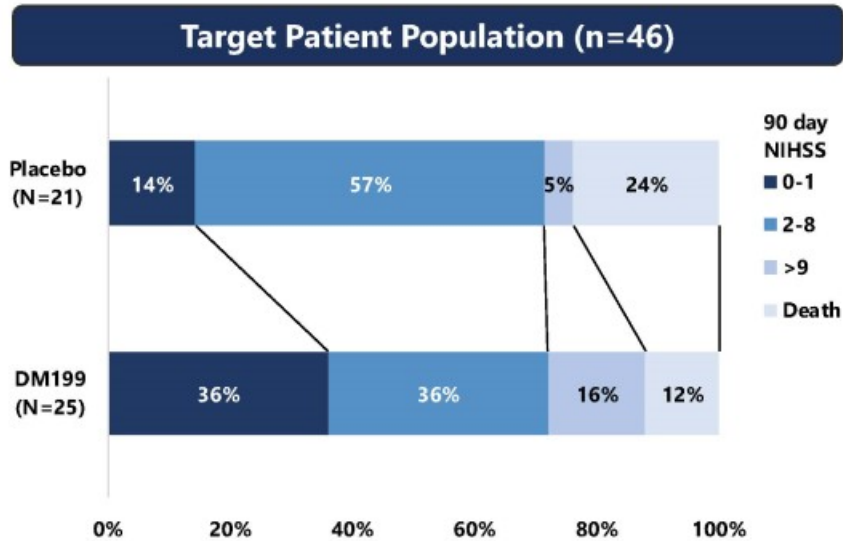
- Mechanical thrombectomy (MT) is a catheter-based procedure intended to physically remove the clot
 - Procedure possible for patients with large vessel occlusions who present at qualified medical institutions
- 49% of patients in REMEDY had MT performed
 - ~6% of patients undergo this procedure in the US
- Majority of patients receiving both MT+tPA patients fell into placebo group
 - 6 of 12 MT+tPA patients in Placebo group fully recovered compared to 0 of 5 in DM199 group



DM199 NIHSS SHIFT ANALYSIS: TARGET PATIENT POPULATION (EXCLUDE MT)

DM199 Increased Full and Near-Full Recoveries (+157%) and Reduced Deaths (-50%)

24 Hour Therapeutic Window (~6x tPA)

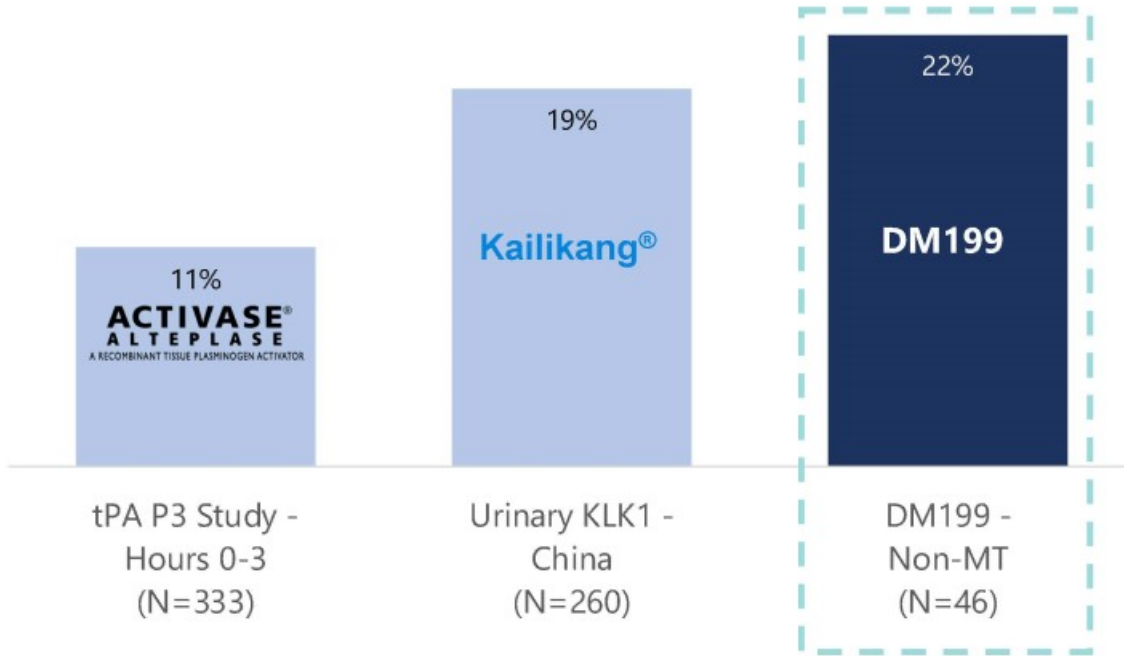


DM199 Showed Positive Efficacy Signal in Group Most Closely Aligned with Target Patient Population

