For Immediate Release

DIMERIX TO PRESENT AT EUROZ HARTLEYS HEALTHCARE FORUM 2026

MELBOURNE, Australia, 05 February 2026: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical asset in kidney disease, is pleased to advise that CEO and Managing Director, Dr Nina Webster, will be presenting at the Euroz Hartleys Healthcare Forum held in Perth, WA on 05 February 2026.

Dr Webster will present an update on the following:

- Phase 3 global clinical trial in FSGS kidney disease, including updated patient numbers and a breakdown on recruitment by country
- Commercial partnering status
- Company growth strategy

A copy of the presentation is attached.

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

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Follow us on **LinkedIn** and **X**

Authorised for lodgement by the Board of the Company

—END—

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's 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 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 characterised 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 disease 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.

About 

FSGS Phase 3 Study

The ACTION3 Phase 3 study is a pivotal Phase 3, multi-centre, randomised, double-blind, placebo-controlled study of the efficacy and safety of DMX-200 in patients with FSGS who are receiving a stable dose of a blood pressure medication known as an angiotensin II receptor blocker (ARB). Once the ARB dose is stable, patients are then randomised to receive either DMX-200 (120 mg capsule, twice daily) or placebo for a 2-year treatment period. The single Phase 3 trial in FSGS patients is designed to capture evidence of proteinuria reduction 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).

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

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ACTION3
FSGS CLINICAL STUDY

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

Investor Presentation

Euroz Hartleys Healthcare Forum

5 February 2026

Authorised for lodgement by the Board of the Company

Forward looking statements

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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, including but not limited to those factors outlined in the most recent Dimerix Limited Annual Report.

Overview | Phase 3 Global Opportunity

Phase 3 trial **recruitment complete** in trial of DMX-200 in focal segmental glomerulosclerosis (FSGS)

FSGS indication is a **rare disease** that causes scarring of the kidney, leading to irreversible damage[1]

No approved treatments specifically for FSGS: damage can lead to **dialysis, transplant or death**[1]

Orphan drug designations regulatory, marketing exclusivity and pricing **benefits** in key territories[2]

4 commercial partners **DMX-200 licensed** in USA, Europe, Canada, Australia, NZ, Japan and GCC[3]

up to $1.4 billion in total development and sales milestone payments **plus** royalties[3]

>$65 million in total upfront **payments received** to date[3]

Dimerix

1. Guruswamy Sangameswaran KD, Baradhi KM. Focal Segmental Glomerulosclerosis (July 2021), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/; 2. ASX releases: 14 December 2015, 21 November 2018, 07 June 2021; 3. ASX release 05 October 2023, 27 May 2024, 07 January 2025 and 01 May 2025

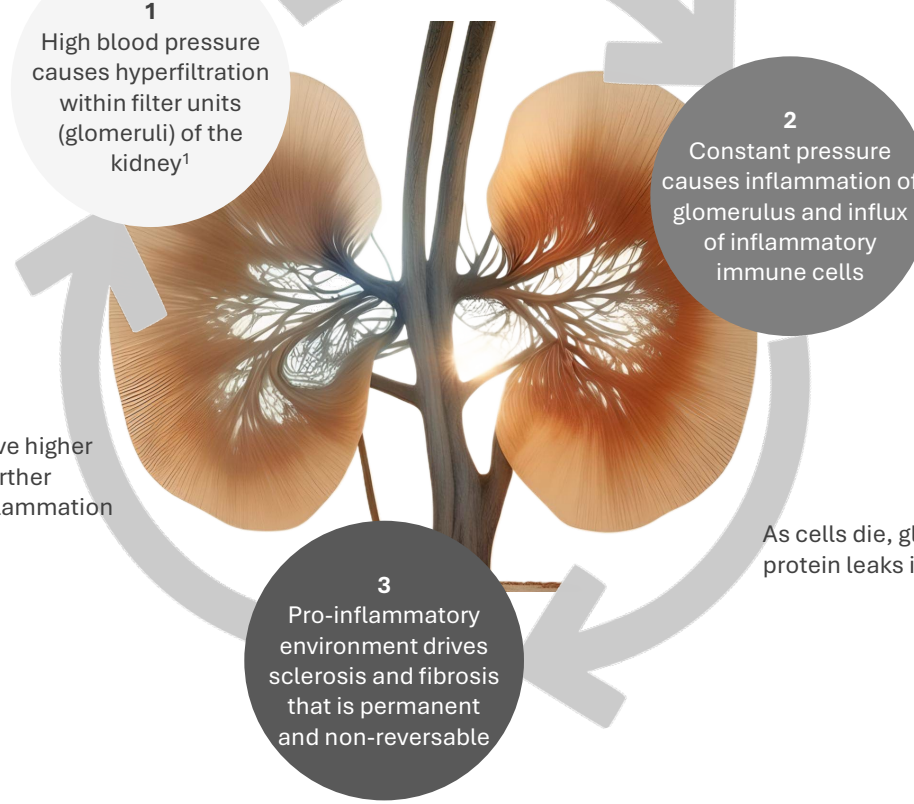
Cycle of damage :

What is FSGS?	
Focal	**= some**
Segmental	**= sections**
Glomerulo	**= of the kidney filtering units**
Sclerosis	**= are scarred**

in glomerular diseases

Existing blood pressure medication

DMX-200



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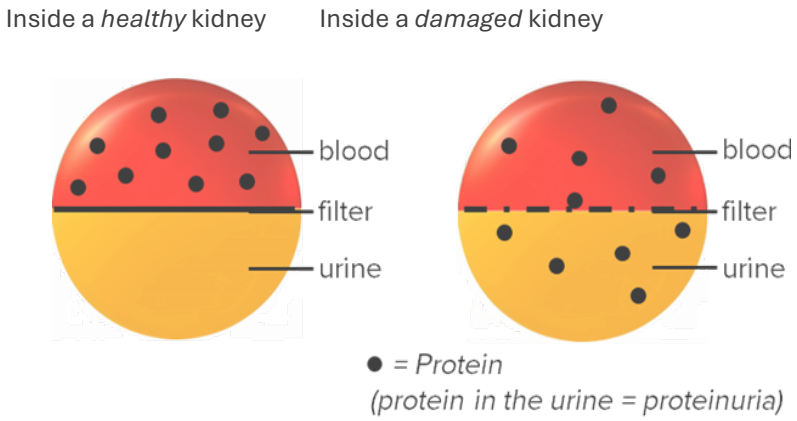
1. Lewis, E. J. et al. (2001), New Engl J Medicine 345, 851–860

Measuring kidney damage – surrogate endpoints

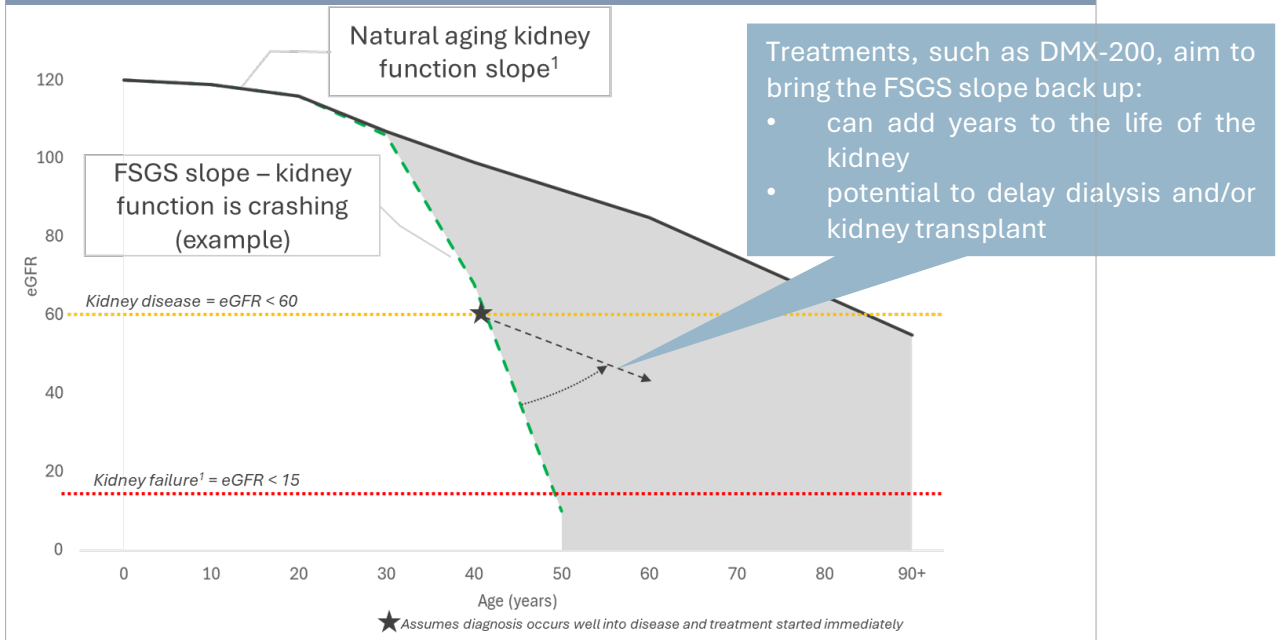
1. Proteinuria

- A healthy kidney is a good filter and allows little to no protein into the urine[2]



