

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 19th 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

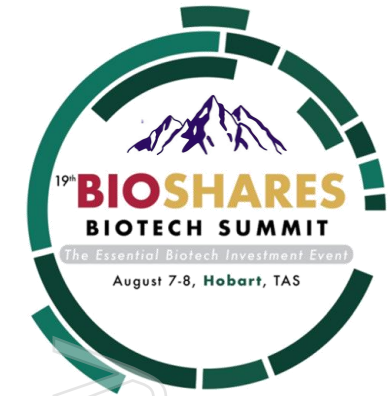
FSGS is a rare, serious kidney disorder characterized by progressive scarring (sclerosis) in parts of the glomeruli—the kidney's filtering units. This scarring leads to proteinuria, progressive loss of kidney function, and often end-stage renal disease. FSGS is increasingly understood to have an inflammatory 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.¹ 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,² 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

- ¹ *Nephcure FSGS Facts* (<https://nephcure.org/>)
- ² *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



STOP THE CLOCK

We have a lot to get through!

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)?

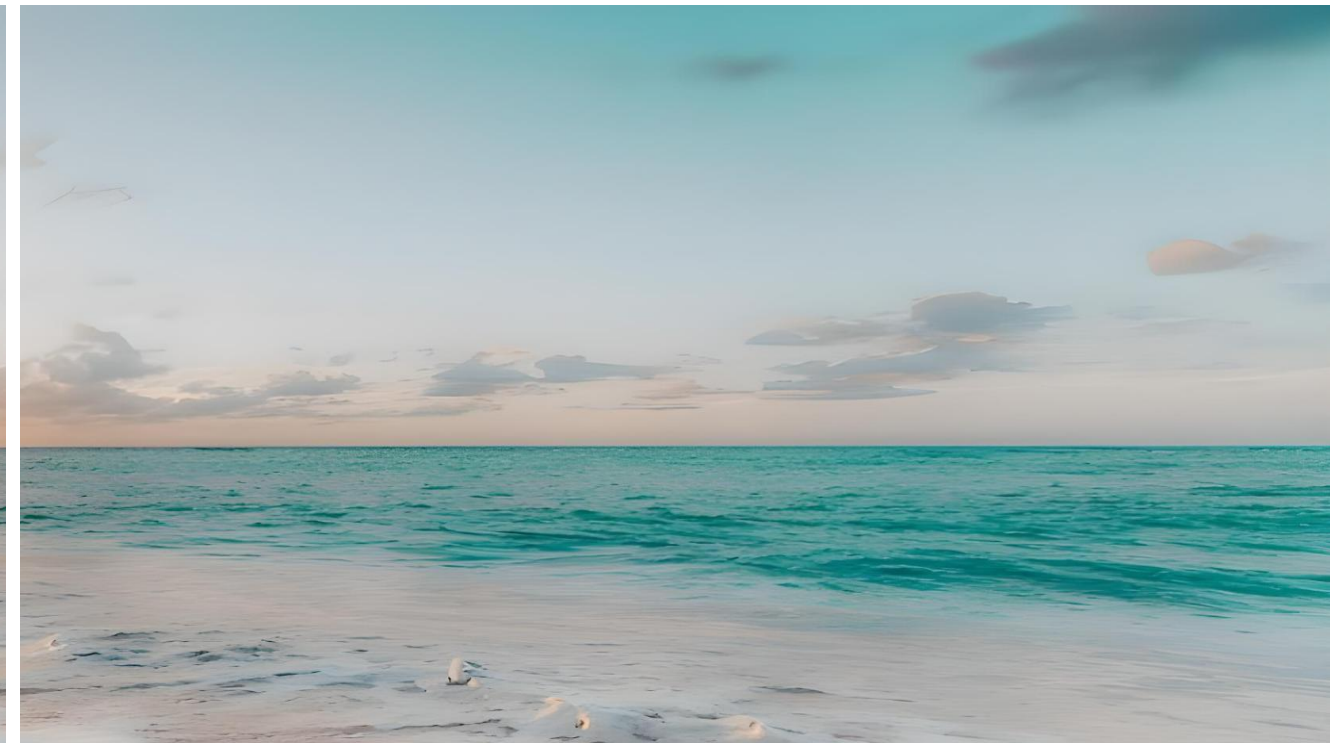
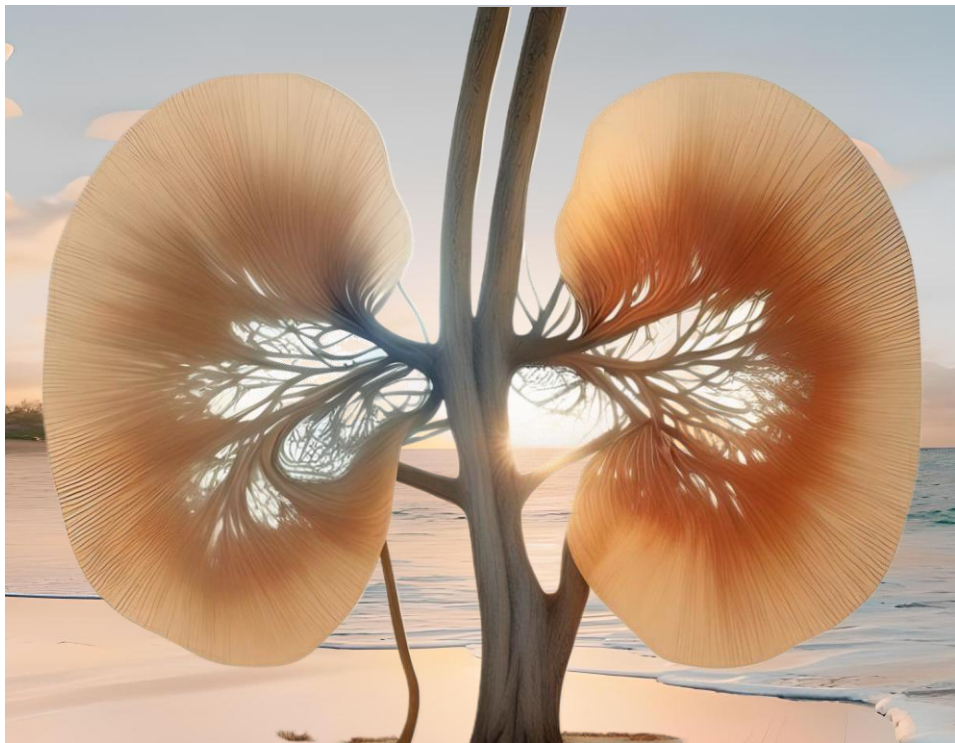
Forward looking statements

