

## **DIMERIX PRESENTS AT BIOSHARES BIOTECH SUMMIT**

MELBOURNE, Australia, 7 August 2025: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical asset in inflammatory disease, is pleased to advise that CEO and Managing Director, Dr Nina Webster, will be presenting at the 19<sup>th</sup> Bioshares Biotech Summit in Hobart on 7 August 2025.

The Bioshares Biotech Summit's unique format brings together biotechnology companies and equity capital markets participants to explore not just what biotechnology companies do but just as importantly, what outside influences can impact development programs. In keeping with this purpose, Dr Webster was asked to focus on the ACTION3 Phase 3 clinical trial next steps and commercial partnering rationale.

A copy of the presentation is attached.

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

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Authorised for lodgement by the Board of the Company

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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.

### **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. 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, 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

<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

Leading the Way

Bioshares Summit
7 August 2025

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



## Conference theme: Leading the Way

Discuss Phase 3 clinical trial next steps and commercial partnering rationale



## Questions posed to Dimerix:

- 1. What are the Project PARASOL process and next steps?
- 2. How does trial unblinding work, and what are the key considerations in any unblinding process?
- 3. What is it about your current partners businesses that made them the partners of choice for DXB?
- 4. How is pricing expected to differ between the US, Europe and other regions (in rare kidney disease)?



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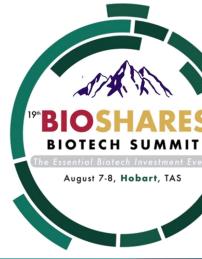
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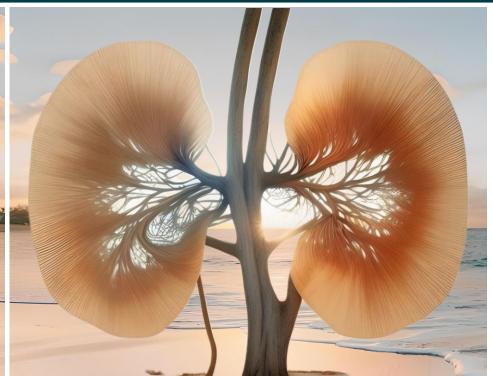
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# DIMERIX - IN CONTEXT











## Overview

## Phase 3 Global Opportunity

Candidate

OMX-200 in a Phase

3 clinical trial for

Focal segmental

glomerulosclerosis

(FSGS)

FSGS Indication a rare disease that causes scar tissue of kidneys, which leads to irreversible kidney damage<sup>1</sup>

# No approved treatments

available to treat FSGS: damage can lead to dialysis, transplant or death<sup>1</sup>

## Orphan drug designation

regulatory,
marketing
exclusivity and
pricing **benefits** in
key territories<sup>2</sup>

4

DMX-200 licensing partners across key territories<sup>3</sup>

## ~\$1.4 billion

in total upfront & potential development and sales milestone payments **plus** royalties<sup>3</sup>

