Dimerix

For Immediate Release

DIMERIX ANNOUNCES POSITIVE ADDITIONAL DATA TO SUPPORT DMX-200 DEVELOPMENT IN KIDNEY DISEASE

- DMX-200 demonstrated a reduction in proteinuria across both Phase 2 studies and a clear benefit to patients with both FSGS and diabetic kidney disease
- DMX-200 reduced inflammatory biomarker by 39% versus placebo: translates to reduced inflammation and subsequent fibrosis
- Inflammatory biomarker data supports previously announced positive data for both studies
- Following detailed review of the FSGS data, the Medical Advisory Board unanimously agrees with progression of DMX-200 to a pivotal study in FSGS patients
- DMX-200 safe and well-tolerated across all studies to date; benefits outweigh any potential risk to patients
- Preparation of pivotal FSGS clinical study underway with pathway to accelerated approval

MELBOURNE, Australia, 27 October 2020: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, is pleased to announce new positive data from both the Phase 2a clinical study in Focal Segmental Glomerulosclerosis (FSGS) patients and the Phase 2 clinical study in diabetic kidney disease patients that supports the continued development of DMX-200 in kidney diseases. The additional data can be seen in the updated Investor Presentation attached, and is also available on the Dimerix website, www.dimerix.com.

DMX-200 treatment resulted in a decline in proteinuria in FSGS patients and in diabetic kidney disease patients in all treatment groups across both Phase 2 clinical studies (slides 9, 12, 17 and 19 in the attached presentation). Additionally, for diabetic kidney disease patients with a marginally higher starting baseline, treatment with DMX-200 versus placebo showed statistically significant reduction in proteinuria versus placebo. The Medical Advisory Board unanimously agrees that the encouraging data supports the ongoing development of DMX-200, and that it should be confirmed by a larger pivotal randomised controlled trial for patients with FSGS as was discussed between Dimerix and the FDA in November 2019.

A high correlation was observed between the severity of patient proteinuria and the molecular target of DMX-200 – an inflammatory molecule called Monocyte Chemoattractant Protein-1 (MCP-1) – across both studies (slides 11 and 18 in the attached presentation). In addition to the reduction in proteinuria, DMX-200 reduced the inflammatory biomarker MCP-1 by 39% versus placebo in the FSGS study and this translates to reduced inflammation and subsequent fibrosis (scarring) in the kidney. The data further supports the proposed mechanism of action of DMX-200 being effective in diseases where active inflammatory processes are driving disease progression.

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An order of treatment effect was noted in both FSGS and diabetic kidney disease studies, where the treatment group receiving DMX-200 first did not return to baseline during the wash-out period, resulting in a significantly lower starting baseline proteinuria in the second period (slides 12 and 19 in the attached presentation). A potential disease modifying effect has not been ruled out, where the patient may have continued DMX-200 benefit through the washout period, after they had stopped taking DMX-200. This can be an indicator that the drug may be having a lasting positive effect on the function of the kidney. No concomitant medications effect trends were noted in either study.

"I believe that the results of this Phase 2a FSGS study further validates Dimerix' lead candidate, DMX-200, in sclerotic kidney diseases. The positive signals suggest that treatment with DMX-200 may indeed result in clinically meaningful improvements in kidney function when added to the standard of care in patients with FSGS," commented Dr Hiddo Heerspink, Chair of the Dimerix Medical Advisory Board. "I am very excited at what this may mean for future studies in patients with FSGS."

Dr Nina Webster, CEO and Managing Director of Dimerix, also commented "The positive correlation of reduced inflammatory biomarkers with a reduction in proteinuria following treatment with DMX-200 further strengthens our understanding of how DMX-200 is delivering clinically meaningful outcomes for these kidney patients. The significant body of clinical evidence Dimerix has established with DMX-200 supports progressing into a larger, randomised, controlled pivotal clinical trial in FSGS, with a pathway to accelerated approval."

Further analysis of the remaining data and planning of next steps for diabetic kidney disease are underway with the Medical Advisory Board.

For further information, please visit our website at www.dimerix.com or contact:

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Authorised for lodgement by the Board of the Company

—END—

About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company developing innovative new therapies in areas with unmet medical needs for global markets. Dimerix is currently developing its proprietary product DMX-200 for Diabetic Kidney Disease, Focal Segmental Glomerulosclerosis (FSGS) and Acute Respiratory Distress Syndrome (ARDS), as well as DMX-700 for Chronic Obstructive Pulmonary Disease (COPD). DMX-200 and DMX-700 were both identified using Dimerix' proprietary assay, Receptor Heteromer Investigation Technology (Receptor-HIT), which is a scalable and globally applicable technology platform enabling the understanding of receptor interactions to rapidly screen and identify new drug opportunities. Receptor-HIT is licensed non-exclusively to Excellerate Bioscience, a UK-based pharmacological assay service provider with a worldwide reputation for excellence in the field of molecular and cellular pharmacology.

About DMX-200

DMX-200 is the adjunct therapy of a chemokine receptor (CCR2) antagonist administered to patients already receiving irbesartan, an angiotensin II type I (AT1) receptor blocker and the standard of care treatment for hypertension and kidney disease. DMX-200 is protected by granted patents in various territories until 2032.

In 2017, Dimerix completed its first Phase 2a study in patients with a range of chronic kidney diseases. No significant adverse safety events were reported, and all study endpoints were achieved. In a subsequent sub-group analysis, significant clinical efficacy signals were seen in the diabetic group. DMX-200 administered to patients already taking stable irbesartan reduced proteinuria levels by a further 36%. This reduction in proteinuria is highly correlated with improved renal function and delay in kidney failure and dialysis. The compelling results from this study prompted the decision to initiate two different clinical studies in 2018: one for patients with Diabetic Kidney Disease; and the second for patients with another form of kidney disease, Focal Segmental Glomerulosclerosis (FSGS). DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

It is estimated that 40% of people with diabetes have kidney disease and many may not know it yet. With the incidence of diabetes growing so rapidly globally, so too will the incidence of kidney disease. This is a rapidly growing market, with few treatment options at this time. Dimerix reported statistically and clinically significant outcomes in a Phase 2 study in diabetic kidney disease patients in September 2020.

FSGS is a serious and rare disease that attacks the kidney's filtering units (glomeruli) causing serious scarring which leads to permanent kidney damage and kidney failure and for which there is a recognised medical need for a new or improved treatment. FSGS affects both children and adults. Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

DMX-200 for FSGS has been granted Orphan Drug Designation by the FDA and EMA. Orphan Drug Designation is granted to support the development of products for rare diseases and qualifies Dimerix for various development incentives including: seven years (FDA) and ten years (EMA) of market exclusivity if regulatory approval is received, exemption from certain application fees, and an abbreviated regulatory pathway to approval.