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

2. Estimated glomerular filtration rate (eGFR)



- Kidney function is measured using the estimated rate of blood filtered by the kidney per minute (millilitres per minute)
- eGFR slope naturally declines as we age[1]
- In FSGS patients, kidney function is decreasing rapidly

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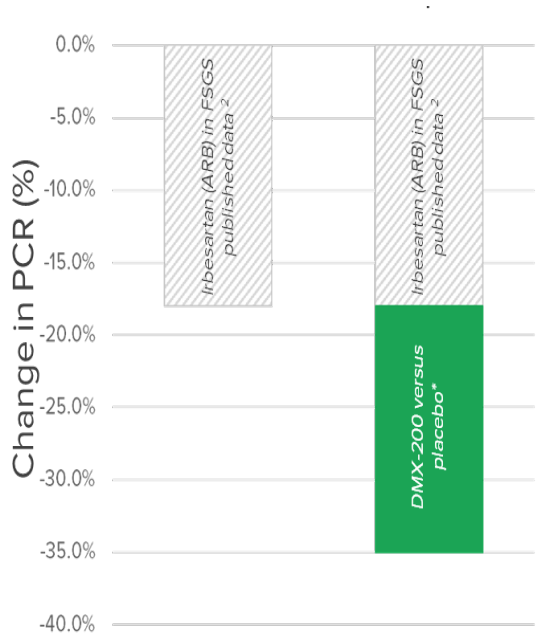
1. National Kidney Foundation: Estimated Glomerular Filtration Rate (eGFR): https://www.kidney.org/atoz/content/gfr; 2.Guruswamy Sangameswaran KD, Baradhi KM. Focal Segmental Glomerulosclerosis (July 2021), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/; 3. Nephcure FSGS living with the disease (2024) at https://nephcure.org/livingwithkidneydisease/ns-and-other-glomerular-diseases/understanding-fsgs/

DMX-200: Phase 2 met primary and secondary endpoints

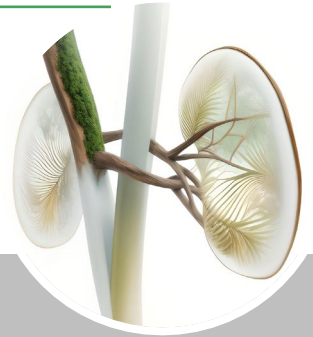
Clinically encouraging outcomes achieved for patients,[1,2] with no safety concerns noted[3]

Average reduction of **17%** in proteinuria after 16 weeks treatment on DMX-200 versus placebo[3]



"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[2]



EFFICACY

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

SAFETY

- No safety concerns – reduced development risk

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PCR = protein creatinine ratio; ARB = angiotensin receptor blocker; 1. Trachtman, et al., 2018. J Amer Soc Nephrology 29(11):2745-2754; 2. Troost JP et al (August 2020); doi.org/10.1053/j.ajkd.2020.04.014; 3. Repeated measures mixed model analysis per protocol; top line data was reported as grouped analysis on 29 July 2020, study not designed for statistical significance;

ACTION3 phase 3 clinical trial

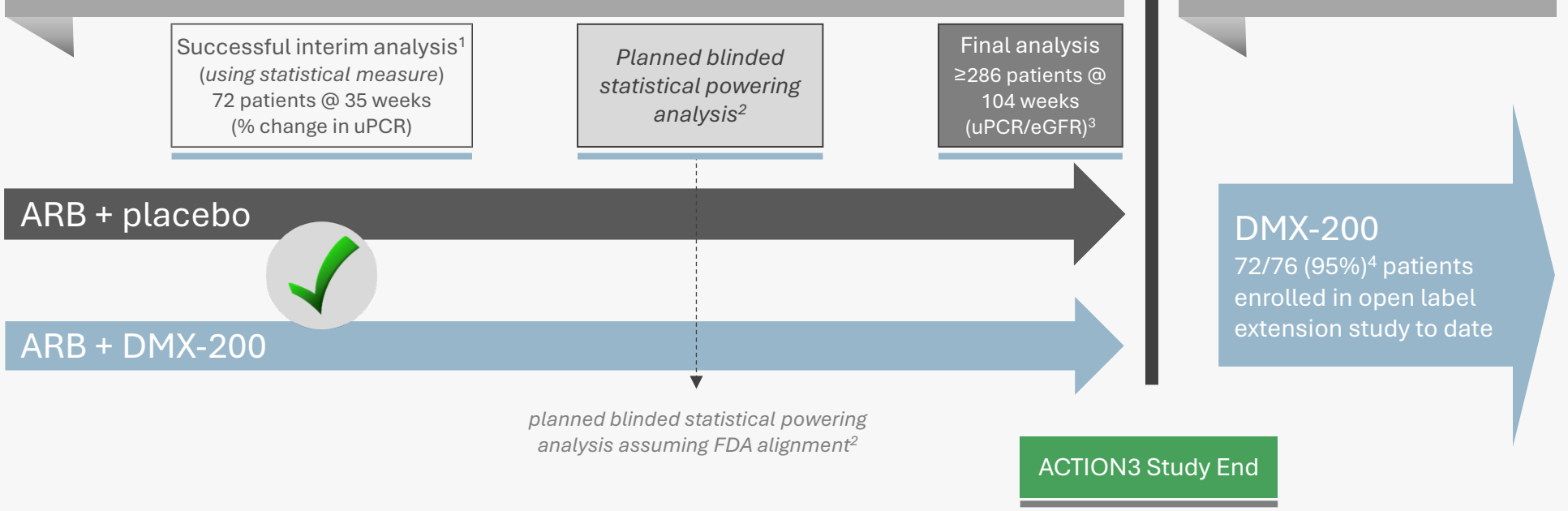
FSGS CLINICAL STUDY

A randomised, double-blind, multi-centre, placebo-controlled study of renal outcomes of DMX-200 in patients with FSGS receiving an ARB (n=≥286)

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
72/76 (95%)[4] patients enrolled in open label extension study to date

1. Interim Phase 3 analysis data does not guarantee a statistically significant outcome at the end of the trial, ASX release 11 March 2024; 2. 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, discussions with the appropriate regulatory authorities such as the FDA in the US and blinded statistical powering outcomes; 3. Regardless of any accelerated (conditional) approval potential, ACTION3 study will complete full 2 year analysis and regulatory submission for potential traditional (full) approval; 4. number and % of eligible patients who have completed 2 years treatment as at 04 February 2026; ARB = angiotensin receptor blocker; uPCR = urinary proteinuria; eGFR = estimated glomerular filtration rate (kidney function);

