



Dimerix

Licensing Webinar - Japan

January 2025

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



Forward looking statements

This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Dimerix to be materially different from the statements in this presentation.

Actual results could differ materially depending on factors such as the availability of resources, the results of clinical studies, the timing and effects of regulatory actions, the strength of competition, the outcome of legal proceedings and the effectiveness of patent protection.

Overview | Phase 3 Global Opportunity

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 damage¹
- FSGS kidney damage can lead to dialysis, kidney transplants or death¹
- There are currently **no approved treatments** available to treat FSGS



Commercial and Technical Validation

- **Three commercial licensing deals** achieved:
 - ~\$458m in total upfront & potential milestone payments + royalties²
- **Successful Phase 3 interim analysis:** Analysis showed DMX-200 had performed better than placebo in reducing proteinuria³



Focal Segmental Glomerulosclerosis (FSGS)

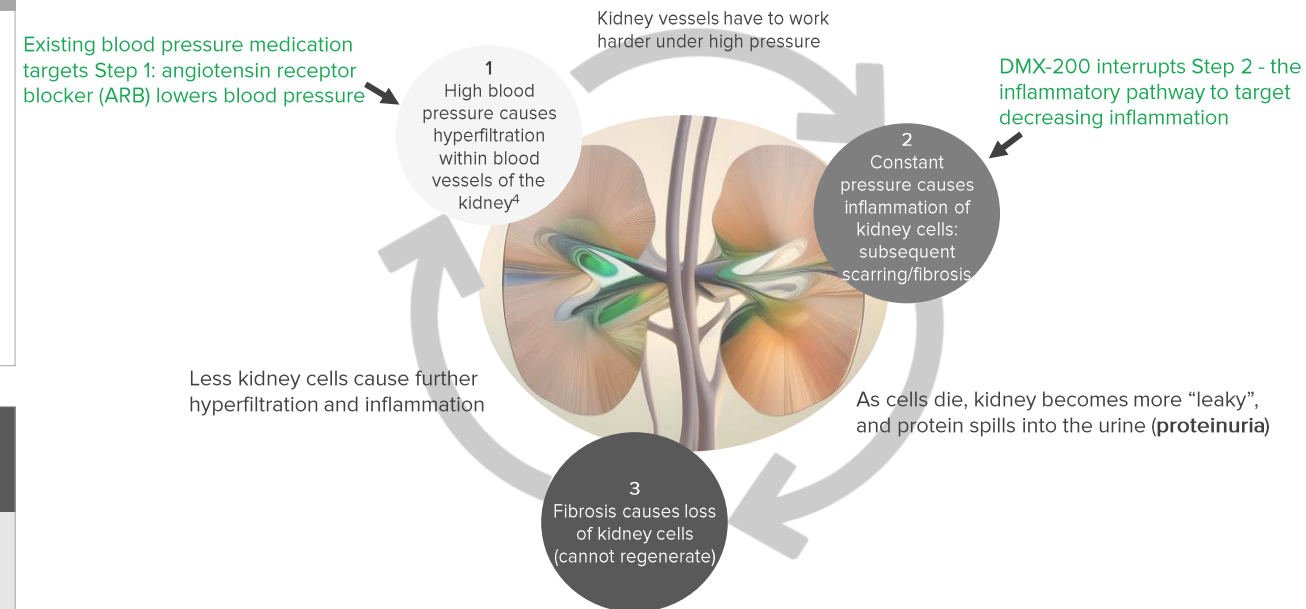
What is FSGS?

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

How do you measure kidney function?

- Historically, measured using “hard” endpoints for kidney disease (kidney failure) -which may not be reached for decades¹
- Regulatory agencies and national bodies now consider estimated glomerular filtration rate (eGFR) and proteinuria decline as surrogate end points for kidney failure in certain conditions²

FSGS Kidney Damage³



Approximately 1,400 patients received treatment specifically for FSGS in Japan in 2023⁵



FUSO Pharmaceutical Industries, Ltd.