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DIMERIX - IN CONTEXT



Overview

Phase 3 Global Opportunity

Lead Drug Candidate
DMX-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 damage¹

No approved treatments available to treat FSGS: damage can lead to **dialysis, transplant or death**¹

Orphan drug designation regulatory, marketing exclusivity and pricing **benefits** in key territories²

4
DMX-200 licensing partners across key territories³

~\$1.4 billion in total upfront & potential development and sales milestone payments **plus** royalties³

>\$65 million in total **payments received** to date¹



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1. Guruswamy Sangameswaran KD, Baradhi KM. Focal Segmental Glomerulosclerosis (July 2021), online: <https://www.ncbi.nlm.nih.gov/books/NBK532272/>; 2. ASX releases: 14Dec15, 21Nov18, 07Jun21; 3. ASX release 05 October 2023, 27 May 2024, 07 January 2025 and 01 May 2025

Key achievements since Bioshares Summit 2024

3rd

development and license agreement for DMX-200 in Japan¹

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



4th

license agreement for DMX-200 in the United- States²

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



1st

paediatric clinical trial sites initiated³

Adolescent dose confirmed for ACTION3 clinical trial⁴



>50

patients completed 2-year ACTION3 study⁵

Eligible patients rolled over into open label extension study



FDA

meeting and alignment on endpoints⁶

Confirmed proteinuria acceptable endpoint for full marketing approval in US



S&P ASX

Dimerix admitted into All Ordinaries⁷

Top 500 companies listed on the ASX



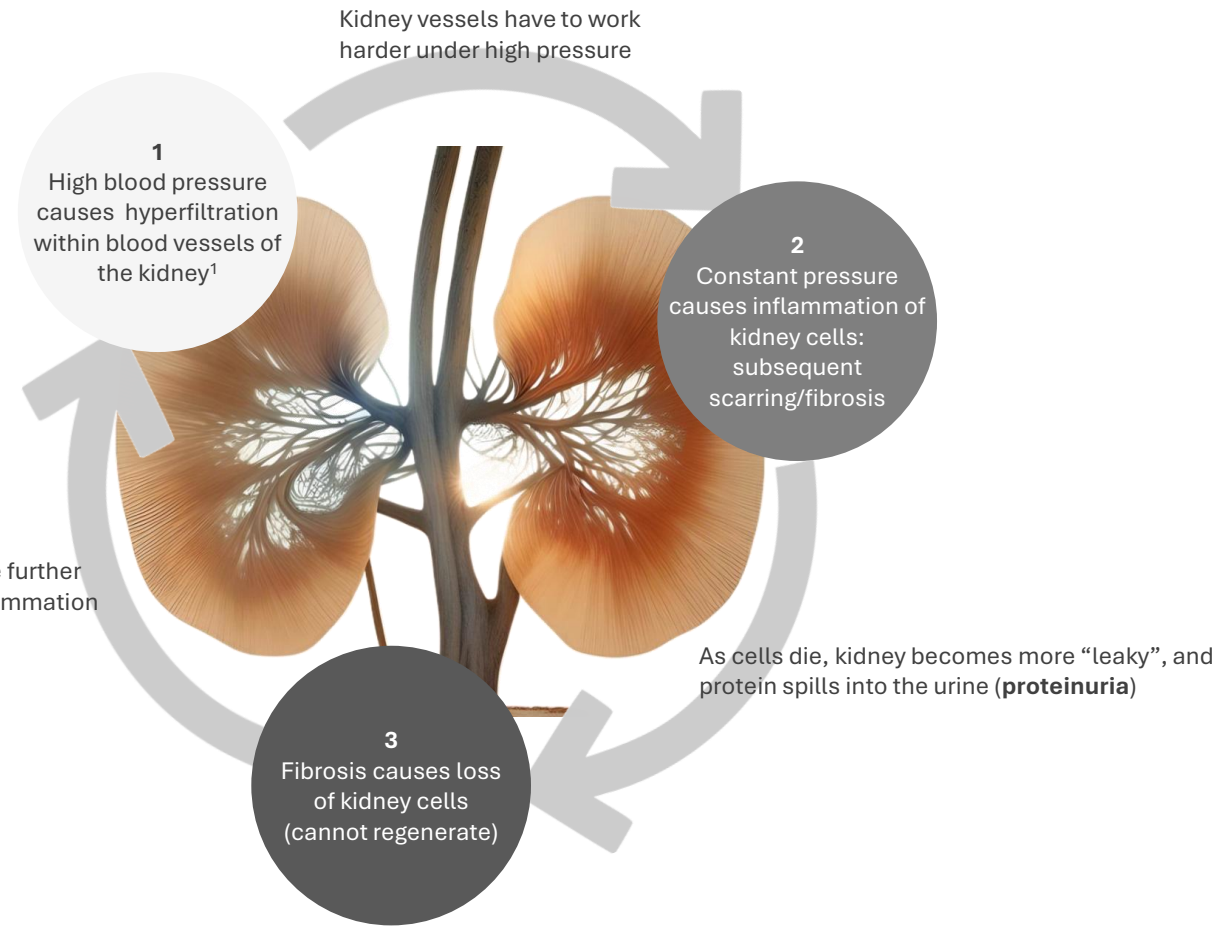
1. ASX release 07 January 2025, before tax; 2. ASX release 01 May 2025, before tax; 3. ASX release 12 September 2025; 4. ASX release 04 July 2024; 5. ASX release 25 July 2025; 6. ASX release 28 April 2025; 7. ASX release 07 March 2025

Cycle of damage :

in glomerular diseases

What is FSGS?

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



1. Lewis, E. J. et al. (2001), *New Engl J Medicine* 345, 851–860

Cycle of damage :

What is FSGS?

