



DM199 REDUX Phase 2 CKD Interim Results

June 29 2021

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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

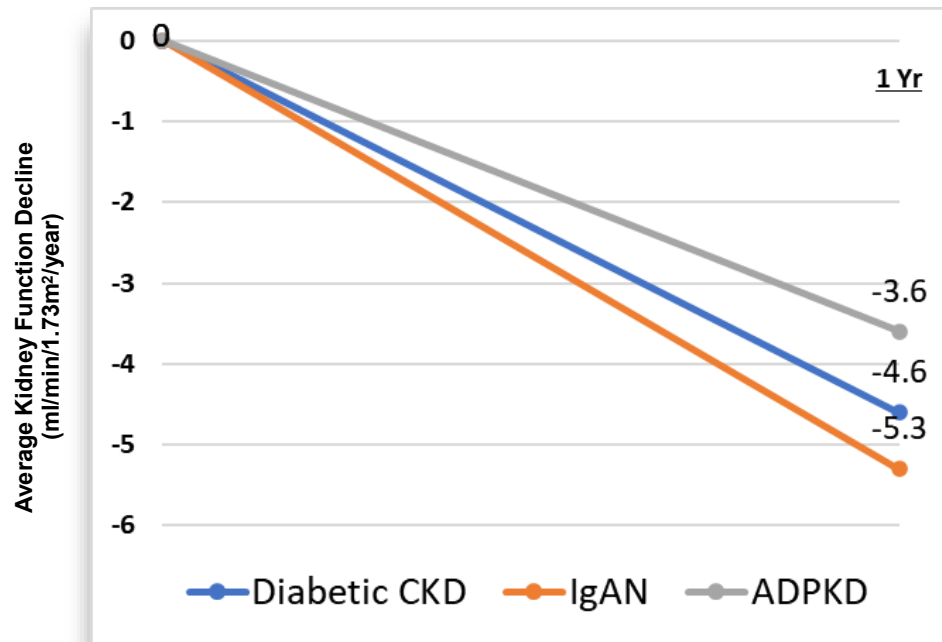
- ~6 million African Americans with CKD
- 3x – 4x more kidney failure than Caucasians
- Exhibit lower KLF1 levels and lower renal blood flow
- APOL1 gene mutation = higher risk of ESRD
 - Potential rare disease

Diabetic Kidney Disease (DKD)

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

CKD Patients - Kidney Function Worsens Over Time

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



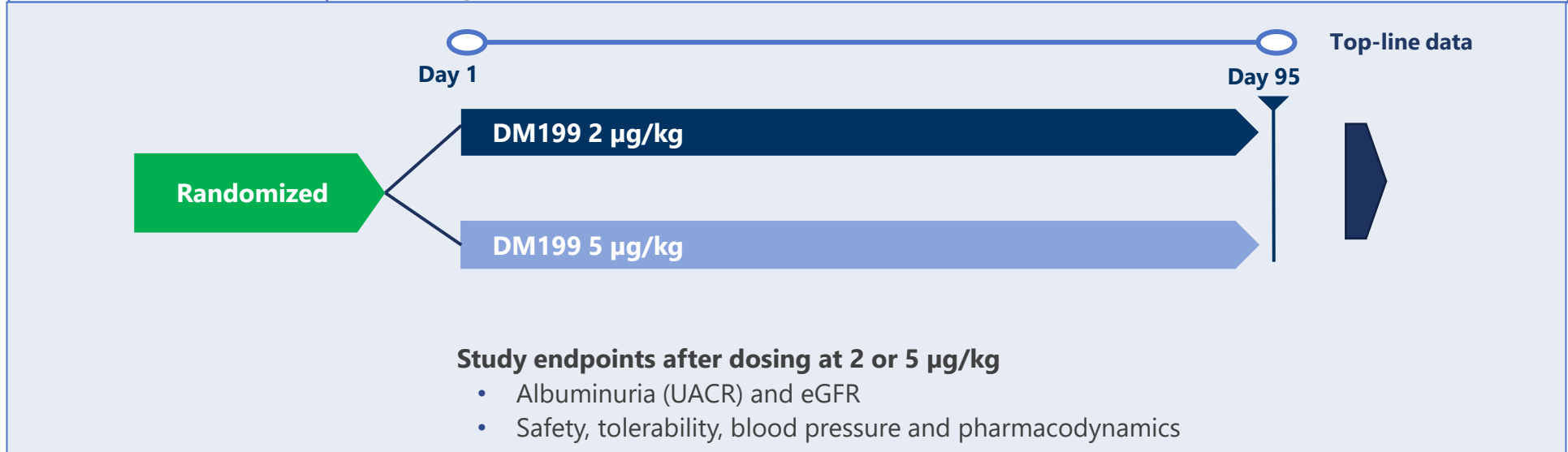
- Slowing eGFR decline an important endpoint in kidney disease
- Reducing UACR is a surrogate endpoint for predicting kidney disease progression and allows for earlier measurement of a therapeutic impact on kidney disease