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Investor Presentation: additional study analysis

27 October 2020

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Forward looking statements

This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Dimerix to be materially different from the statements in this presentation.

Actual results could differ materially depending on factors such as the availability of resources, the results of clinical studies, the timing and effects of regulatory actions, the strength of competition, the outcome of legal proceedings and the effectiveness of patent protection.

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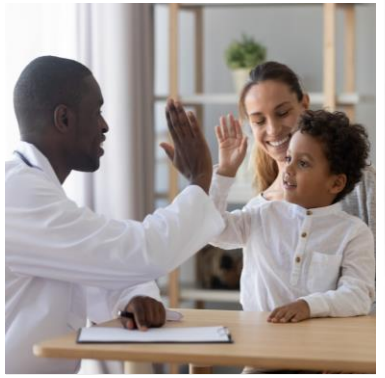
Key Points

Medical Advisory Board unanimously agrees with progression of DMX-200 to pivotal phase in FSGS

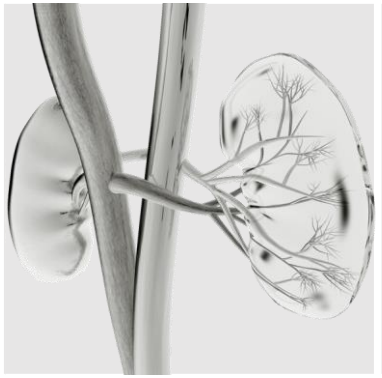
DMX-200 demonstrated reduction in proteinuria across both studies and clear benefit to patients

DMX-200 safe and well-tolerated in all studies to date



Biomarker data supports previously announced positive data for both FSGS and diabetic kidney disease

DMX-200 reduced inflammatory biomarker by 39%: translates to reduced inflammation and fibrosis



Preparation of pivotal FSGS clinical study underway with strategy for accelerated approval

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Medical Advisory Board

Professor Hiddo Heerspink
PhD
Chairman

Professor of Clinical Trials and Personalized Medicine: University Medical Center Groningen, the Netherlands. He specialises in the research of novel treatment approaches to slow the onset of diabetic cardiovascular and renal disease. Hiddo has been instrumental in interactions between industry, researchers and regulatory agencies in the validation of surrogate endpoints for renal trials.

Professor Alessia Fornoni
MD, PhD, FASN
Member

Professor of Medicine & Molecular & Cellular Pharmacology: University of Miami. Chief of the Katz Family Division of Nephrology and Hypertension. She has an extensive history of translational excellence for patients with renal disease and has uncovered novel pathogenetic mechanisms and therapeutic approaches for glomerular disorders.

Professor Jonathan Barratt
MD, PhD, FRCP
Member

Mayer Professor of Renal Medicine: Department of Cardiovascular Sciences; University of Leicester and Nephrologist. Jonathan is the IgA nephropathy Rare Disease Group lead for the UK National Registry of Rare Kidney Diseases (RaDaR) and a member of the steering committee for the International IgA Nephropathy Network.

Associate Professor Lesley Inker
MD, MS, FRCPC
Member

An attending physician and Director of the Kidney and Blood Pressure Center in the Division of Nephrology at Tufts Medical Center. Lesley's major research interest is in the estimation and measurement of glomerular filtration rate (GFR) and in defining alternative endpoints for CKD progression trials based on GFR decline and changes in albuminuria.

Dr Muh Geot Wong
MBBS, PhD, FRCP
Member

Renal Physician and Head of the Renal Clinical trials at the Royal North Shore hospital, Sydney, Australia. Muh Geot's main areas of research are in understanding the mechanisms of kidney fibrosis, biomarkers research, and identifying strategies in delaying progressive kidney disease including glomerular diseases.

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Medical Advisory Board Recommendation

"The positive signals suggest that treatment with DMX-200 may indeed result in clinically meaningful improvements in kidney function when added to the standard of care in patients with FSGS"

"The study achieved encouraging data to support the ongoing development of DMX-200 for FSGS"

"This should be confirmed by a larger pivotal randomised controlled trial as was discussed by Dimerix with the FDA in November last year"

"Our assessment is that these data puts DMX-200 in a great position in the global development efforts for new treatments for FSGS"

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DMX-200 clinical experience

Phase 1 study (DMX-200-101)
- Healthy volunteers
  - ➢ Pharmacokinetic, metabolism & safety clinical study

Phase 2a study (DMX-200-201)
- Chronic Kidney Disease
  - ➢ Safety and tolerability study, with efficacy endpoints included

Phase 2a study (DMX-200-202)
- Focal Segmental Glomerulosclerosis
  - ➢ Safety and efficacy endpoints

Phase 2 study (DMX-200-203)
- Diabetic kidney disease
  - ➢ Efficacy and safety endpoints

- Positive efficacy signals across studies
- 240mg oral delivery daily - 120mg capsule administered twice daily
- Consistently safe and well tolerated in both healthy volunteers and renal patients (total of 95 patients dosed)
- DMX-200 safety profile and efficacy outcomes compares favourably to compounds currently in development
- Consistent data collectively leading to DMX-200 future development

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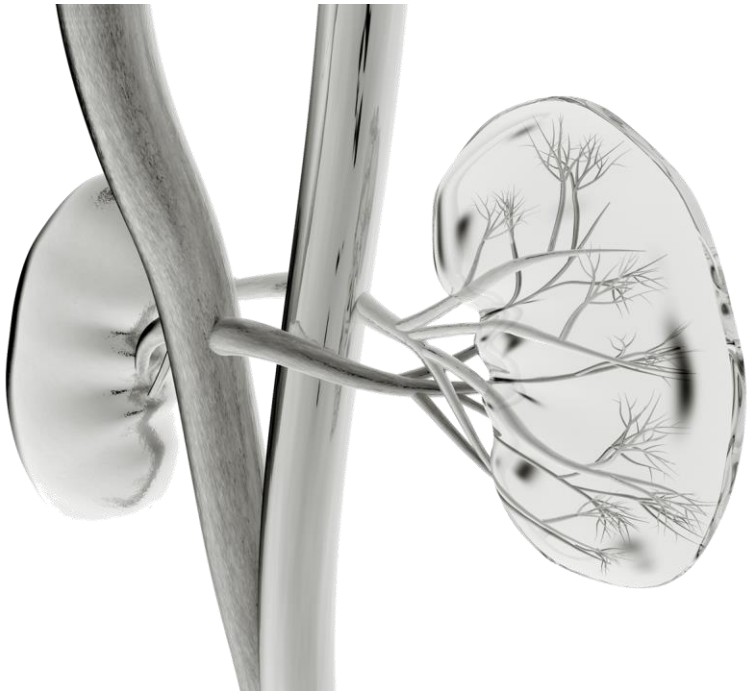


