

# DIMERIX TO PRESENT AT BIO INTERNATIONAL CONVENTION

MELBOURNE, Australia, 6 June 2022: Dimerix Limited (ASX: DXB), a biopharmaceutical company with Phase 3 clinical studies in inflammatory diseases, is pleased to advise that CEO & Managing Director, Dr Nina Webster, will be presenting the Dimerix opportunity to potential partners at the BIO International Convention in San Diego, California during the week commencing Monday 13 June 2022, US time. The one-on-one meetings are being scheduled via the BIO partnering system. Furthermore, Dimerix will provide US investor briefings across the US during the week commencing Monday 6 June 2022.

The presentation highlights the clear unmet need in kidney disease, the late-stage competitive pipeline and how Dimerix is overcoming the global challenges with its ACTION3 Phase 3 FSGS kidney study, currently being activated across 75 sites in 12 different countries globally.

BIO is the world's largest advocacy association representing member companies, state biotechnology groups, academic and research institutions, and related organizations across the United States and in 30+ countries. The BIO International Convention is the world's largest gathering of the biotechnology industry. It attracts more than 15,000 biotechnology and pharma leaders for one week of intensive networking to discover new opportunities and promising partnerships.

A copy of the presentation is attached.

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

Dr Nina Webster Rudi Michelson

Dimerix Limited Monsoon Communications

Chief Executive Officer & Managing Tel: +61 3 9620 3333

Director Mob: +61 (0)411 402 737

Tel: +61 1300 813 321 E: rudim@monsoon.com.au

E: investor@dimerix.com

Follow us on **LinkedIn** and **Twitter** 

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 Focal Segmental Glomerulosclerosis (FSGS), respiratory complications associated with COVID-19 and Diabetic Kidney Disease, and is developing 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 an angiotensin II type I receptor (AT1R) blocker - the standard of care treatment for hypertension and kidney disease. DMX-200 is protected by granted patents in various territories until 2032, with patent applications submitted globally that may extend patent protection to 2042.

In 2020, Dimerix completed two Phase 2 studies: one in FSGS and one in diabetic kidney disease, following a successful Phase 2a trial in patients with a range of chronic kidney diseases in 2017. No significant adverse safety events were reported in any trial, and all studies resulted in encouraging data that could provide meaningful clinical outcomes for patients with kidney disease. DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

### **FSGS**

FSGS is a rare disease that attacks the kidney's filtering units, where blood is cleaned (called the 'glomeruli'), causing irreversible scarring. This leads to permanent kidney damage and eventual end-stage failure of the organ, requiring dialysis or transplantation. For those diagnosed with FSGS the prognosis is not good. The average time from a diagnosis of FSGS to the onset of complete kidney failure is only five years and it affects both adults and children as young as two years old. For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney. At this time, there are no drugs specifically approved for FSGS anywhere in the world, so the treatment options and prognosis are poor.

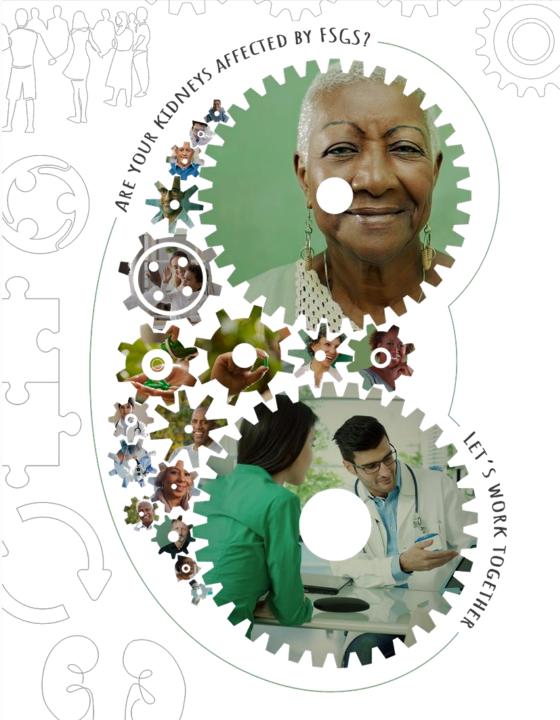
FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,<sup>3</sup> and worldwide about 210,000. The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year<sup>3</sup>. Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for FSGS. 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 a fast-tracked regulatory pathway to approval. Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

### References

1 Guruswamy Sangameswaran KD, Baradhi KM. Focal Segmental Glomerulosclerosis (July 2021), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/

3 Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/

<sup>2</sup> DelveInsight Market Research Report (2020); Focal Segmental Glomerulosclerosis (FSGS)- Market Insight, Epidemiology and Market Forecast -2030





# Partnering and Investor Presentation

June 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

FSGS Phase 3 clinical study opening across 12 countries globally<sup>1</sup>

ClinicalTrials.gov (Study Identifier: NCT05183646) or Australian New Zealand Clinical Trials Registry (ANZCTR) (Study Identifier ACTRN12622000066785) Demonstrated **clinical efficacy**<sup>2</sup>; drug well understood, with **strong safety profile**<sup>2</sup>

