



**Immediate Release**

## **DIMERIX PRESENTS AT EUROZ HARTLEYS INSTITUTIONAL CONFERENCE 2024**

MELBOURNE, Australia, 13 March 2024: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company with late-stage clinical assets, is pleased to advise that CEO and Managing Director, Dr Nina Webster, will be presenting at the Euroz Hartleys Institutional Conference on Rottnest Island, WA on 13 March 2024.

A copy of the presentation is attached.

For further information, please visit our website at [www.dimerix.com](http://www.dimerix.com) or contact:

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*Authorised for lodgement by the Board of the Company*

**—END—**

**Dimerix is a biopharmaceutical  
company developing innovative new  
therapies in areas with unmet  
medical needs.**

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### **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 study in patients with a range of chronic kidney diseases in 2017. No significant adverse safety events were reported in any study, 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.<sup>1</sup> For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney.<sup>2</sup> 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/>
- 2 *DelveInsight Market Research Report (2020); Focal Segmental Glomerulosclerosis (FSGS)- Market Insight, Epidemiology and Market Forecast -2030*
- 3 *Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis*, online <https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/>



# Dimerix

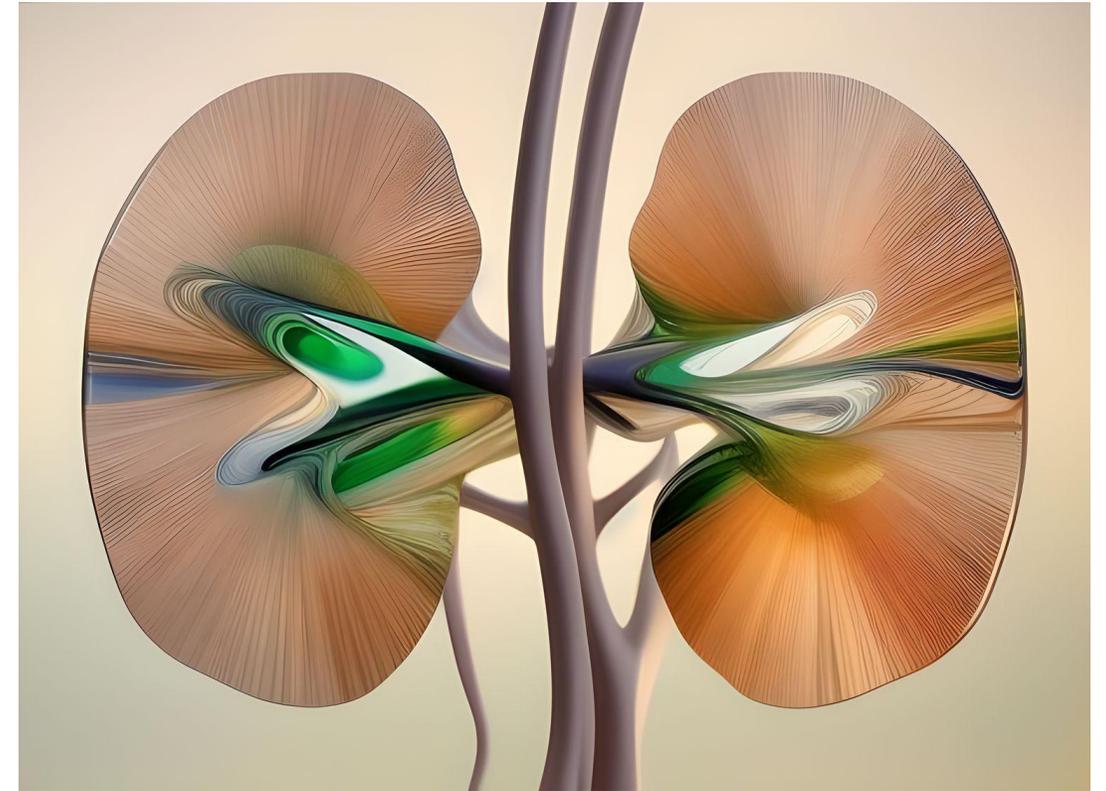
(ASX:DXB)

Developing new therapies to treat inflammatory causes of kidney and respiratory disease with unmet clinical needs