DMX-200
FSGS

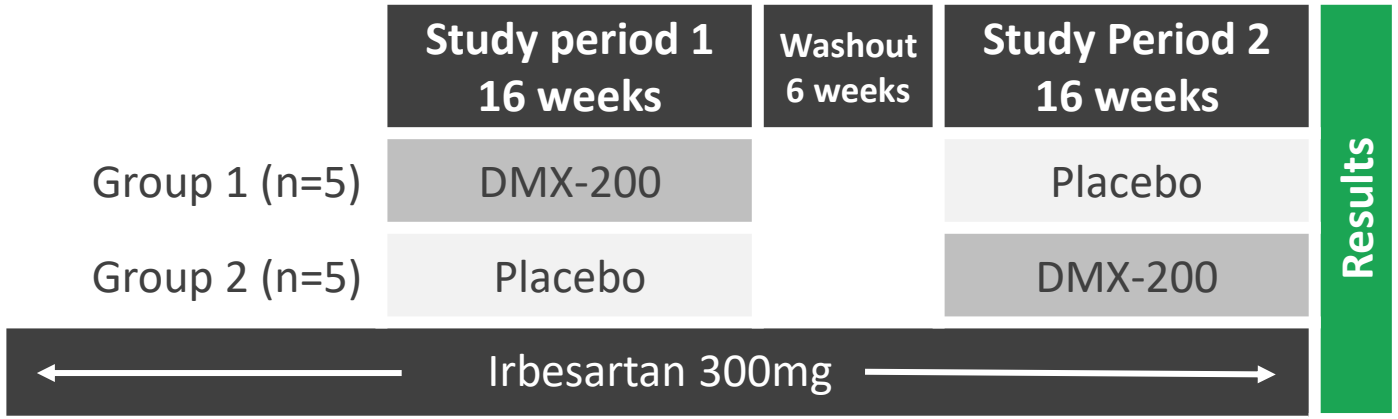
Phase 2a trial in FSGS completed

Phase 2a DMX-200-202 (ACTION for FSGS): Phase 2a, Double-blind, Randomised, Placebo-Controlled, Crossover Study Evaluating the Safety and Efficacy of DMX-200 in Patients with Primary Focal Segmental Glomerulosclerosis who are Receiving Irbesartan

- *10 patients enrolled, 7 patients qualified for the evaluable population and final analysis*
- *Primary endpoint: safety. Secondary endpoint: proteinuria and biomarker analysis.*
- *Patient population: Patients with primary FSGS who are receiving irbesartan*

Analysis population criteria defined in Statistical Analysis Plan (SAP)

10 patients enrolled in study: 7 qualified for the final analysis



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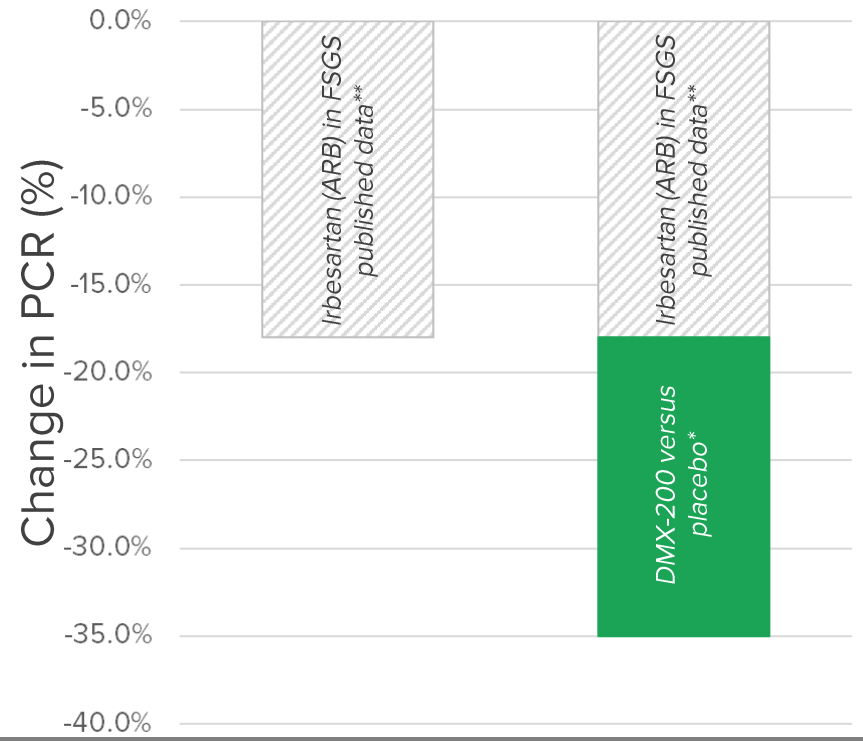
DMX-200 treatment group met primary and secondary endpoints

Reduction in proteinuria after 16 weeks treatment on DMX-200 versus placebo compared to standard of care alone in FSGS patients



No safety concerns – reduced development risk

DMX-200 compares favourably to compounds currently in development

Patients with treatment emergent adverse event during study period

	DMX-200	Placebo
Any	7	6
Drug-related	0	0
Serious	1^	0
Leading to dose interruption	0	0
Leading to study withdrawal	0	0
Death	0	0

^tendonitis

- DMX-200 demonstrated clear benefit to patients with FSGS
  - 86% of patients demonstrated reduced proteinuria on DMX-200 versus placebo
  - 29% of patients demonstrated >40% reduction in proteinuria
  - Results comparable to other compounds in development
- DMX-200 was safe and well-tolerated
- DMX-200 may be complementary to other development compounds, such as sparsentan

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PCR = protein creatinine ratio
**Repeated measures mixed model analysis; top line data was reported as grouped analysis*
***Trachtman, et al., 2018. J Amer Soc Nephrology 29(11):2745-2754 (note: study design differs)*

