



**Dimerix**  
(ASX:DXB)

# Partnering and Investor Presentation

September 2022



# 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.*

# About Dimerix

Dimerix is a biopharmaceutical company developing innovative new therapies in areas with unmet medical needs, with a core focus on developing new therapies to treat inflammatory causes of kidney and respiratory disease

**Lead Drug Candidate  
DMX-200**

**FSGS Phase 3 clinical  
study recruiting across  
~70 sites globally<sup>1</sup>**

**Proven efficacy and  
safety**

**Demonstrated clinical  
efficacy<sup>2</sup>; drug well  
understood, with strong  
safety profile<sup>2</sup>**

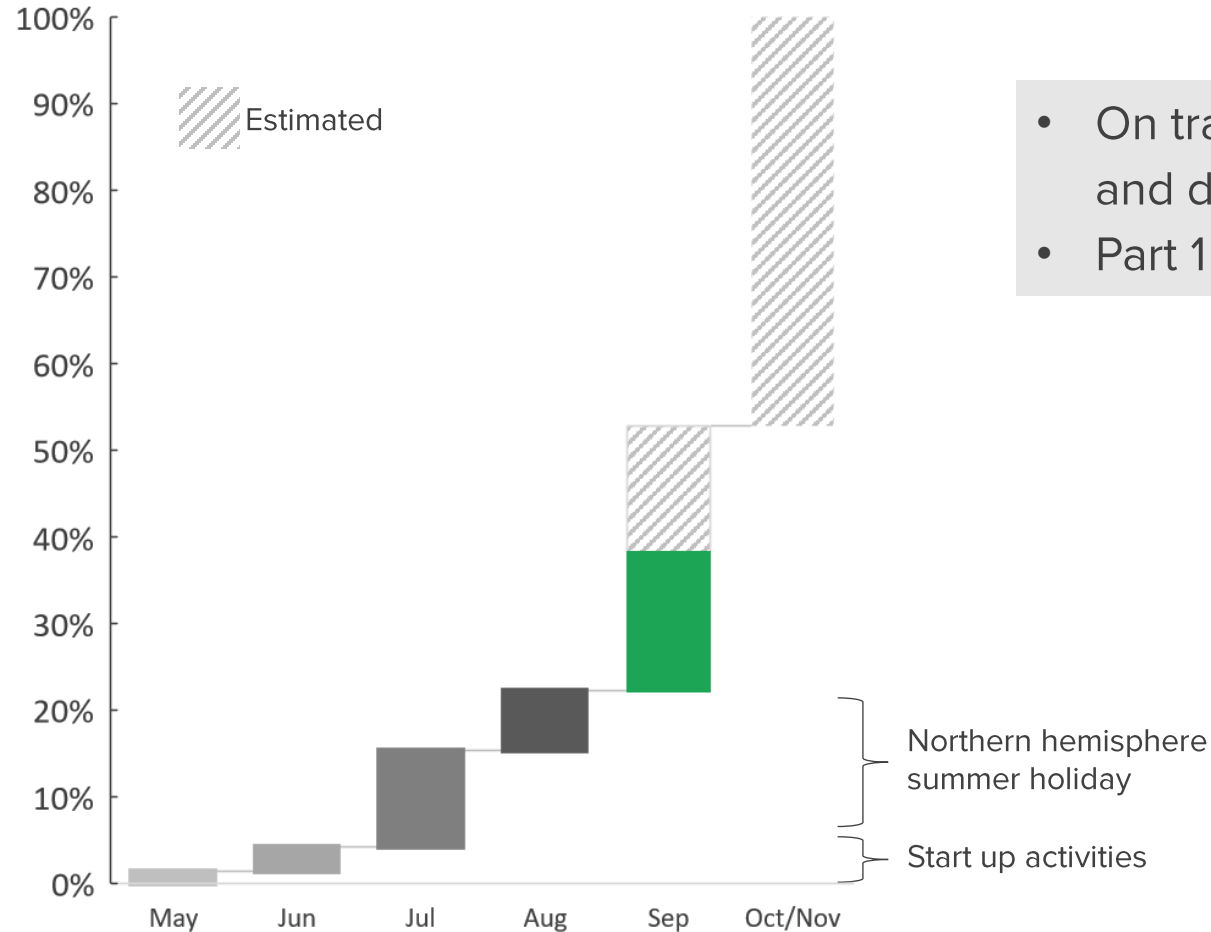
**Commercial Ready**

**Patent protected  
products with  
commercial  
manufacturing  
established**

**Strong Pipeline**






**Strong outlook with  
potential for  
significant value<sup>2</sup> upside**

Patients recruited\*:



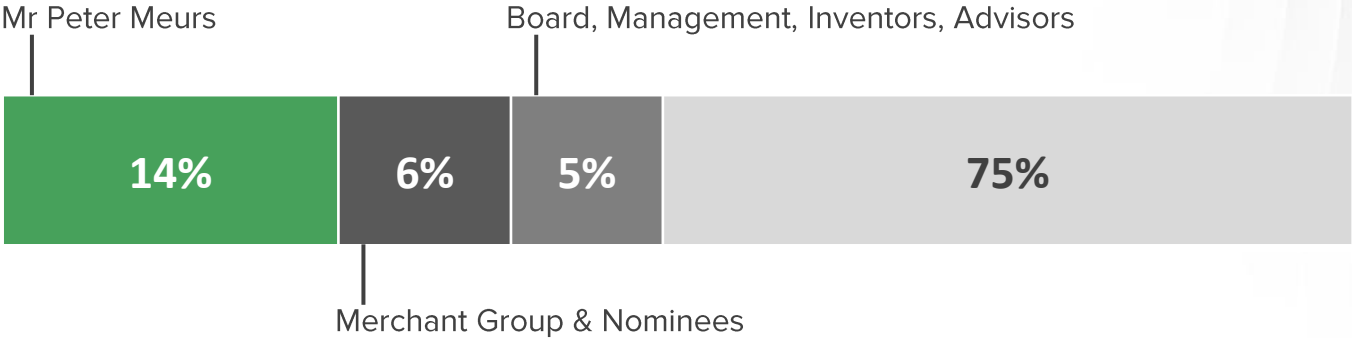
- On track to complete Part 1 recruitment and dosing Q4 2022
- Part 1 data outcome anticipated mid-2023

# Corporate overview

 ASX	Ticker Symbol	ASX:DXB
	Cash Balance (30Jun22)	A\$9.6 million
	Market Capitalisation	~A\$45 million
	Share price	~A\$0.14
	Total ordinary shares on issue	320,873,666



## Shareholders<sup>1</sup>



# Development pipeline

Program	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Key milestones
DMX-200	Focal Segmental Glomerular Sclerosis (FSGS)					Phase 2a demonstrated encouraging efficacy & safety <sup>1</sup> ; Phase 3 underway across ~70 sites globally <sup>2</sup> , Part 1 completion anticipated mid-23 <sup>3</sup>
	Diabetic Kidney Disease					Phase 2 demonstrated promising efficacy and safety <sup>1</sup> , next study planned with support from Australian Centre for Diabetes Innovation; anticipated H123 <sup>4</sup>
	Late COVID pneumonia – REMAP-CAP					Study recruitment across Europe, recruitment closed pending analysis by REMAP-CAP, will update market upon receipt <sup>5</sup>
	Early COVID respiratory – CLARITY 2.0					Study recruitment across India, recruitment closed pending analysis by CLARITY, will update market upon receipt <sup>6</sup>
DMX-700	Chronic Obstructive Pulmonary Disease (COPD)					Pre-clinical studies reported 80% decrease in lung injury; clinical study design underway with study start anticipated H1 23 <sup>7</sup>
DMX-xxx	Undisclosed (multiple)					Additional target opportunities identified using Receptor-HIT; preliminary exploratory work underway

