

## **DIMERIX TO PRESENT AT MELBOURNE TWILIGHT INVESTOR BRIEFING**

MELBOURNE, Australia, 20 May 2025: 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 Monsoon Twilight Investor Briefing in Melbourne on 20 May 2025.

**Key points that will be covered:**

- Phase 3 global clinical trial in FSGS kidney disease status and update
- Commercial partnering update

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*

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The Phase 3 study, which is titled “Angiotensin II Type 1 Receptor (AT1R) & Chemokine Receptor 2 (CCR2) Targets for Inflammatory Nephrosis”, or ACTION3 for short, is a pivotal (Phase 3), multi-centre, randomized, double-blind, placebo-controlled study of the efficacy and safety of DMX-200 in patients with FSGS who are receiving a stable dose of an angiotensin II receptor blocker (ARB). Once the ARB dose is stable, patients will be randomized to receive either DMX-200 (120 mg capsule twice daily) or placebo.

The single Phase 3 trial in FSGS patients has two interim analysis points built in that are designed to capture evidence of proteinuria and kidney function (eGFR slope) during the trial, aimed at generating sufficient evidence to support marketing approval. Further information about the study can be found on ClinicalTrials.gov (Study Identifier: NCT05183646) or Australian New Zealand Clinical Trials Registry (ANZCTR) (Study Identifier ACTRN12622000066785).

#### **About Dimerix Limited**

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company working to improve the lives of patients with inflammatory diseases, including kidney diseases. Dimerix is currently focused on developing its proprietary Phase 3 product candidate DMX-200, for Focal Segmental Glomerulosclerosis (FSGS) kidney disease, and is also developing DMX-700 for respiratory disease. 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. For more information, please visit the company’s website at [www.dimerix.com](http://www.dimerix.com) and follow on [X](#) and [LinkedIn](#).

#### **About DMX-200**

DMX-200 is 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 addition to Orphan Drug Designation granted by the FDA in the United States.

#### **About FSGS**

FSGS is a rare, serious kidney disorder characterized by progressive scarring (sclerosis) in parts of the glomeruli—the kidney’s filtering units. This scarring leads to proteinuria, progressive loss of kidney function, and often end-stage renal disease. FSGS is increasingly understood to have an inflammatory component, with monocyte and macrophage activation contributing to glomerular injury. In the United States, more than 40,000 people are estimated to be living with FSGS, including both adults and children.<sup>1</sup> There are no therapies specifically approved for FSGS in the U.S., and management

relies on non-specific immunosuppressive and supportive therapies. In patients with progressive or treatment-resistant FSGS, the average time from diagnosis to end-stage kidney disease can be as short as five years. Even among those who undergo kidney transplantation, disease recurrence occurs in up to 60% of cases,<sup>2</sup> underscoring the urgent need for new, disease-modifying treatments.

### **Dimerix Forward Looking Statement**

This release includes forward-looking statements that are subject to risks and uncertainties. Although management believes that the expectations reflected in the forward looking statements are reasonable at this time, Dimerix can give no assurance that these expectations will prove to be correct. Readers are cautioned not to place undue reliance on forward-looking statements. Actual results could differ materially from those anticipated. Reasons may include risks associated with drug development and manufacture, risks inherent in the regulatory processes, delays in clinical trials, results of clinical trials, contractual risks, risks associated with patent protection, future capital needs or other general risks or factors, along with those factors outlined in the most recent Dimerix Limited Annual Report.

### **References**

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<sup>1</sup> *Nephcure FSGS Facts* (<https://nephcure.org/>)

<sup>2</sup> *Front. Immunol.*, (July 2019) | <https://doi.org/10.3389/fimmu.2019.01669>



# Dimerix

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

## Twilight Briefing

*20 May 2025*



# Forward looking statements

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# Overview | Phase 3 Global Opportunity



## Four commercial licensing deals:

~AU\$1.4 billion

in total upfront & potential development and sales milestone payments plus royalties<sup>2</sup>

### Lead Drug Candidate

- DMX-200 is currently in a **Phase 3 clinical trial** for focal segmental glomerulosclerosis (FSGS)
- DMX-200 has **orphan drug designation** in key territories

### FSGS Indication

- FSGS is a **rare 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>
- There are currently **no approved treatments** available to treat FSGS

### Successful Phase 3 interim analysis:

- Analysis showed DMX-200 had performed better than placebo in reducing proteinuria<sup>3</sup>