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

This synergistic activity of both agents disrupts the cycle of damage in FSGS

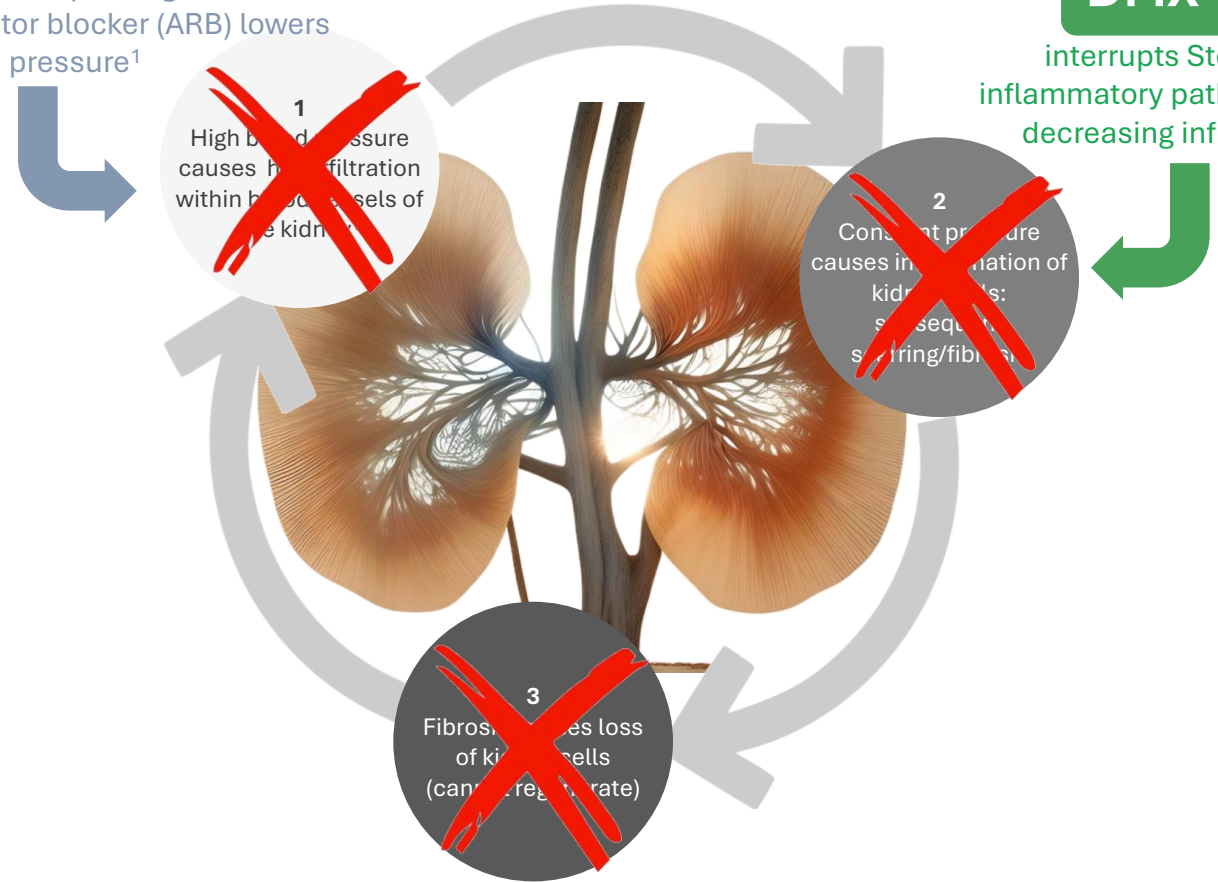
in glomerular diseases

Existing blood pressure medication

targets Step 1: angiotensin receptor blocker (ARB) lowers blood pressure¹

DMX-200

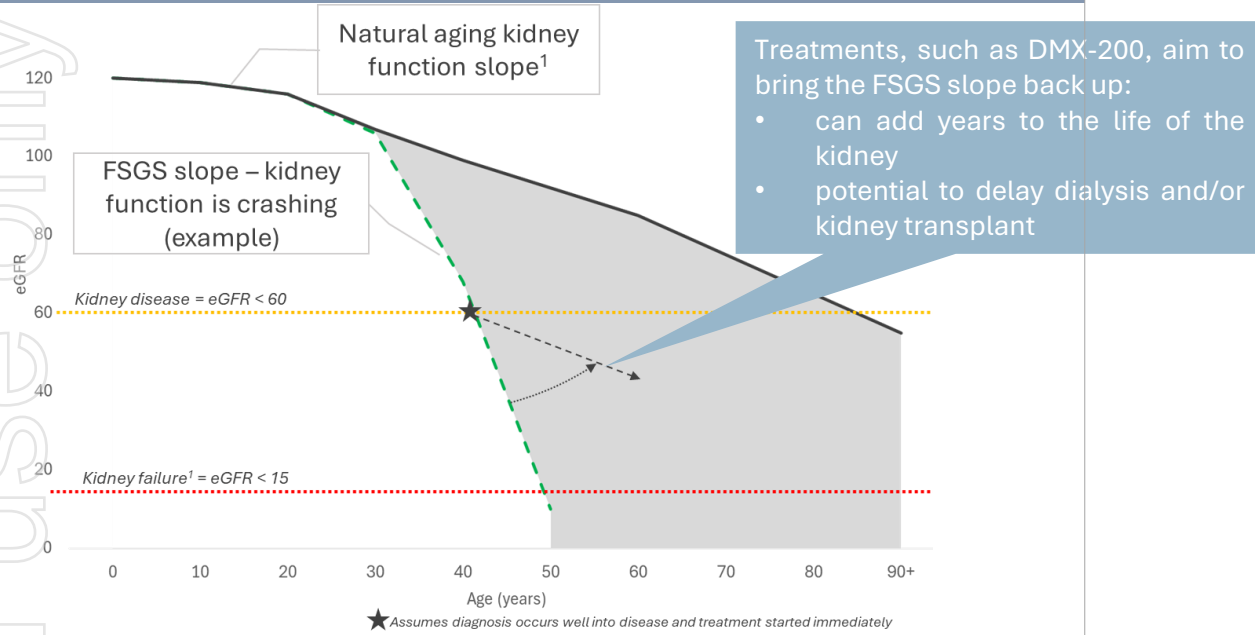
interrupts Step 2 - the inflammatory pathway to target decreasing inflammation