Fuso brings a wealth of experience in pharmaceutical development, sales and marketing across Japan

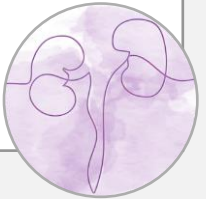
Specialty pharmaceutical company in the field of dialysis and renal/urology



Developed Japan's first dialysis fluid, strong contribution to development of dialysis treatment



As a pioneer in dialysis products, Fuso plans to continue to improve patients' lives by developing patient-friendly renal products



“Supporting Life, Nurturing Life”

Dimerix/ **FUSO**: strategic partners in kidney disease

“We, FUSO, are greatly honoured to be involved in the development of a new drug for FSGS, as there are currently no approved drugs for the treatment of FSGS. It is a truly valuable opportunity for us to partner with Dimerix, and we will work together with Dimerix to do our best to quickly deliver safe and effective new drugs to patients suffering from FSGS.”

Mikio Toda, President and Representative Director, FUSO Pharmaceutical Industries, Ltd.

“We are delighted to partner with FUSO for the commercialisation of DMX-200 in Japan. This partnership reflects a confidence not only in the significant potential for DMX-200 in FSGS patients but also in Dimerix’ capabilities in the development of DMX-200. FUSO’s expertise and resources will be invaluable in supporting Dimerix to advance our shared goal of developing and commercialising DMX-200 and bringing hope to those patients desperately in need of treatment options.”

Dr Nina Webster, CEO & Managing Director, Dimerix

Key elements of **FUSO** partnership

FUSO acquires exclusive license to commercialise DMX-200 for FSGS in Japan

Dimerix to receive up to ¥10.5 billion (~AU\$107 million*) million in upfront and milestone payments, plus royalties

- ¥300 million (~AU\$3.1 million*) within 40 days of signing
- ¥400 million (~AU\$4.1 million*) first development milestone due on first clinical site initiation in Japan, anticipated Q1 2025
- up to ¥3 billion (~AU\$30.6 million*) in further potential development milestones
- up to ¥6.8 billion (~AU\$69.4 million*) in potential sales milestones
- 15-20% royalties on net sales

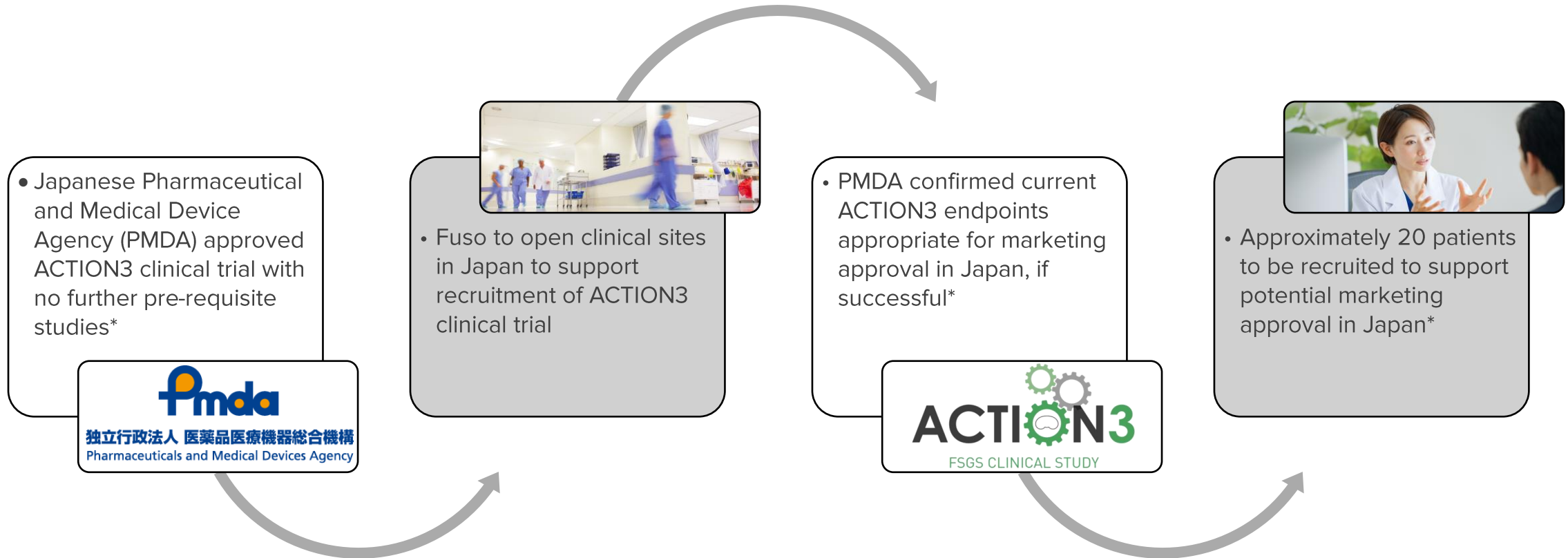
FUSO will be responsible for all costs in Japan, including site identification, contracting and initiation; patient recruitment; site management; investigator costs; any further non-clinical studies (if required)