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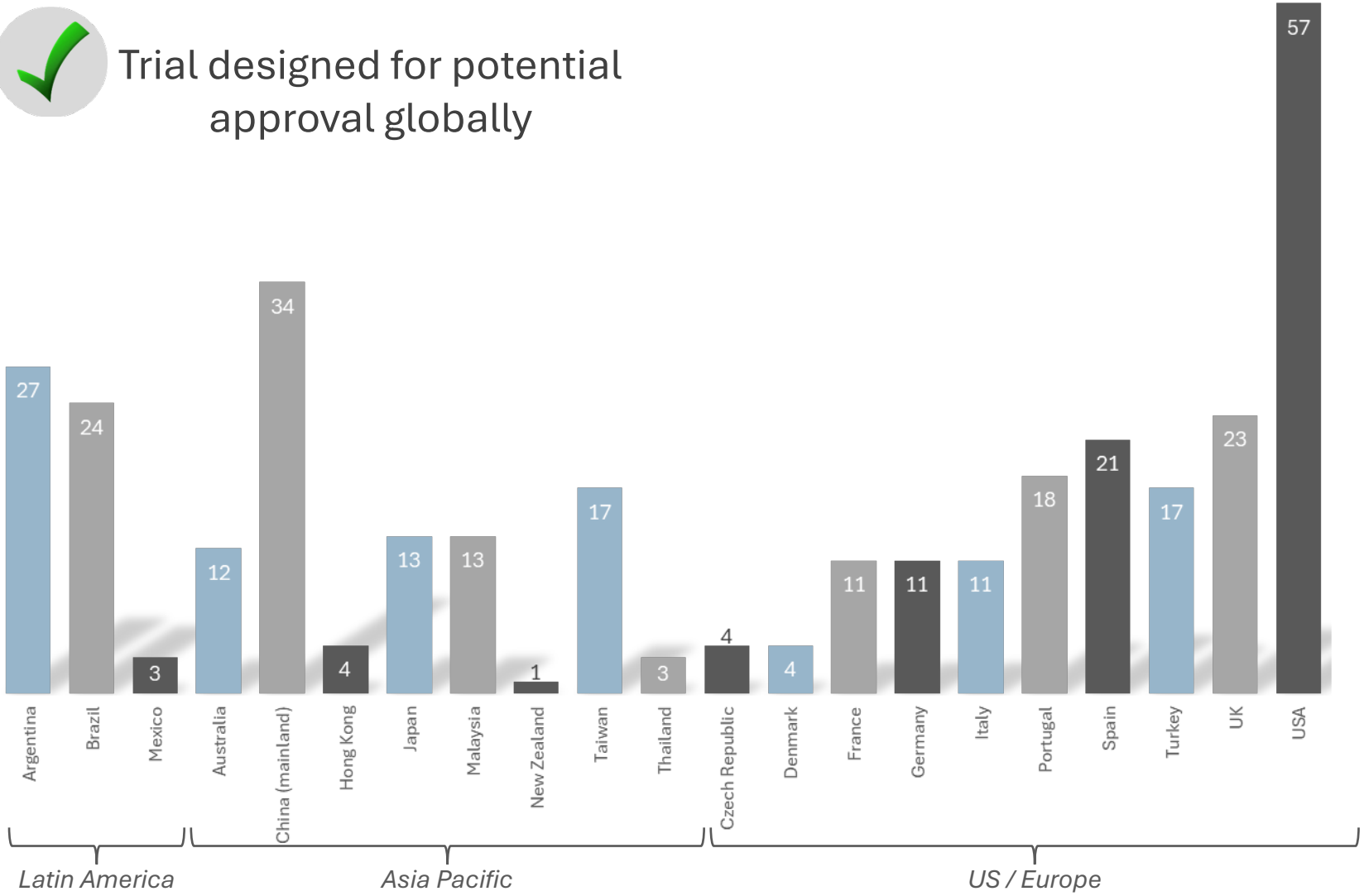
Adult patient recruitment by territory

Trial designed for potential approval globally



Recruitment completed

(adult population)[1]

328

Adult patients recruited, randomised and dosed (target ≥286)[2]

5

Paediatric patients recruited, randomised and dosed[2]

1. ASX release 15 December 2025; 2. As at 04 February 2026, allowing for those recruited to complete stabilisation and second screening; paediatric patients will continue to recruit, and will not impact final analysis timelines

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ACTION3 next steps

FSGS CLINICAL STUDY

PARASOL working group conducted “ACTION3-like” population analysis of larger PARASOL observation dataset[1,2]

- Results of this analysis are generally consistent with the broader PARASOL analysis conducted in 2024
- Potential relationship between proteinuria at 12 months and subsequent risk of kidney failure observed that may support proteinuria as an endpoint for marketing approval

Step 1

PARASOL FSGS working group 12-month data analysis received[1]

Step 2

Seek FDA alignment on endpoints and process for traditional approval and potential accelerated approval endpoints[2]

When FDA aligned with endpoints

Step 3

Blinded statistical powering analysis for final endpoints and ACTION3 clinical study protocol updates[2,3]

Timing of analysis based on protocol update in each territory

Step 4

Final decision timeline for traditional and/or accelerated approval analysis[2,3]

~early 2026[2]

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1. ASX release 08 October 2025; 2. ASX release 28 April 2025 and 24 December 2025; 3. The potential for unblinding and accelerated (or conditional) approval submissions will be assessed based agreement with the appropriate regulatory authorities such as the FDA in the US and the outcomes of the planned blinded statistical powering analysis;

Competitive landscape in FSGS

- Low competition in inflammatory treatment options, huge unmet medical need
- DMX-200 is the only inflammatory modulator in development

	Phase 1	Phase 2	Phase 3	Company
DMX-200	*Inflammatory modulator*			Dimerix
Sparsentan	*AT1R/ETAR dual antagonist – Failed Phase 3 eGFR endpoint: resubmitted to FDA on proteinuria endpoints*			Travere Therapeutics
VX-147	*APOL1 inhibitor – targeting a specific type of genetic FSGS*			Vertex Pharmaceuticals
BI-764198	*TRPC6 inhibitor*			Boehringer Ingelheim
Atrasentan	*ETAR antagonist*			Chinook
Frexalimab, Brivekimig, Rilzabrutinib (basket)	*CD40L antagonist, TNF-α/OX40L antagonist, TKI*			Sanofi
R3R01	*Lipid modifying*			River 3 Renal

Sources: Company Documents, Statutory and Regulatory Filings

Rare kidney disease – a potential growth market

Biopsy

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

7 per 1,000,000

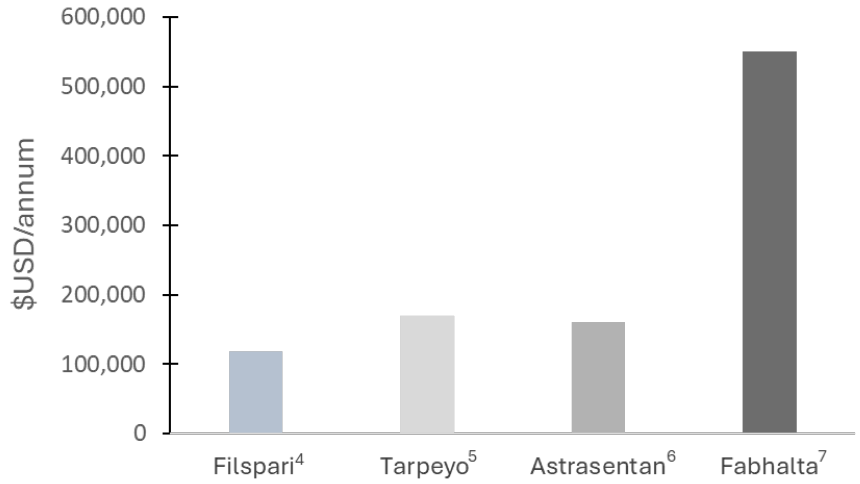
Global incidence rate of FSGS per capita, per year[1]

FSGS is the most frequent primary glomerular disease that reaches end-stage renal failure in the US[2]

DMX-200

Commercial manufacturing sites established in USA[3]

Example pricing: USA retail price for IgA Nephropathy products



Example price for other rare kidney disease drugs per patient:

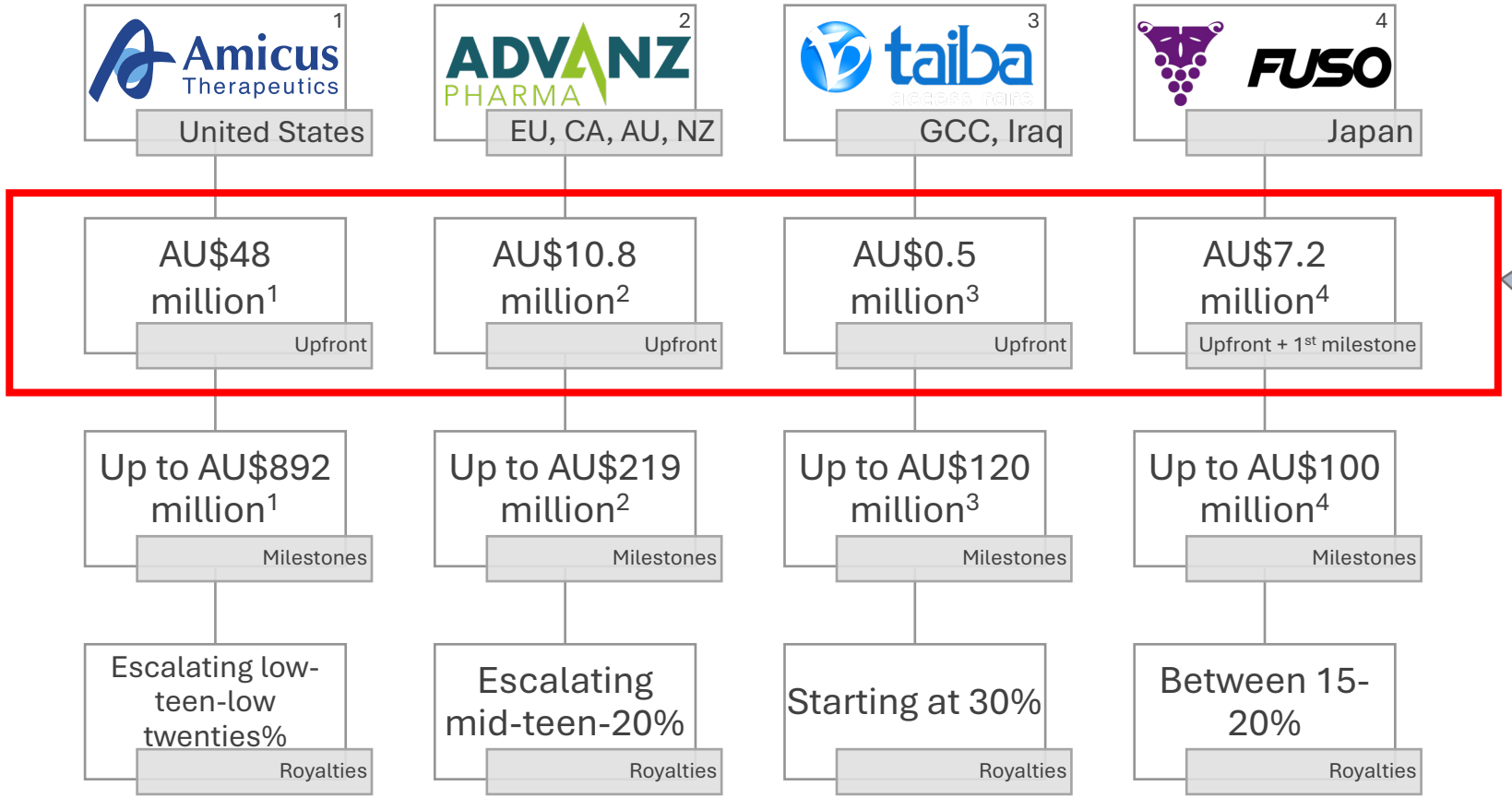
- *in the US (i.e. Kinpeygo/Tarpeyo in IgAN)[8]:* ***US$15,123 per month***
- *in the UK (Kinpeygo/Tarpeyo in IgAN)[9]:* ***US$8,797 per month***

Other key territories, including Middle East and China, use US and/or Europe as pricing reference[10,11]

1. Kitiyakara et al Trends in the epidemiology of focal segmental glomerulosclerosis. Semin Nephrol. 2003 Mar;23(2):172-82. doi: 10.1053/snep.2003.50025. PMID: 12704577; 2. The United States Renal Data System (USRD), 2023 Annual Report, End Stage Renal Disease; 3. ASX investor presentation 09Mar20; 4. https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-approves-travere-therapeutics-kidney-disorder-drug-2023-02-17/; 5. http://www.vanrafia.com; 6. Ito, et al., 2025. https://doi.org/10.1182/blood.2024025176; 7. https://endpts.com/fda-clears-traveres-rare-kidney-disease-drug-will-come-with-rems-program; 8. Micromedex Red Book (2025) Comprehensive drug pricing and product information; 9. UK list price (2025) https://www.nice.org.uk/guidance/TA937/chapter/2-information-about-targeted-release-budesonide; 10. J Mark Access Health Policy. 2016 Mar 15;4:10.3402/jmahp.v4.30458. doi: 10.3402/jmahp.v4.30458

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[1]

Over

AU$65 million

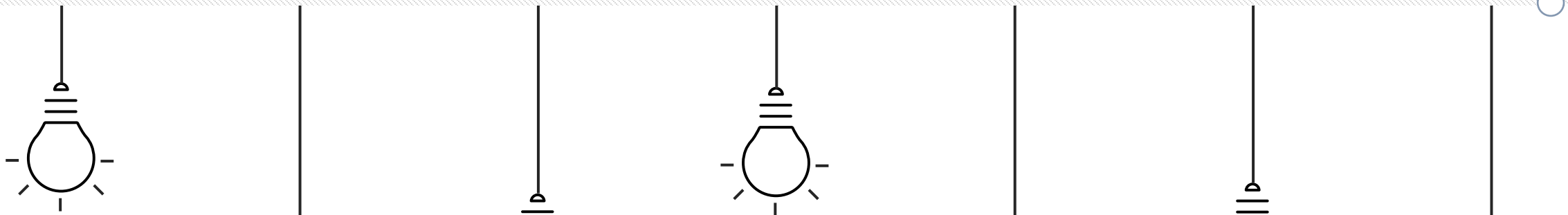
in total payments received

Significant potential additional global **deal value remains**, as Dimerix pursues and progresses **licensing opportunities** with potential partners outside the licensed territories

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

Intellectual property portfolio

DMX-200



Exclusivity
7/10 years
Orphan exclusivity from marketing approval date in many territories[1]
+
Paediatric
exclusivity period extension[1]

Portfolio 1
Exp.2032
(2033 in US)
Method of Use
Granted in key territories[2]

Portfolio 2
Exp.2042
(if granted)
Method of Use & Formulation
Global application[3]

Portfolio 3
Exp.2042
(if granted)
Formulation
Global application[3]

Portfolio 4
Exp.2044
(if granted)
Method of Use & Formulation
Global application[3]

Portfolio 5
Exp.2045/6
(if granted)
Method of Use
Provisional application[4]

Trademarks
Various trademarks
Global applications

1. DMX-200 is a "New Chemical Entity: an active moiety not previously approved, which can attract exclusivity periods in various territories; 2. Granted patents US9,314,450, US10,058,555, US10,525,038, US11,382,896, US12,083,102, CN2012800046165, CA2,821,985, EP12734251.7, HK 1404477.8, IL227414, JP2013-547780, SA2013/5897, AU2012206945; 3. Patent applications: PCT/AU2022/050013, PCT/AU2022/050249 and PCT/AU2024/050416; 4. US Provisional Application 63/887,984

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Growth strategy

Deliver ACTION3 Phase 3 clinical trial

- Ensure drug supply continuity and patient visits for recruited patients
- Complete recruitment of paediatric patients
- Maintain regulatory engagement (FDA, EMA, PMDA, NMPA + others)
- With partners, prepare for potential market approval and launch readiness

Expand global commercial partnerships

- Build on existing licensing agreements and relationships
- Secure additional partnerships to expand and accelerate market access

Advance pipeline development

- Identify and progress new assets in renal and/or rare disease indications
- Leverage DMX-200 platform for additional indications

Grow sustainable shareholder value through clinical success, global partnerships, and pipeline diversification