# Focal Segmental Glomerulosclerosis (FSGS)

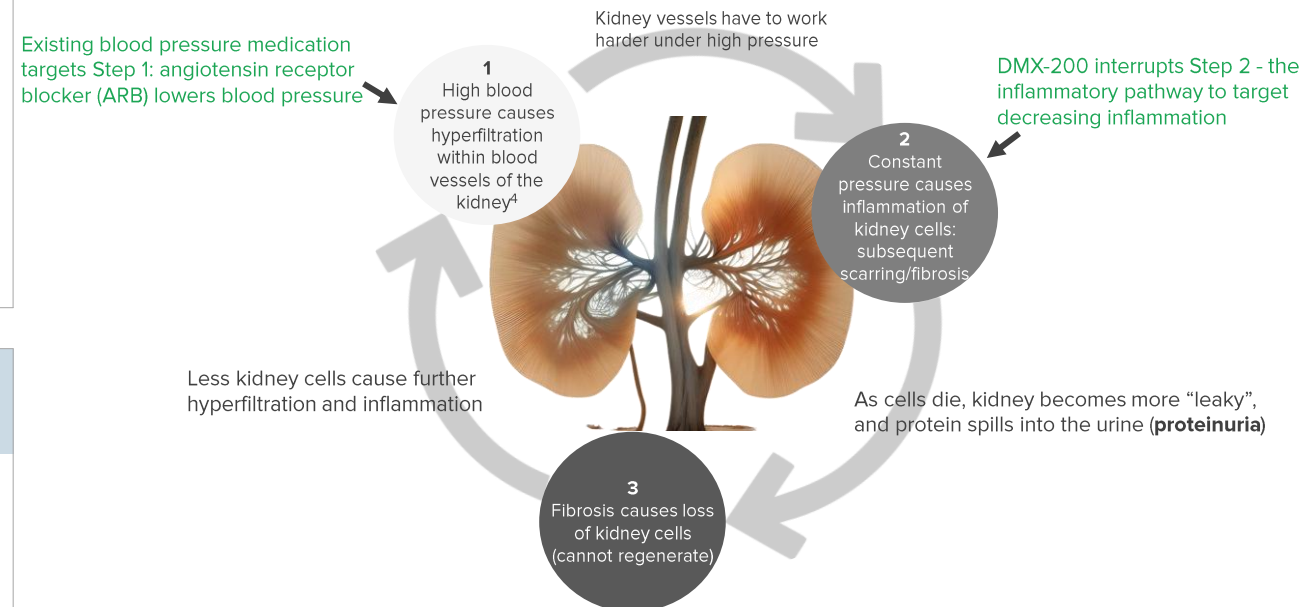
## What is FSGS?

<b>Focal</b>	<b>= some</b>
<b>Segmental</b>	<b>= sections</b>
<b>Glomerulo</b>	<b>= of the kidney filtering units</b>
<b>Sclerosis</b>	<b>= are scarred</b>

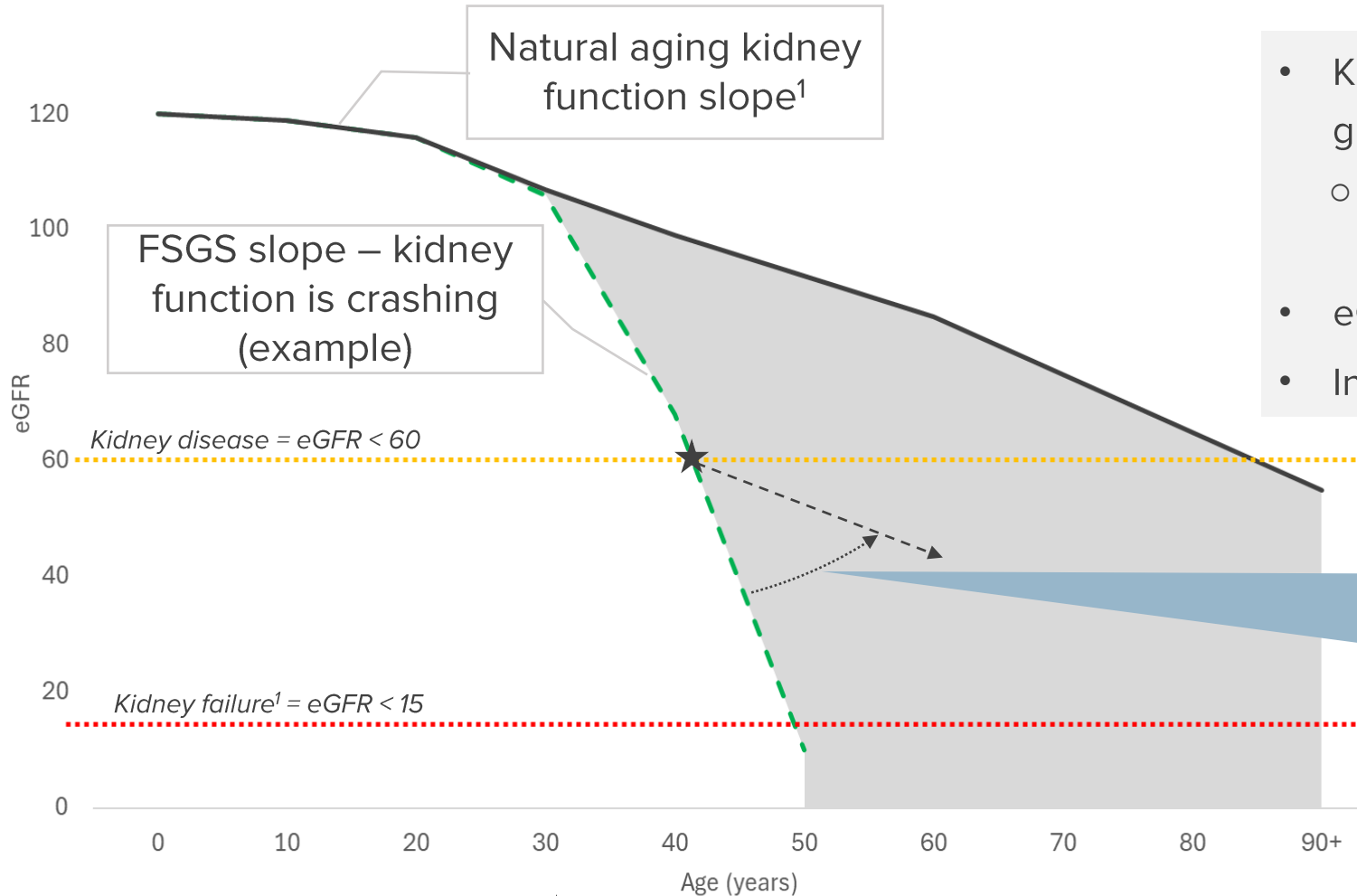
## How do you measure kidney function?