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

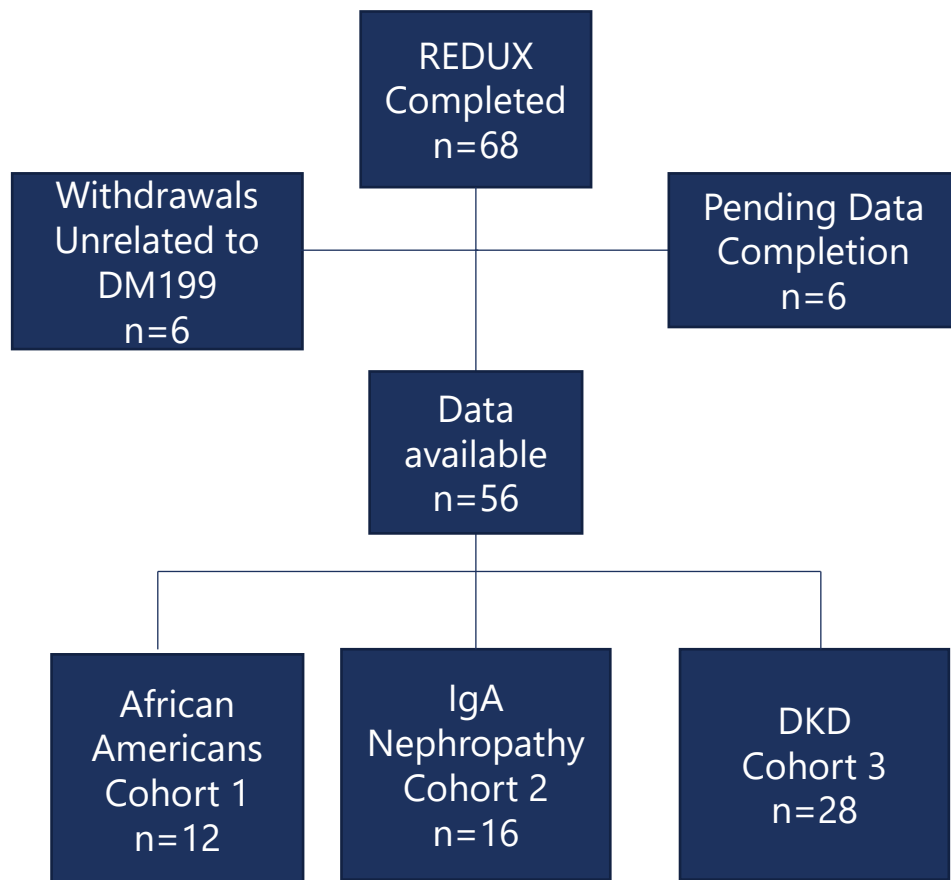
DM199 REDUX Phase 2 CKD Study Design

Study Includes 3 Distinct Causes of CKD

Design	Phase 2, Open Label, Multi-Center (14 US Sites), Randomized Study of 2 Dose Levels		
Sample Size (3 Cohorts)	African Americans, hypertensive with CKD IgA Nephropathy Diabetic Kidney Disease	Target n=~30 n=~30 n=~30	Interim Analysis n=14 n=17 n=31
Eligibility Criteria	eGFR 30-90 mL/min Albuminuria: 150 – 5,000		
Treatment	95 days of treatment SC dosing, 2x week		