Patent protected products with commercial manufacturing established

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



ASX releases: 28Jan22, 01Feb22

ASX releases: 12Jul17, 18Oct17, 27Mar18, 29Jul20, 14Sep20, 27Oct20, 28Jan21, 24Mar21, 03Jun21, 07Jun21, 19Jul21

<sup>&</sup>lt;sup>3</sup> See slides 12 and 19 for market potential

# Corporate overview



Ticker Symbol

**ASX:DXB** 



Cash Balance (31Mar21)

A\$16.8 million



Market Capitalisation

~A\$55 million



Share price

~A\$0.17



Total ordinary shares on issue

320,873,666



Average volume

512,341



Top 20 Shareholders own

38%

# Chart generated on 3/6/2022 at 4:33 pm Output Output



Top shareholders							
Position	Holder Name	Holding	% IC				
1	Mr Peter Meurs	44,179,309	13.8%				
2	Merchant Group & Nominees	17,925,000	5.6%				
3	Mr Andrew Coates & Mrs Melinda Coates	9,500,000	3.0%				
4	Bavaria Bay Pty Ltd	7,316,992	2.3%				
5	Yodambao Pty Ltd	6,362,603	2.0%				
6	Solequest Pty Ltd and Nominees	3,687,302	1.1%				
7	Pfleger Family A/C and Nominees	3,137,874	1.0%				
8	Tamer Yigit Property Group Pty Ltd	3,000,000	0.9%				
9	Mr James Victor Camilleri	2,866,873	0.9%				
10	Rubi Holdings Pty Ltd	2,500,000	0.8%				
10	Mr Taylor Nicholas Green	2,500,000	0.8%				
TOTAL (TOP 10)		102,975,953	32.2%				

# 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 75 sites in 12 different countries <sup>2</sup> , 1 <sup>st</sup> interim data anticipated H1 23 <sup>3</sup>
	Diabetic Kidney Disease					Phase 2 demonstrated promising efficacy and safety <sup>1</sup> , planning of next study design anticipated mid-2022 following FSGS start up activities
	Late COVID pneumonia – REMAP-CAP					Study recruitment across Europe <sup>4</sup> , recruitment paused pending analysis <sup>5</sup> , data analysis underway by REMAP-CAP, will update market upon receipt
	Early COVID respiratory – CLARITY 2.0					Recruitment underway across India <sup>6</sup> , ethics approval in Australia <sup>7</sup> , data from CLARITY 1.0 study (use of angiotensin receptor blockers in COVID patients) anticipated imminently <sup>8</sup> , interim data from India now anticipated Q2 22 <sup>3</sup>
DMX-700	Chronic Obstructive Pulmonary Disease (COPD)					Pre-clinical studies underway to support entry into clinical studies; data anticipated Q2 22
DMX-xxx	Undisclosed (multiple)					Additional target opportunities identified using Receptor-HIT; preliminary exploratory work underway



<sup>1.</sup> ASX releases: 12Jul17, 18Oct17, 27Mar18, 29Jul20, 14Sep20, 27Oct20, 28Jan21, 24Mar21, 03Jun21, 07Jun21, 19Jul21

<sup>2.</sup> ASX releases: 21Oct21, 01Feb22 (Australia, Denmark); + further countries subsequently approved

<sup>3.</sup> Subject to recruitment

<sup>4.</sup> ASX release: 23Apr21, 16Dec21

<sup>5.</sup> ASX release 28Feb22

<sup>6.</sup> ASX release: 11Jan22

 <sup>7.</sup> ASX release: 23Dec21
 8. CLARITY 1.0 data outcomes may influence study design of CLARITY 2.0 study

# 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)



Small molecule

New Chemical Entity status with granted patents and applications across key countries



Clear Development Path

FDA/EMA recognising surrogate markers, such as proteinuria and eGFR as registration endpoints<sup>1,2</sup>



Easy and convenient dosing

2 x 120mg capsule daily



Extensive regulatory
engagement
US IND open;<sup>3</sup>
orphan drug designation
secured in US, EU and UK<sup>4</sup>



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

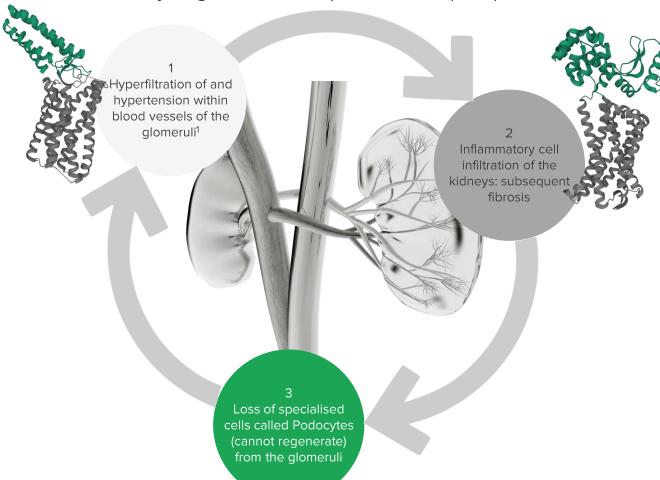
<sup>2.</sup> FDA pulication, (2021); FDA approves first drug to decrease urine protein in IgA nephropathy, a rare kidney disease https://www.fda.gov/drugs/fda-approves-first-drug-decrease-urine-protein-iga-nephropathy-rare-kidney-disease