- Historically, measured using “hard” endpoints for kidney disease (kidney failure) – which may not be reached for decades<sup>1</sup>
- Regulatory agencies and national bodies now consider estimated glomerular filtration rate (eGFR) and proteinuria decline as surrogate end points for kidney failure in certain conditions<sup>2</sup>

## FSGS Kidney Damage<sup>3</sup>



# Significance of stabilising eGFR curve: primary endpoint



★ Assumes diagnosis occurs well into disease and treatment started immediately

- Kidney function can be measured using estimated glomerular filtration rate (eGFR):
  - how many millilitres of blood is filtered by the kidney per minute
- eGFR slope naturally declines as we age<sup>1</sup>
- In FSGS patients, it is crashing

Treatments, such as DMX-200, aim to bring the FSGS slope back up towards that which occurs with natural aging:

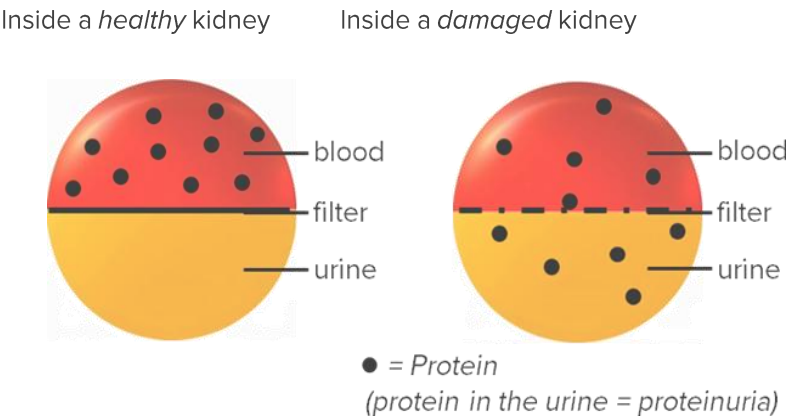
- This can add years to the life of the kidney
- Potential to delay dialysis and/or kidney transplant



# Significance of decreasing proteinuria: primary endpoint

## Why are kidneys important?

- A healthy kidney is a good filter and allows little to no protein in the urine<sup>1</sup>



- When kidneys are damaged, protein can leak into the urine causing proteinuria
- Proteinuria represents an important early marker of kidney function<sup>2</sup>

## Symptoms of proteinuria

	More frequent urination		Shortness of breath
	Nausea and vomiting		Tiredness
	Swelling in the face, stomach, feet and/or ankles		Lack of appetite
	Muscle cramping at night		Foamy or bubbly urine
	Puffiness around the eyes, especially in the morning		

DMX-200 aims to reduce the inflammation of the kidneys:

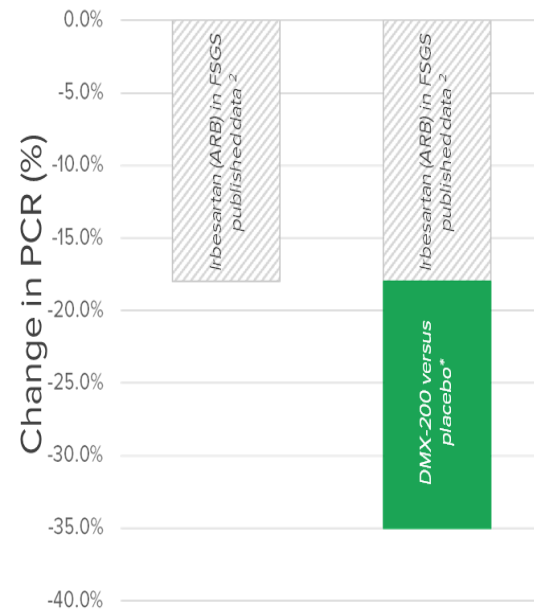
- if DMX-200 reduces inflammation, the amount of proteinuria should decrease

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

 Clinically meaningful outcomes achieved for patients,<sup>2,3</sup> with no safety issues



Average reduction of **17%** in proteinuria after 16 weeks treatment on DMX-200 versus placebo<sup>1</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>3</sup>*



## EFFICACY

- **86%** of patients demonstrated reduced proteinuria
- DMX-200 reduced inflammatory biomarker by **39%** vs placebo



## SAFETY

- No safety concerns – reduced development risk

# 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



286  
Total number of patients required - anticipated H2 2025<sup>1</sup>

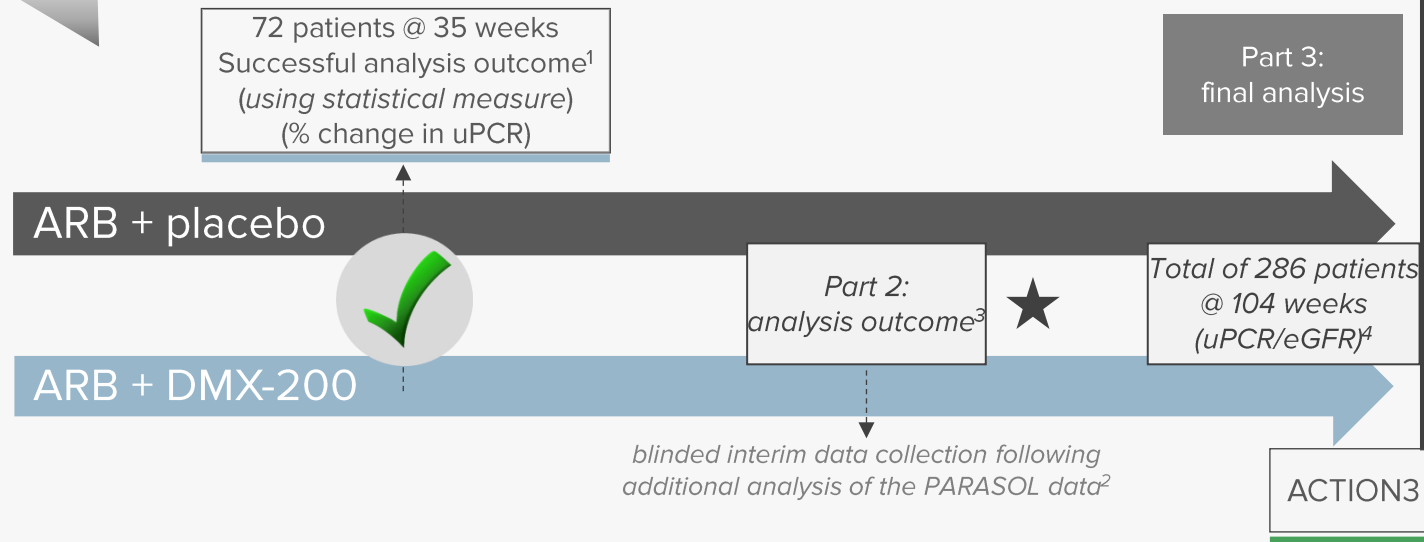
191  
Patients recruited, randomised and dosed<sup>2</sup>

43  
Patients enrolled over into Open Label Extension Study<sup>2</sup>

## 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



## Open Label Extension

DMX-200

★ Potential to submit for conditional marketing approval, subject to FDA discussion<sup>3</sup>

Positive Type C meeting held in March 2025 with US Food & Drug Administration (FDA) on proteinuria trial endpoints, and potential for accelerated approval for DMX-2003

FDA confirmed that a proteinuria-based endpoint for full marketing approval in the US, which may be either:

- the proportion of patients meeting the proteinuria responder definition; or
- percentage change in proteinuria from baseline



Dimerix is working PARASOL working group on additional analysis of existing PARASOL data to further assess what may represent an appropriate and meaningful endpoint for accelerated approval in FSGS<sup>3</sup>

- This additional work may provide the justification to support an accelerated approval endpoint, which will be discussed with the FDA prior to any potential submission

3-6  
months<sup>3</sup>

# Key elements of partnership

Dimerix to receive:

up to **US\$590 million**  
**(~AU\$940 million\*)**

in upfront and potential development and sales milestone payments, plus royalties

Amicus acquires exclusive license to commercialise DMX-200 for all indications in United States

Amicus will be responsible for preparation, submission and maintenance of the regulatory dossier in the United States, as well as all sales and costs of marketing activities

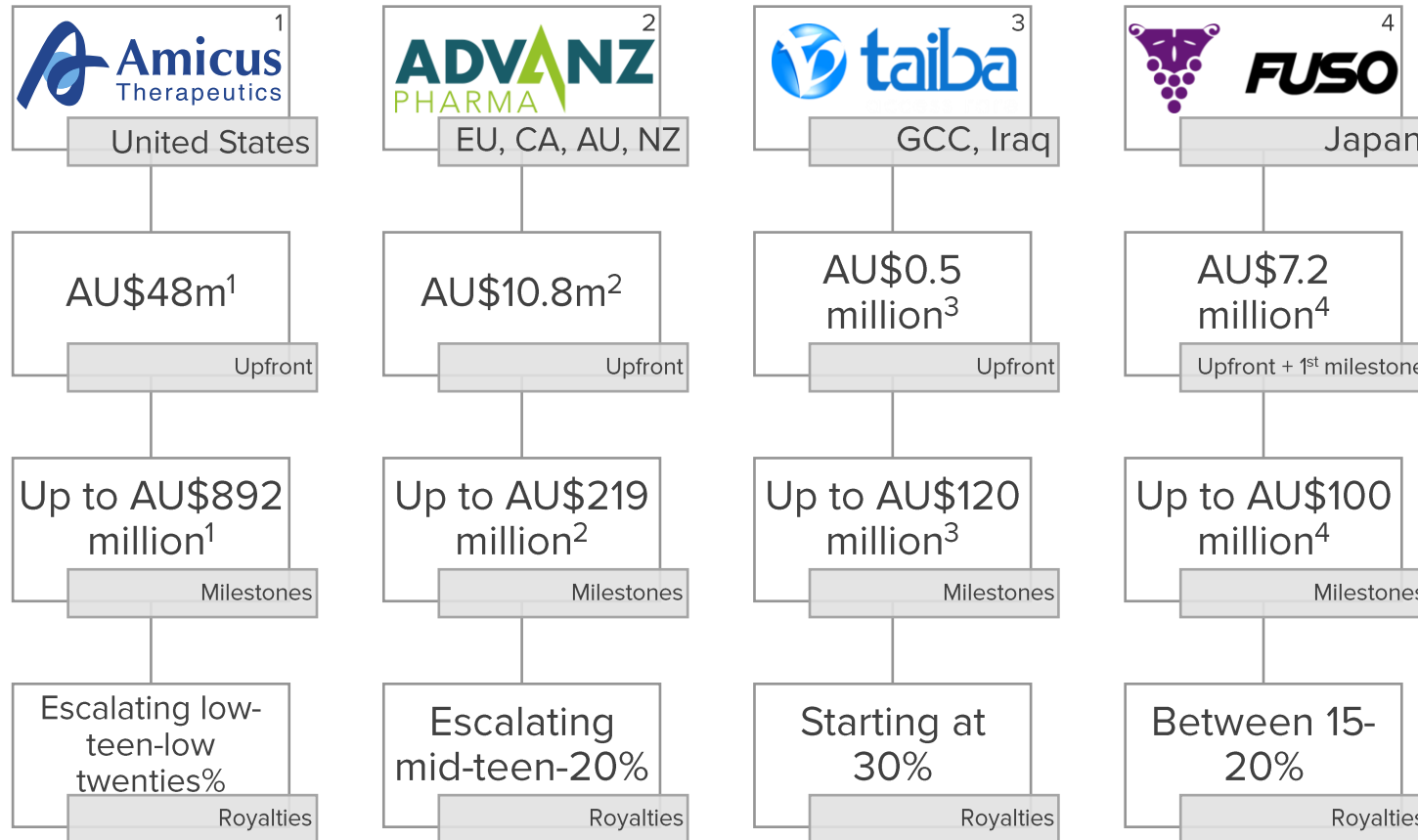
- US\$30 million (~AU\$48 million\*) on execution
- up to US\$75 million (~AU\$119 million\*) in potential development milestones
- US\$35 million (~AU\$56 million\*) on first sale of DMX-200
- up to \$410 million (~AU\$653 million\*) in potential sales milestones
- US\$40 million (~AU\$64 million\*) in potential future indications milestone
- Tiered low-teen to low-twenties royalties on net sales