>\$65 million

in total payments received to date<sup>1</sup>



persona



















## Key achievements since Bioshares Summit 2024

3rd

development and license agreement for DMX-200 in Japan<sup>1</sup>

Up to ¥10.5 billion (~AU\$107m) in upfront/milestones; plus royalties



>50

patients completed 2year ACTION3 study<sup>5</sup>

Eligible patients rolled over into open label extension study



4<sup>th</sup>

license agreement for DMX-200 in the United- States<sup>2</sup>

Up to US\$590 million (~AU\$940m) in upfront/milestones; plus royalties



**FDA** 

meeting and alignment on endpoints<sup>6</sup>

Confirmed proteinuria acceptable endpoint for full marketing approval in US



paediatric clinical trial sites initiated<sup>3</sup>

Adolescent dose confirmed for ACTION3 clinical trial<sup>4</sup>



S&P ASX

Dimerix admitted into All Ordinaries<sup>7</sup>

Top 500 companies listed on the ASX

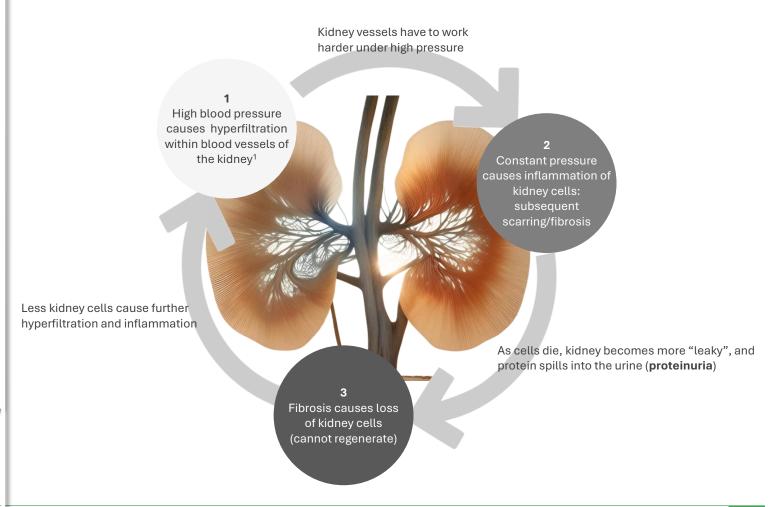




# Cycle of damage:

# What is FSGS? = some **Segmental** = sections Comerulo = of the kidney filtering units For personage = are scarred

## in glomerular diseases



## Cycle of damage:

## What is FSGS? = some **Segmental** = sections Comerulo = of the kidney filtering units **Se**lerosis = are scarred This synergistic activity of both agents disrupts the cycle of damage in FSGS

# in glomerular diseases

Fibros

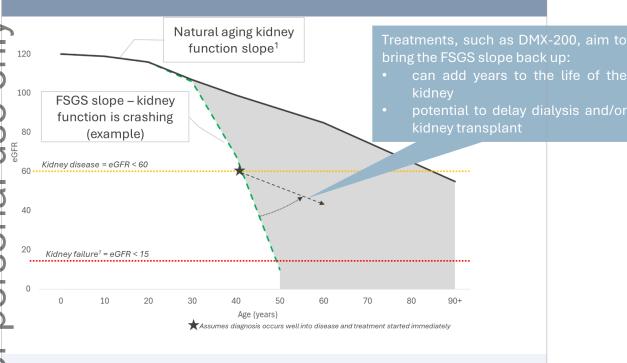
targets Step 1: angiotensin receptor blocker (ARB) lowers blood pressure

High by dessure causes by filtration within by dessure causes of the cause of the



# Measuring kidney damage – surrogate endpoints

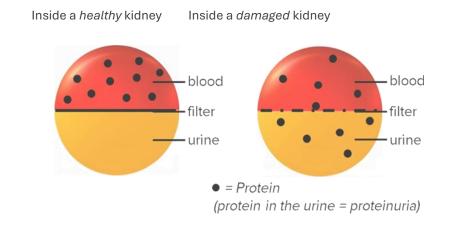
## 1. Estimated glomerular filtration rate (eGFR)



- Kidney function can be measured using 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

## 2. Proteinuria

 A healthy kidney is a good filter and allows little to no protein in the urine<sup>2</sup>



- When kidneys are damaged, protein can leak into the urine causing proteinuria
- Proteinuria represents an important early marker of kidney function<sup>3</sup>