13 March 2024

## Euroz Hartleys

## Rottnest Conference Presentation



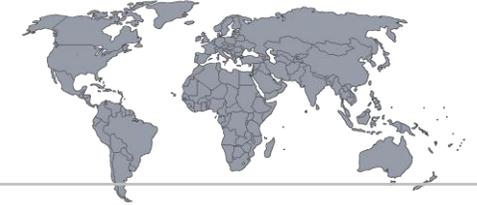
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# Forward looking statements

*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.*

# Summary | Phase 3 Global Opportunity



## Lead Drug Candidate

- DMX-200 is currently in a **Phase 3 clinical trial** for focal segmental glomerulosclerosis (FSGS)

## FSGS

- FSGS is a disease that causes scar tissue of kidneys, which leads to irreversible kidney damage<sup>1</sup>
- FSGS kidney damage can lead to dialysis, kidney transplants or death<sup>1</sup>

## Market Opportunity

- Estimated  $\sim >200,000$  people with FSGS in the 7 major markets (makes **FSGS a rare disease**)<sup>2</sup>
- Estimated 40,000<sup>1</sup> – 80,000<sup>2</sup> people in the US alone
- Drugs for rare kidney diseases can be priced at  **$\sim \text{US\$}120,000$  per annum** in the US<sup>3</sup>
- There are currently **no approved treatments** available to treat FSGS

## Commercial Validation

- Licensing deal already achieved** in October 2023 for EEA, UK, SUI, CA, AU and NZ<sup>4</sup>
- AUD\$10.8m received upfront,  $\sim \text{\$}220\text{m}$  in potential milestone payments & mid-teen-20% tiered royalties
- DMX-200 is currently performing better than placebo** in reducing proteinuria (using a statistical measure<sup>1</sup>) in the Phase 3 interim analysis: a significantly larger cohort than our prior Phase 2 study

## Upcoming Milestones

- Execution of potential licensing deals** for available jurisdictions, including the US & China<sup>5</sup>
- Recruitment** and dosing of 144 patients for Part 2
- Part 2 – **second interim analysis** outcome estimated mid-2025
- Announcements which relate to DXB's secondary assets

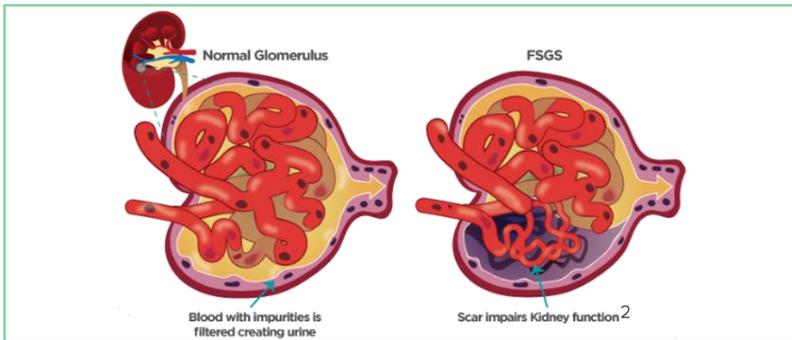
# Focal Segmental Glomerulosclerosis (FSGS)

Focal = some  
Segmental = sections  
Glomerulo = of the kidney filtering units  
Sclerosis = are scarred

## What is FSGS?

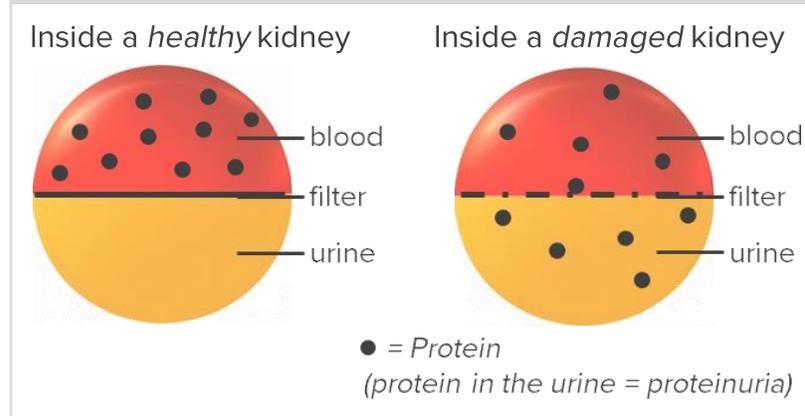
FSGS is a rare kidney disease that attacks part of the kidney filtering units, causing **inflammation** and irreversible scarring to the kidneys<sup>1</sup>