Dimerix will continue to fund and execute the global ACTION3 Phase 3 study for DMX-200 in FSGS patients (outside of Japan)

Dimerix retains all rights to DMX-200 in all other unlicensed territories

# Summary of licensing deals for DMX-200 to date

Dimerix has successfully partnered DMX-200 across key markets



Licensing deals collectively valued up to

**~AU\$1.4 billion**

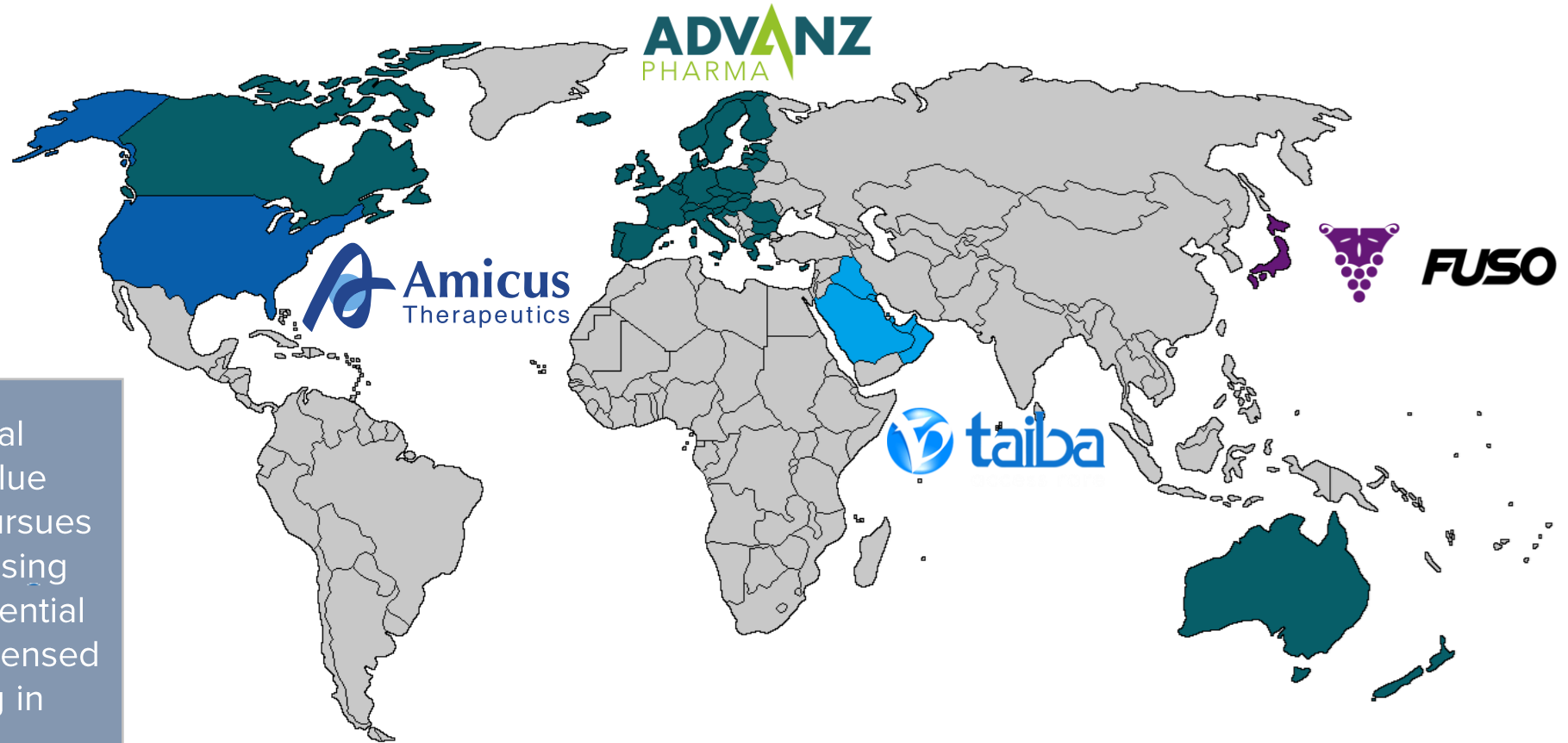
*in total upfront and potential milestone fees plus royalties<sup>1</sup>*