DM199 RESULTS VS. tPA & KAILIKANG APPROVAL STUDIES

tPA is the Only FDA-Approved Drug for AIS

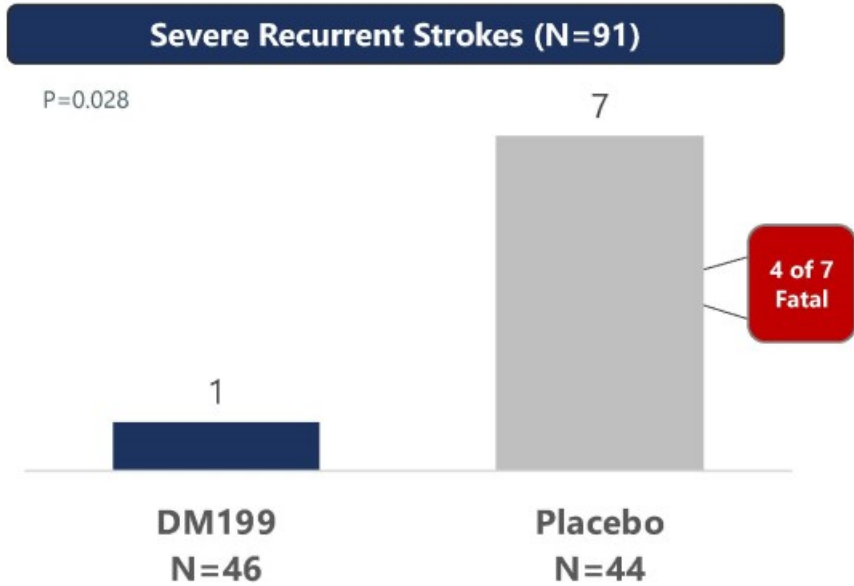
Full Recoveries – Increase in % of NIHSS Scores of 0-1 vs. Placebo*



1. New England Journal of Medicine, Volume 333, Number 24, December 14, 1995
2. Chen et al. Brain Behav. 2020;10:e01461.

DM199 REDUCED RECURRENT STROKES

DM199 Lowered Risk of Recurrent Stroke vs. Placebo
Results Consistent with Kailikang[®], Human Urinary KLK1¹



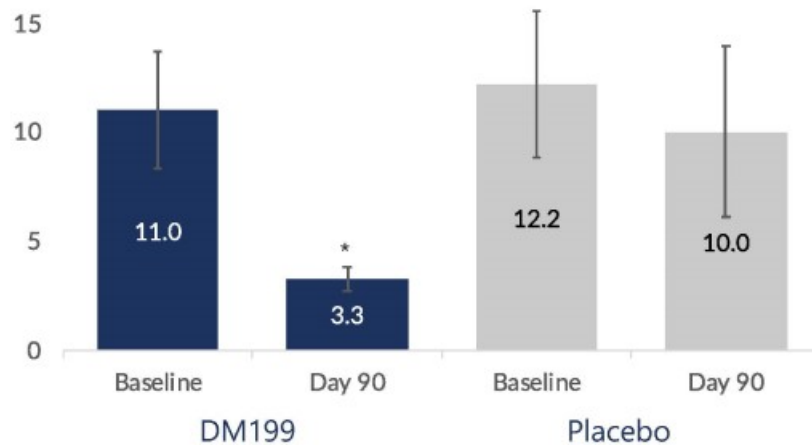
DM199 May Reduce Recurrent Strokes

1. Brain Behav, Human Urinary Kallidinogenase decreases recurrence risk and promotes good recovery, 2018:8e01033.

DM199 SIGNIFICANTLY REDUCES C-REACTIVE PROTEIN (CRP) KEY INFLAMMATION BIOMARKER

Observed Decrease in DM199 Treated Subjects

CRP Levels – Baseline to Day 90



DM199 Reduced High Cardiovascular Risk (CRP 3 – 10 mg/L)