1. Lewis, E. J. et al. (2001), *New Engl J Medicine* 345, 851-860

Measuring kidney damage – surrogate endpoints

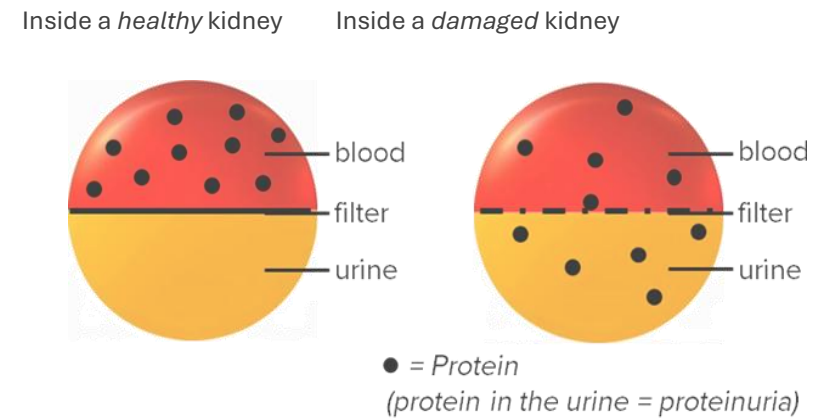
1. Estimated glomerular filtration rate (eGFR)



- 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 age¹
 - In FSGS patients, it is crashing

2. Proteinuria

- A healthy kidney is a good filter and allows little to no protein in the urine²



- When kidneys are damaged, protein can leak into the urine causing proteinuria
- Proteinuria represents an important early marker of kidney function³

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



~286
Total number of patients required - anticipated H2 2025¹

225
Patients recruited, randomised and dosed²

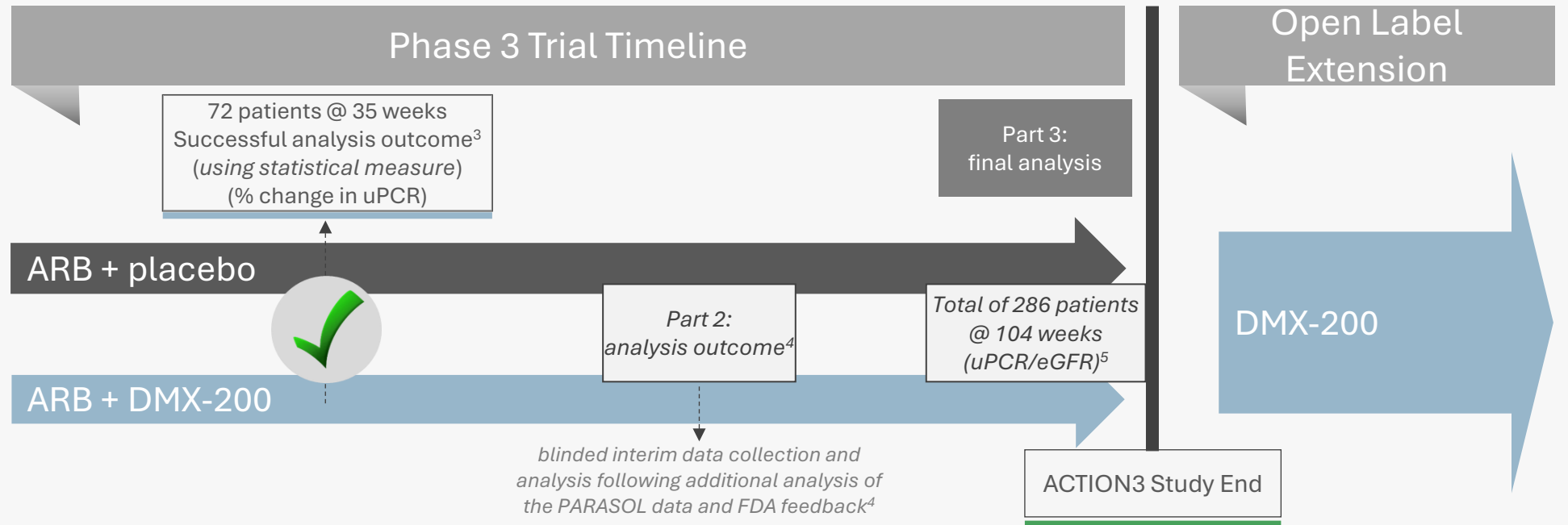
52
Patients enrolled over into Open Label Extension Study²

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

★ Potential to submit for conditional marketing approval, subject to FDA discussion³

Phase 3 Trial Timeline

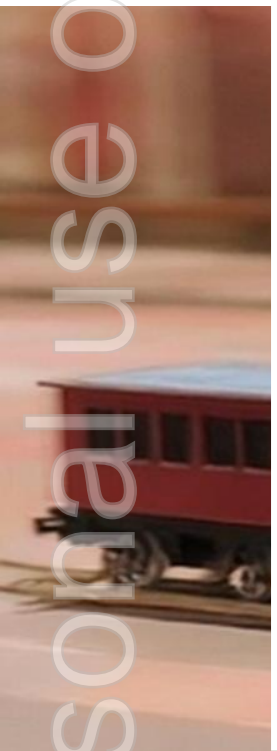


1. ASX release 30 Dec 2024; 2. As at 05 Aug 2025, including 223 adults and 2 paediatric patients; 3. Interim Phase 3 analysis data does not guarantee a statistically significant outcome at the end of the trial, ASX release 11 March 2024; 4. The potential for accelerated (or conditional) approval submissions, following the second interim analysis and any required unblinding, will be assessed based on outcomes from PARASOL analysis, recommendations of the IDMC and discussions with the appropriate regulatory authorities such as the FDA in the US; 5. Regardless of any accelerated (conditional) approval potential, ACTION3 study will complete full 2 year analysis and regulatory submission for potential traditional (full) approval; uPCR = urinary proteinuria; eGFR = estimated glomerular filtration rate (kidney function);

FSGS WORKING GROUP - PARASOL



only



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 measures¹

1

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 Sponsors²

- 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**

2

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 12-month, 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 **full** approval, and potential for accelerated approval for DMX-200¹

Step 1

Receive PARASOL FSGS working group 12-month data analysis¹

Assuming strong correlation to risk of kidney failure identified



Step 2

Seek FDA alignment on interim endpoints for accelerated approval and interim powering¹

Assuming FDA aligned with mid-trial endpoints



Step 3

Blinded statistical powering interim analysis outcome and update ACTION3 clinical study protocol^{1,2}

Timing subject to regulatory acceptance of the protocol in each territory



Step 4

Final decision on accelerated approval application^{1,2}

From today:

1-3 months

~3 months³

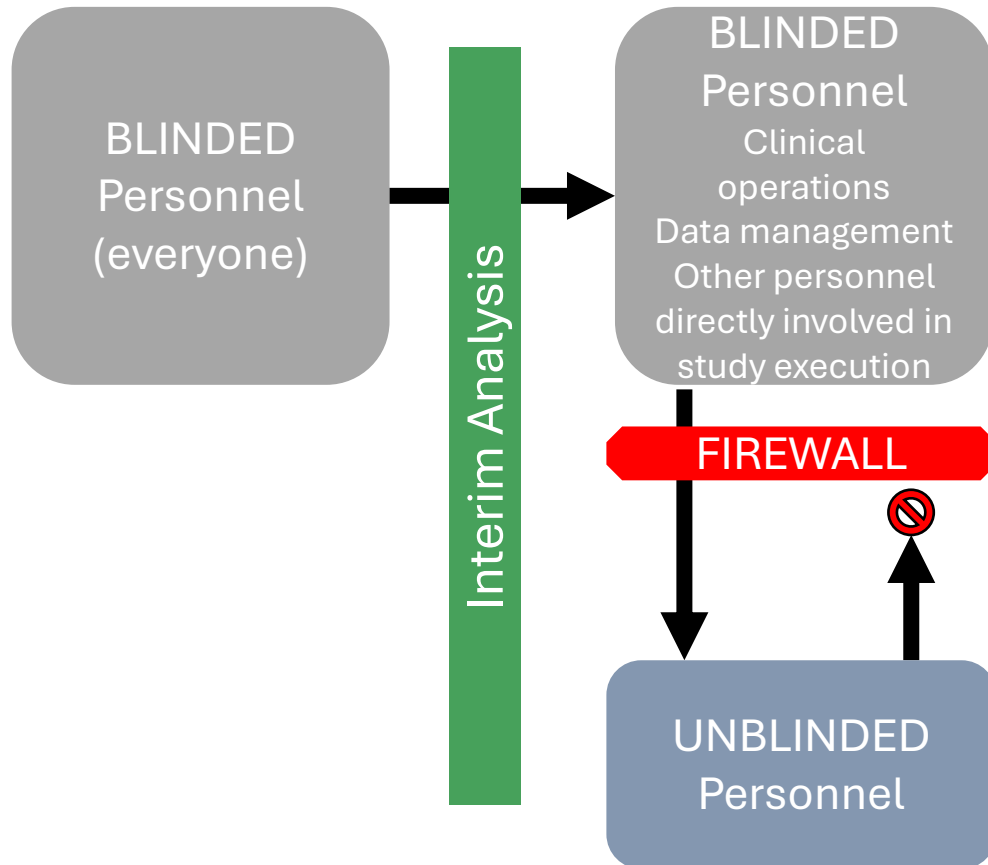
~1 month³

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

1. ASX release 28 April 2025; 2. The potential for unblinding and accelerated (or conditional) approval submissions, following the second interim analysis, will be assessed based on outcomes from PARASOL analysis, recommendations of the IDMC and agreement with the appropriate regulatory authorities such as the FDA in the US; 3. Timing subject to PARASOL outcome, FDA feedback and regulatory acceptance in each territory

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:

1. 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

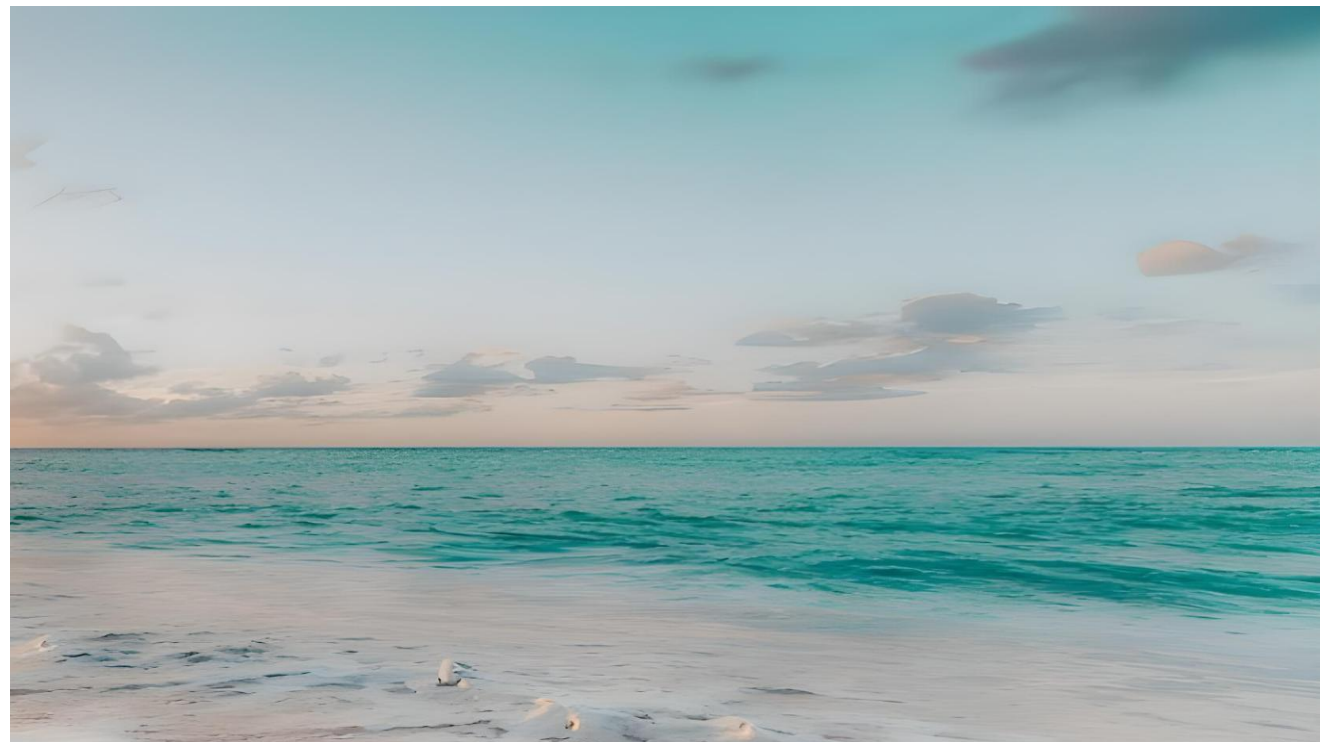
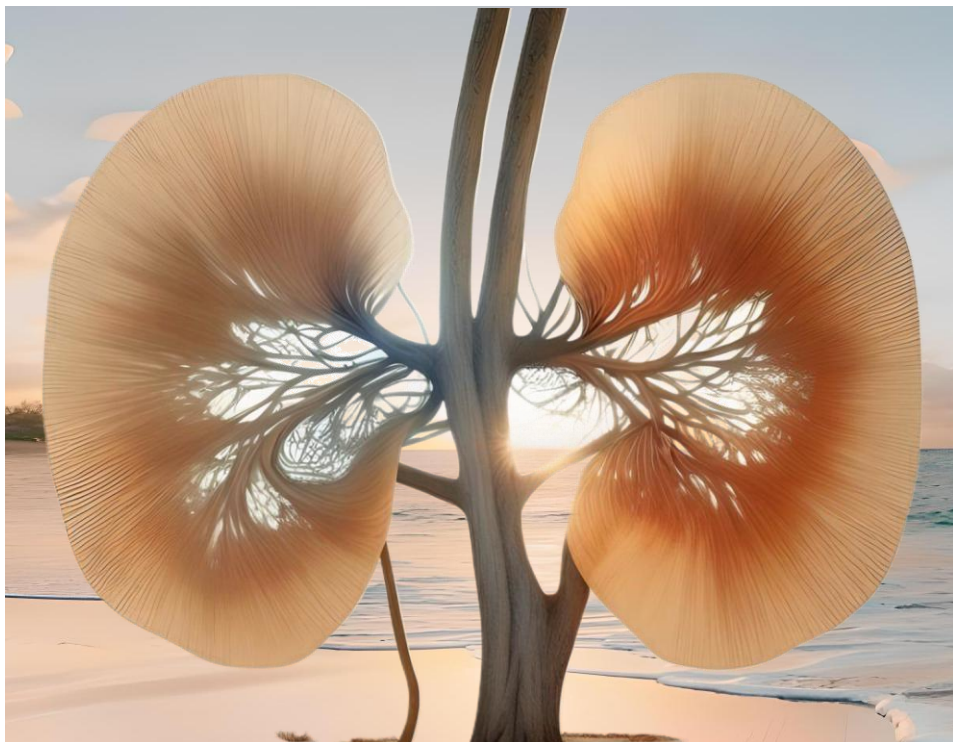
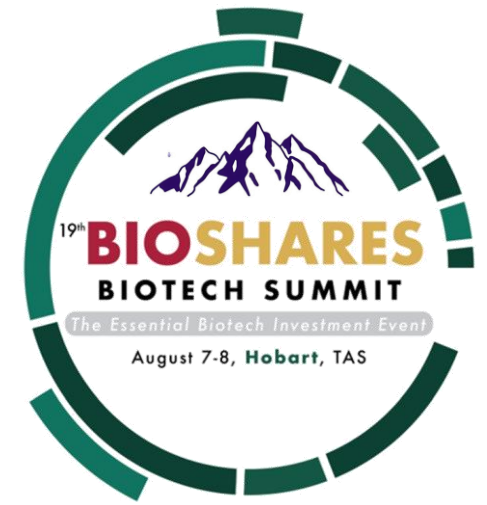
Aligning global regulatory pathways