Over

**AU\$60 million**

*in total upfront payments*

# Potential for additional partnering opportunities



Significant potential additional global value remains, as Dimerix pursues and progresses licensing opportunities with potential partners outside the licensed territories, including in Mainland China

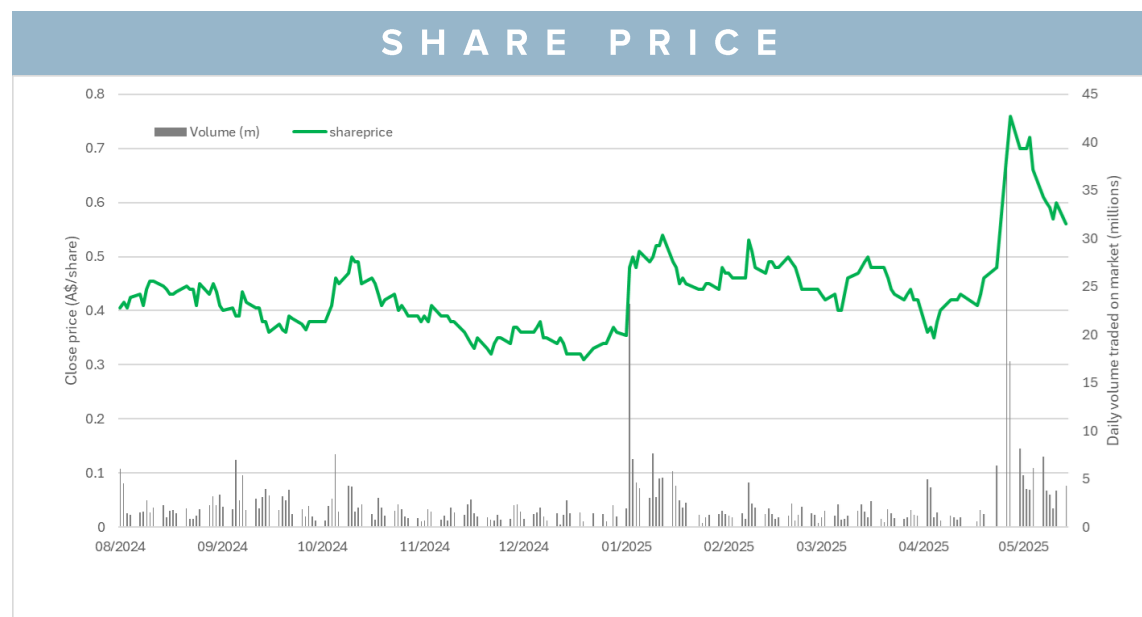


# Corporate overview

Ticker Symbol	ASX: DXB
Cash Balance (Mar25)*	\$17 million
Market Capitalisation <sup>1</sup>	\$324 million
Share price <sup>1</sup>	\$0.56
Total ordinary shares on issue <sup>1</sup>	578,623,955
Average Daily Liquidity by value for past 30 trading days <sup>2</sup>	\$3.8 million

\*Cash balance does not include:

- ~\$48 million - upfront fee due from Amicus Therapeutics licensing agreement (ASX release 1 May 2025)
- ~\$4.1 million - payment anticipated on 1st clinical site opening in Japan from Fuso licensing agreement Q2 2025
- Up to \$6.3 million - potential conversion of 41,026,596 DXB options (as at 31 March 2025) exercisable at 15.4c per share (expire 30 June 2025)