DM199 CRP decreased significantly vs baseline ($p < 0.05$). Placebo group was not statistically significant vs baseline ($p > 0.05$). These changes did not reach statistical significance compared to placebo

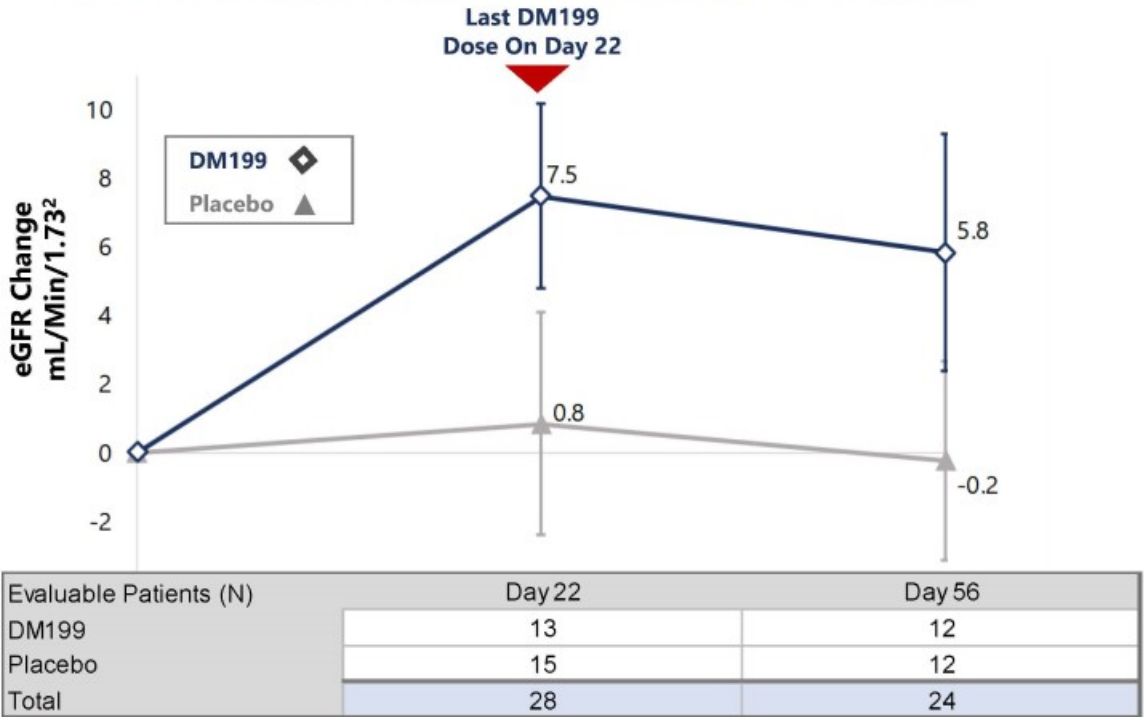
**eGFR & GLUCOSE
BIOMARKERS**



CHANGE IN KIDNEY FUNCTION – eGFR < 70 ML/MIN

(Pre-Defined Endpoint: eGFR < 70 mL/Min/1.73² at Baseline)

DM199 Increased eGFR +7.5 mL/Min vs Baseline (p=0.017) at Day 22
Trend in eGFR Improvement Maintained 34 Days After Last Dose



Day 22: DM199 increased +6.6 vs. placebo (p=0.14)

Day 56 (34 days off drug): DM199 +6.1 vs. placebo (p=0.19)

eGFR CHANGES @ DAY 22 (LAST DOSE)