# Focal Segmental Glomerulosclerosis

Focal = some

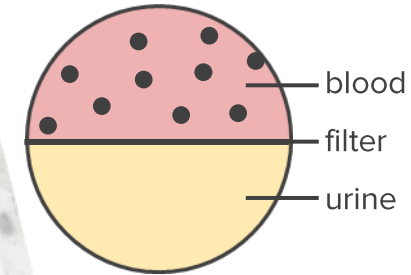
Segmental = sections

Glomerulo = of the kidney filtering units

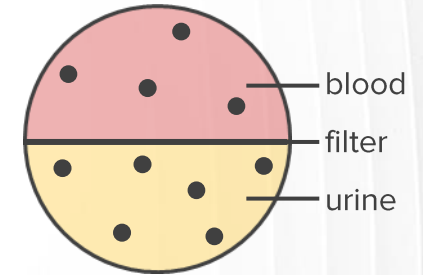
Sclerosis = are scarred

A healthy kidney has little to no protein in the urine

Inside a *healthy* kidney



Inside a *damaged* kidney



● = Protein  
Protein in the urine = proteinuria)

- A rare disease that attacks part of the kidney, causing inflammation and irreversible scarring<sup>1</sup>;
- Leads to permanent kidney damage and eventual end-stage kidney failure, requiring dialysis or transplantation

# FSGS: unmet need and market potential

No therapies yet approved for FSGS

**~40,000**  
people in the US are  
diagnosed with FSGS<sup>1</sup>



**50%**  
of patients with FSGS  
will progress to kidney  
failure<sup>2</sup>

**~1000**  
FSGS patients in US  
receive a kidney  
transplant each year<sup>2</sup>

**>US\$7,000**  
cost of average orphan  
drug per month in US<sup>5</sup>  
(US\$84,000/yr)

**20,000**  
FSGS patients in US  
have kidney failure<sup>2</sup>

**2x**  
more common in  
males<sup>4</sup>

**>5,400**  
patients in the US are  
diagnosed with FSGS  
each year<sup>1</sup>

**20%**  
of child nephrotic  
syndrome cases  
caused by FSGS<sup>2</sup>



**60%**  
patients have  
reoccurring FSGS after  
first kidney transplant<sup>3</sup>

# Renal disease landscape

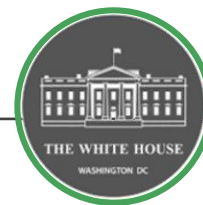
*“A squeaky wheel waiting for grease: 50 years of kidney disease management in the US”<sup>1</sup>*



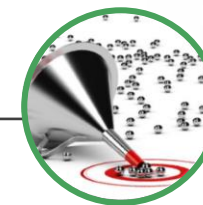
Historical lack of incentives and public policy have contributed to high costs and poor health outcomes for renal patients<sup>1</sup>



2018: workshops and regulatory acceptance of surrogate end points in trials of kidney diseases<sup>2</sup>



2019 changes in US federal policy and rapid adoption of treatment guidelines have contributed to a sea change in the management of renal disease<sup>3</sup>



Public health policy, legislation and product innovation have converged to accelerate change in renal space today

*“More change in the past 24 months than the past 24 years: The rapid evolution of [kidney disease] management”<sup>1</sup>*

# Policy change: renal disease healthcare economic burden

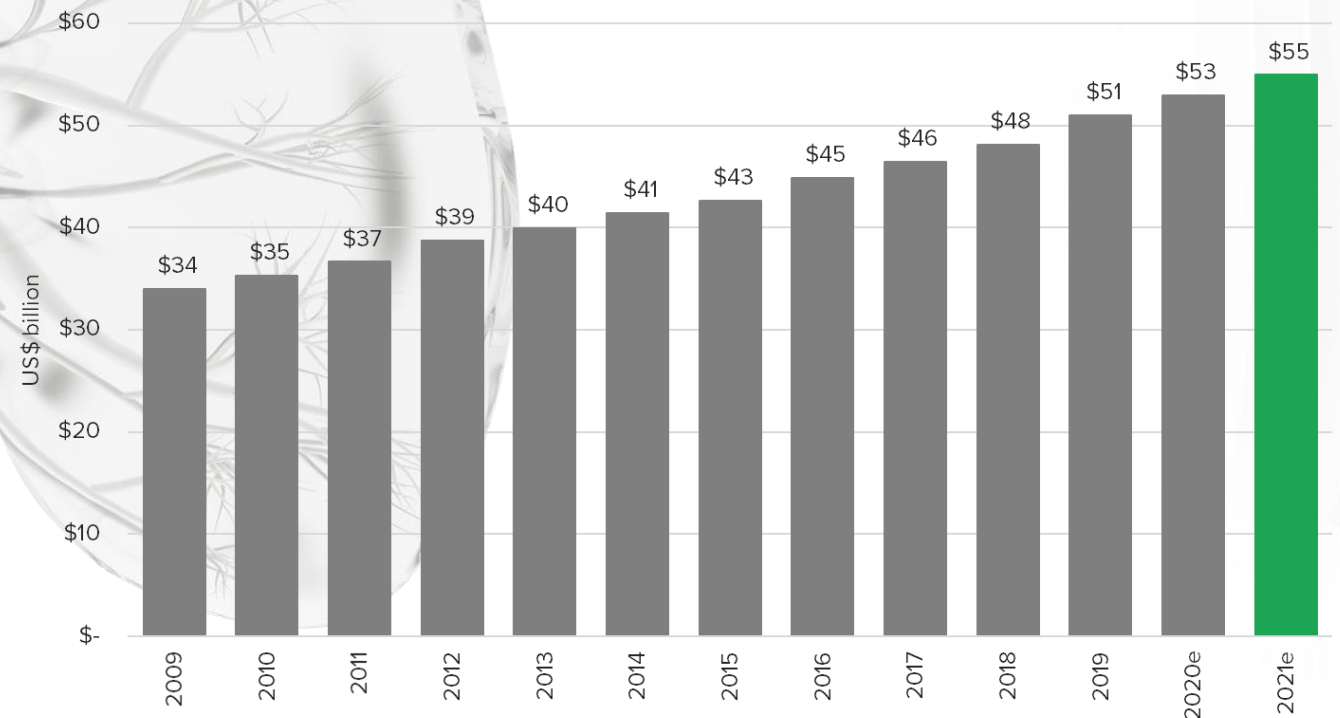
**~40 million**  
adults have kidney  
disease (~15% of the  
adult population) in the  
US in 2021<sup>1</sup>