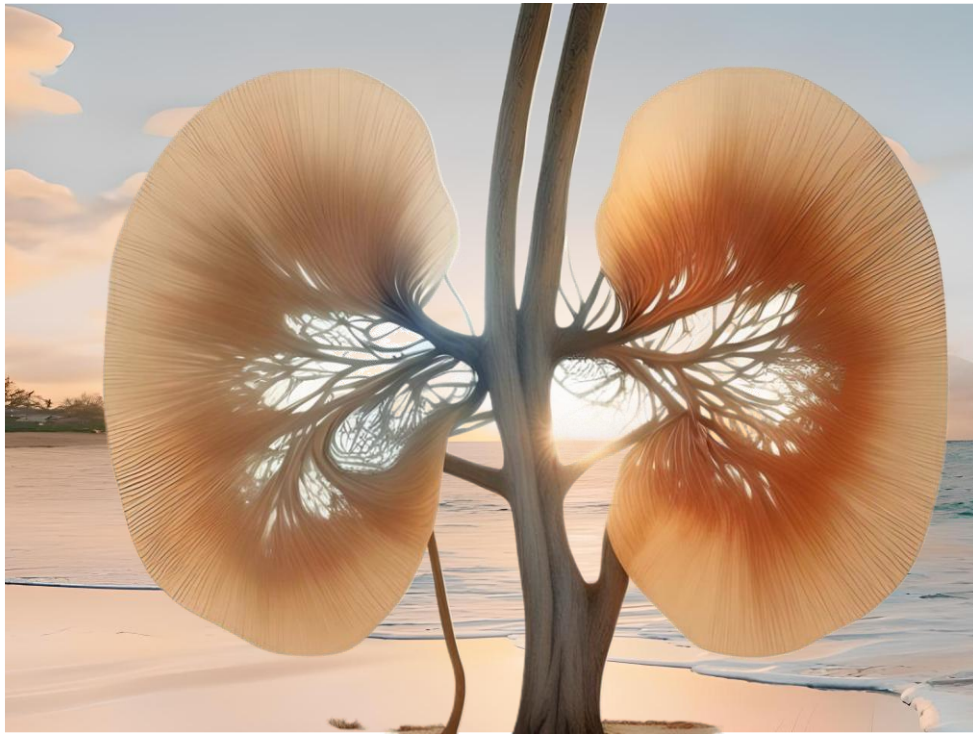


SUBSTANTIAL SHAREHOLDERS <sup>3</sup>			
Position	Holder Name	Holding	% IC
1	Mr P Meurs	87,259,311	15.1%
<b>TOTAL (TOP 5) Shareholders</b>		<b>146,477,154</b>	<b>25.3%</b>

1. As at 19 May April 2025; 2. Past 30 trading days liquidity as at 19 May 2025;  
3. Shareholder register as at 19 May 2025



# Potential catalysts



## 2025

### Q1/Q2 2025

- Confirmed **FDA meeting** to discuss alternative endpoints<sup>1</sup>
- ~AU\$4.1 million<sup>2</sup> **development milestone** anticipated from FUSO<sup>1</sup>

### Q3/Q4 2025

- Planned blinded **interim data collection** anticipated in H2 2025<sup>3</sup>
- Potential for **accelerated (or conditional) approval** submission, subject to FDA feedback<sup>1,3</sup>
- **Full study recruitment** of 286 adult patients anticipated in CYH2 2025<sup>3</sup>

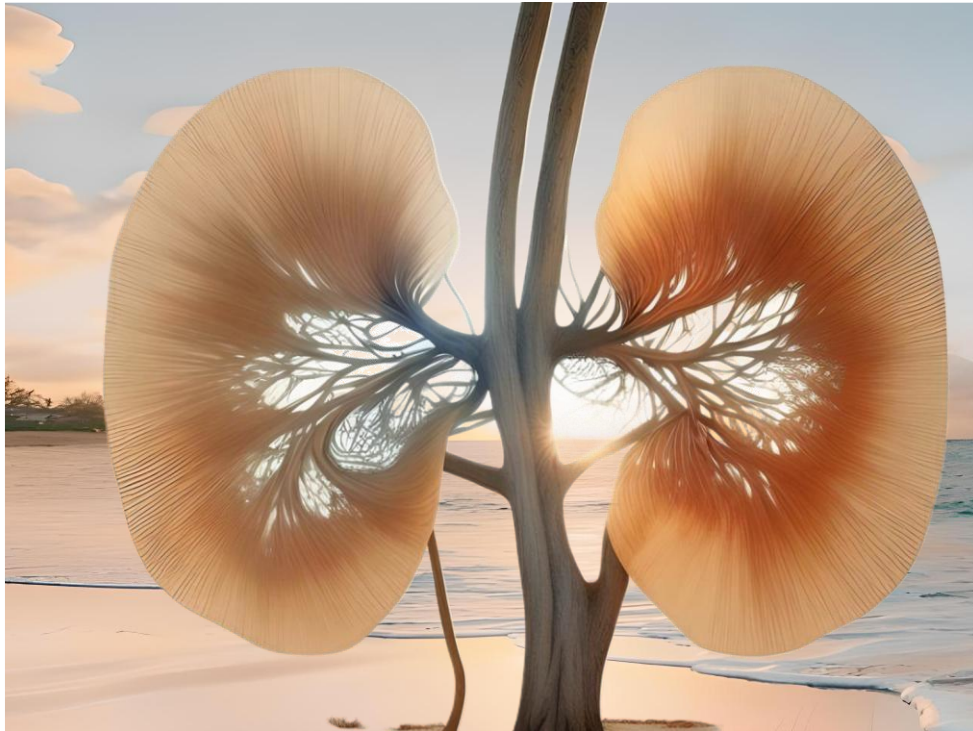
### Potential upside – at any time

- Additional **licensing partners** for DMX-200: Dimerix continues to pursue potential licensing opportunities in un-licensed territories, including China



# Dimerix

(ASX:DXB)



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 AGAINST STRATEGIC PLAN

### **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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