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

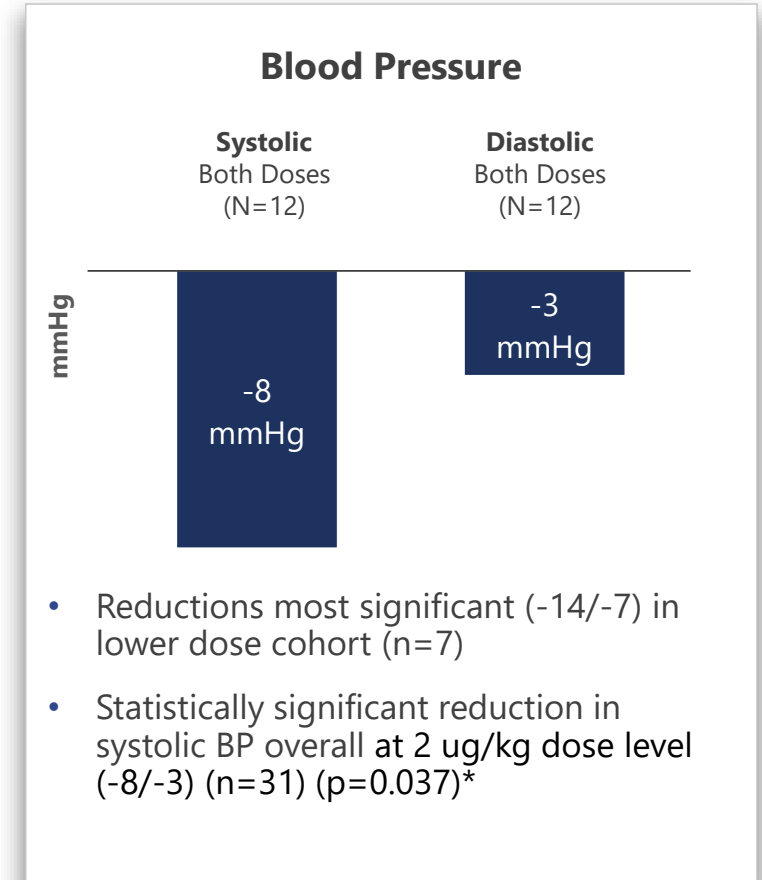
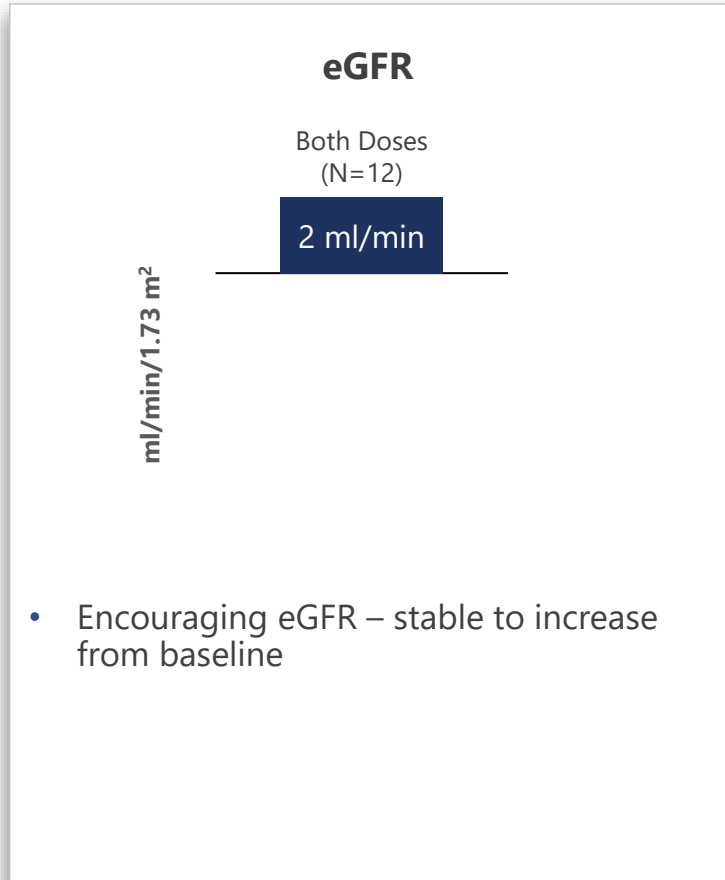