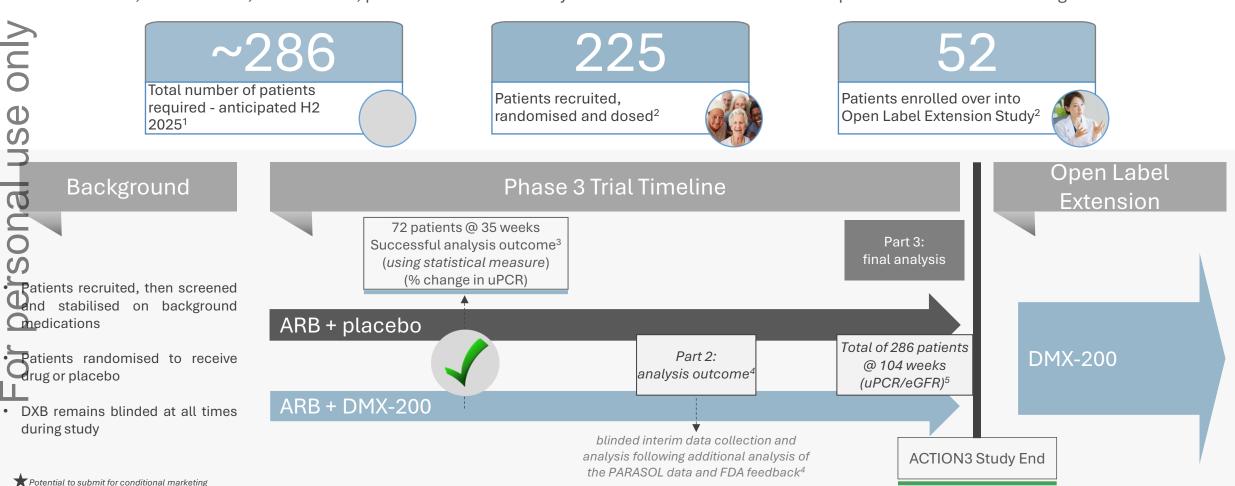


# ACTION3 phase 3 clinical trial



**FSGS CLINICAL STUDY** 

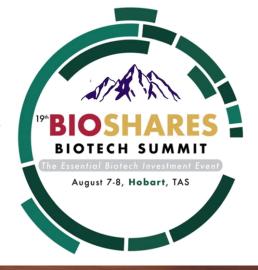
A randomised, double-blind, multi-centre, placebo-controlled study of renal outcomes of DMX-200 in patients with FSGS receiving an ARB





approval, subject to FDA discussion 3

# FSGS WORKING GROUP - PARASOL









# Project PARASOL – an FDA-led working group

Working groups not uncommon to review and recommend potential endpoints for indications without any approved therapies as new information comes to light, for example, results from other trials or identification of better biomarkers or surrogate outcome measures<sup>1</sup>

## Project PARASOL: 24-month data analysis



- ➤ PARASOL formed to address the need to validate alternative surrogate endpoints for FSGS
- ➤ Coalition of nonprofit organizations, academia, registries, trials and Sponsors<sup>2</sup>
- PARASOL confirmed: eGFR slope is a valid endpoint for predicting progression of kidney disease
- PARASOL demonstrated proteinuria is a valid endpoint for predicting progression of kidney disease
- FDA confirmed: a reduction in proteinuria is a validated endpoint for DMX-200 for **full marketing approval for FSGS at 24-months**