This inflammation and scarring leads to permanent kidney damage and eventually end-stage kidney failure, requiring dialysis or transplantation



## Why are kidneys important?

A healthy kidney is a good filter and allows little to no protein in the urine



## Why is proteinuria important?

When kidneys are damaged, protein can leak into the urine causing proteinuria, hence proteinuria can represent an important early marker of kidney function

↑ proteinuria suggests damaged kidney

↓ little / no proteinuria suggests healthy kidney

DMX-200 aims to reduce the inflammation of the kidneys: if DMX-200 reduces inflammation = the amount of proteinuria should decrease

Proteinuria: an important endpoint for DMX-200 study

# FSGS causes and prognosis

Focal segmental glomerulosclerosis (FSGS) is one of the most common forms of acquired glomerular disease leading to end stage kidney disease (ESKD), requiring dialysis or transplant

- ▶ Caused by a variety of conditions - primary FSGS, genetic FSGS, FSGS of unknown cause and secondary FSGS<sup>2</sup>
- ▶ Significant burden on global health systems
  - Patients end up on dialysis (est cost US\$90,000/patient/year)<sup>3</sup>
  - Patients requiring kidney transplant (est cost US\$442,500 per transplant + ongoing medication fees)<sup>4</sup>
  - 60% patients have reoccurring FSGS even after first kidney transplant<sup>5</sup>



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Approved drugs anywhere in the world