з. ASX release: 09May2022

<sup>4.</sup> ASX releases: 14Dec15, 21Nov18, 07Jun21

# 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>

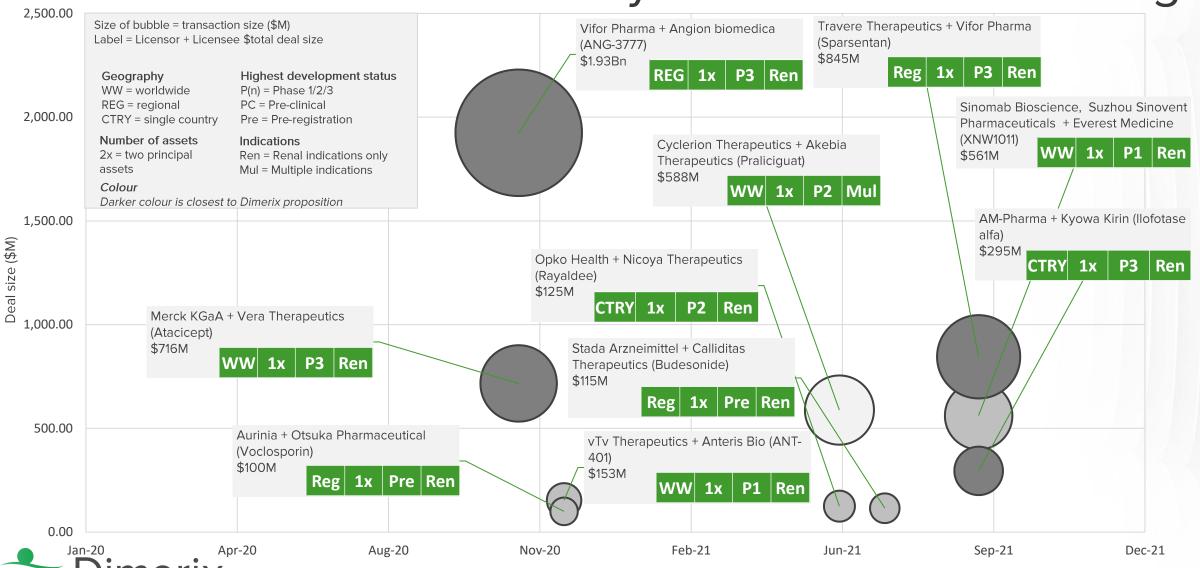
Certain kidney cells express both receptors, thus using only 1 compound does not block activation and results in only a partial response<sup>2,3</sup>

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

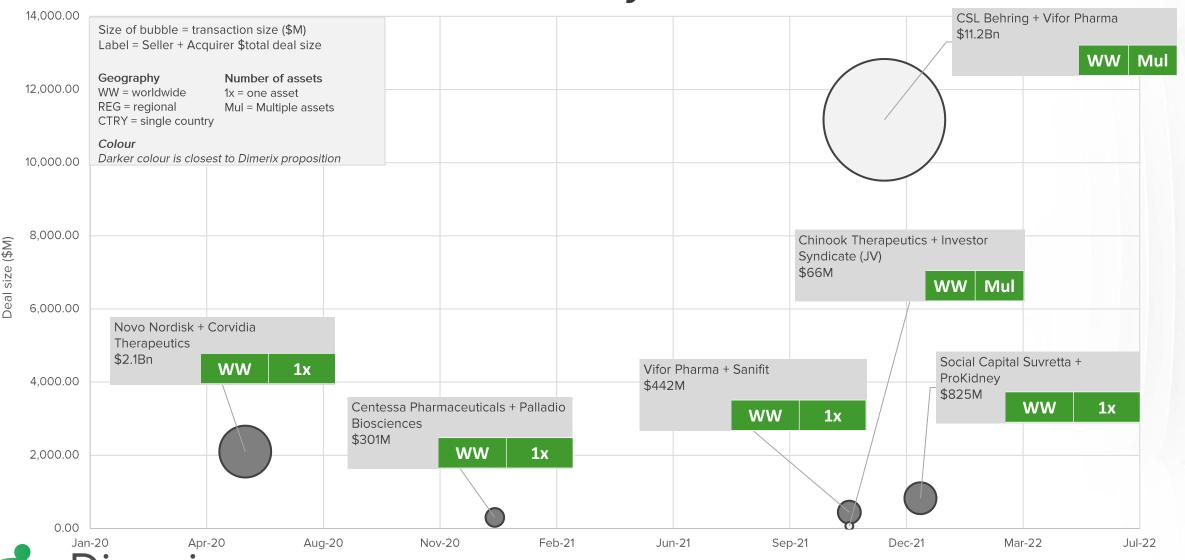


Less filtering cells cause further hyperfiltration and inflammation

# Increased interest in kidney transactions: licensing



# Increased interest in kidney transactions: M&A



# Renal disease landscape

"A squeaky wheel waiting for grease: 50 years of kidney disease management in the US"