Achievements and potential catalysts

1 FY 2024/25

- ✓ DMX-200 **licensed in US** for up to ~AU$940 million[1]
- ✓ DMX-200 **licensed in Japan** for up to ~AU$107 million[2]
- ✓ Positive Type C meeting: **FDA confirmed** proteinuria-based endpoint acceptable for full marketing approval in the US[3]
- ✓ First **development milestone** received from FUSO of AU$4.1 million [4]

2 FY 2025/26

- ✓ Outcome of PARASOL working group **analysis received**[5]
- ✓ Phase 3 trial **recruitment complete** with >286 adult patients[6]
- ➢ FDA outcome on endpoints anticipated Q1 CY 2026[7]
- ➢ Blinded interim data collection anticipated in Q1 CY 2026[7]
  - Potential for accelerated (or conditional) approval submission, subject to FDA feedback and blinded analysis outcomes[3,7]
- ➢ Additional **pipeline** opportunity(s) to be announced

3 Potential upside

- ➢ Additional **commercial licensing partners** for DMX-200: Dimerix continues to pursue potential licensing opportunities in un-licensed territories, including China
- ➢ Additional development **milestone payments** from existing licensees if milestone achieved

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1. ASX release 01 May 2025; 2. ASX release 07 January 2025 3. FDA Meeting Outcomes, ASX release 28 April 2025; 4. ASX release 30 June 2025; 5. ASX release 08 October 2025; 6. ASX release 15 December 2025; 7. ASX Release 24 December 2025;

Corporate overview

Ticker Symbol	ASX: DXB
Cash Balance (Dec25)	$38.5 million
Market Capitalisation[1]	$318 million
Share price[1]	$0.53
Total ordinary shares on issue[1]	600,396,776
Average Daily Liquidity by value for past 30 trading days[2]	$0.99 million

SHARE PRICE

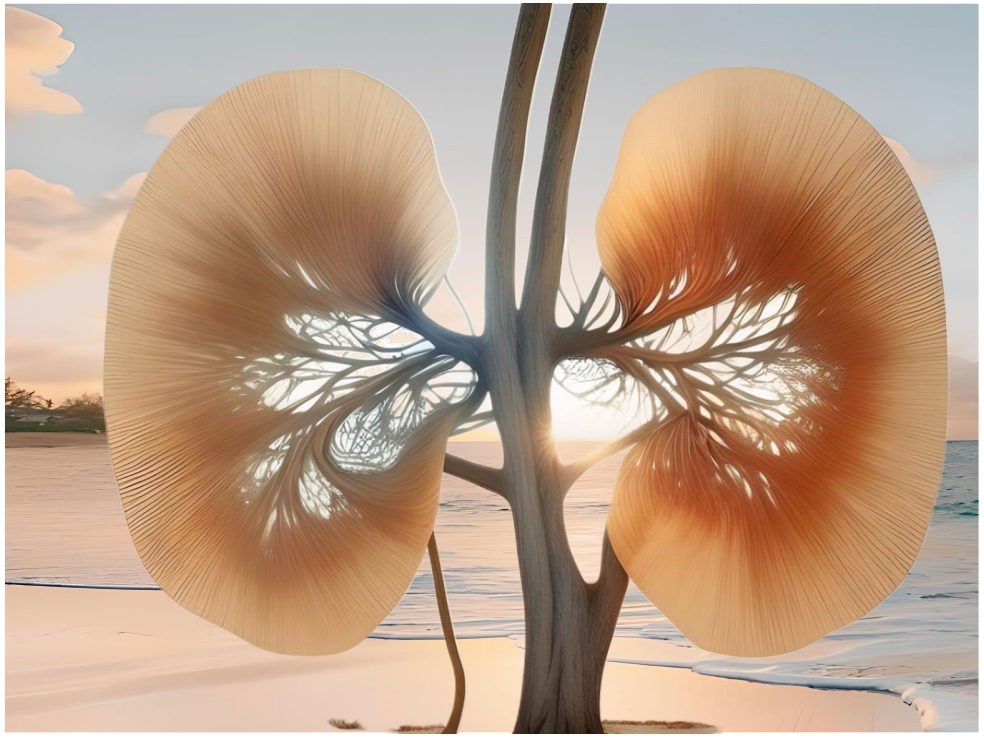
SUBSTANTIAL SHAREHOLDERS[3]

Position	Holder Name	Holding	% IC
1	Mr P Meurs	87,259,311	14.5%
TOTAL (TOP 5) Shareholders		**146,759,306**	**24.4%**

1. As at 04 February 2026; 2. Past 30 trading days liquidity as at 04 February 2026;
3. Shareholder register as at 04 February 2026

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.

SCAN ME

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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E. investor@dimerix.com

Dimerix board

Mark Diamond
BSc, MBA
Non-Executive Chairman

Previous experience:

percheron THERAPEUTICS · Pfizer (Faulding)[1]

- Senior pharmaceutical executive with a demonstrated record of achievement and leadership over more than 30 years within the pharmaceutical and biotechnology industries
- Significant accomplishments in capital raising initiatives, pipeline development and licensing
  - ✓ BSc – Chemistry
  - ✓ MBA – Business

Nina Webster
PhD, MBA,M.IP.Law
CEO & Managing Director

Previous experience:

Wyeth[2] · ACRUX · immuron

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

Hugh Alsop
BSc (Hons), MBA
Non-Executive Director

Previous experience:

mayne pharma[1] · ACRUX · HatchTech · KINOXIS

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

Sonia Poli
PhD
Non-Executive Director

Previous experience:

Roche · addex · AC Immune · minoryx

- Experienced executive in pharmaceutical operations
- Background in small molecules development and analytical development
  - ✓ BSc (Hons) – Chemistry
  - ✓ PhD – Industrial Chemistry

Clinton Snow
BEng (Hons), BCom
Non-Executive Director

Previous experience:

Woodside Energy · PolyActiva · icetana AI

- Experienced technology and governance professional with a focus in operations, risk management, assurance, and AI
- Provides advisory services to a family office with multiple Australian biotech investments
  - ✓ BEng (Hons) – Chemical Engineering
  - ✓ BCom – Commerce

1. Acquired by Pfizer in 2015; 2. Acquired by Pfizer in 2009

Dimerix management

Nina Webster
PhD, MBA,M.IP.Law
CEO & Managing Director

Previous experience:

Wyeth[1] ACRUX immuron

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

Mike Tonroe
BSc (Hons) FCA, MAICD
CFO & Company Secretary

Previous experience:

IMUGENE OPTHEA Genetic Technologies

- Experienced finance and governance executive with extensive experience of both ASX and NASDAQ-listed companies.
- Brings more than 30 years' international finance leadership experience across Australia, US, Canada, the UK and Hong Kong.
  - ✓ BSc (Hons) – Business Studies
  - ✓ MIACD
  - ✓ Chartered Accountant

David Fuller
B. Pharm (Hons), MBBS
CMO

Previous experience:

RACE ONCOLOGY Syneos Health genzyme

- 35 years international experience in drug development, commercialization and corporate leadership
- Planning, Financing, Pre-clinical, Clinical Development, Regulatory Approval, Product Launch, Pharmacovigilance, and Medical Affairs
  - ✓ B.Pharm (Hons) - Pharmacy
  - ✓ MBBS - Medicine and Surgery

Robert Shepherd
PhD, MBA,
COO

Previous experience:

Medicines Development for Global Health

- Experienced pharmaceutical executive in project management, clinical development and research translation
- BD and strategic alliance leader
- Led multidisciplinary R&D&C teams for 13 years
  - ✓ BSc (Hons) – Genetics
  - ✓ PhD – Molecular Immunology
  - ✓ MBA – Business & Leadership

1. Acquired by Pfizer in 2009;

Medical Advisory Board

Professor
Hiddo Heerspink
PhD

Professor of Clinical Trials and Personalized Medicine: University Medical Center Groningen, the Netherlands. He specializes 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
Alessia Fornoni
MD, PhD, FASN

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.

Professor
Jonathan Barratt
MD, PhD, FRCP

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.

Associate Professor
Lesley Inker
MD, MS, FRCPC

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.

Dr Muh Geot Wong
MBBS, PhD, FRCP

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.