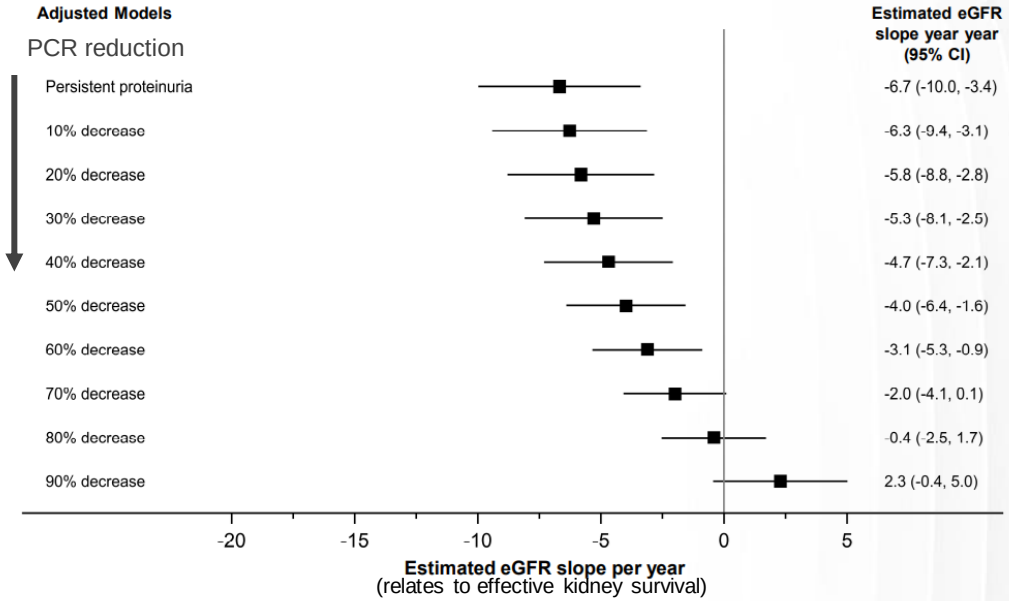
DMX-200 data is clinically meaningful

"Any reduction in proteinuria could yield years of preserved native kidney function and delay the onset of kidney failure and its attendant morbidity"

Kidney survival study - Troost et al, August 2020

"Kidney survival study (2020): incremental proteinuria reductions are also important":

- *"reductions ~20% in proteinuria translated to clinically meaningful differences in eGFR slope >1 to 2 mL/min/ 1.73 m2 per year"*



DMX-200 treatment resulted in clinically meaningful improvements in kidney function of FSGS patients

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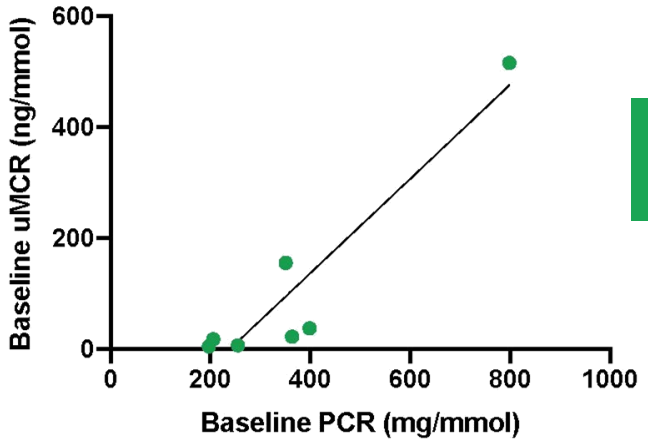
Troost JP et al (August 2020); Proteinuria Reduction and Kidney Survival in Focal Segmental Glomerulosclerosis, Amer J Kidney Dis; https://doi.org/10.1053/j.ajkd.2020.04.014
eGFR: estimated Glomerular Filtration Rate – measure of kidney function

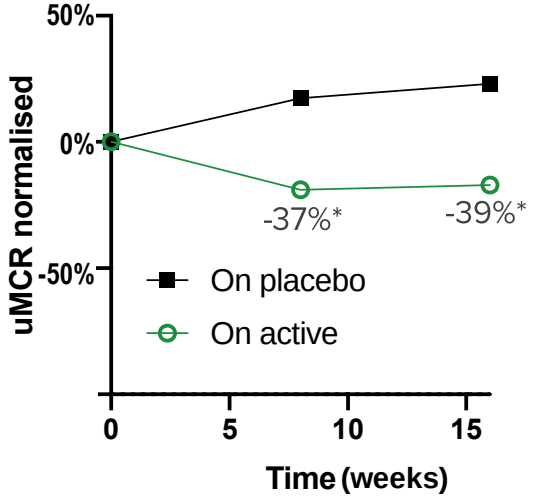
DMX-200 effect on inflammatory biomarker



High MCP-1 correlates to high proteinuria

- Monocyte chemoattractant protein-1 (MCP-1/CCL2):
  - key chemokine that regulates migration & infiltration of immune cells responsible for inflammation
  - lower levels of MCP-1 translates to less inflammation
- CCR2 is the receptor for MCP-1/CCL2
- DMX-200 is a CCR2 inhibitor

MCP-1 levels reduced when on DMX- 200 treatment



16 weeks treatment with DMX-200 vs placebo reduced inflammatory biomarker by 39%: translates to reduced inflammation and subsequent fibrosis (scarring) in the kidney

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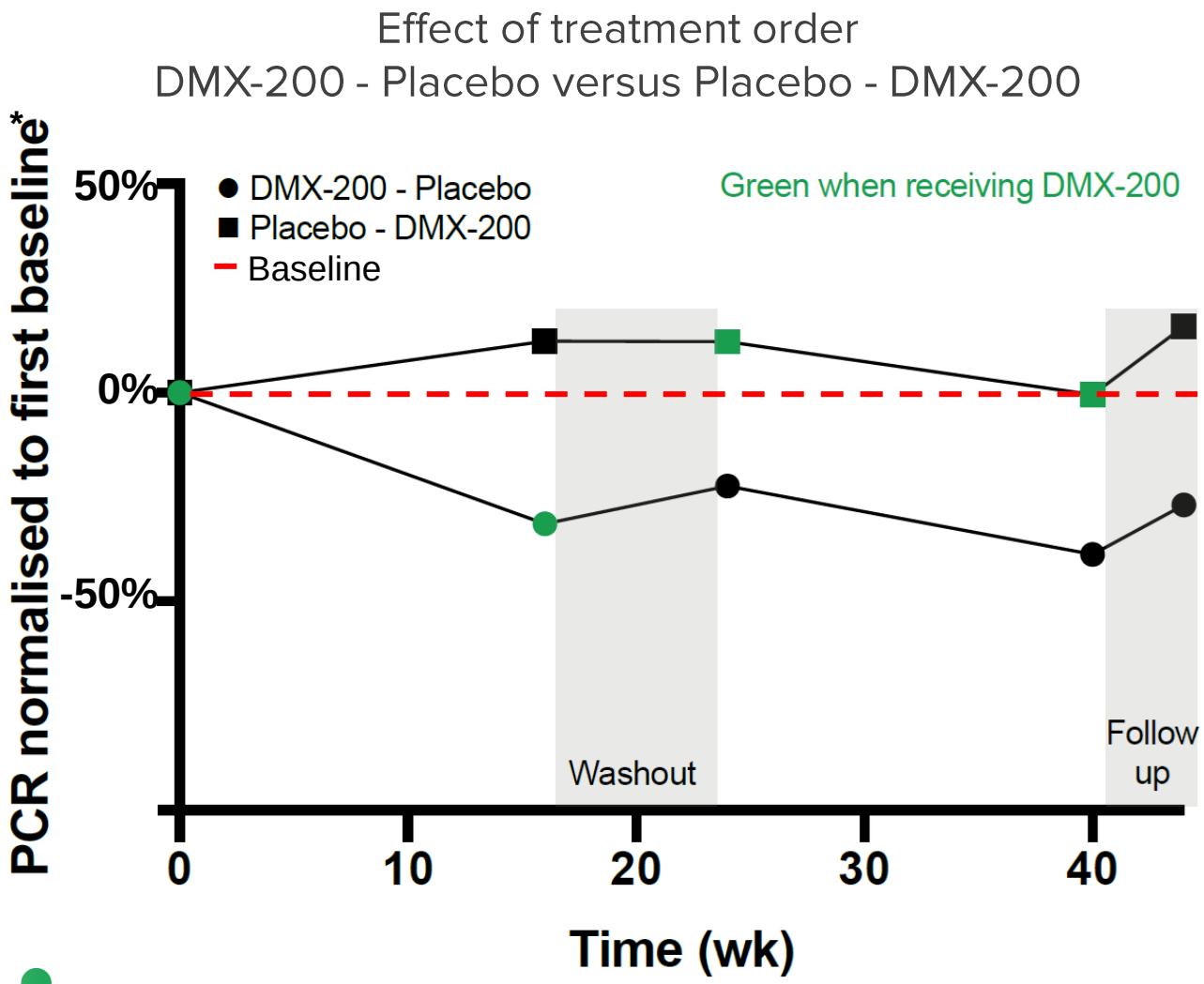
uMCR = Urinary MCP-1 creatine ratio
PCR = protein creatinine ratio
**placebo adjusted difference*