**US\$88 billion**  
estimated total US  
Medicare expenses  
costs/year for renal  
patients in 2021<sup>1,3</sup>

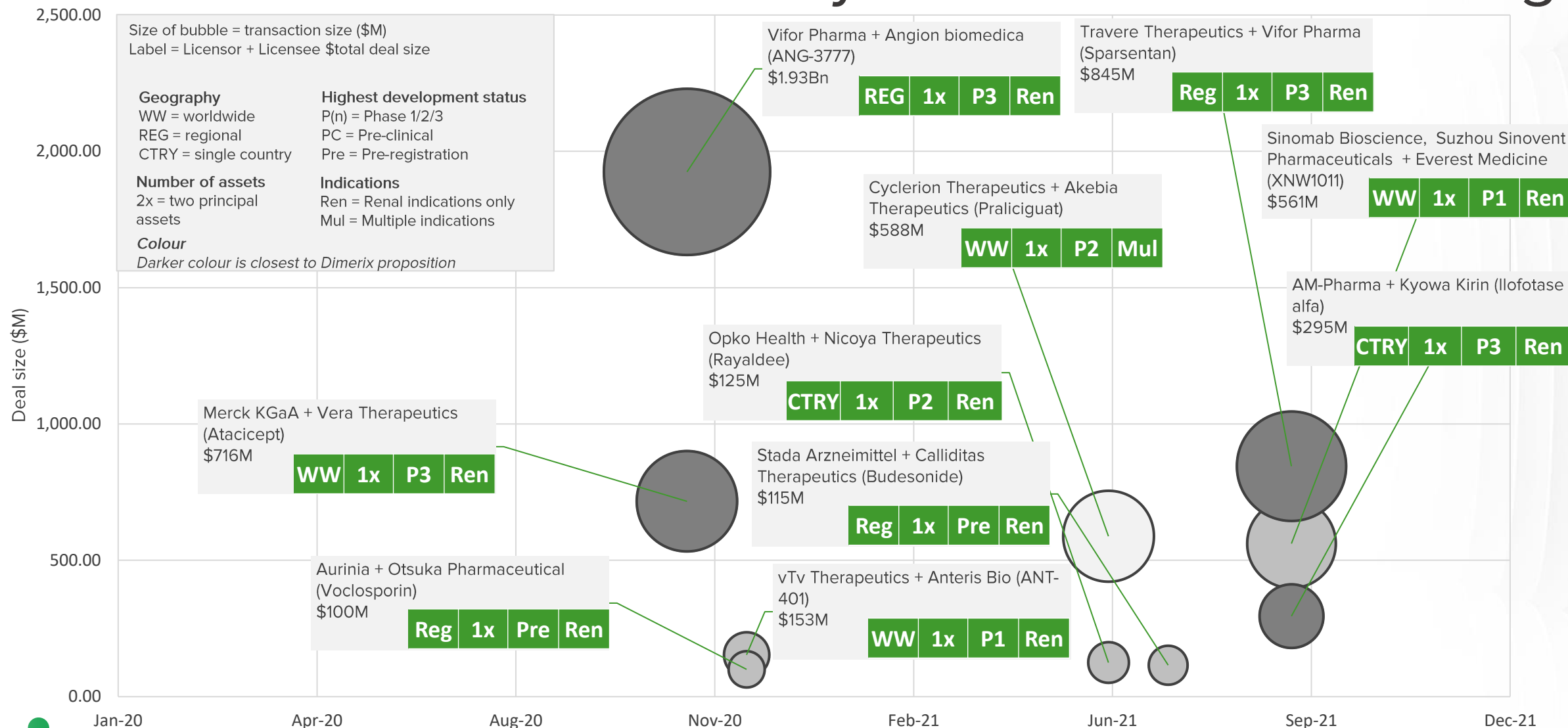
**2019**  
White House executive  
order issued: incentives  
for providers to delay  
patient progression to  
renal failure<sup>2</sup>

## Economic cost of kidney failure in the US

Total Medicare expenses per year costs for kidney failure patients (2009-2021E)<sup>3</sup>

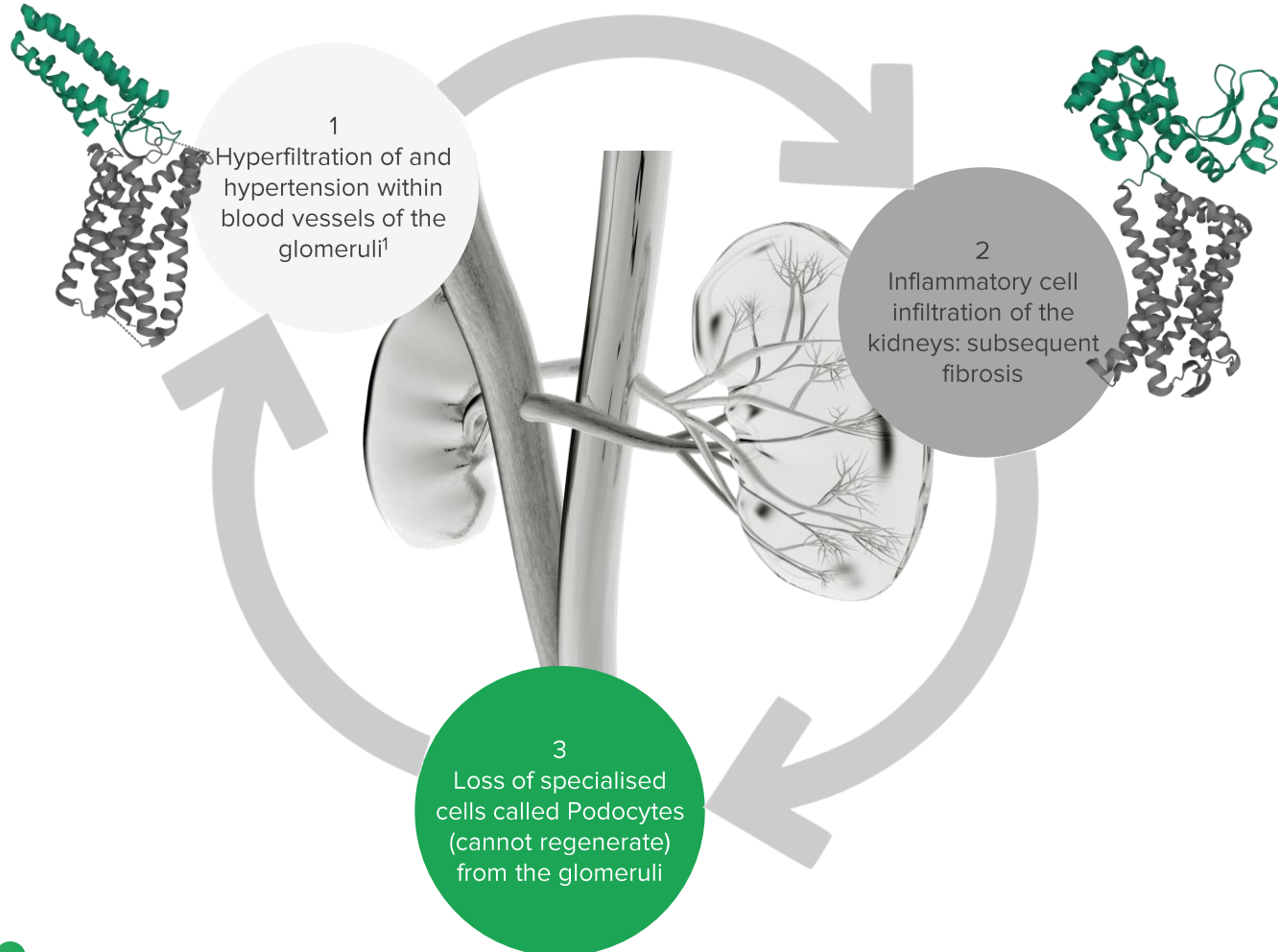


# Increased interest in kidney transactions: licensing



# 3 key mechanisms that cause sclerotic kidney disease

AT1R – blocked by angiotensin receptor blocker (ARB)



CCR2 – CCR2 is the receptor for MCP-1; DMX-200 inhibits CCR2 to block attraction of inflammatory cells into the kidneys<sup>3</sup>

*GPCR signalling*

Dimerix' proprietary discovery tool determined a functional interaction between AT1R and CCR2<sup>2</sup>

Certain kidney cells express both receptors, thus using only 1 compound does not block activation and results in only a partial response<sup>2,3</sup>

**DMX-200 unique proposition:**  
total benefit is greater than the sum of the two individual effects<sup>2,3</sup>

# Phase 3 studies investigating FSGS treatments

No therapies yet approved specifically for FSGS

Study	Drug candidate	Mode of action	Comparator	Primary interim (accelerated approval) endpoint
ACTION3 <sup>1</sup>	DMX-200	CCR2 inhibitor	Placebo	Percent change in uPCR and eGFR slope at week 35
DUPLEX <sup>2</sup>	Sparsentan	Dual angiotensin/endothelin A receptor antagonist	Irbesartan	Proportion of patients achieving uPCR $\leq 1.5\text{g/g}$ and $>40\%$ reduction from baseline uPCR at week 36