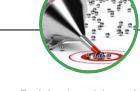
Historical lack of incentives and public policy have contributed to high costs and poor health outcomes for renal patients<sup>1</sup>



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"



# Policy change: renal disease healthcare economic burden

### ~40 million

adults have kidney disease (~15% of the adult population) in the US in 2021 1

### US\$88 billion

estimated total US Medicare expenses costs/year for renal patients in 2021 1,3

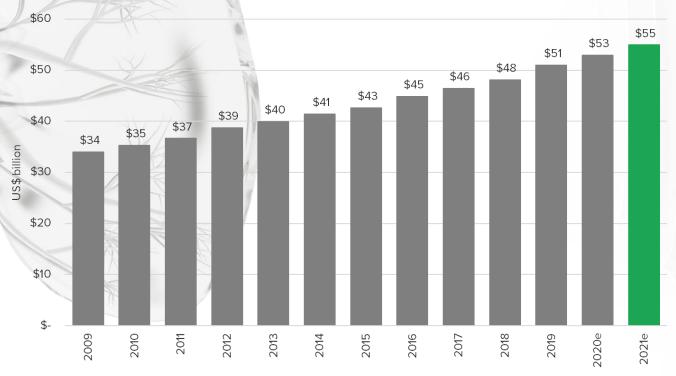
### 2019

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>



<sup>1.</sup> Garibaldi A, et al (2021) The Evolution of Kidney Health Management and the Next Frontier; https://www.lek.com/insights/ei/evolution-kidney-health-management-and-next-frontier 2. https://www.federalregister.gov/documents/2019/07/15/2019-15159/advancing-american-kidney-health;

3. The United States Renal Data System (USRDS) Annual Report 2021; (2020 & 2021 estimates based on CAGR 2014-2019)

# Clinical study change: use of surrogate endpoints

A surrogate endpoint is an intermediate outcome which substitutes the clinically meaningful endpoint

> US FDA, European EMA, and US National Kidney Foundation hold scientific workshop on proteinuria & glomerular filtration rate (GFR) as endpoints for clinical studies in kidnev disease <sup>2</sup>

FDA publish willingness to consider fixed glomerular filtration rate (GFR) and proteinuria decline as surrogate end points for kidney failure in certain conditions 3

2019

drug based on **Publications** demonstrate relationship between proteinuria as a continuous variable and

kidney survival in FSGS

patients 4

2020

2021

FDA grants first accelerated approval proteinuria endpoint in a rare kidney disease, IgA nephropathy 5

> Dimerix starts recruiting patients for global Phase 3 study in FSGS patients using approvable

> surrogate endpoints 6

2022

2018

Pre-2018

reached for decades 1

"Hard" endpoints for

kidney disease (kidney failure) may not be



# Focal Segmental Glomerulosclerosis

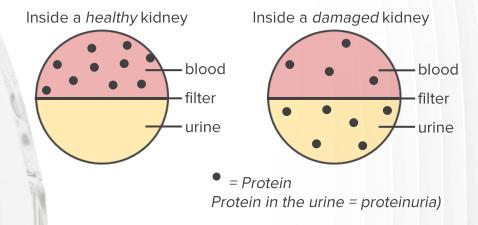
Focal = some

Segmental = sections

Glomerulo = of the kidney filtering units

Sclerosis = are scarred

### A healthy kidney has little to no protein in the urine



- 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>



- Nephcure Understanding FSGS 2022: https://nephcure.org/livingwithkidneydisease/ns-and-other-glomerular-diseases/understanding-fsgs/
- Nephcure FSGS factsheet 2022: https://leu46v1g93c11mayx1nfvwg6-wpengine.netdna-ssl.com/wp-content/uploads/2021/02/nc.factSheet.FSGS\_210106.pdf
- Front. Immunol., 17 July 2019 | https://doi.org/10.3389/fimmu.2019.01669
- Nephron 2020;144:413-427, https://doi.org/10.1159/000508099 2018, IQVIA, Orphan Drugs in the United States: Growth Trends in Rare Disease Treatments

# 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 relationship at week 35
DUPLEX <sup>2</sup>	Sparsentan	Dual angiotensin/endothelin A receptor antagonist	Irbesartan	Proportion of patients achieving uPCR ≤ 1.5g/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>

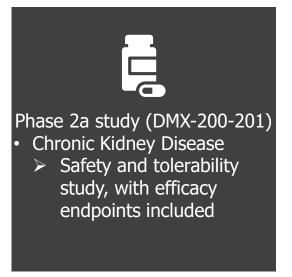


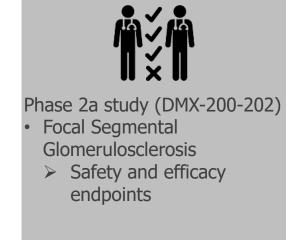
Kidney Disease Development Overview



# DMX-200 clinical experience









Phase 2 study (DMX-200-203)