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^{1,2}

	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 ¹	Yes Accelerated Approval program	Yes Conditional Marketing Authorisation	Yes Sakigake program

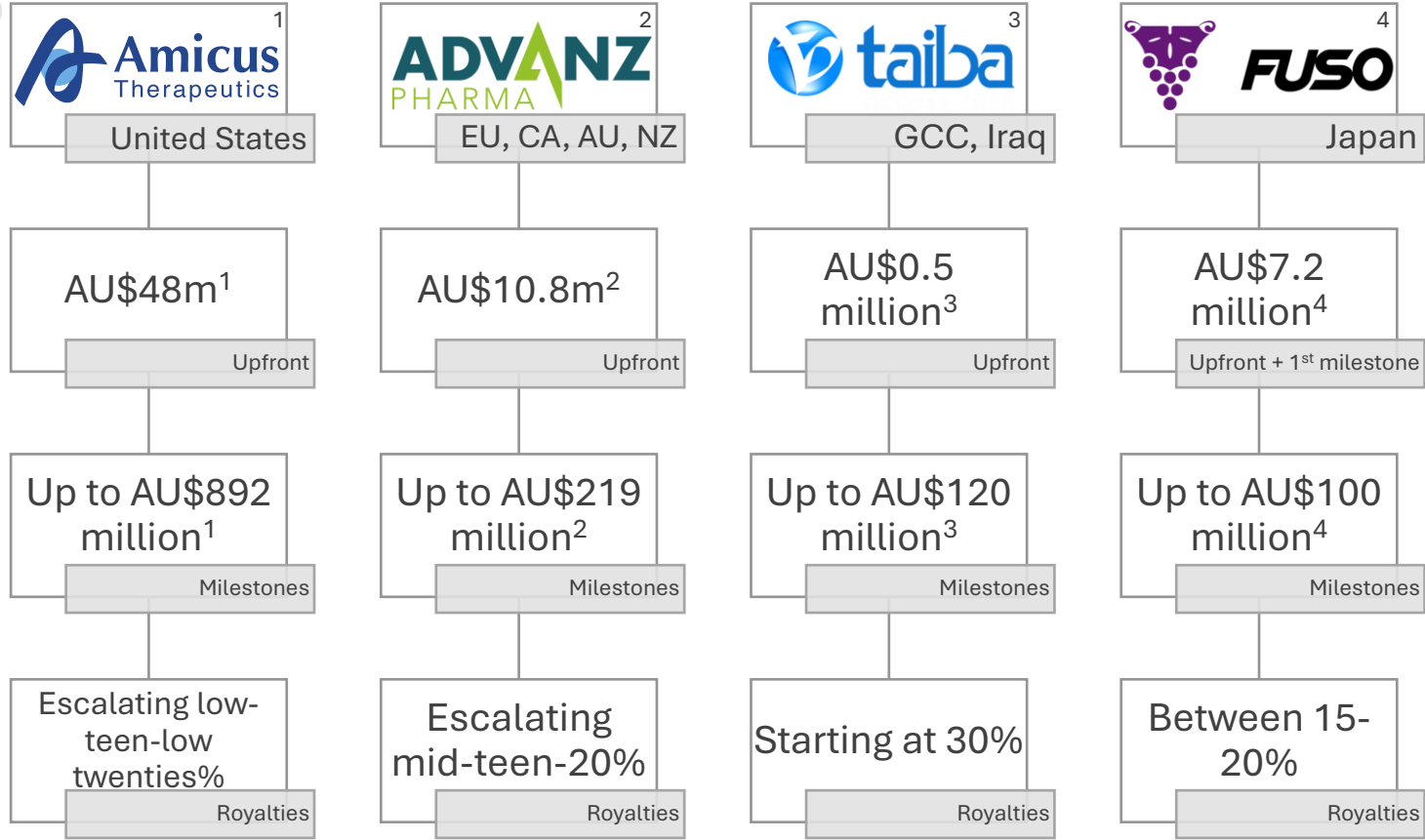
1. Franco, P., Jain, R., Rosenkrands-Lange, E. et al. Regulatory Pathways Supporting Expedited Drug Development and Approval in ICH Member Countries. *Ther Innov Regul Sci* 57, 484–514 (2023). <https://doi.org/10.1007/s43441-022-00480-3>;
2. There is no guarantee that territories will accept DMX-200 for accelerated/conditional approval in FSGS