Professor
Howard Trachtman
MD, FASN

Graduated from Haverford College and the University of Pennsylvania School of Medicine. He has been a practicing pediatric nephrologist for 35 years. Has been the PI of NIDDK and industry sponsored clinical trials in glomerular disease and am a Co-Investigator in the NEPTUNE and CureGN observational cohort studies.

Associate Professor
Laura Mariani
MD, MSCE

Assistant Professor in the Division of Nephrology at the University of Michigan. Interest in observational studies in glomerular disease, including NEPTUNE and CureGN. Lead on PARASOL program to define FSGS endpoints with by applying statistical methods for clinical outcome definition and prediction of kidney disease progression.

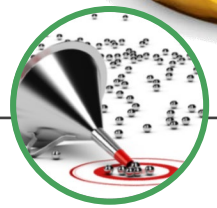
Renal disease landscape

"A squeaky wheel waiting for grease: 50 years of kidney disease management in the US"[1]

Historical lack of incentives and public policy have contributed to high costs and poor health outcomes for renal patients[1]

2018: workshops and regulatory acceptance of surrogate end points in trials of kidney diseases [2]

2019 changes in US federal policy and rapid adoption of treatment guidelines have contributed to a sea change in the management of renal disease [3]



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"[1]

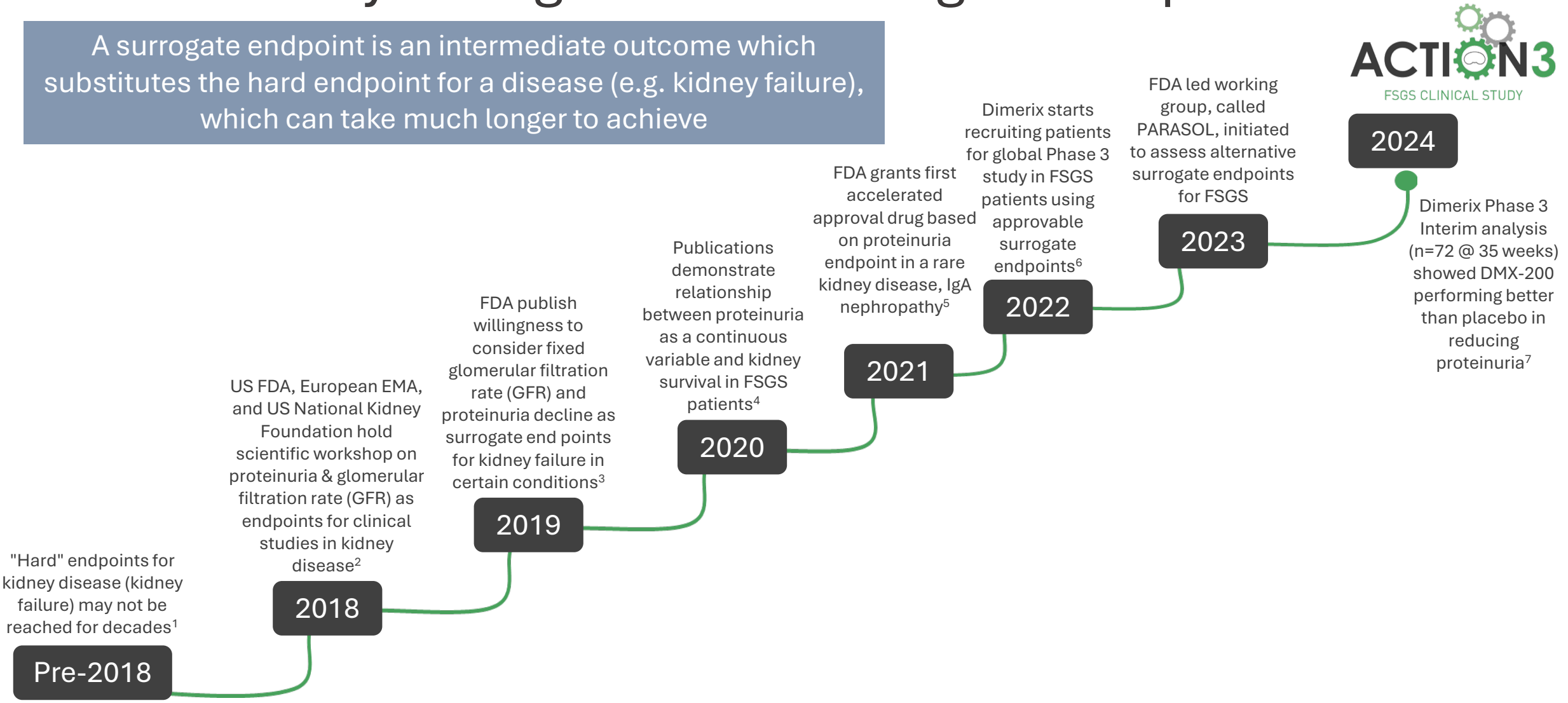
Dimerix

1.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. FDA, EMA, National Kidney Foundation Workshop Summary: https://www.kidney.org/news/accelerating-new-clinical-trials-and-treatments-kidney-disease; 3. Thompson, A et al (2019) Change in Estimated GFR and Albuminuria as End Points in Clinical Trials: A Viewpoint From the FDA DOI: 10.1053/j.ajkd.2019.08.007

Clinical study change: use of surrogate endpoints

A surrogate endpoint is an intermediate outcome which substitutes the hard endpoint for a disease (e.g. kidney failure), which can take much longer to achieve

ACTION3
FSGS CLINICAL STUDY



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1.Hartung E, (2015), Pediatric Nephrology volume 31, pages381–391 DOI: 10.1007/s00467-015-3104-8; 2. FDA, EMA, National Kidney Foundation Workshop Summary: https://www.kidney.org/news/accelerating-new-clinical-trials-and-treatments-kidney-disease; 3. Thompson A et al, (2019) Am J Kidney Dis.; 75(1):4-5: doi.org/10.1053/j.ajkd.2019.08.007; 4. Troost JP et al, (2020) Am J Kidney Dis.; 77(2):216-225: doi.org/10.1053/j.ajkd.2020.04.014; 5. FDA Drug Approvals: https://www.fda.gov/drugs/fda-approves-first-drug-decrease-urine-protein-iga-nephropathy-rare-kidney-disease; 6. ASX release 23Dec2021; 7. Predictive Power statistical model, using industry standard as set by the independent renal biostatistician consultant for Dimerix, . Interim Phase 3 analysis data does not guarantee a statistically significant outcome at the end of the trial, ASX release 11 March 2024;