- Diabetic kidney disease
  - Efficacy and safety endpoints

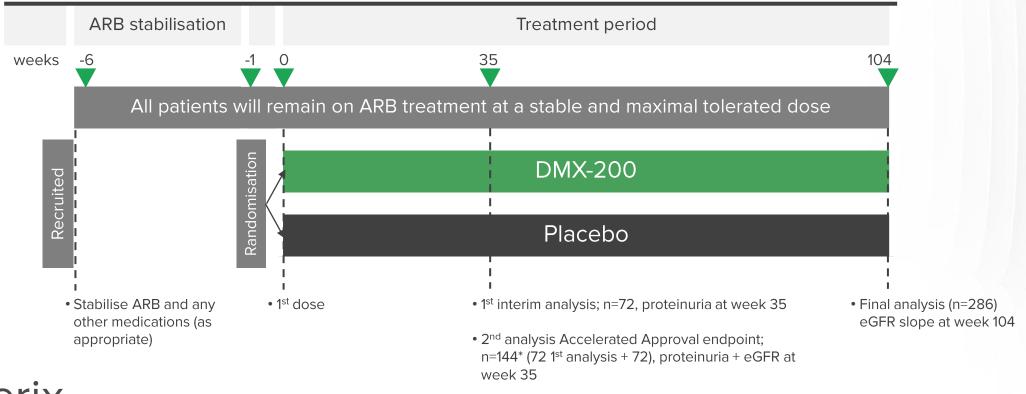
- Positive efficacy signals across studies
- 240mg oral delivery daily 120mg capsule administered twice daily
- Consistently safe and well tolerated in both healthy volunteers and renal patients (total of 95 patients dosed)
- DMX-200 safety profile and efficacy outcomes compares favourably to compounds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



# FSGS phase 3 study design



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





ARB: Angiotensin Receptor Blocker
\*Subject to recruitment rate and conditional power

# FSGS phase 3 study locations



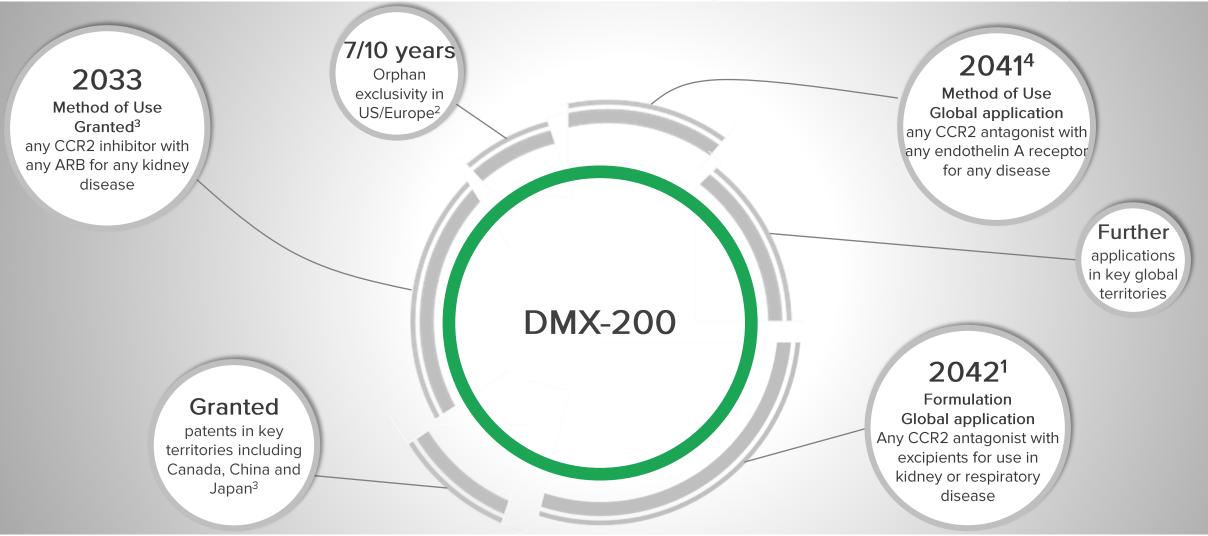
A randomised, double-blind, multi-centre, placebocontrolled study of renal outcomes of DMX-200 in patients with primary FSGS receiving an ARB

### Global study with ~70 sites in 12 countries:

Country	Regulatory and/or ethics approval	
Australia	✓	
Argentina	✓	
Brazil	✓	
Denmark	✓	
France	✓	
Hong Kong	✓	
New Zealand	✓	
South Korea	✓	
Spain	✓	
Taiwan	✓	
UK	✓	
USA	$\checkmark$	