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 plus royalties¹

Over
AU\$65 million
in total payments received

1. ASX release 01 May 2025; 2. Based on Euro conversions & further terms outlined in ASX Announcement on 5 October 2023; 3. Based on US dollar conversions & further terms outlined in ASX Announcement on 27 May 2024; 4. Based on Japanese Yen conversions & further terms outlined in ASX Announcement on 7 January 2025

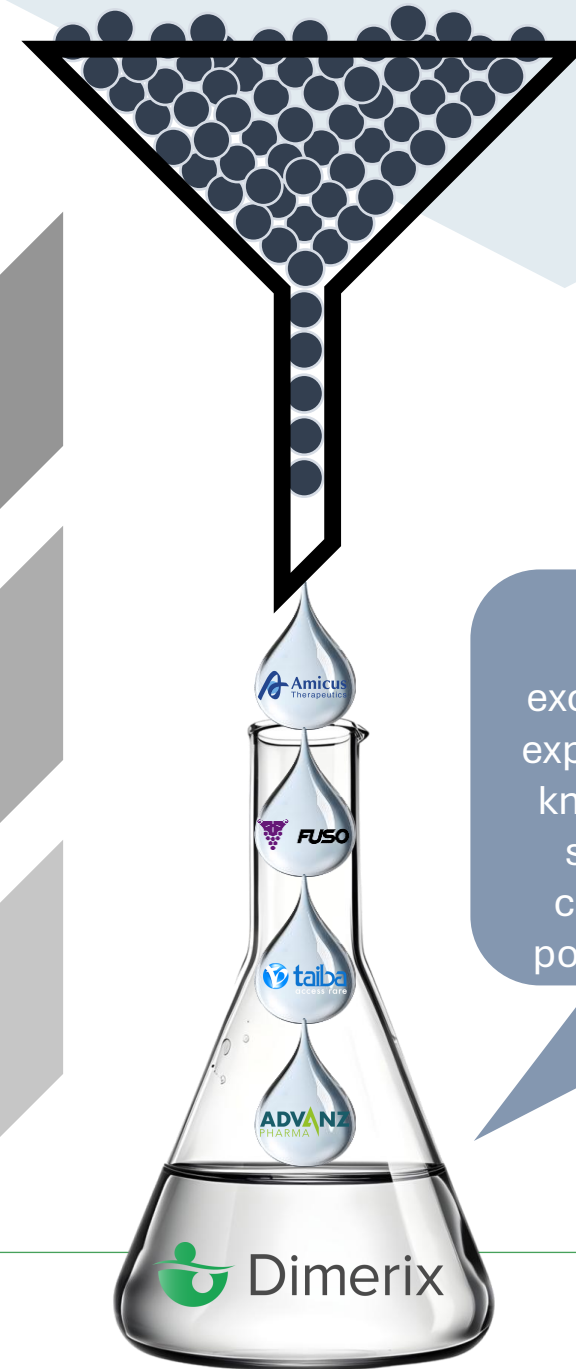
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Selecting our partners

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

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

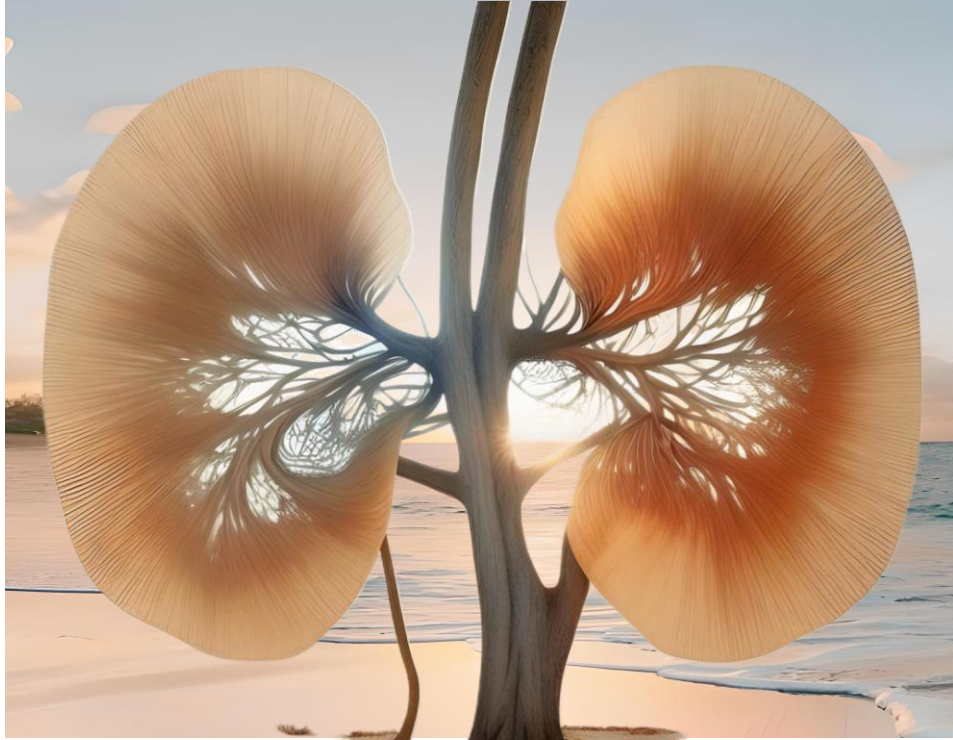
A partner with a collaborative approach who will work almost as an extension of the Dimerix team to achieve the best outcome for the product and the patient