Phase 2a FSGS – effect of treatment order



Proteinuria declined after treatment with DMX-200 in both treatment periods

Treatment order effect trend noted:

- treatment group receiving DMX-200 first did not return to baseline during wash-out
  - possibly due to disease modifying effect with continued benefit after they have stopped taking DMX-200

No change to trends of DMX-200 effect on proteinuria observed when patients on other concomitant medications

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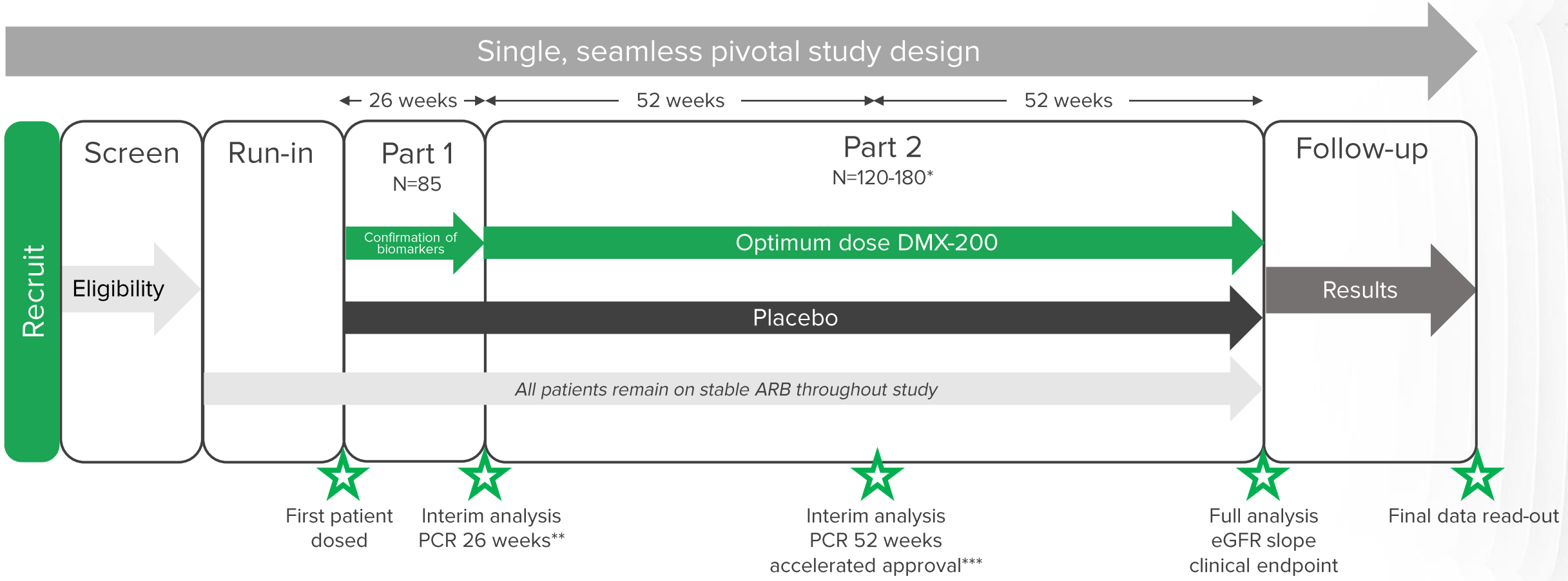
PCR = protein creatinine ratio
** Geometric mean;*