## DIMERIX & PARASOL project: earlier data point analysis

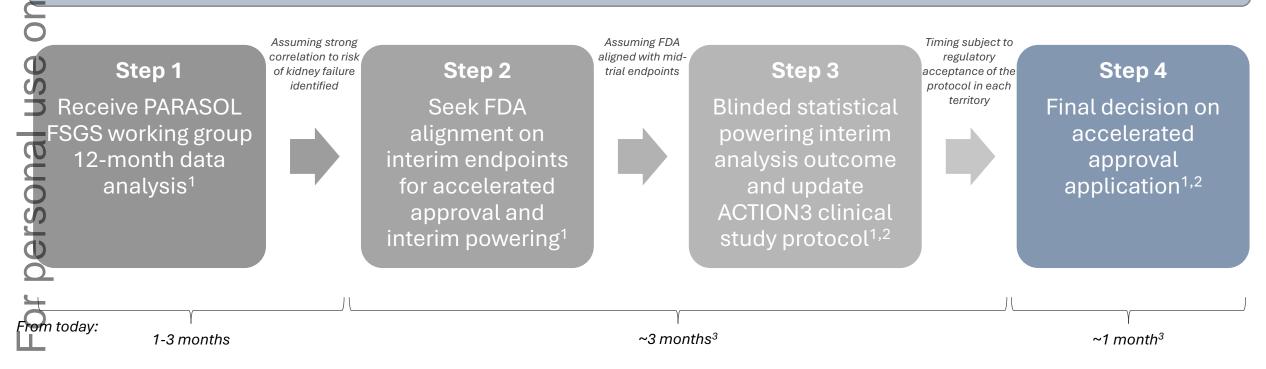


- ➤ Initial analysis conducted primarily on available 24-month data
- ➤ Initial analysis conducted on population similar, but not identical, to ACTION3
- Analysis of PARASOL population overlaid on ACTION3 population required
- Relationship between earlier time points, such as 12month, and 24-month data required
- Assuming strong correlation to risk of kidney failure identified at 12-months, seek FDA alignment for accelerated approval



## Interim analysis process

Positive Type C meeting held in March 2025 with US Food & Drug Administration (FDA) on proteinuria trial endpoints for <u>full</u> approval, and potential for accelerated approval for DMX-200<sup>1</sup>



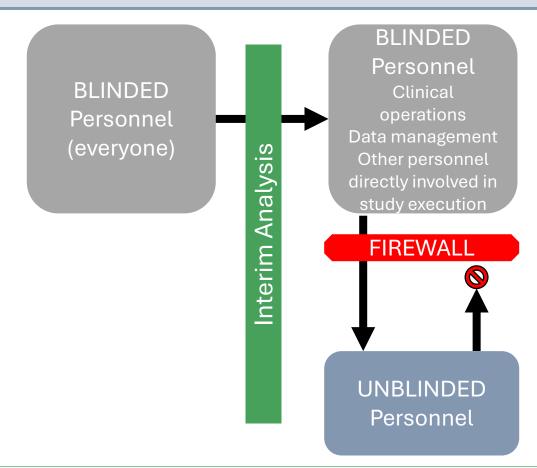
In line with best practice, endpoints must be set prior to any potential unblinding of data, to maintain integrity of the study



# or personal use on

## Interim analysis unblinding process

Regulators require that any interim analysis process not compromise the statistical and medical integrity of the trial and not introduce biases



## **Governing principles:**

- Restrict unblinded data access to those who (absolutely)
  need it and only when they (absolutely) need it
- 2. Establish, document and confirm firewalls between those blinded to the interim analysis and those unblinded



## Aligning global regulatory pathways

To accelerate patient access to much needed treatment in areas of serious and life-threatening diseases and unmet medical need, many regulatory authorities have put in place regulatory pathways to expedite drug development and approval<sup>1,2</sup>

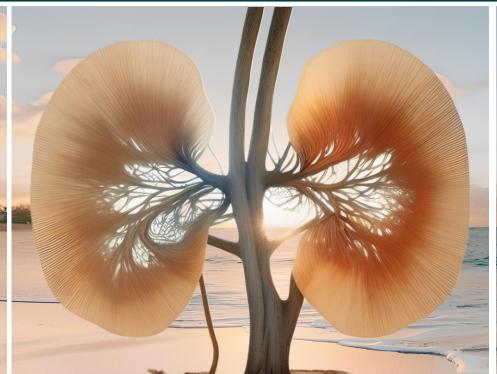
|   | USA                                 | EU  | Japan                   |
|---|-------------------------------------|---|-------------------------|
| Current primary endpoints for <u>traditional</u> approval for FSGS            | Proteinuria or eGFR                 | eGFR  | eGFR                    |
| Faster access to market if interim endpoint agreed by regulators <sup>1</sup> | Yes<br>Accelerated Approval program | Yes<br>Conditional Marketing<br>Authorisation | Yes<br>Sakigake program |