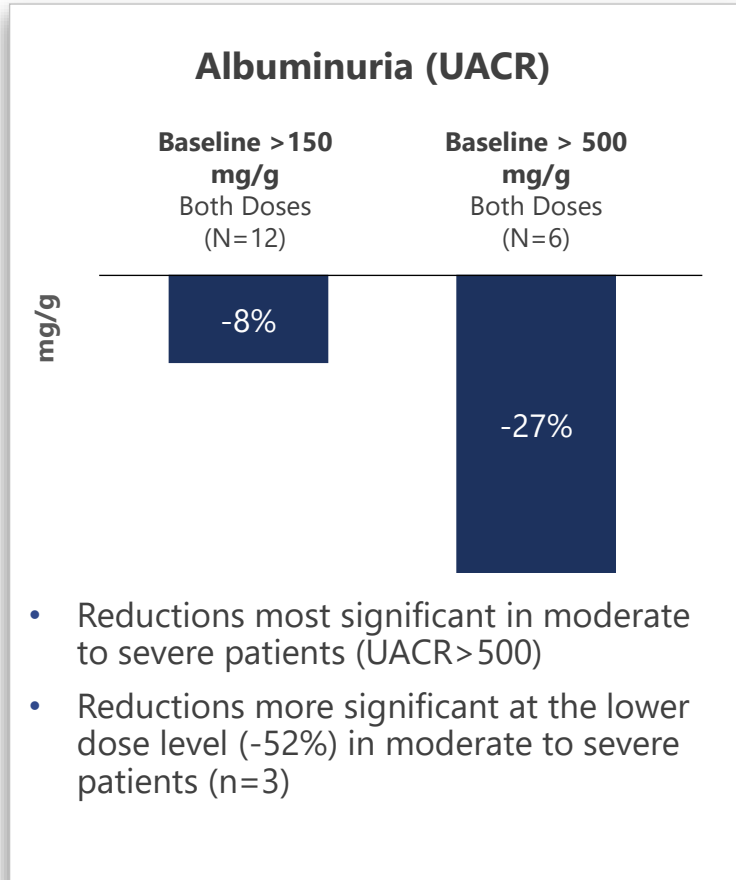
Excellent Safety and Tolerability of DM199 - Consistent with Earlier Studies