Proposed pivotal FSGS study design overview*



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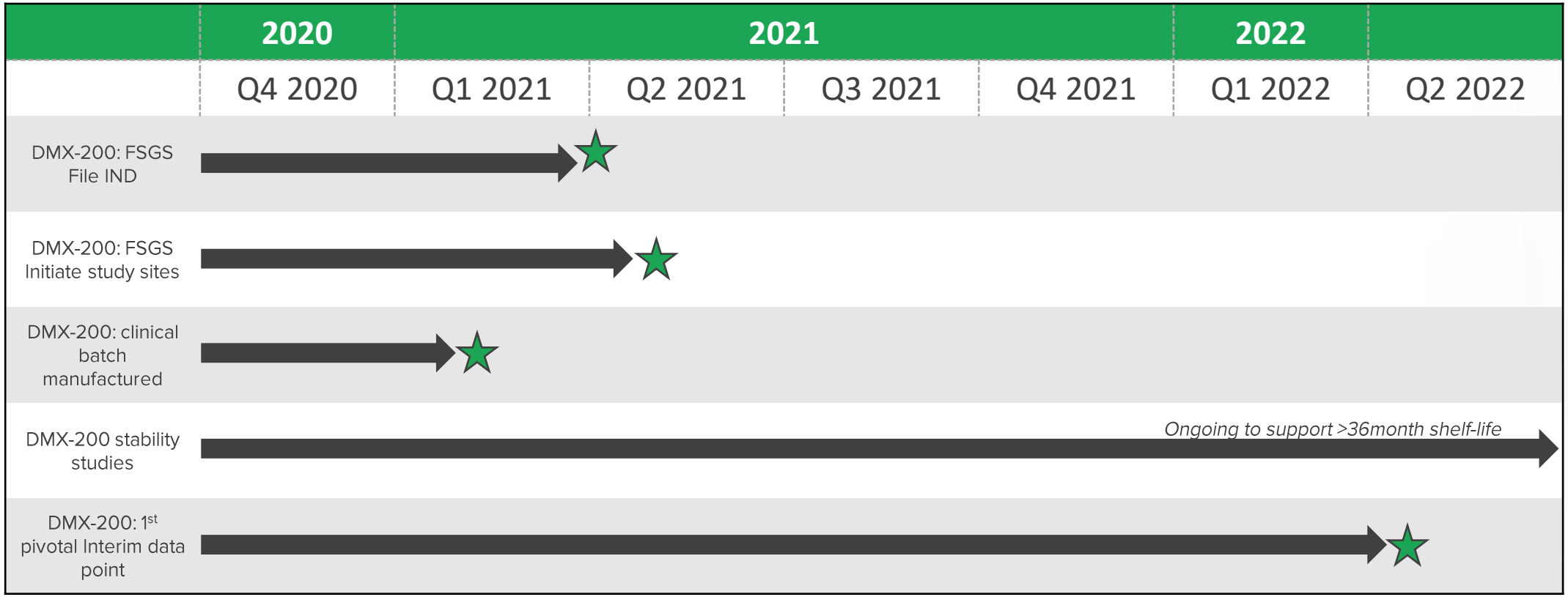
* *Subject to approval of the study design/procedures by FDA (or equivalent) and review by biostatistician*
** *Confirmation of biomarker response and pre-specified analysis*
*** *Accelerated approval = marketing approval for "serious conditions that fill an unmet medical need based on a surrogate or an intermediate clinical endpoint*

FSGS value creation points



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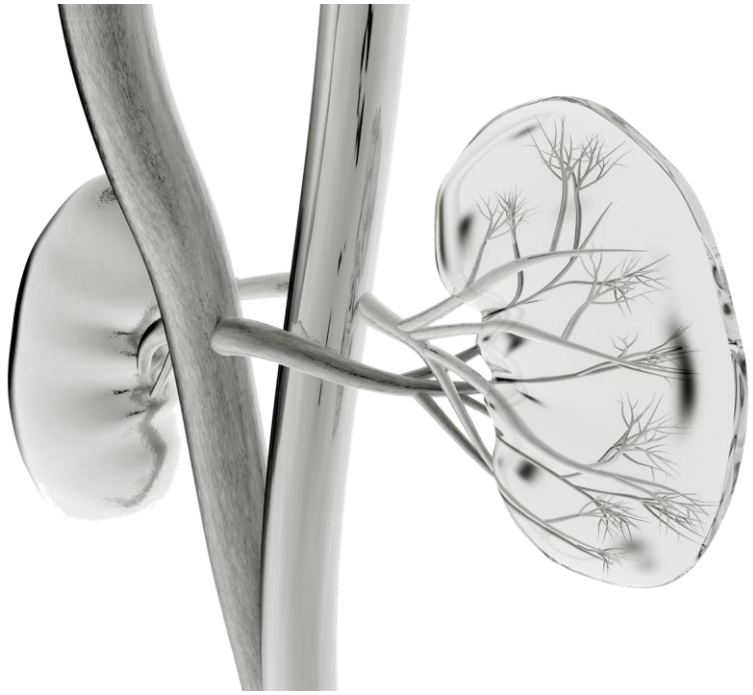

DMX-200
Diabetic Kidney Disease

Phase 2 trial in diabetic kidney disease completed

Phase 2 DMX-200-203 (ACTION for diabetic kidney disease) is a Phase 2, Double-blind, Randomised, Placebo-Controlled, Crossover Study Evaluating the Safety and Efficacy of DMX-200 in Patients with Diabetic Kidney Disease who are Receiving Irbesartan

- 45 patients enrolled, 40 patients qualified for the evaluable population and final analysis
- Indication: for the treatment of elevated serum creatinine and albuminuria in patients with diabetic kidney disease

Analysis population criteria defined in statistical analysis plan (SAP)

45 patients enrolled:
40 qualified for final analysis*;
26 qualified for sub-analysis

	Study period 1 12 weeks	Washout 6 weeks	Study Period 2 12 weeks
Group 1 (n=20)	DMX-200		Placebo
Group 2 (n=20)	Placebo		DMX-200
Irbesartan 300mg			

Results

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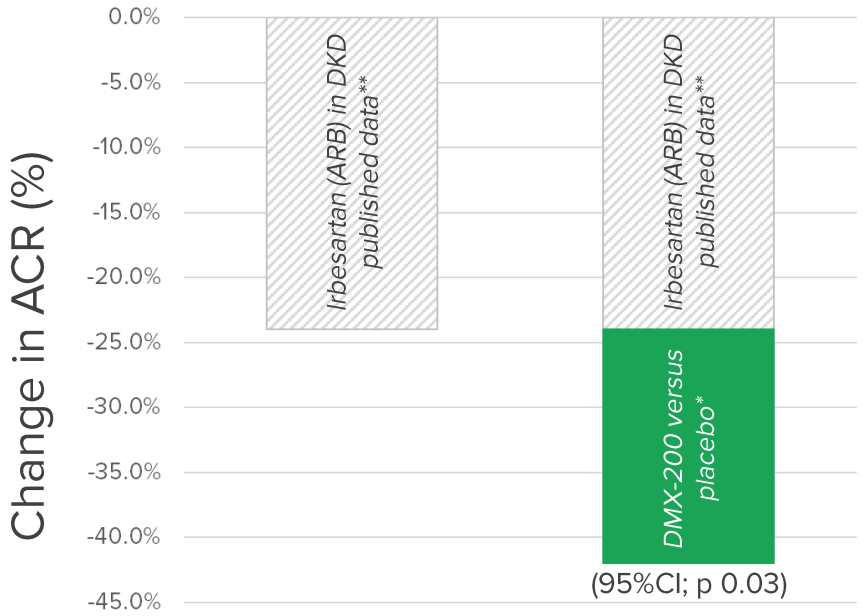
* Reported on 14Sep2020

DMX-200 treatment - statistical and clinical significance

Reduction in proteinuria after 12 weeks DMX-200 treatment versus placebo compared to standard of care alone in diabetic kidney disease patients with baseline starting albuminuria >500mg/g (57 mg/mmol); n=26