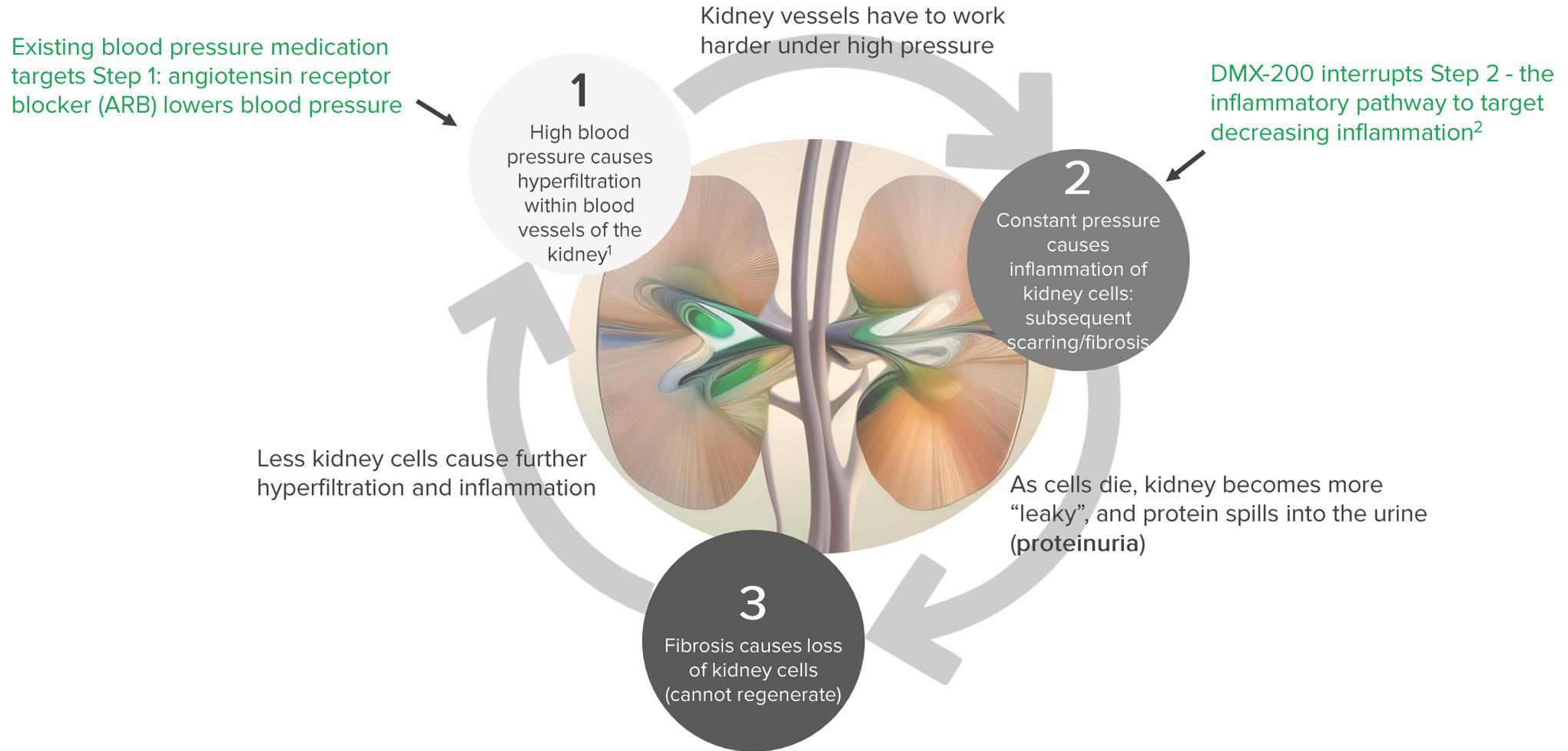
60%

Patients have reoccurring FSGS even after first kidney transplant<sup>6</sup>

5

Average time (years) to kidney failure after onset of proteinuria<sup>1</sup>

# Progression of FSGS kidney disease

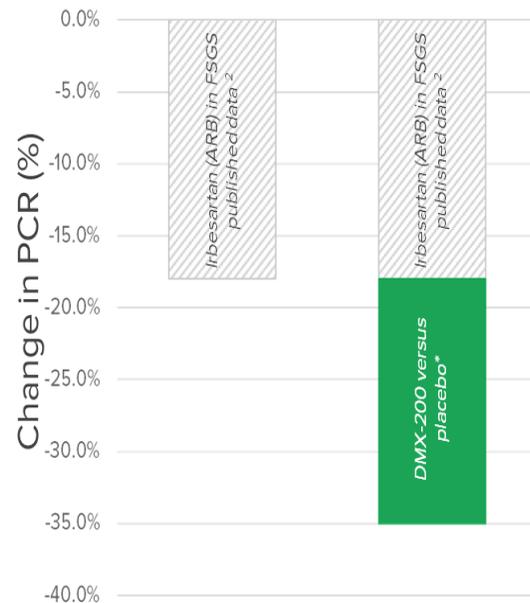


# DMX-200: Phase 2 met primary and secondary endpoints



 Clinically meaningful outcomes achieved for patients, with no safety issues

Average reduction of 17% in proteinuria after 16 weeks treatment on DMX-200 versus placebo<sup>1</sup>



## EFFICACY

- 86% of patients demonstrated reduced proteinuria
- 29% of patients demonstrated >40% reduction in proteinuria



## SAFETY

- No safety concerns – reduced development risk
- DMX-200 compares favourably to compounds currently in development<sup>2,3</sup>