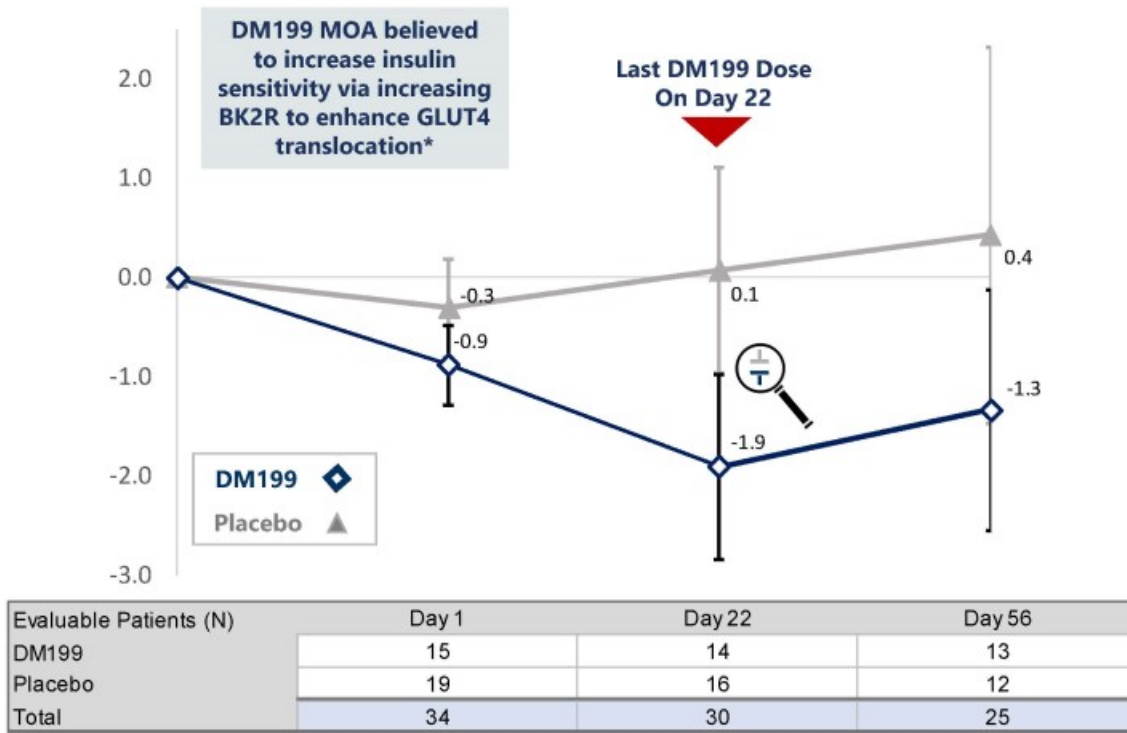
Greater Proportion of DM199 Patients with Increased Kidney Function

| eGFR Δ | % of patients (n=28) | | | P-Value* |
|---------------|----------------------|----------------|----------|----------|
| | DM199 (N=13) | Placebo (N=15) | Δ | |
| +0 mL/Min | 85% | 40% | + 45% | 0.02 |
| +1 mL/Min | 77% | 27% | + 50% | 0.01 |
| +2 mL/Min | 77% | 20% | + 57% | 0.007 |
| +3 mL/Min | 62% | 20% | + 42% | 0.35 |



CHANGE IN GLUCOSE – BASELINE > 7 MMOL/L

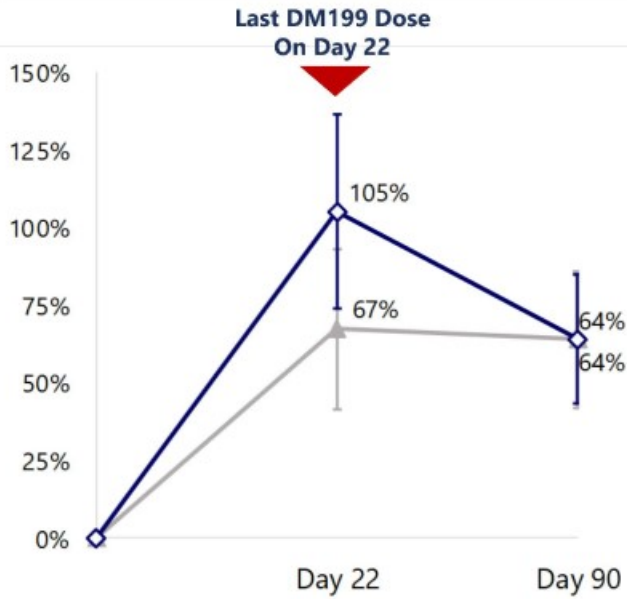
DM199 Reduced Elevated Blood Glucose Levels by 1.9 Mmol/L vs Baseline (P=0.06) at Day 22