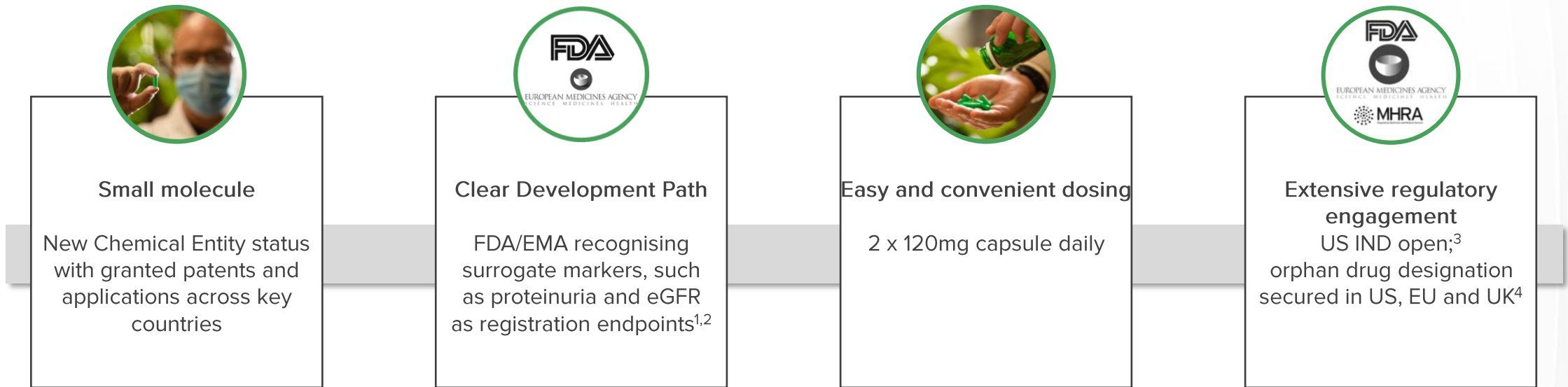
- DMX-200 given to patients already taking an angiotensin receptor blocker, such as irbesartan (current standard of care)
- Data suggests DMX-200 may be complementary to other development compounds, such as sparsentan<sup>3</sup>

# Kidney Disease Development Overview



# DMX-200 – working on inflammatory signalling pathway

A CCR2 inhibitor working synergistically alongside the current standard of care (AT1R blocker): G protein-coupled receptor (GPCR)



1. Thompson et al., (2019) CJASN, 14 (3) 469-481; <https://doi.org/10.2215/CJN.08600718>

2. FDA publication, (2021); FDA approves first drug to decrease urine protein in IgA nephropathy, a rare kidney disease <https://www.fda.gov/drugs/fda-approves-first-drug-decrease-urine-protein-iga-nephropathy-rare-kidney-disease>

3. ASX release: 09May2022

4. ASX releases: 14Dec15, 21Nov18, 07Jun21

# DMX-200 clinical experience



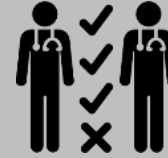
## Phase 1 study (DMX-200-101)

- 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)

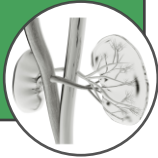
- Diabetic kidney disease
  - Efficacy and safety endpoints

- 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

# DMX-200 treatment group met primary and secondary endpoints

- **86%** of patients demonstrated reduced proteinuria on DMX-200 versus placebo
- **29%** of patients demonstrated >40% reduction in proteinuria

## Efficacy



- No safety concerns – reduced development risk
- DMX-200 compares favourably to compounds currently in development<sup>2,4</sup>

## Safety



- **17%** reduction of uPCR in addition to ARB: mixed model, repeat measures statistical test; (grouped analysis model shows a 25% drop in uPCR)<sup>1</sup>

## Clinically Meaningful

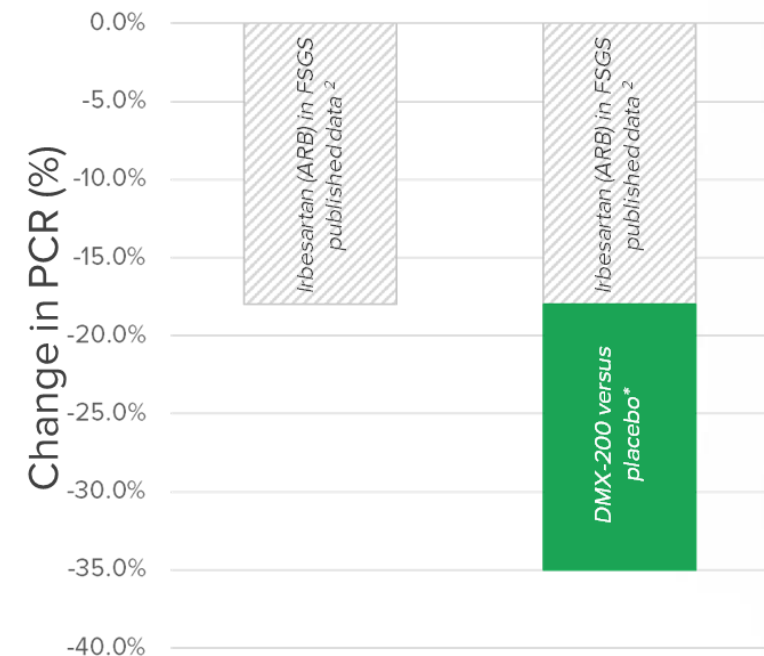


- Results comparable to other compounds in development<sup>2</sup>
- DMX-200 may be complementary to other development compounds, such as sparsentan<sup>3</sup>

## Competitive



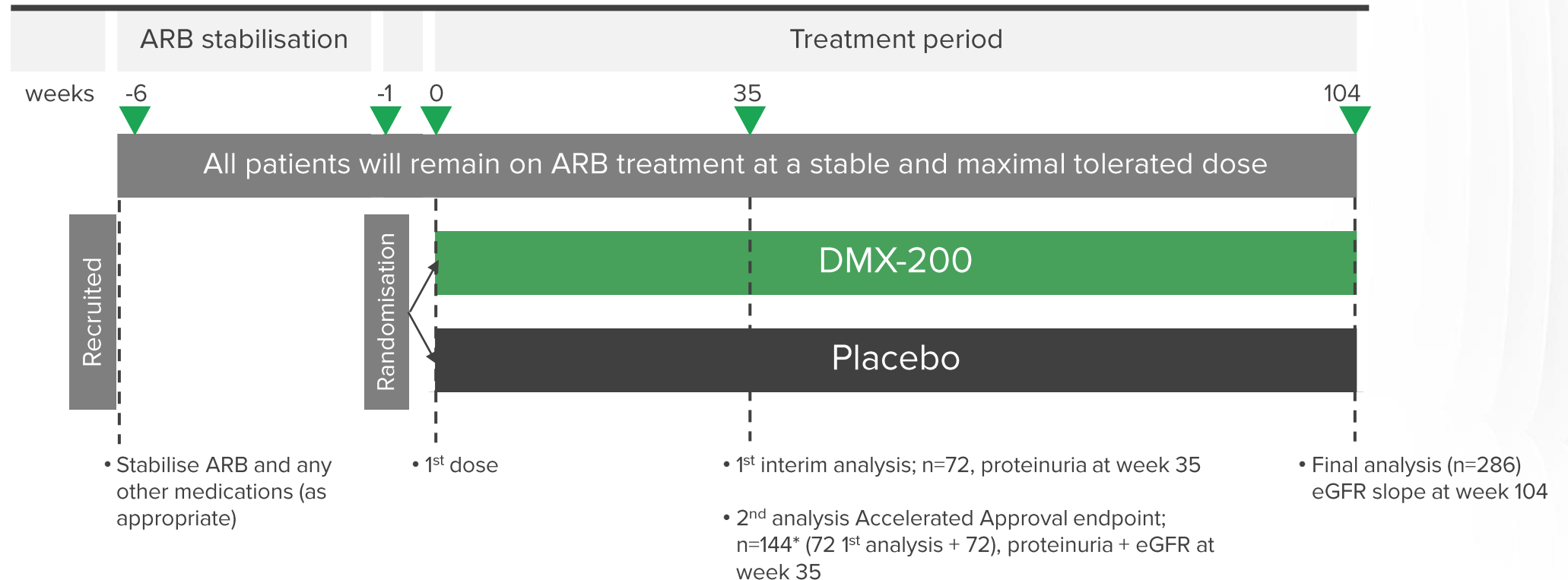
Average reduction in proteinuria after 16 weeks treatment on DMX-200 versus placebo compared to standard of care alone in FSGS patients<sup>1</sup>