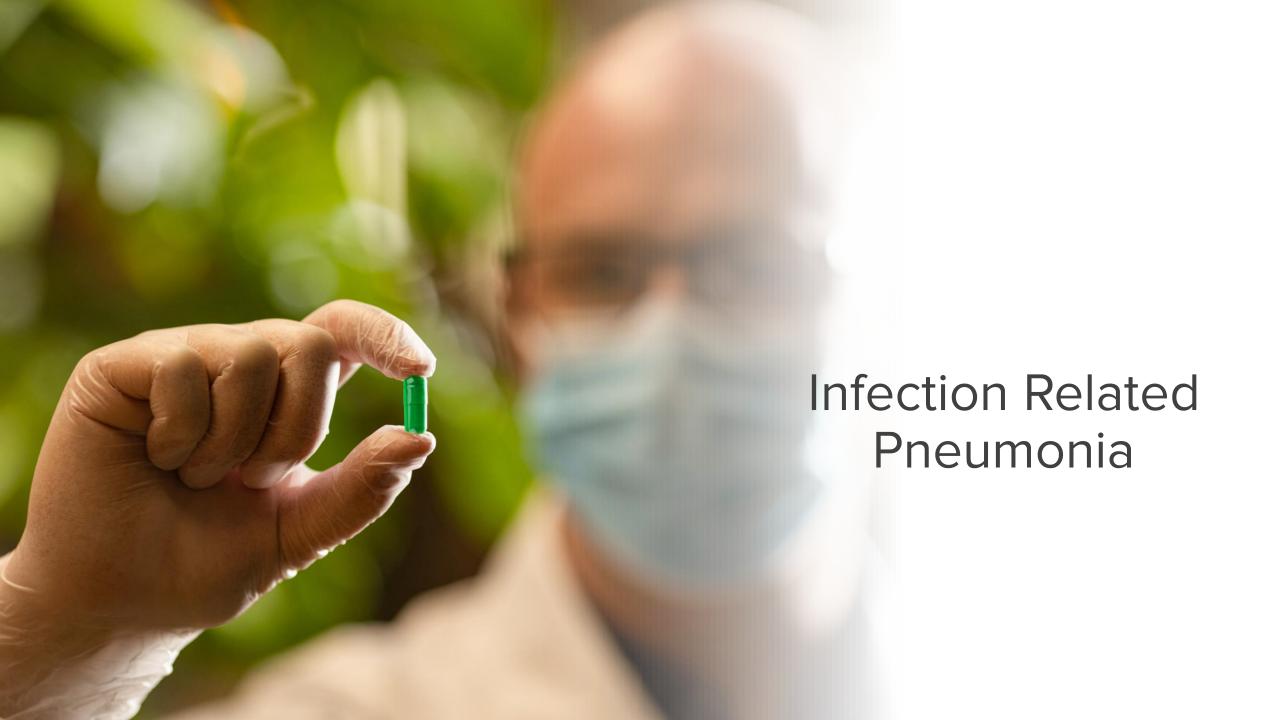
# DMX-200 Intellectual property and exclusivity





- 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



# Pneumonia (including COVID-19) market potential

### 3 million

deaths annually caused by lower respiratory tract infections pre-COVID1



### **US\$17** billion

pre-COVID: Pneumonia responsible for US\$17 billion in healthcare costs each year in the US1

### US\$18.5 billion

market forecast expected by 2029, growing at 10%/year<sup>3</sup>

### 4.5 million:

COVID-19: caused 476 million cases globally to date, resulting in >6.1 million deaths and counting<sup>2</sup>

### 20-30%

of all patients with pneumonia require admission to Intensive Care Units<sup>1</sup>



### \$ 2,300-4,600

The cost of treatment with Tocilizumab (IL-6 receptor antagonist used for COVID-19): IV single dose<sup>4</sup>



- REMAP-CAP background: https://www.remapcap.org/background
- WHO COVID dashboard: https://covid19.who.int/
- Data Bridge Market Research 2022, https://www.databridgemarketresearch.com/reports/global-acute-respiratory-distress-syndrome-ards-market 77
- Dose and therefore cost varies with patient weight; PharmacoEconomics & Outcomes News 2021; volume 879, p.28

# Potential benefits of DMX-200





Antiviral medications:

Typically effective at preventing damage caused by a virus when administered

within 3-5 days of infection<sup>1</sup>

when many are asymptomatic





Does not rely on early inhibition of viral replication

DMX-200 aims to prevent damaging immune response regardless of vaccination or antiviral treatment



### DMX-200:

patients with a wide range of respiratory diseases in addition to COVID<sup>2</sup>

specific for a virus and sometimes even the



# Two investigator-led phase 3 studies in COVID-19 patients

- REMAP-CAP analysis underway and will be reported as soon as received by Dimerix;
- Further recruitment paused pending interim data analysis<sup>1</sup>



- ~779 patients recruited to the study domain
- WHO endorsed study
- Primary endpoint = 21 day mortality

Population: COVID-19 pneumonia in ICU

Patients were randomised patients to receive one of:

- Angiotensin receptor blocker (ARB) alone
- 2. Angiotensin converting enzyme (ACE) inhibitor alone
- 3. ARB simultaneously with DMX-200
- 4. No RAS inhibitor (no placebo)

- CLARITY 1.0 analysis to be published imminently;
- CLARITY 2.0 analysis to report after initial "80 patients now anticipated Q2 22



Population: COVID-19 respiratory complications

- Recruiting >600 patients in India and Australia
- Primary endpoint = 14 day WHO Clinical Health Score
- Interim analysis once first 80 patients recruited

Patients randomised patients to receive one of:

- 1. Angiotensin receptor blocker (ARB) + Placebo
- 2. ARB simultaneously with DMX-200
- 3. Placebo + Placebo



Secondary endpoints: recovery and quality of life post hospitalisation (long-COVID assessment)