# PARTNERING TO PERFECT



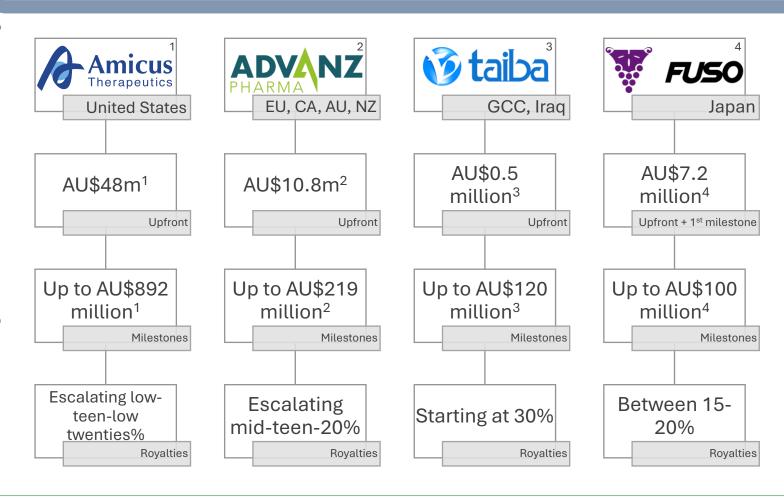






## Dimerix financials transformed

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 <u>plus</u> royalties<sup>1</sup>

AU\$65 million

in total payments received

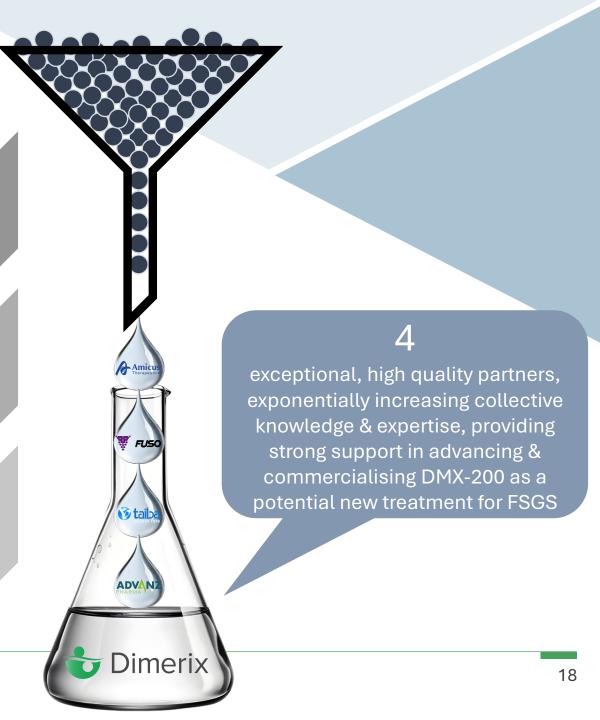


# Selecting our partners

A partner that has existing/proven infrastructure to deliver DMX-200 to as many FSGS patients in need of treatment

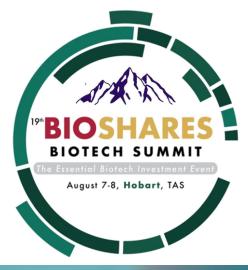
partner that recognises the overall value of the asset and views it as a strategic priority

partner with a collaborative approach who will work almost as an extension of the Dimerix team to achieve the best outcome for the product and the patient