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

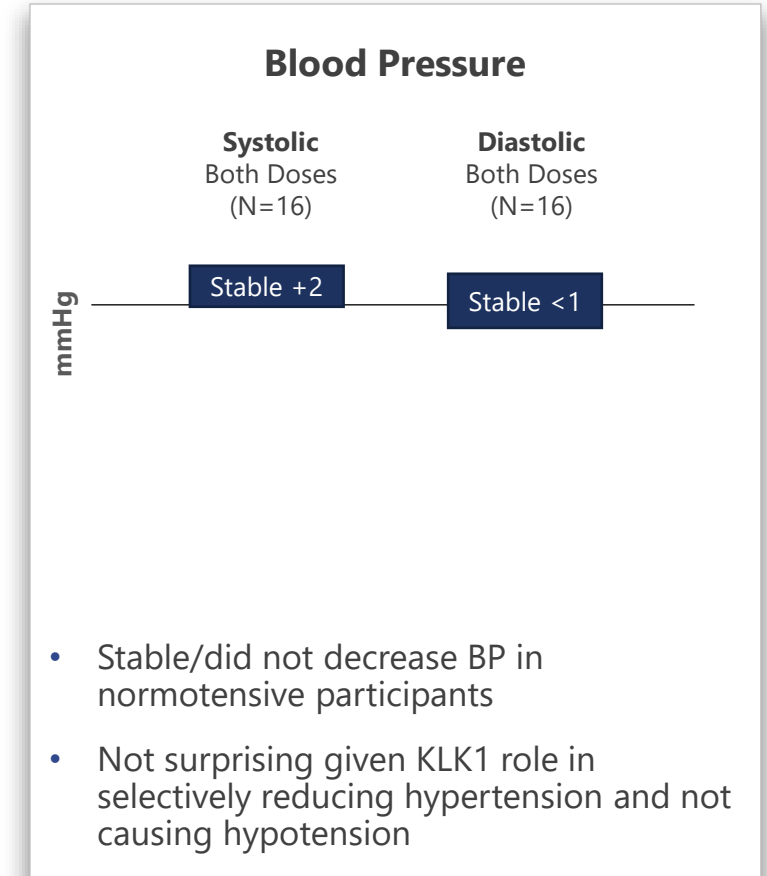
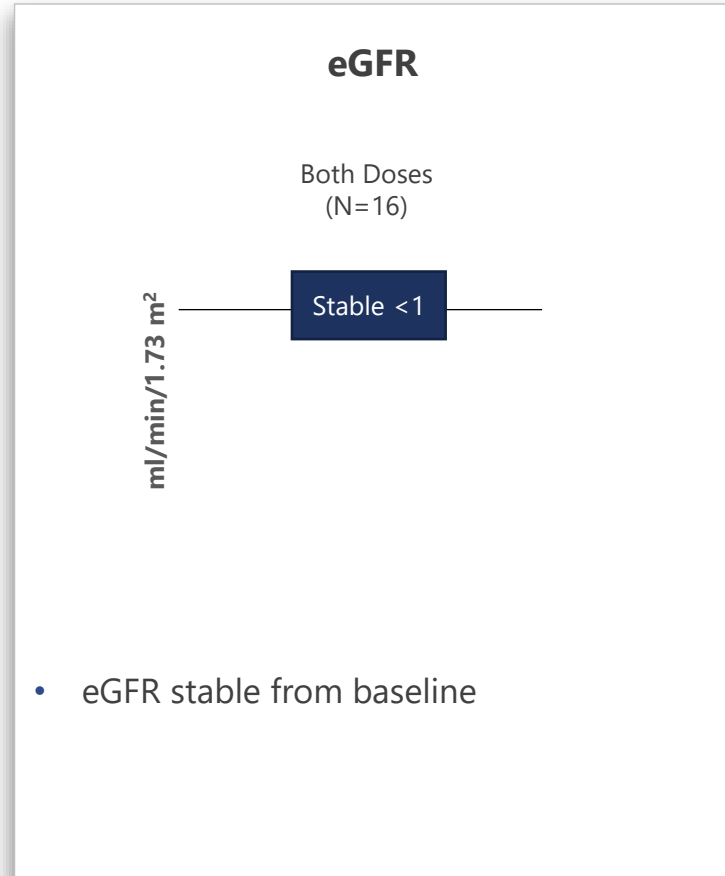
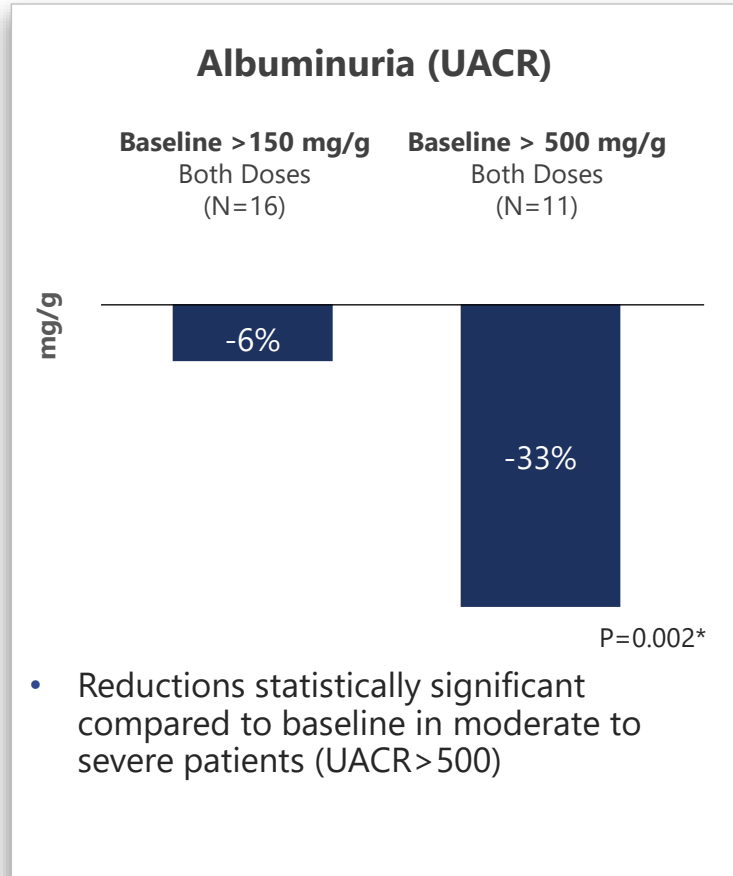
Hypertensive African Americans with CKD – Interim Analysis