# Additional asset value propositions

Longer term opportunities



DMX-200 Diabetic Kidney Disease Diversifying risk and potential sources of revenue

DMX-700 Chronic Obstructive Pulmonary Disease



Addressable market

US\$1.1 billion\*

Key driver is the rise in diabetes global incidence

Global COPD treatment market (2017)

US\$14 billion\*\*



<sup>2017</sup> IQVIA ARB prescription and pricing data;

https://www.marketwatch.com/press-release/chronic-obstructive-pulmonary-disease-copd-therapeutics-market-global-industry-analysis-trends-market-size-and-forecasts-up-to-2030-2021-11-10?tesla=y



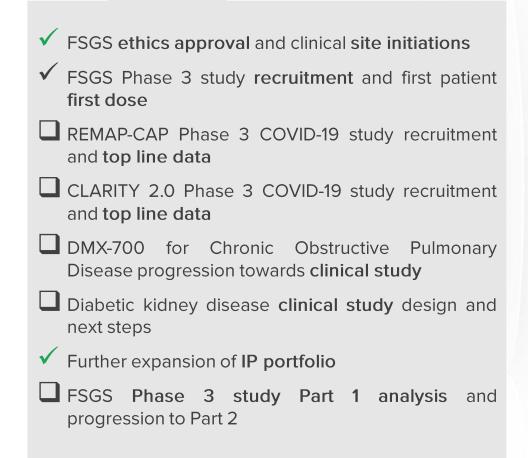
# Corporate Outlook

# 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







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

### ESG Statement



# Dimerix board



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

Non-Executive Chairman

- · 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

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



BSc (Hons), MBA
Non-Executive Director

Mayne Pharma, Acrux, Hatchtech, Kinoxis

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



Hoffman la Roche, Addex, AC

Non-Executive Director

 Experienced executive in pharmaceutical operations

Immune, Minoryx

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



# Dimerix management



Wyeth (Pfizer), Acrux, Immuron

**CEO & Managing Director** 

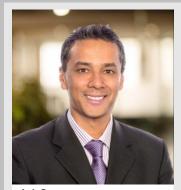
- Experienced in product development, commercial strategy development & execution
- Successfully commercialised multiple pharmaceutical products globally
- ✓BSc (Hons) Pharmacology
- ✓ PhD Pharmaceutics
- ✓ MBA Business
- ✓M.IP.Law Intellectual Property Law



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 R & D Director

### 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 Product Development Director

### 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

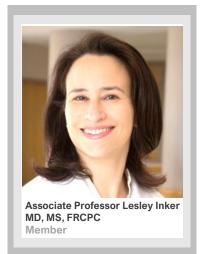
Professor of Clinical Trials and Personalized Medicine: University Medical Center Groningen, the Netherlands. He specialises in the research of novel treatment approaches to slow the onset of diabetic cardiovascular and renal disease. Hiddo has been instrumental in interactions between industry, researchers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



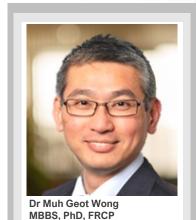
Professor of Medicine & Molecular & Cellular Pharmacology: University of Miami. Chief of the Katz Family Division of Nephrology and Hypertension. She has an extensive history of translational excellence for patients with renal disease and has uncovered novel pathogenetic mechanisms and therapeutic approaches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



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.



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.



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.

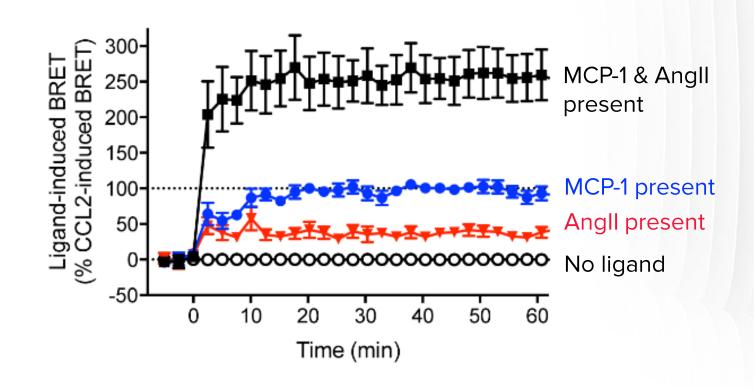


# AT1R and CCR2 form functional heteromers

### Unique pharmacology of AT1R/CCR2 heteromer

Proprietary discovery platform (Receptor-HIT) identified:

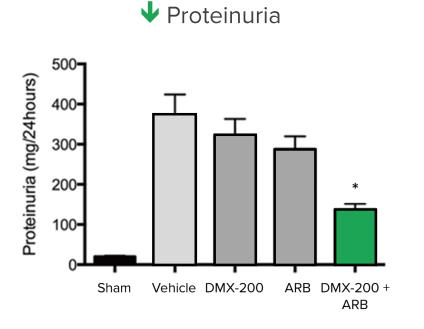
- Formation of AT1R and CCR2 heteromers:
- Novel pharmacology (potentiation of signaling)
- Dual antagonism required for completed inhibition