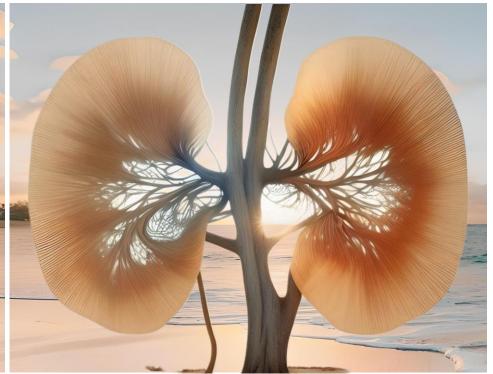














# FSGS market – potential for growth

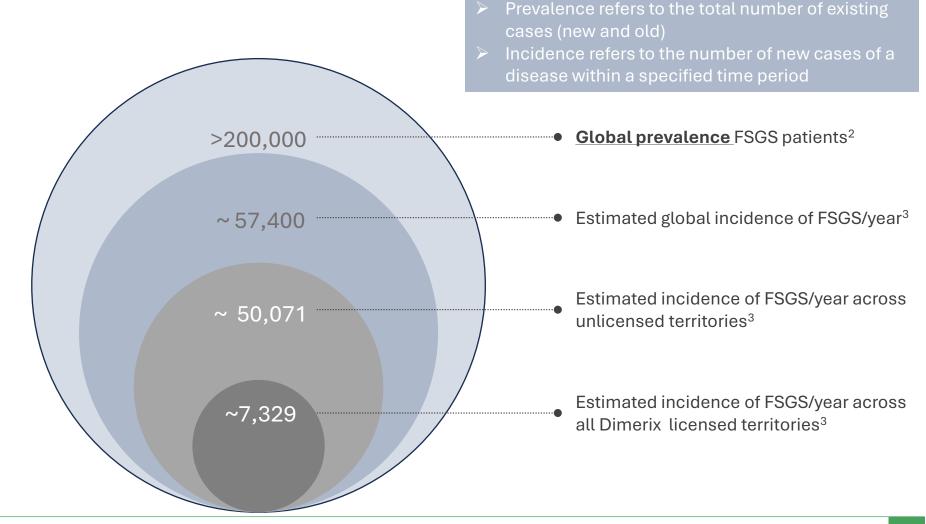
## **Biopsy**

FSGS diagnosis driven by rates of biopsy - growth potential as biopsy rates increase

FSGS is the most frequent primary glomerular disease that reaches end-stage renal failure in the US<sup>1</sup>

0

Approved treatments specifically for FSGS





# Rare kidney disease pricing examples

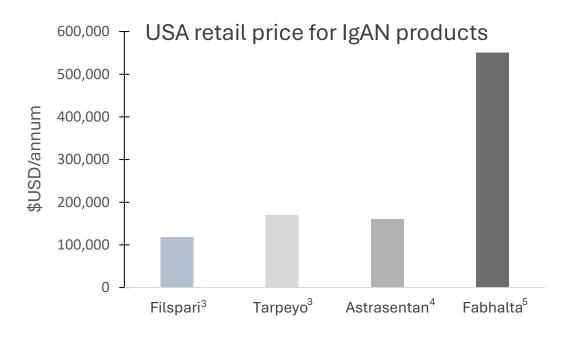
US Medicare Drug Price Negotiation Program<sup>1</sup>

US Medicare Drug Price Negotiation Program **exempts orphan drugs** that treat "only one rare disease or condition" from drug price negotiations



**DMX-200** 

Commercial manufacturing sites established in USA<sup>3</sup>



Example ex-US pricing for other rare kidney disease drugs:

- in the US (i.e. Filspari in IgAN)<sup>6</sup>: **US\$9,900 p/month**
- in Europe/UK (i.e. Kinpeygo/Tarpeyo)<sup>7</sup>: **US\$8,267 p/month**
- Other key territories, including Middle East and China, use US and/or Europe as pricing reference<sup>8.9</sup>



## Outcome driven strategy

Clear strategy, detailed business plan Clear investment proposition to shareholders

Operational excellence in execution

Deliver on promise & within budget







# Recognition: drug development is a team sport

Team 👉 Dimerix 2025











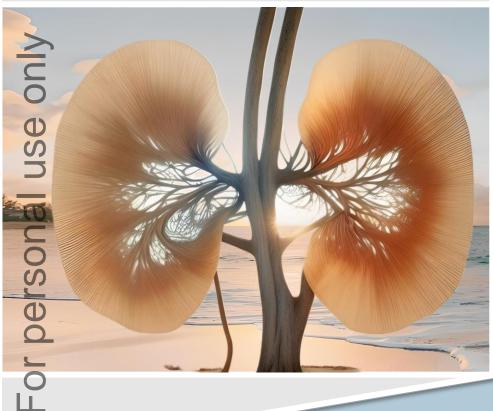






...a recipe for success...





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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