# ACTION3 - FSGS phase 3 study design

FSGS CLINICAL STUDY

A randomised, double-blind, multi-centre, placebo-controlled study of renal outcomes of DMX-200 in patients with FSGS receiving an ARB



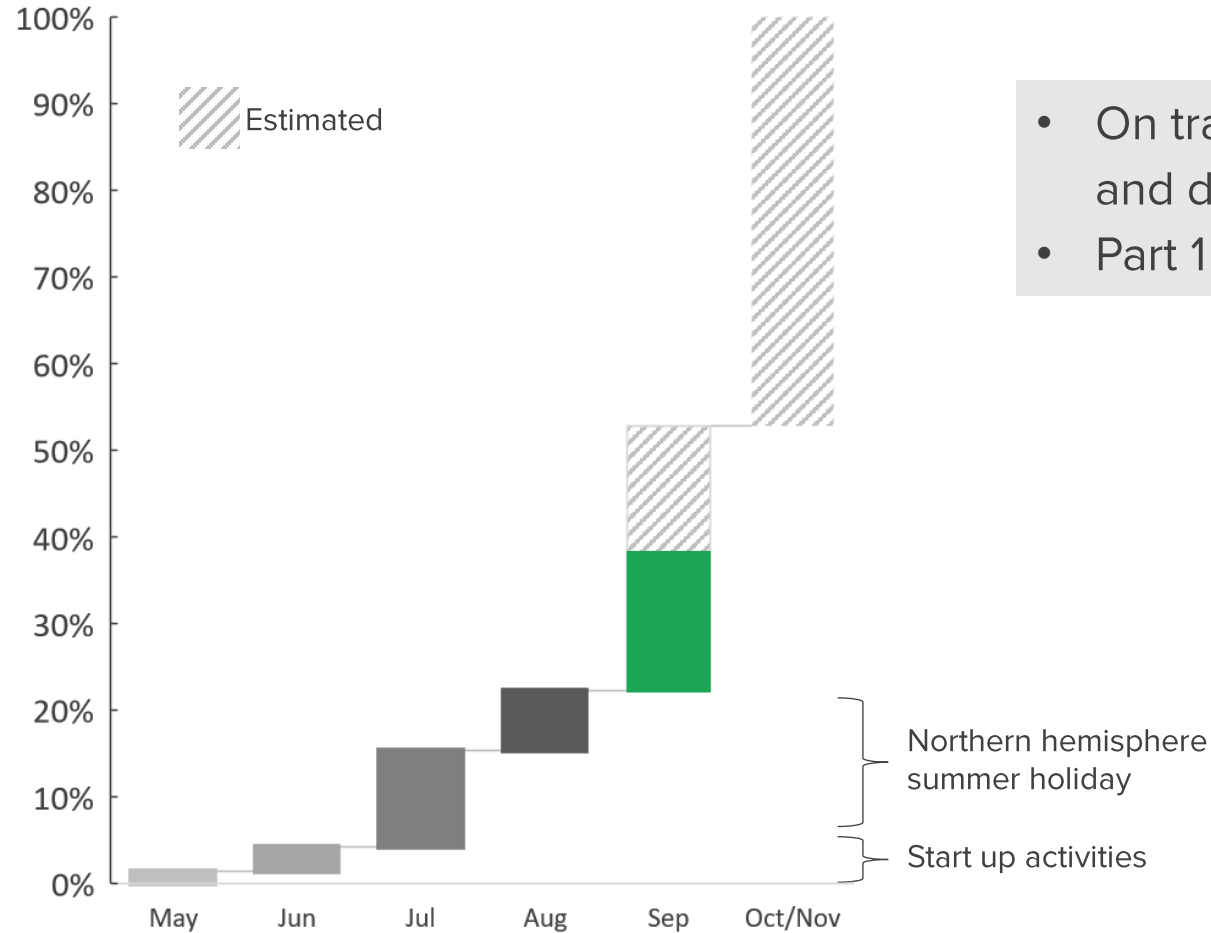
A randomised, double-blind, multi-centre, placebo-controlled study of renal outcomes of DMX-200 in patients with FSGS receiving an ARB

Global study recruiting across ~70 sites:

- Australasia: 9 sites
- Asia: 9 sites
- Europe 18 sites
- Latin America 11 sites
- UK 6 sites
- USA 20 sites



Patients recruited\*:



- On track to complete Part 1 recruitment and dosing Q4 2022
- Part 1 data outcome anticipated mid-2023

# DMX-200 Intellectual property and exclusivity



1. If patent applications are granted: PCT/AU2022/050013;

2. DMX-200 is a New Chemical Entity (NCE): an active moiety not approved before which can attract exclusivity periods in various territories

3. Granted patents US9,314,450; US10,058,555; US10,525,038; CN2012800046165; CA2,821,985; EP12734251.7; HK 4104477.8; IL227414; JP2013-547780; SA203/5897; AU2012206945

4. If patent applications are granted: PCT/AU2022/50249

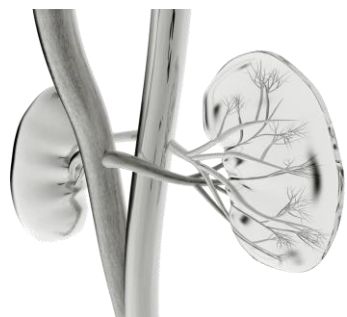
ARB: angiotensin receptor blocker; CCR2: chemokine receptor 2 inhibitor