“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>4</sup>*

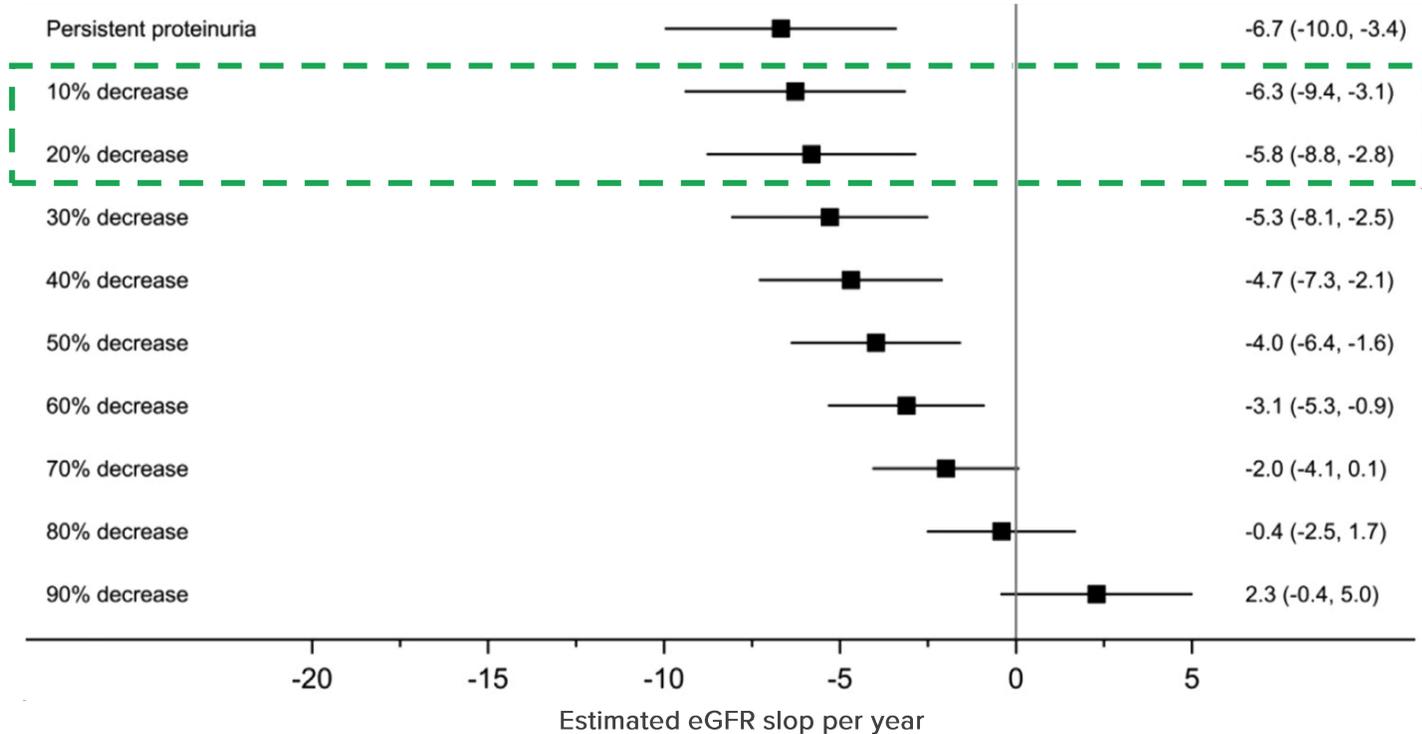
# DMX-200: Phase 2 met primary and secondary endpoints



17% average reduction of proteinuria in Phase 2 is clinically meaningful<sup>1</sup>

Adjusted models

uPCR reduction



FDA & EMA recognise surrogate markets, such as proteinuria & EGFR as registration endpoints in rare kidney disease

“reductions ~10% in proteinuria translated to clinically meaningful differences in eGFR”  
Kidney survival study – Troost et al, August 2020<sup>1</sup>

# PHASE 3 CLINICAL TRIAL

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# Phase 3 opportunity

# Successful interim analysis

## Lead Drug Candidate – DMX-200 in focal segmental glomerulosclerosis (FSGS)

 ACTION3 Phase 3 trial **successfully passes first interim analysis** using proteinuria efficacy endpoint

 **DMX-200 is currently performing better than placebo** in reducing proteinuria (using a statistical measure<sup>1</sup>) in patients with FSGS in a significantly larger cohort than our prior Phase 2 study

 Passing this early interim analysis suggests **a statistically significant and clinically meaningful result** in reducing proteinuria at the end of the study may be possible<sup>2,3</sup>

 IDMC has again noted **no safety concerns to date**, which is entirely consistent with the existing and growing strong safety profile of DMX-200