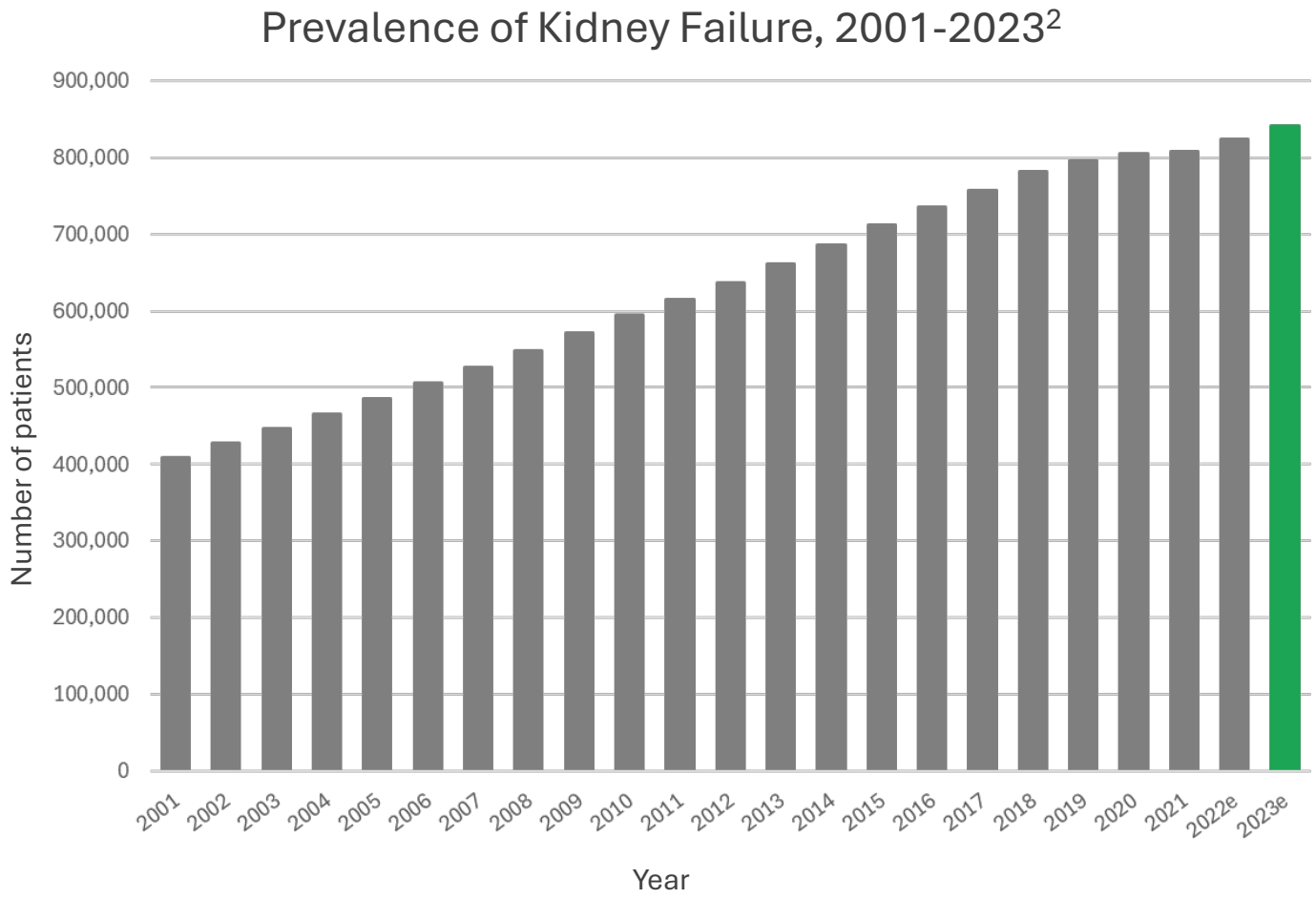
Kidney disease is high interest area for pharma

Kidney disease is the third-fastest-growing cause of death globally[1]

- In the US alone, the number of people with kidney failure increased by >200% from 2001 to 2023[2]
- By 2040, it is expected to become the fifth-highest cause of years of life lost[1,2]

The US government-funded health-care plan (Medicare) spent US$130 billion in 2023 to treat kidney disease patients

- the majority being on dialysis[1,3]



1. Editorial, Time to sound the alarm about the hidden epidemic of kidney disease, Nature 628, 7-8 (2024) doi: https://doi.org/10.1038/d41586-024-00961-5; 2. The United States Renal Data System (USRDS) Annual Report 2023; (2022 & 2023 estimates based on average growth 2001-2021)
3. Francis et al. (2024), Nature Rev. Nephrol. https://doi.org/10.1038/s41581-024-00820-6

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)

New Chemical Entity status, with orphan exclusivity (7 years US/10 years EU)[2]; and with granted patents and applications across key countries	2 x 120mg capsule daily 	Consistently safe and well tolerated in both healthy volunteers and renal patients (more than 200 patients dosed)[3]	4 clinical studies completed to date: positive efficacy signals across studies[3]
Small molecule	**Easy & convenient dosing**	**Strong safety profile [3]**	**Positive efficacy signals [3]**

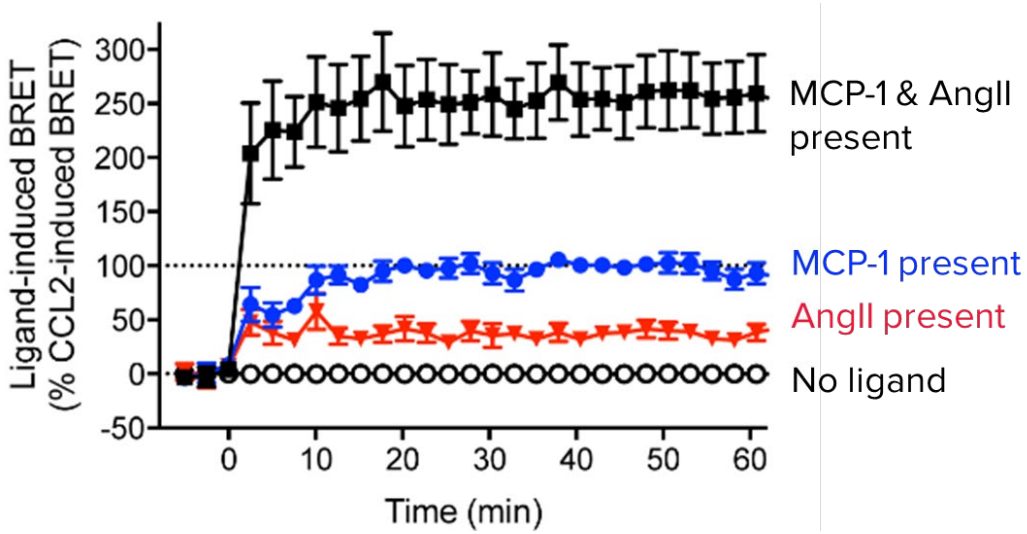
Dimerix

1. ASX release: 09May2022; 2. ASX releases: 14Dec15, 21Nov18, 07Jun21; 3. ASX release and investor presentation 29Jul20 and ASX release 11Mar24

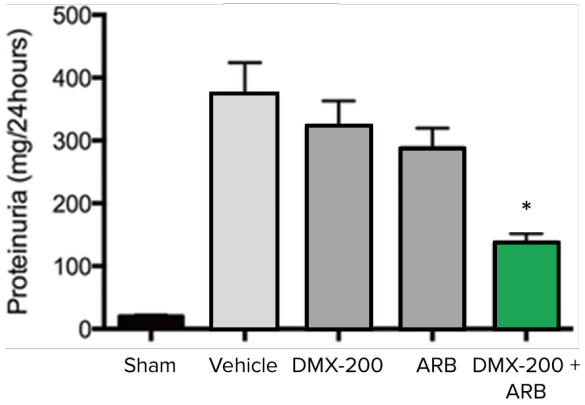
DMX-200 unique heteromer pharmacology

Proprietary discovery platform (Receptor-HIT) identified:

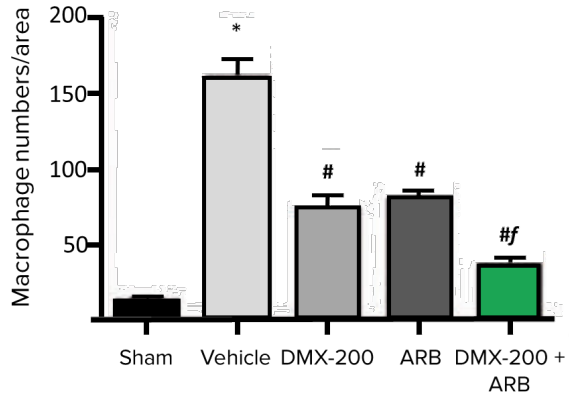
- Formation of AT1R and CCR2 heteromers;
- Novel pharmacology (potentiation of signaling)
- Dual antagonism required for completed inhibition



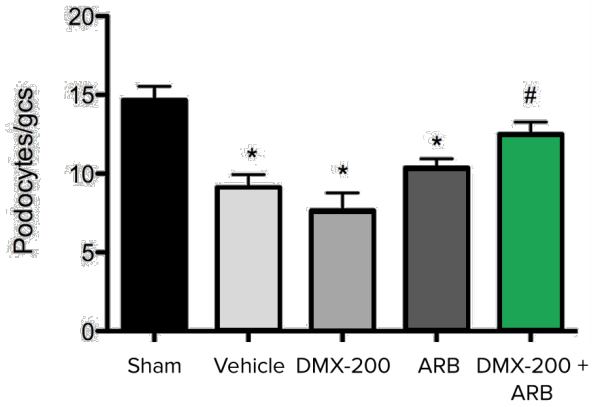
↓ Proteinuria



↓ Macrophage infiltration



Retained podocyte numbers

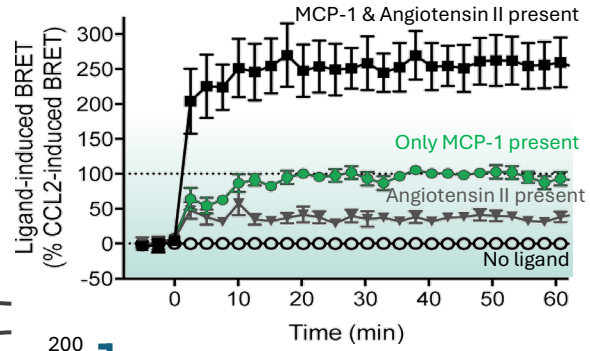


Proposed non-clinical safety package suitability for NDA confirmed with FDA[1]