Patients with treatment emergent adverse event during study period (n=45)

	DMX-200	Placebo
Any	26	27
Serious	4^	3
Drug-related	0	0
Leading to dose interruption	0	0
Leading to study withdrawal	2 (not assigned to drug or placebo)	
Death	0	0

^appendicitis, device infection, respiratory tract infection, fall

- DMX-200 demonstrated clear benefit to patients with diabetic kidney disease
  - Patients with marginally high baseline proteinuria (>57mg/mmol) demonstrated statistically and clinically significant reduction in proteinuria (p=0.03; n=26)
- DMX-200 was safe and well-tolerated

No safety concerns – reduced development risk

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ACR = albumin creatinine ratio
**Repeated measures mixed model as was reported in top line data*
***Lewis, et al., 2001. N Engl J Med 345:851-860 (note: study design and population differs)*

DMX-200 effect on inflammatory biomarker

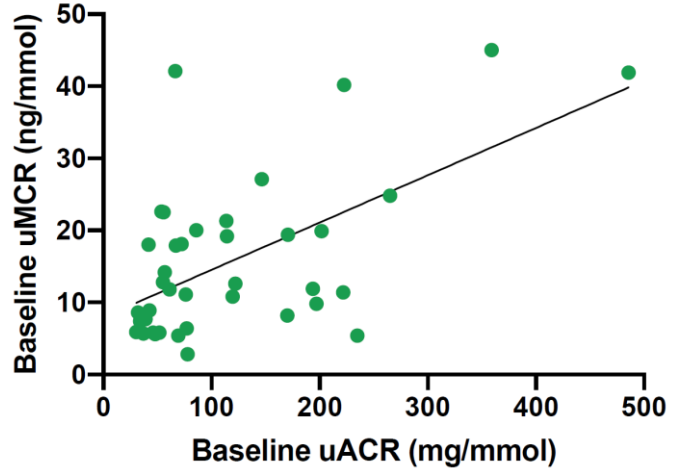
High MCP-1 correlates to high albuminuria

Patients with starting baseline proteinuria less than 57 mg/mmol also had low presence of MCP-1 inflammatory biomarker, i.e. little or no inflammation

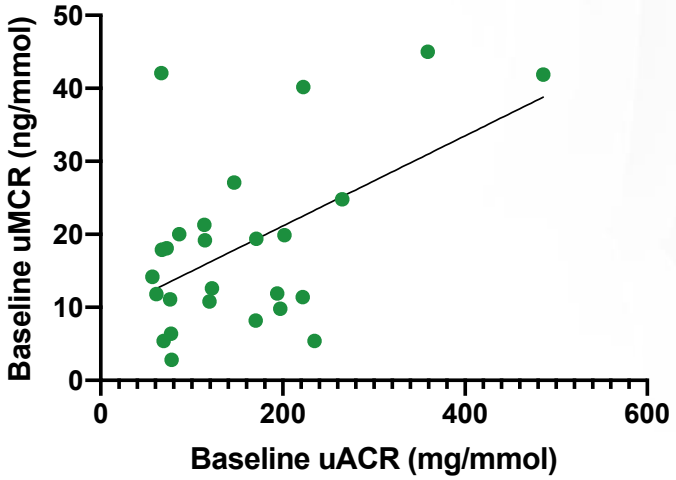
Data further supports proposed mechanism of action of DMX-200 being effective in diseases where active inflammatory processes are driving disease progression

Reduction in MCP-1 should translate to reduced inflammation and subsequent fibrosis (scarring)

Full study cohort; n=40



Starting Albuminuria >57mg/mmol; n=26



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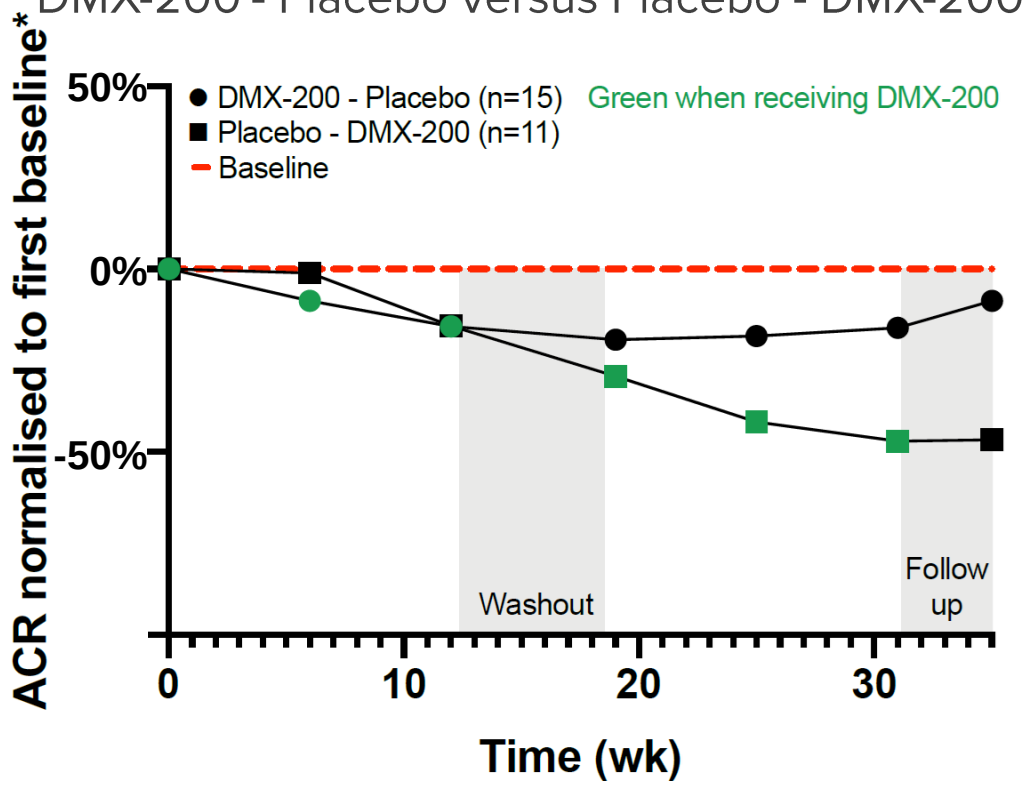
uMCR = urinary MCP-1 creatine ratio
ACR = albumin creatinine ratio

Phase 2 diabetic kidney disease – treatment order effect

Effect of treatment order
DMX-200 - Placebo versus Placebo - DMX-200 (n=26)



Additional analysis and planning of next steps underway with Medical Advisory Board