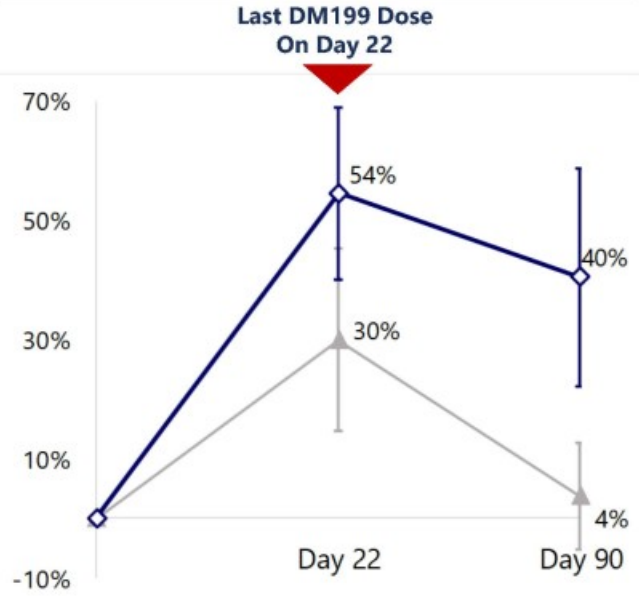
CHANGES IN KEY MECHANISM BIOMARKERS (NO & PGE2)

DM199 Trend in Increased Nitric Oxide and Prostaglandin (PGE2) Levels

Change in Nitric Oxide (Serum)



Change in PGE2 (Serum)



DM199¹ ◆ Placebo² ▲

1. DM199: NO – N=33 and N=28 at day 22 and 90, respectively | PGE2 –N=33 and N=29 at day 22 and 90, respectively
2. Placebo: NO – N=34 and N=25 at day 22 and 90, respectively | PGE2 –N=34 and N=26 at day 22 and 90, respectively

**CONCLUSIONS
& NEXT STEPS**



KEY TAKEAWAYS FROM REMEDY PHASE II STUDY

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-

Potential Treatment Option Up to 24 Hours Post Acute Ischemic Stroke (AIS)

* CKD definition based on eGFR at baseline of <70 ml/min, a pre-defined study endpoint

NEXT STEPS

Remedy Study Results Are Encouraging and Support Moving to the Next Level

1

Meet with Regulators to Discuss ReMEDy Results, Future AIS Study Requirements and Breakthrough Therapy / Accelerated Review

2

Engage SAB, Health Economists and Payers to Design and prepare for Phase II/III Study

3

Evaluate Potential Strategic Partnerships

- 
- Maintain Tight Fiscal Discipline
 - Laser-Focused On Completion of REDUX PII Study for CKD patients (60 patients)

DiaMedica Well Capitalized with \$12.6M of Cash and No Debt as of 3/31/20

KEY UPCOMING PHASE II MILESTONE IN CKD

Ongoing 60 Patient Phase II Study in CKD

REDUX PHASE 2 CKD

Trial Design

- Two cohorts: IgA Nephropathy and Hypertensive African Americans (non-diabetic), with 30 patients in each
- Accessing two dose levels of DM199: 2 and 5 µg/kg (SubQ dosing 2x weekly)
- Key Eligibility Criteria: eGFR 30 – 90 ml/min, Proteinuria 150 – 5,000 mg/g
- Key Endpoints: Safety, PK/PD, eGFR, and Albumin to Creatine Ratio (UACR)

Enrollment Status:

- Began enrolling patients in Dec of 2019
- Enrollment delayed due to COVID, with expectation to pickup
- No patient drop-outs due to COVID

IgA Nephropathy

- Rare form of CKD caused from damage to the glomerulus (filters) by build up of IgA protein
- 140,000 patients in the U.S., 200,000 in EU, and more than 2 million in China
- 50% of IgAN patients progress to end-stage renal diseases within 10-20 years

Hypertensive African Americans

- High unmet need – 5.9 million AA in the U.S. with CKD (3x – 4x more likely to suffer kidney failure than Caucasians)
- Hypertension is 2nd leading cause of kidney failure among AA; salt sensitivity may be a contributing factor to hypertension
- APOL1 gene mutation confers significantly higher risk of progressing to end-stage kidney disease

Q&A