4

exceptional, high quality partners, exponentially increasing collective knowledge & expertise, providing strong support in advancing & commercialising DMX-200 as a potential new treatment for FSGS

THE OPPORTUNITY



FSGS market – potential for growth

Biopsy

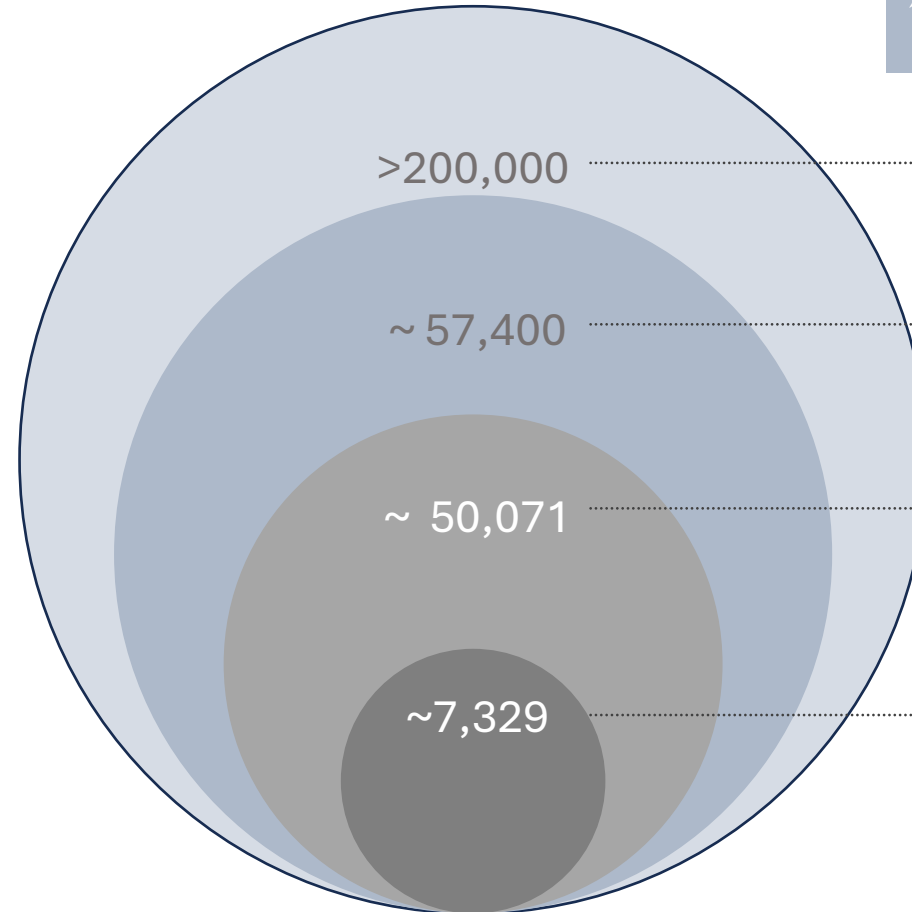
FSGS diagnosis driven by rates of biopsy - growth potential as biopsy rates increase

FSGS is the most frequent primary glomerular disease that reaches end-stage renal failure in the US¹

0

Approved treatments specifically for FSGS

- Prevalence refers to the total number of existing cases (new and old)
- Incidence refers to the number of new cases of a disease within a specified time period



- **Global prevalence** FSGS patients²
- Estimated global incidence of FSGS/year³
- Estimated incidence of FSGS/year across unlicensed territories³
- Estimated incidence of FSGS/year across all Dimerix licensed territories³

1. The United States Renal Data System (USRD), 2023 Annual Report, End Stage Renal Disease; 2. Delve Insight Market Research Report (2022): Focal segmental glomerulosclerosis (FSGS) – Market Insight, Epidemiology and market forecast – 2032; 3. Assuming referenced incidence rates and based on global and country populations as at 16 June 2025 <https://www.worldometers.info/world-population/>

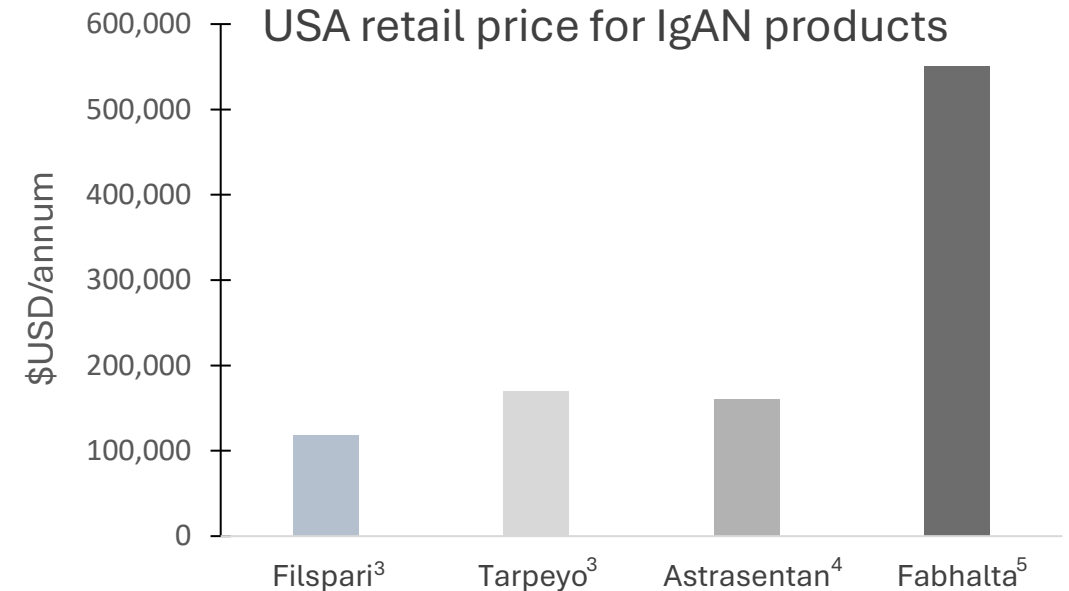
Rare kidney disease pricing examples

US Medicare Drug Price Negotiation Program¹

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 USA³



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

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

Outcome driven strategy

Clear strategy,
detailed business
plan

Clear investment
proposition to
shareholders

Operational
excellence in
execution

Deliver on promise
& within budget



ersonal use only

Recognition: drug development is a team sport

Team  Dimerix 2025



Team Webster



Teams:



...a recipe for success...



Dimerix

(ASX:DXB)



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.

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.

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