Proteinuria declined after treatment with DMX-200 in both treatment periods

DMX-200 resulted in statistically & clinically significant reduction in proteinuria versus placebo

Treatment order effect trend noted:

- treatment group receiving DMX-200 first did not return to baseline during wash-out
  - possibly due to disease modifying effect
  - patient may have continued benefit after they have stopped taking DMX-200

No change to trends of DMX-200 effect on proteinuria observed when patients on other concomitant medications

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ACR = albumin creatinine ratio
** Geometric mean; n=26*

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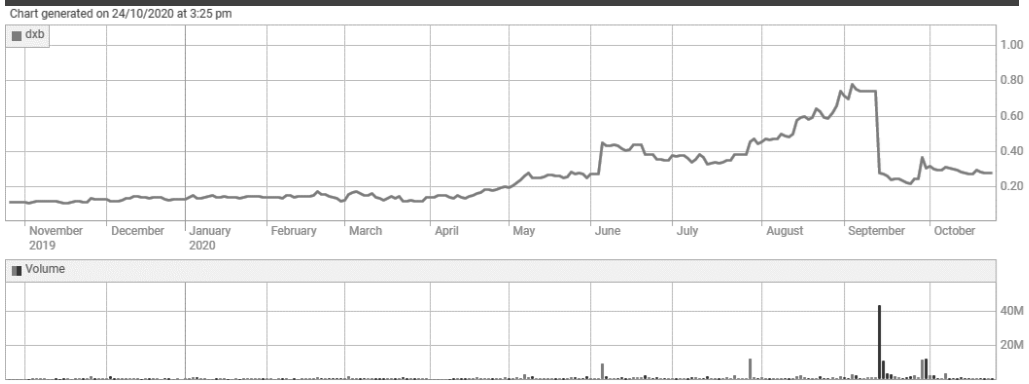
Summary

Corporate overview

Share performance		
ASX	Ticker Symbol	ASX:DXB
	Share price	~A$0.27
	Total ordinary shares on issue	197,749,297
	Market Capitalisation (20Oct20)	~A$53 million
	Trading range (last 12 months)	A$0.10 - 0.78

Key metrics		
	4 week average volume	2,254,401
	52 week change	135%
	Cash Balance (30Sep20*)	A$6.5 million
	Top 20 Shareholders own	33.35%
	Institutional shareholders	<10%

Share price performance



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*includes R&D Tax incentive refund received Oct20

DMX-200 summary

Commercially attractive and growing markets

Unmet need, with little or no current competition

DMX-200 compares favourably to compounds currently in development

Consistent efficacy data in 3 different kidney studies

Product supply secured with FDA approved manufacturing facility

Orphan status for FSGS in both US & EU

New chemical entity with granted patents and additional patents pending

Existing long-term safety data available: lower development risk

Approved by TGA for compassionate use in Australia

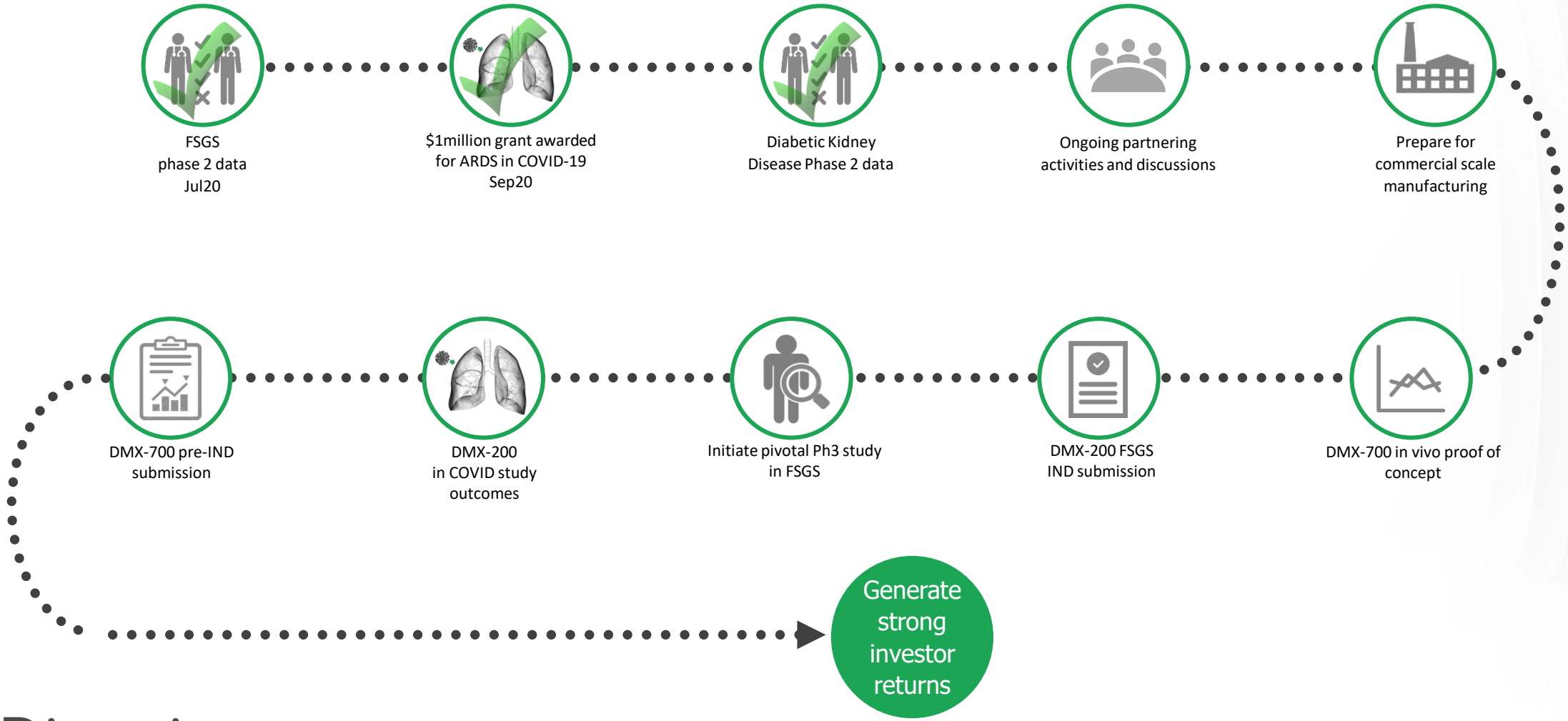
Medical Advisory Board unanimously agrees with FSGS pivotal study progression

FDA confirmed non-clinical & CMC NDA package suitability + Ph3 study design principles

Additional assets to diversify risk and potential sources of revenue

Assets 100% owned by Dimerix

2020/2021 value driving events



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End of Presentation

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