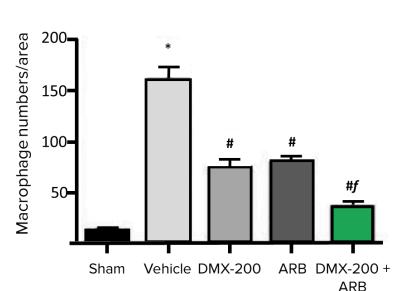




# Reduction in proteinuria in STNx rats

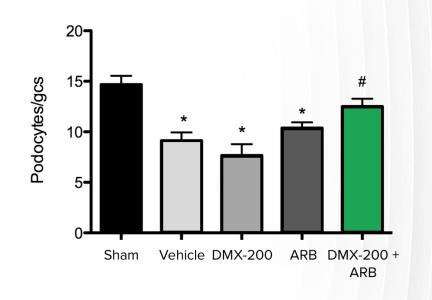
The STNx model is broadly recognised as the gold standard model for FSGS





Macrophage infiltration





Proposed non-clinical package suitability for NDA confirmed with FDA



ARB: Angiotensin Receptor Blocker

\* P<0.05 vs sham

# P<0.05 vs un-treated STNx

f P<0.05 vs STNx+lrb

# 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

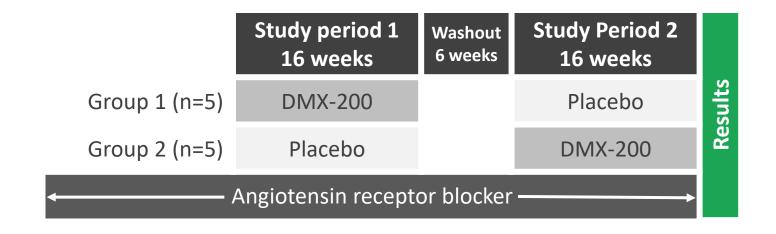
- US based contract manufacturer appointed for commercial supply
- Analytical methods validated
- Manufacturing methodology owned exclusively by Dimerix
- CMC NDA package suitability confirmed with FDA November 2019 and July 2021



# Phase 2a trial in FSGS completed

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

- Primary endpoint: safety. Secondary endpoint: proteinuria and biomarker analysis.
- Patient population: Patients with primary FSGS who are receiving irbesartan





# Phase 2a trial safety

### Patients with treatment emergent adverse event during study period Placebo DMX-200 Any 6 Drug-related 0 0 Serious 1^ 0 Leading to dose interruption 0 0 Leading to study withdrawal 0 0 Death 0 0

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

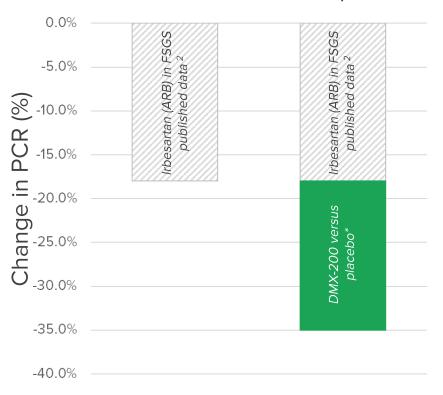
^tendonitis

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



# DMX-200 treatment group met primary and secondary endpoints

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>



- DMX-200 demonstrated clear benefit to patients with FSGS
  - o 86% of patients demonstrated reduced proteinuria on DMX-200 versus placebo
  - 29% of patients demonstrated >40% reduction in proteinuria
  - o 17% reduction of uPCR: mixed model, repeat measures statistical test; (grouped analysis model shows a 25% drop in uPCR)
  - 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>

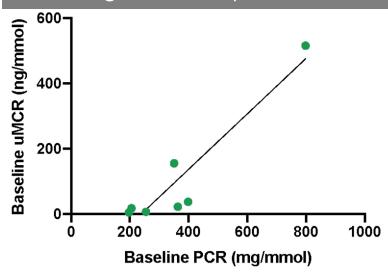
No safety concerns – reduced development risk DMX-200 compares favourably to compounds currently in development<sup>2,4</sup>



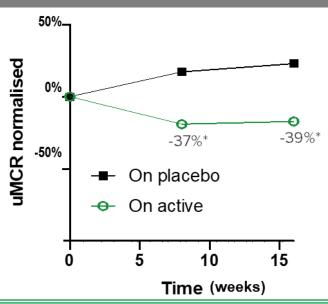
PCR = protein creatinine ratio; ARB = angiotensin receptor blocker

# 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

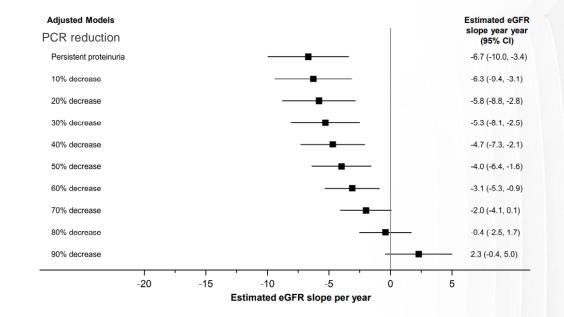


# DMX-200 data is clinically meaningful

"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

"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 m2 per year"





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