Additional longer  
term propositions

# Additional asset value propositions

## Longer term opportunities



DMX-200  
Diabetic Kidney  
Disease

Addressable market  
**US\$1.1 billion<sup>1</sup>**

Key driver is the rise in diabetes global incidence

Diversifying  
risk and  
potential  
sources of  
revenue

DMX-700  
Chronic Obstructive  
Pulmonary Disease



Global COPD treatment market (2017)  
**US\$14 billion<sup>2</sup>**

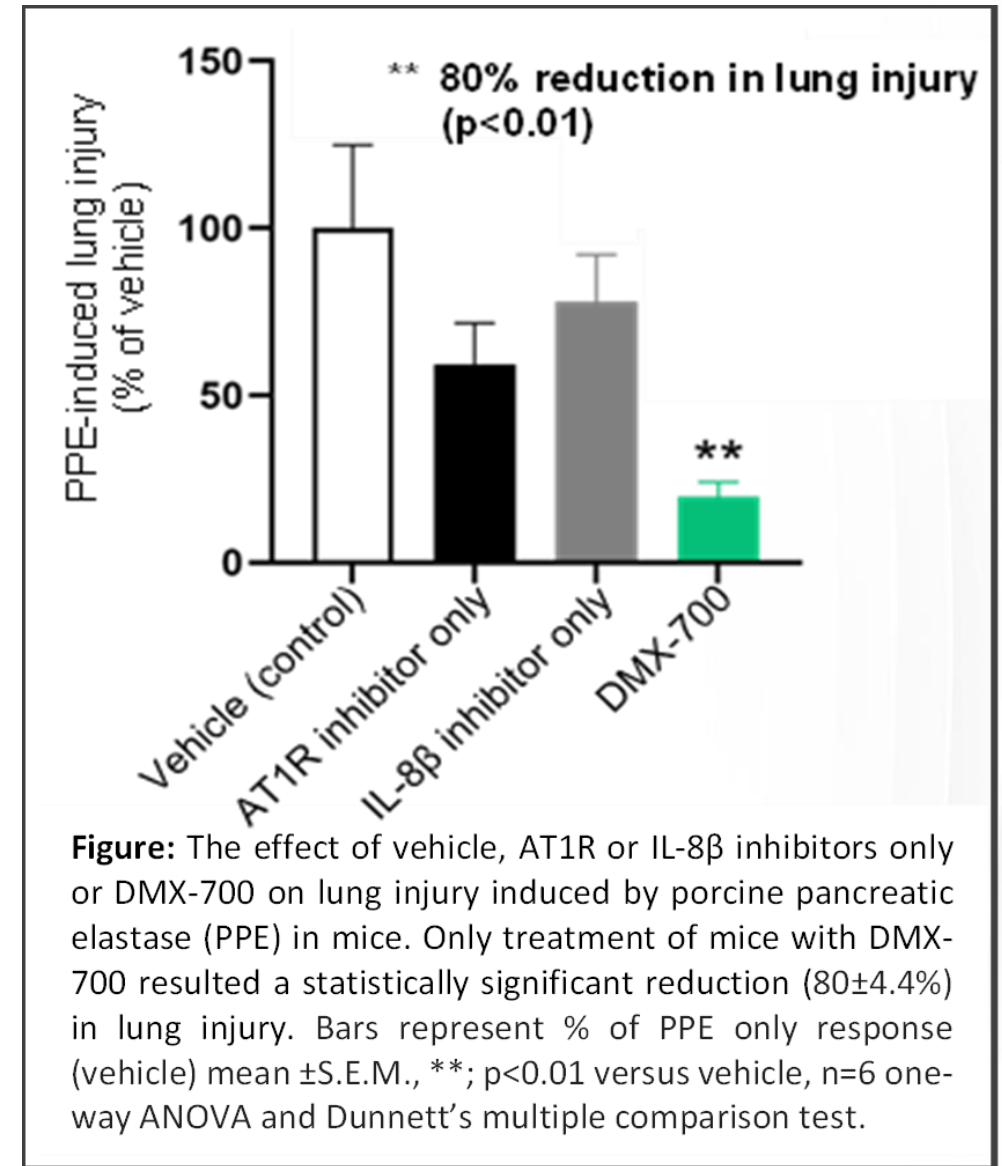
# COPD efficacy

DMX-700 shows significant efficacy with 80% reduction in lung injury of COPD ( $p < 0.01$ ,  $n = 6$ )

The clinical design underway

COPD is the third-leading cause of death in the world, causing 3.23 million deaths globally in 2019<sup>1</sup>

In the United States, COPD affects 1 in 8 Americans age 45 and older, and 1 in 20 Australia aged 45 years, but millions more may have the disease without even knowing it <sup>2,3,4</sup>





# Corporate Outlook

# Potential value driving events

2021

2022

- ✓ DMX-200 demonstrated **encouraging clinical efficacy** and **strong safety profile** across multiple Phase 2 renal clinical studies
- ✓ Consistent advice received from **FDA, EMA and UK MHRA** on FSGS Phase 3 study design
- ✓ Orphan Drug Designation/**accelerated approval pathway** granted by US FDA, EU EMA and UK MHRA for FSGS
- ✓ Two independent Phase 3 clinical studies underway in patients with **COVID-19 respiratory complications**
- ✓ DMX-200 **manufacturing process optimised** to improve commercial scalability and global logistics
- ✓ DMX-700 in COPD progressed further towards **clinical development**
- ✓ Expansion of **IP portfolio**
- ✓ Strong **financial position**

- ✓ FSGS **ethics approval** and **clinical site initiations**
- ✓ FSGS Phase 3 study **recruitment** and first patient **first dose**
- ☐ REMAP-CAP Phase 3 COVID-19 study recruitment and **top line data**
- ☐ CLARITY 2.0 Phase 3 COVID-19 study recruitment and **top line data**
- ✓ DMX-700 for Chronic Obstructive Pulmonary Disease progression towards **clinical study**
- ✓ Diabetic kidney disease **clinical study** design and next steps
- ✓ Further expansion of **IP portfolio**
- ☐ FSGS Phase 3 study **Part 1 analysis** and progression to Part 2



# Dimerix

A biopharmaceutical company developing innovative new therapies in areas with unmet medical needs, with a core focus on inflammatory disease treatments such as kidney and respiratory diseases.

**Advancing three Phase 3 opportunities**

**Well positioned to deliver against strategic plan**

**Dimerix HQ**  
425 Smith St, Fitzroy 3065  
Victoria, Australia  
T. 1300 813 321  
E. [investor@dimerix.com](mailto:investor@dimerix.com)

#### **ESG Statement**

*Dimerix is committed to integrating Environmental, Social and Governance (ESG) considerations across the development cycle of its programs, processes and decision making. The Dimerix commitment to improve its ESG performance demonstrate a strong, well-informed management attitude and a values led culture that is both alert and responsive to the challenges and opportunities of doing business responsibly and sustainably.*



Appendix

# Dimerix board



**James Williams**  
PhD, MBA  
Non-Executive Chairman

*iCeutica, Yuuwa, AdAlta (alternate), Polyactiva*  
Experienced Director of ASX-listed companies

- Co-founded Dimerix, iCeutica
- Co-founded Yuuwa Capital (\$40M venture fund)
- ✓ BSc (Hons) - Biochemistry
- ✓ PhD - Medicine
- ✓ MBA - Business



**Nina Webster**  
PhD, MBA, M.IP.Law  
CEO & Managing Director

*Wyeth (Pfizer), Acrux, Immuron, Linear Clinical Research*

- Experienced in product development, commercial strategy & execution
- Successfully commercialised multiple pharmaceutical products globally
- ✓ BSc (Hons) - Pharmacology
- ✓ PhD - Pharmaceuticals
- ✓ MBA - Business
- ✓ M.IP.Law - Intellectual Property Law



**Hugh Alsop**  
BSc (Hons), MBA  
Non-Executive Director

*Mayne Pharma, Acrux, Hatchtech, Kinosis*

- Extensive biotech drug development & commercial manufacturing experience
- Responsible for successful global commercialisation programs & NDA registrations
- ✓ BSc (Hons) - Chemistry
- ✓ MBA - Business



**Sonia Poli**  
PhD  
Non-Executive Director

*Hoffman la Roche, Addex, AC Immune, Minoryx*

- Experienced executive in pharmaceutical operations
- Background in small molecules development and analytical development
- ✓ BSc (Hons) - Chemistry
- ✓ PhD - Industrial Chemistry

# Dimerix management



**Nina Webster**  
PhD, MBA, M.IP.Law  
CEO & Managing Director

*Wyeth (Pfizer), Acrux, Immuron*

- Experienced in product development, commercial strategy development & execution
- Successfully commercialised multiple pharmaceutical products globally
- ✓ BSc (Hons) - Pharmacology
- ✓ PhD - Pharmaceuticals
- ✓ MBA - Business
- ✓ M.IP.Law - Intellectual Property Law



**Hamish George**  
BCom, CA, GIA(Cert)  
CFO & Company Secretary

*Bio101, Pitcher Partners*

- Experienced CFO & Co.Sec.
- Expertise in Corporate Governance, financial reporting, cash flow management, taxation (including R&D Tax Incentive) & budgeting/forecasting
- ✓ Bcomm – Commerce
- ✓ G.Dip. - Financial Planning
- ✓ M.Acc. – Accounting
- ✓ GIA(Cert)
- ✓ Chartered Accountant



**Ash Soman**  
MBBS MRCP(UK) MBA  
Chief Medical Officer

*Iqvia, AstraZeneca, Sanofi, Oncosil*

- Experienced clinician spanning hospital clinical practice, clinical study design, medical affairs, compliance, patient safety & corporate strategy
- Clinical training in general and respiratory medicine
- ✓ Bachelor of Medicine and Surgery
- ✓ Member of the Royal College of Physicians
- ✓ MBA - Business



**Robert Shepherd**  
PhD  
VP R & D

*Medicines Development, Avecheo*

- Experienced pharmaceutical executive in project management, clinical development and research programs
- Led multidisciplinary R&D teams for over 14 years
- ✓ BSc (Hons) – Genetics
- ✓ PhD – Molecular Immunology
- ✓ MBA - Business



**Bronwyn Pollock**  
BSc (Hons), MBA  
VP Product Development

*Neuren, Prota, Acrux, Hospira, CSL*

- Experienced pharmaceutical executive in Manufacturing (CMC)
- Successfully developed and submitted multiple dossiers to FDA, EMA, TGA
- Background in project management, technical transfer and product launch
- ✓ BSc (Hons) – Applied Biology
- ✓ MBA - Business