 ACTION3 clinical trial will now **formally expand into Part 2** of the study

# ACTION3 Phase 3 clinical trial – next steps

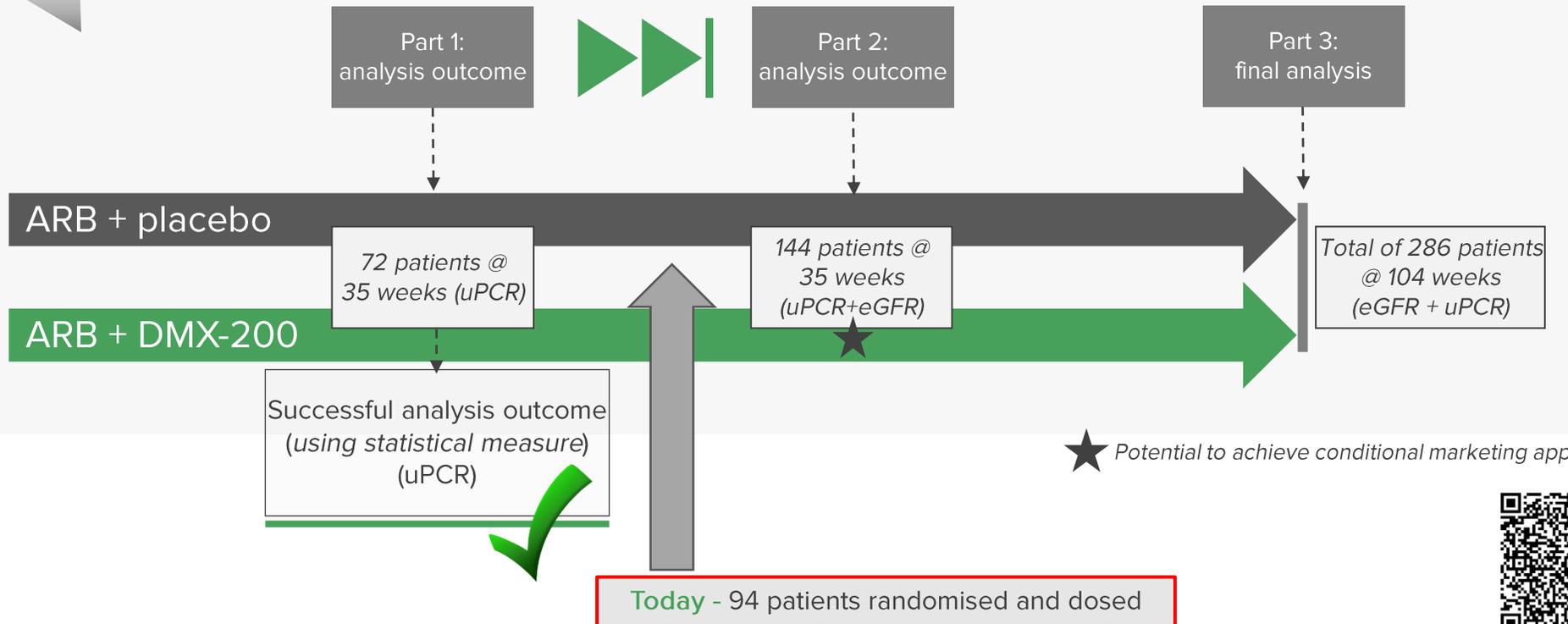
FSGS CLINICAL STUDY

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

## Background

- Patients recruited, then screened and stabilised on background medications
- Patients randomised to receive drug or placebo
- DXB remains blinded at all times during study

## Phase 3 Trial Timeline



# FSGS MARKET OPPORTUNITY

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# Potential FSGS market size

No approved therapies for FSGS



DMX-200 is the only therapy in phase 3 development

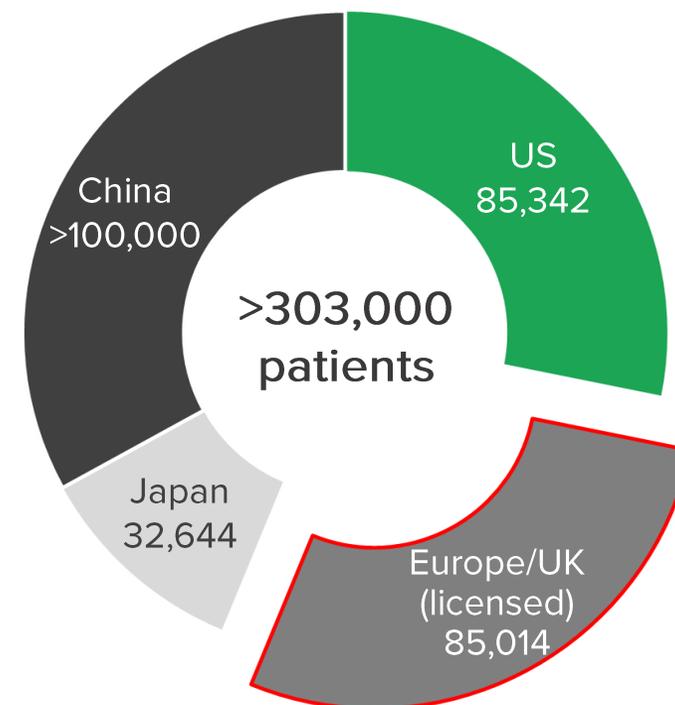


Multi-billion dollar market potential



- ▶ Example pricing for other rare kidney disease drugs :
  - in the US (i.e. Filispari in IgAN)<sup>2</sup> is **US\$9,900 p/month**
  - in Europe/UK (i.e. Kinpeygo/Tarpeyo)<sup>3</sup> is **US\$8,267 p/month (€7,630)**
- ▶ Example annual pricing<sup>2,3</sup>:
  - **~US\$120k per annum** per patient for FSGS drug in US
  - **~€91,560 per annum** per patient for FSGS drug in Europe
- ▶ Next major targets for DXB are **US & China**, with partnering discussions already underway