*ARB: Irbesartan, * P<0.05 vs sham, # P<0.05 vs un-treated STNx, f P<0.05 vs STNx+Irb. Ayoub MA, et al. (2015) PLoS ONE 10(3): e0119803.*
1. FDA written correspondence

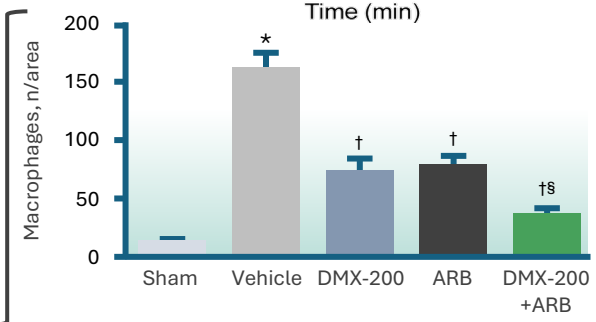
DMX-200: unique pharmacology

in-vitro

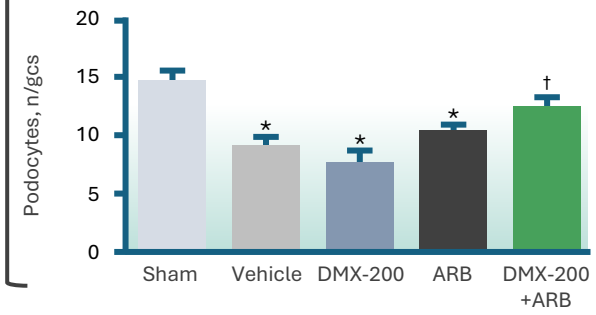


Complex of CCR2 and AT1R increases aberrant signaling when both receptors activated[1]

in-vivo

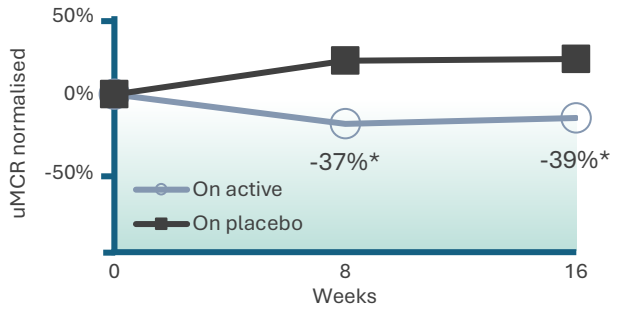


Simultaneous inhibition of CCR2 and AT1R reduces recruitment of monocytes to the kidney[1]



Simultaneous inhibition of CCR2 and AT1R preserves the number of essential filter cells (podocytes) in the kidney[1]

in-human



Unlike other CCR2 antagonists investigated to date, treatment with DMX-200 reduces the urine concentration of the pro-inflammatory ligand of CCR2 called MCP-1[2]

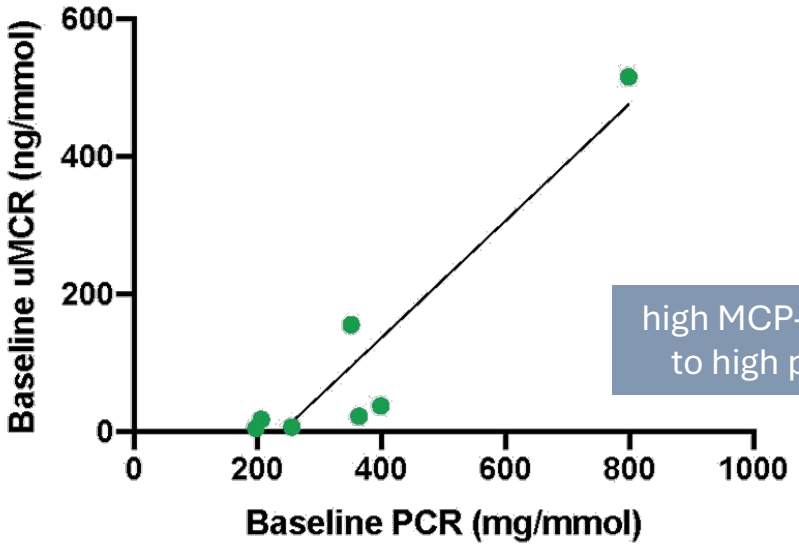
- CCR2 activation promotes recruitment of inflammatory monocytes to the kidney
  - DMX-200 **inhibits** CCR2[1]
- Monocytes promote sclerosis and fibrosis of the kidney
  - DMX-200 **reduces** inflammatory cells[1,2,3]
- Podocytes are the essential filter cells of the kidney
  - DMX-200 **preserves** podocytes[1]

Dimerix

*uMCR = Urinary MCP-1 creatine ratio; PCR = protein creatinine ratio; *placebo adjusted difference; 1. Ayoub MA, et al. (2015) PLoS One; doi.org/10:e0119803; 2. ASX presentation 27 October 2020; 3. Liu Y. et al (2024) Role of MCP-1 as an inflammatory biomarker in nephropathy, Front. Immunol., Sec. Inflammation doi.org/10.3389/fimmu.2023.13030762.4. De Vriese, AS, et al. (2021) Nat Rev Nephrol (2021). https://doi.org/10.1038/s41581-021-00427-1; 2.*

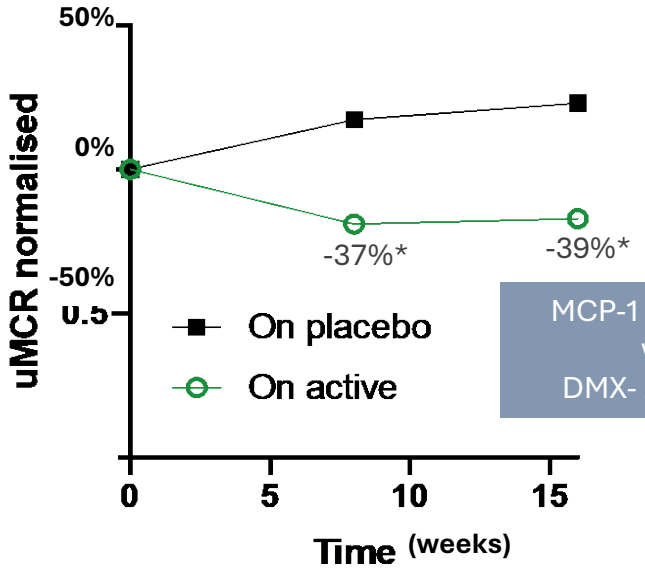
DMX-200 Phase 2 effect on inflammatory biomarker[1]

Average baseline MCP-1 versus average baseline proteinuria



high MCP-1 correlates to high proteinuria

Change in MCP-1 over time on DMX-200 versus placebo



MCP-1 levels reduced when on DMX- 200 treatment

- **16 weeks treatment with DMX-200 vs placebo reduced inflammatory biomarker by 39%:**
  - DMX-200 blocks receptor responsible for inflammation
  - Translates to reduced inflammation and subsequent fibrosis (scarring) in the kidney[2]

Dimerix

*uMCR = Urinary MCP-1 creatine ratio; PCR = protein creatinine ratio; *placebo adjusted difference*

1. ASX presentation 27 October 2020; 2. Liu Y. et al (2024) Role of MCP-1 as an inflammatory biomarker in nephropathy, Front. Immunol., Sec. Inflammation doi.org/10.3389/fimmu.2023.1303076