# 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, FRCP  
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

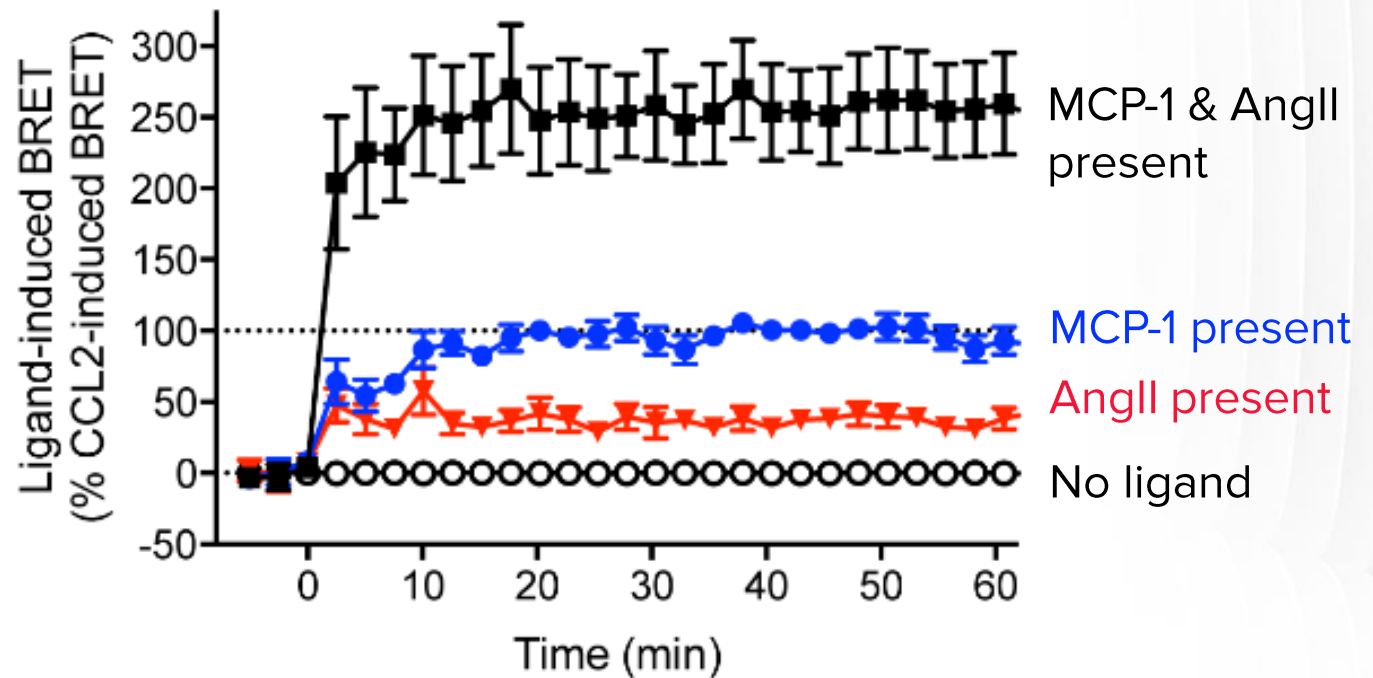
Renal Physician and Head of the Renal Clinical trials at the Royal North Shore hospital, Sydney, Australia. Muh Geot's main areas of research are in understanding the mechanisms of kidney fibrosis, biomarkers research, and identifying strategies in delaying progressive kidney disease including glomerular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

# AT1R and CCR2 form functional heteromers

Proprietary discovery platform (Receptor-HIT) identified:

- Formation of AT1R and CCR2 heteromers;
- Novel pharmacology (potentiation of signaling)
- Dual antagonism required for completed inhibition

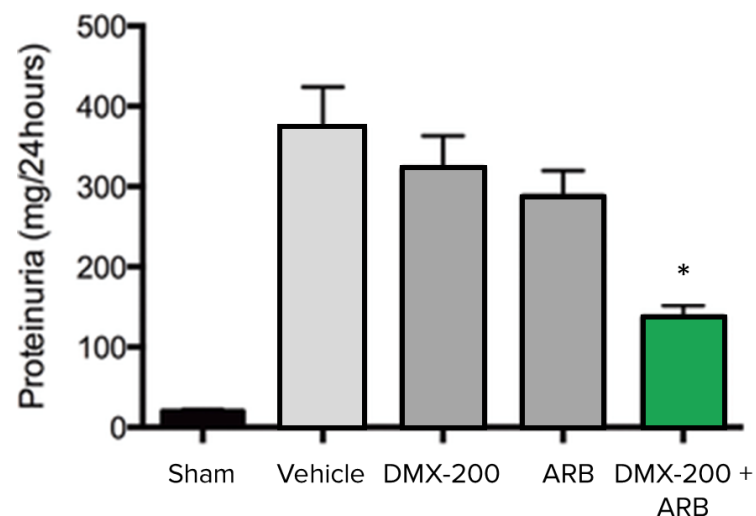
## Unique pharmacology of AT1R/CCR2 heteromer