Estimated 7MM (+China)  
diagnosed patients (2022)<sup>1,4</sup>



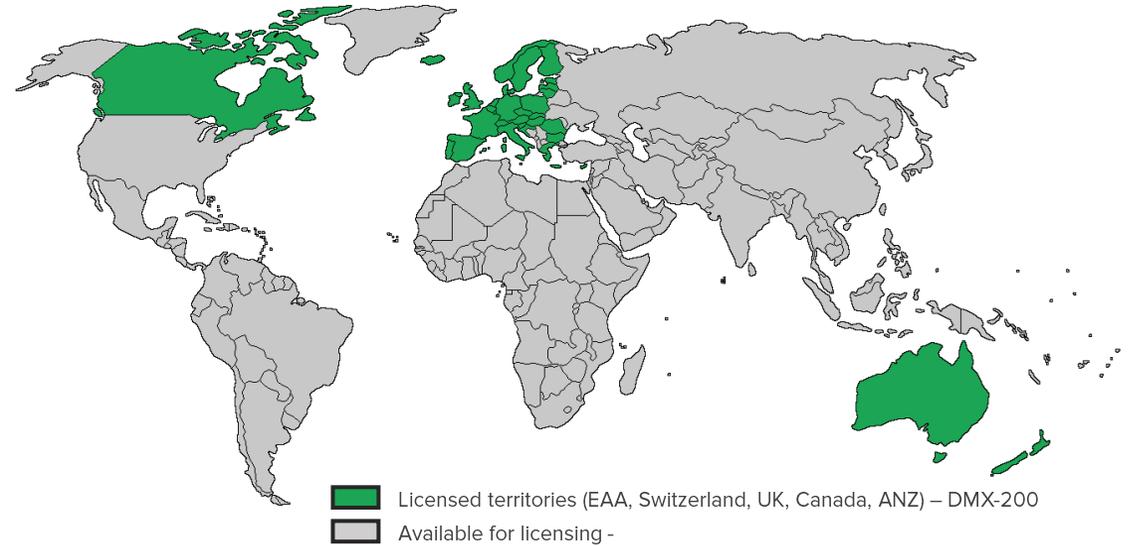
# Dimerix - strategic partners in nephrology

Dimerix has received a significant amount of partnering interest from pharma companies globally

- Received multiple non-binding term sheets for global deals and regional deals<sup>1</sup>
- Multiple parties in data room conducting due diligence and negotiating for various territories<sup>1</sup>

Preference is to work with experienced, capable partners

- Partners with regulatory, sales and marketing infrastructure and experience for desired territories



## Existing partnerships



Dimerix to receive up to ~AU\$230\* million in upfront and milestone payments, plus royalties

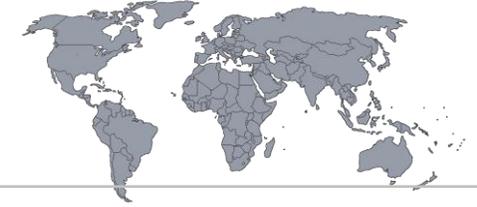
- €6.5 million in upfront payment (AU\$10.8 million) – received in November 2023
- up to €132.5 million (~AU\$218 million\*) in potential development and sales milestones
- Tiered royalties on net sales



## Significant potential upside

Partnering still available for other potential multi-billion dollar markets (incl. the US & China)