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



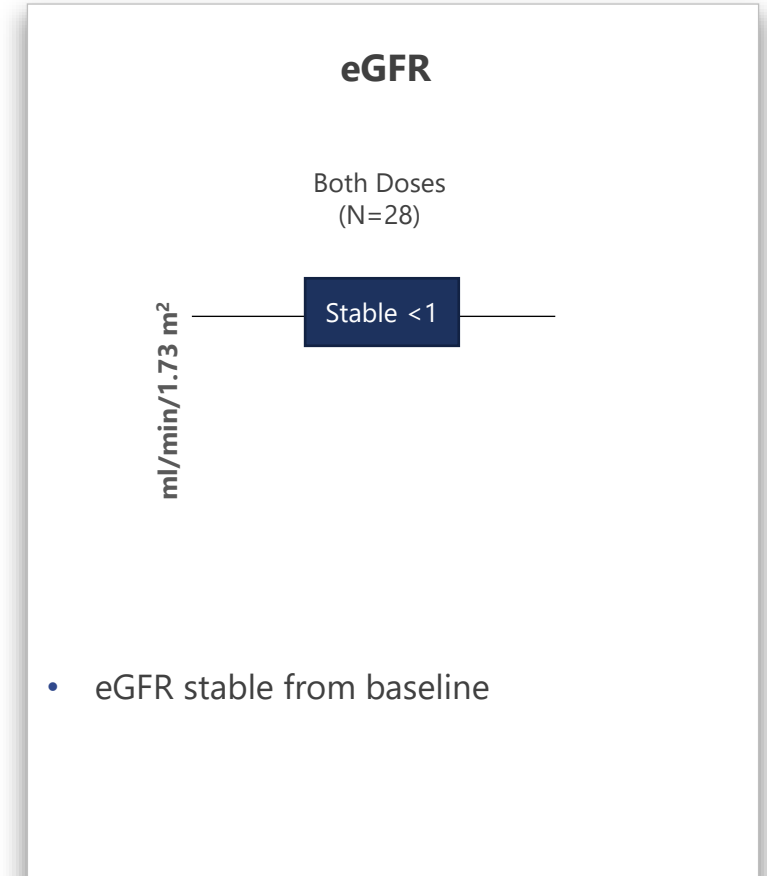
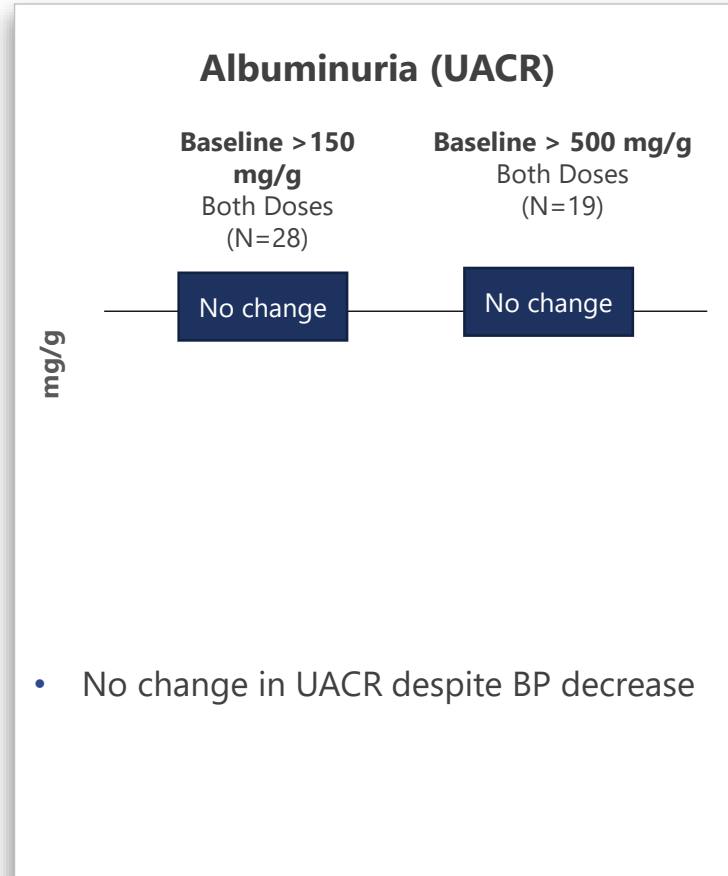
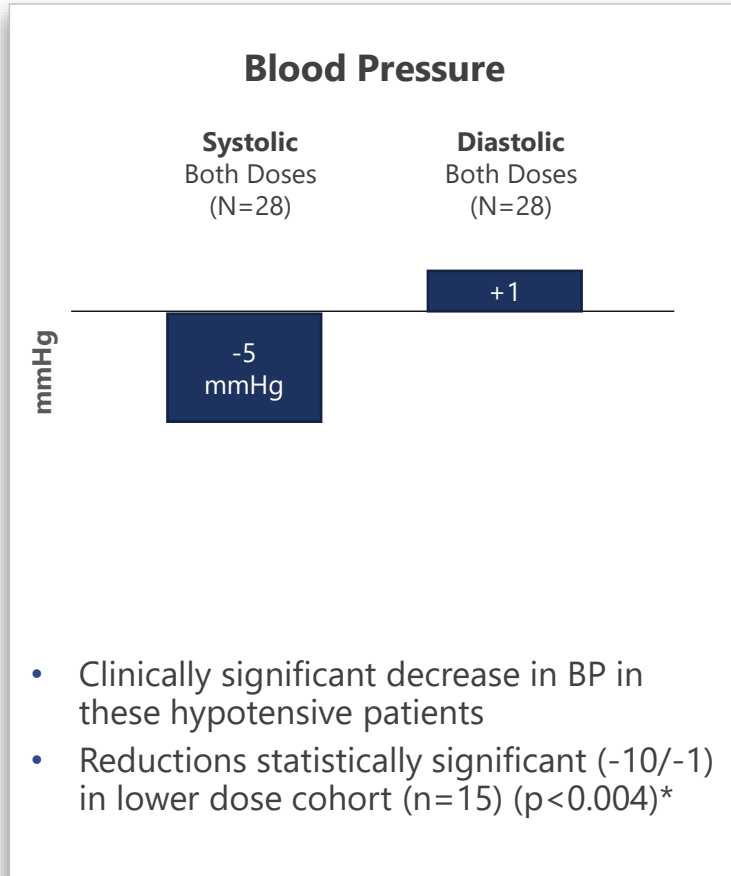
IgA Nephropathy – Interim Analysis

Positive Signals in Decreasing UACR and Stabilizing eGFR



Diabetic Kidney Disease – Interim Analysis

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



Interim Results Affirm Biological Activity and Safety of DM199

Consistent with MOA and Approved KLK1 Product in Asia

- ✓ **Clinically relevant signals in patient 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



NASDAQ: DMAC



Thank you!