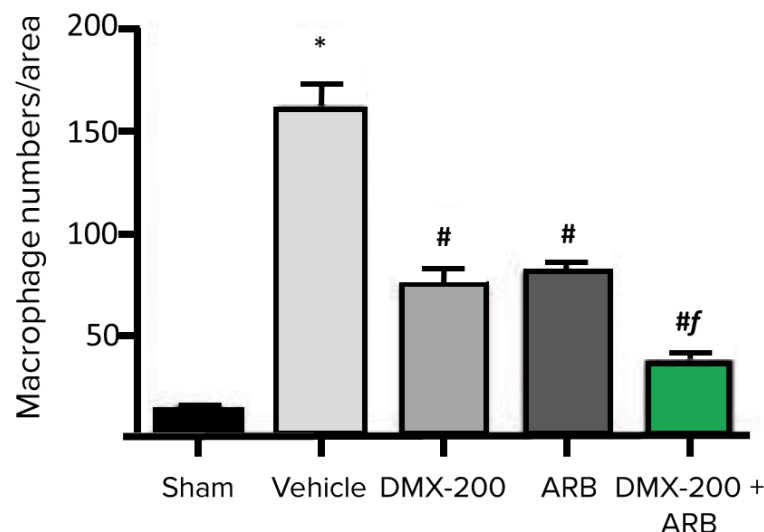
# Reduction in proteinuria in STNx rats

- The STNx model is broadly recognised as the gold standard model for FSGS

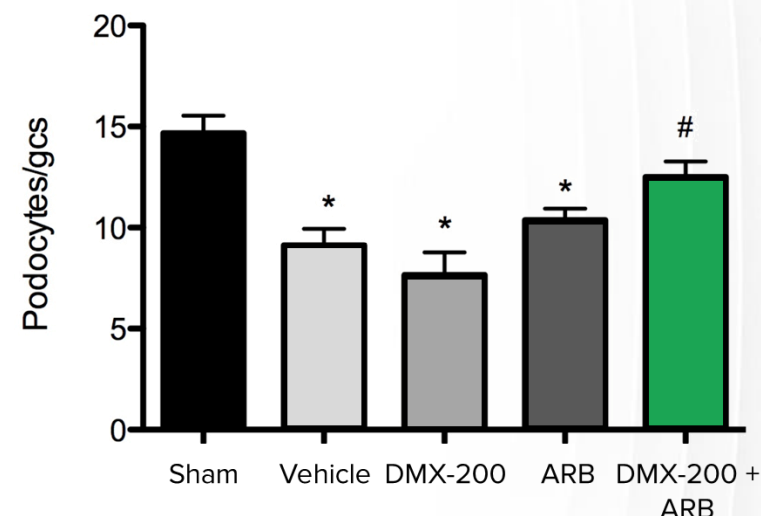
↓ Proteinuria



↓ Macrophage infiltration



↑ Preservation of podocyte numbers



Proposed non-clinical package suitability for NDA confirmed with FDA

# Non-clinical and CMC

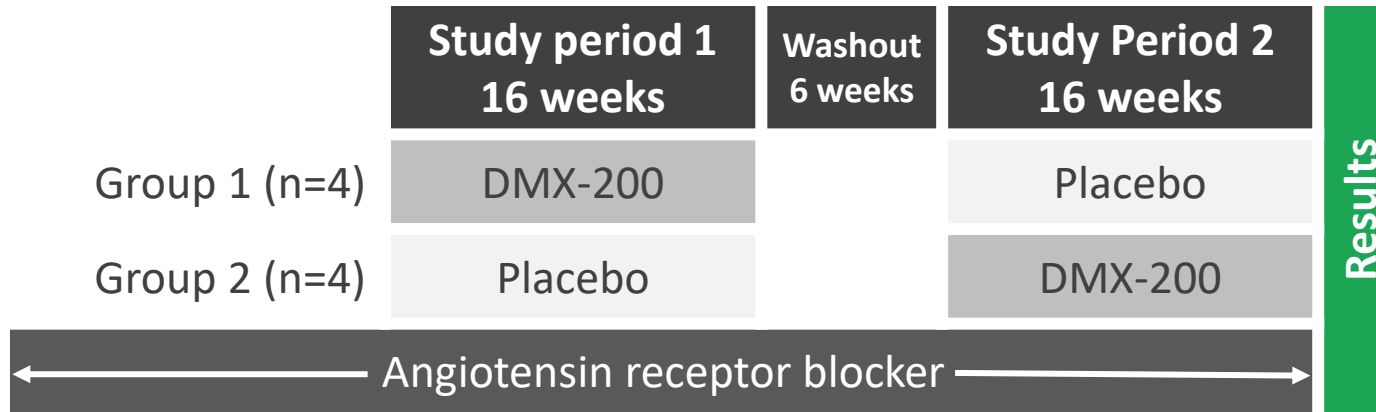
- Non-clinical studies complete
- Non-clinical NDA package suitability confirmed with FDA – November 2019 and July 2021
- **IND opened for Phase 3 study May 2022**

- US based contract manufacturer appointed for commercial supply
- Analytical methods validated
- Manufacturing methodology owned exclusively by Dimerix
- CMC NDA package suitability confirmed with FDA - November 2019 and July 2021

# 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 Focal Segmental Glomerulosclerosis who are Receiving an ARB

- *Primary endpoint: safety; Secondary endpoint: proteinuria and biomarker analysis*
- *Patient population: Patients with FSGS who are receiving an ARB*



# Phase 2a trial safety

## Patients with treatment emergent adverse event during study period

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

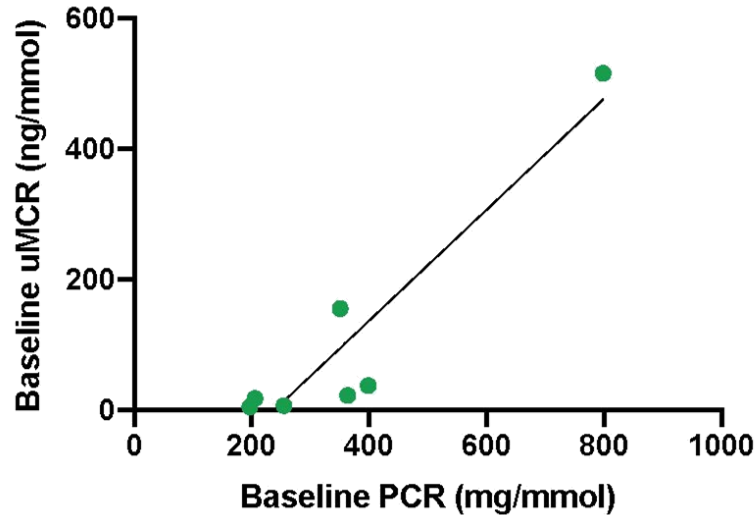
<sup>^</sup>tendonitis

- Consistently safe and well tolerated in both healthy volunteers and renal patients across all studies to date (total of 95 patients dosed)

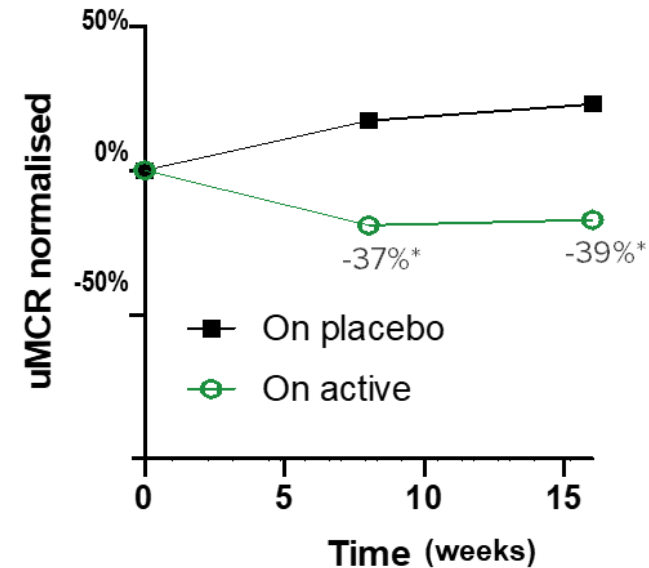
No safety concerns – reduced development risk  
DMX-200 compares favourably to compounds currently in development<sup>1,2</sup>

# DMX-200 inflammatory biomarker

Average baseline MCP-1 versus average baseline proteinuria



Change in MCP-1 over time on DMX-200 versus placebo



16 weeks treatment with DMX-200 vs placebo:

- DMX-200 Phase 2 study confirmed high MCP-1 correlates to high proteinuria in FSGS patients
- 39% reduction inflammatory biomarker MCP-1:
  - DMX-200 blocks receptor responsible for inflammation
  - translates to reduced inflammation and subsequent fibrosis (scarring) in the kidney

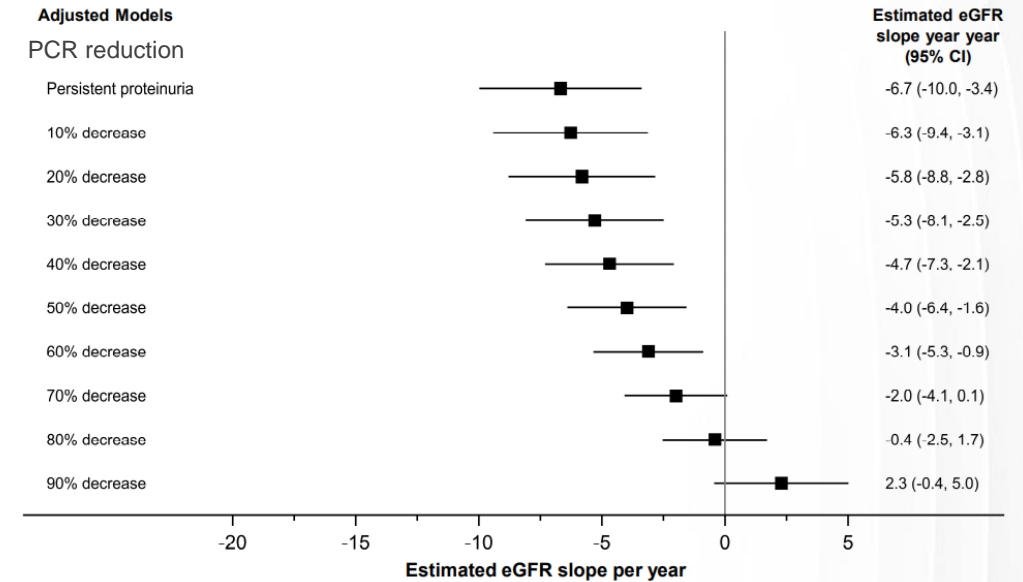
# DMX-200 data is clinically meaningful

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

*Kidney survival study - Troost et al, August 2020 <sup>1</sup>*

*“Kidney survival study (2020)<sup>1</sup>: 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 m<sup>2</sup> per year”*



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