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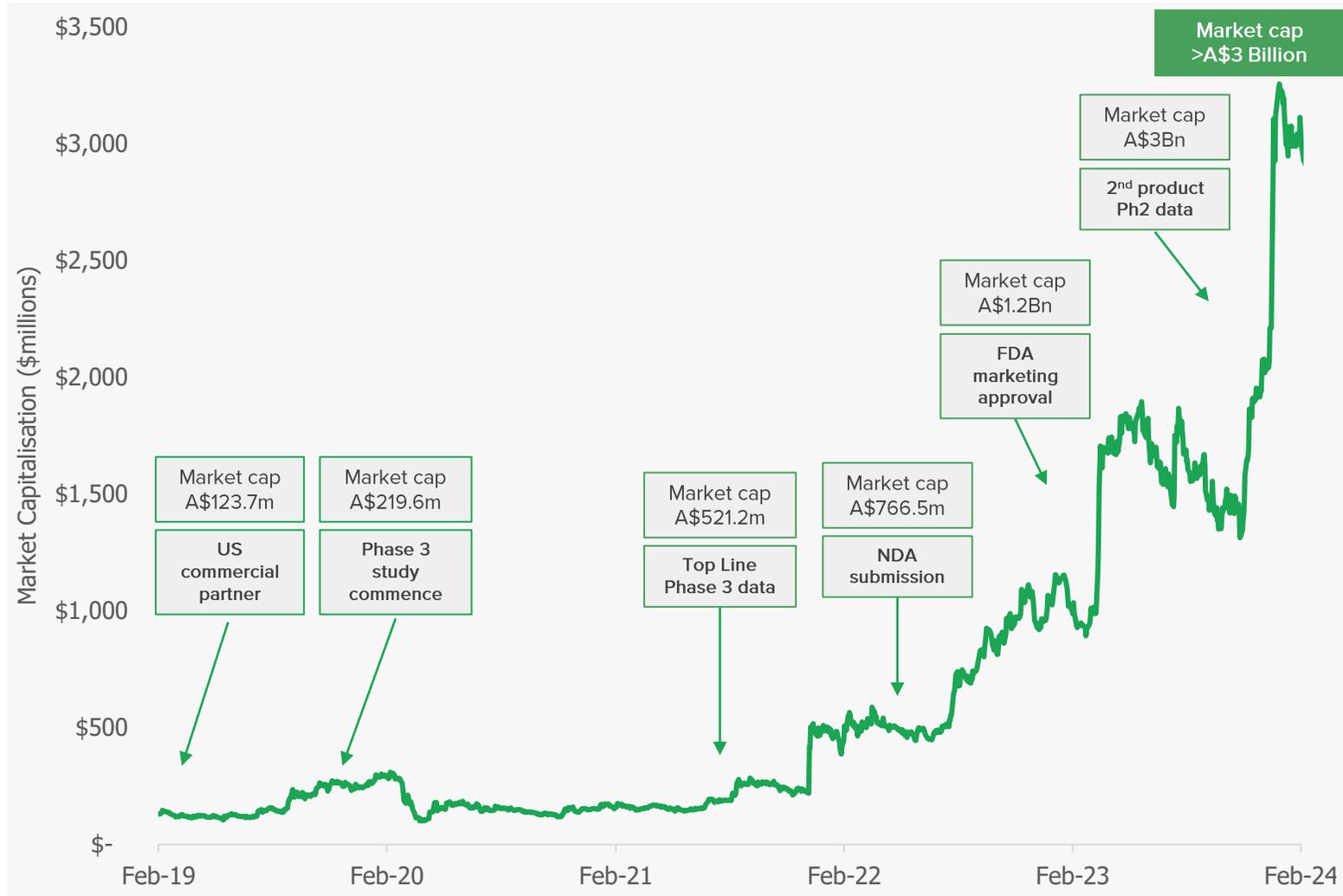
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# Orphan drug case study - Neuren (NEU.ASX)



- Neuren are focussed on **orphan disease treatment** with a pipeline of rare neurodevelopmental disorders
- Lead program/drug, DAYBUE™ (trofinetide) has **orphan designation** and received significant valuation uplifts during and after its **Phase 3** program
  - \$220m market cap at commencement of Phase 3
  - \$520m market cap at read out of Phase 3 results (240% uplift)
  - \$767m market cap prior to New Drug Application (NDA) to FDA (further 150% uplift)
  - \$1.6b market cap post FDA approval of first candidate (further 200% uplift)
- US market assumes pricing of ~US\$375,000<sup>1</sup> and 5,000 diagnosed patients p.a<sup>1</sup>

# Corporate overview

Ticker Symbol	ASX: DXB
Proforma Cash Balance (Dec23) <sup>1</sup>	~A\$34.8 million
Market Capitalisation	~A\$145 million
Share price	~A\$0.315
Total ordinary shares on issue	459,646,772
Average daily liquidity for past 30 days*	5.88 million





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.



## WELL POSITIONED TO DELIVER OUR STRATEGIC PLAN



SCAN ME

### *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.*

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