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

FUSO will be responsible for submission and maintenance of the regulatory dossier in the licensed territories, as well as all sales and costs of marketing activities

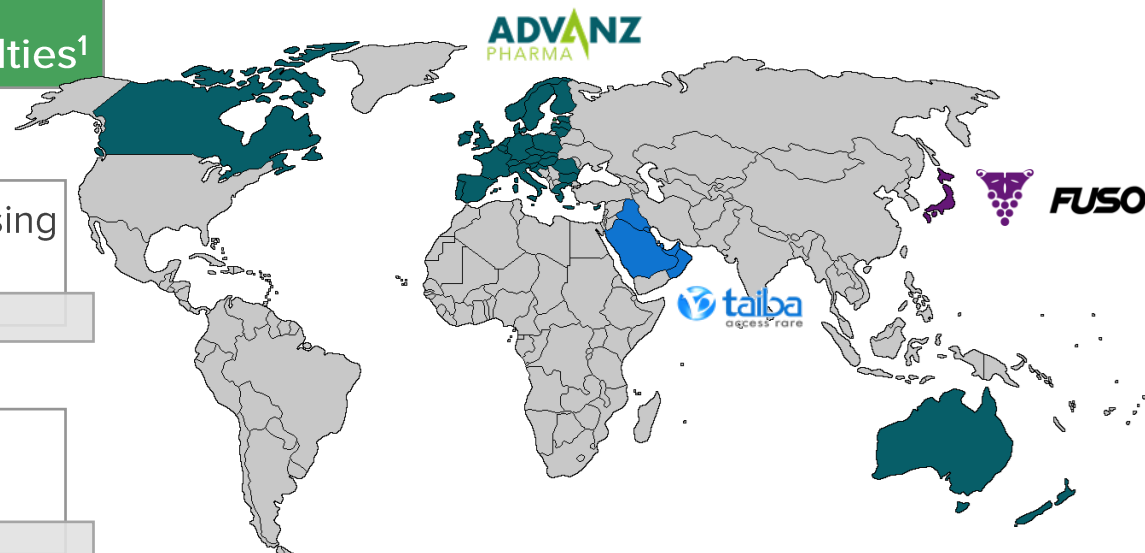
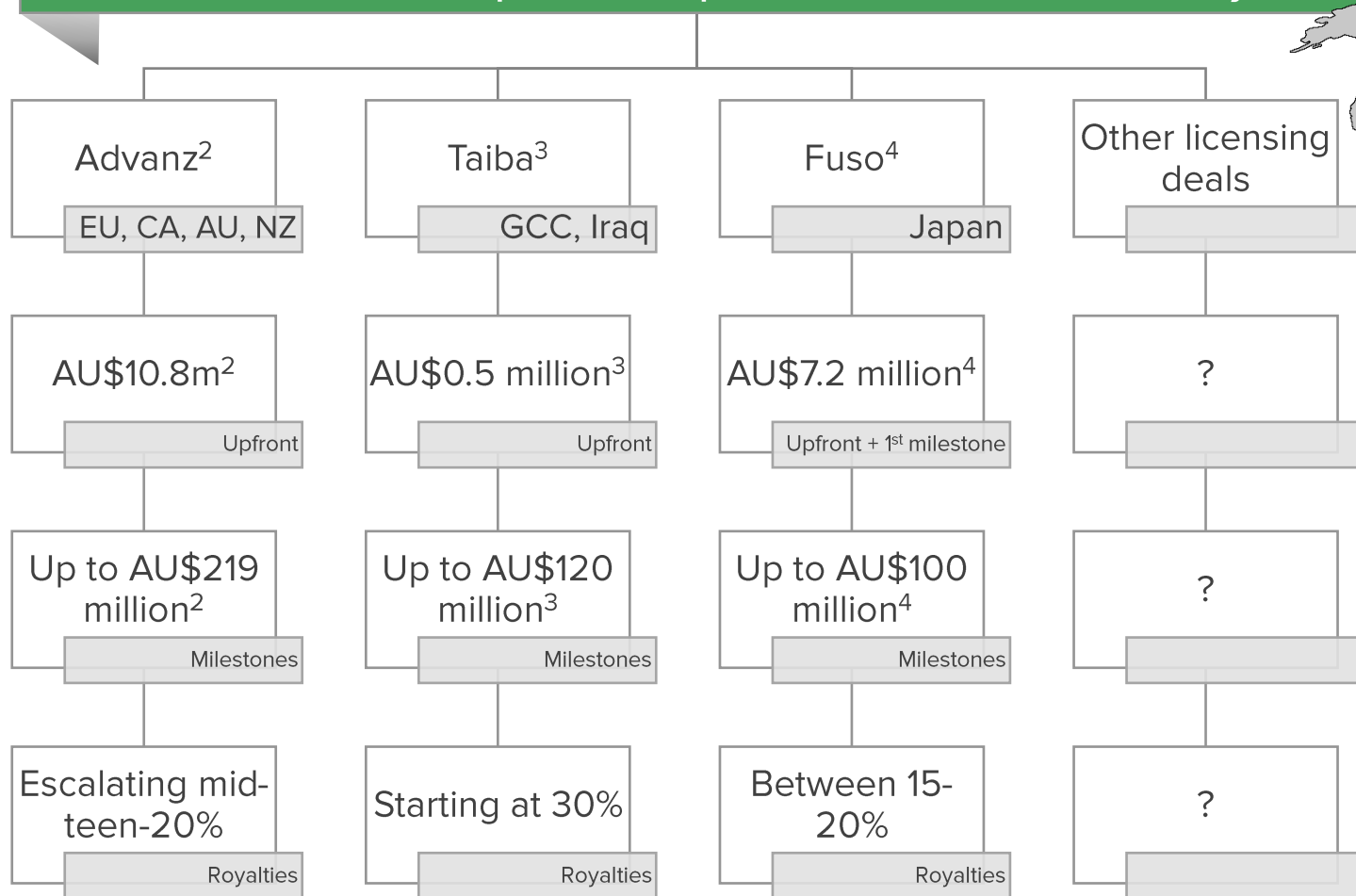
Dimerix retains all rights to DMX-200 in all other unlicensed territories

PMDA regulatory approval received for DMX-200



Summary of licensing deals

Licensing deals collectively valued up to AU\$458 million in total upfront and potential milestone fees + royalties¹



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

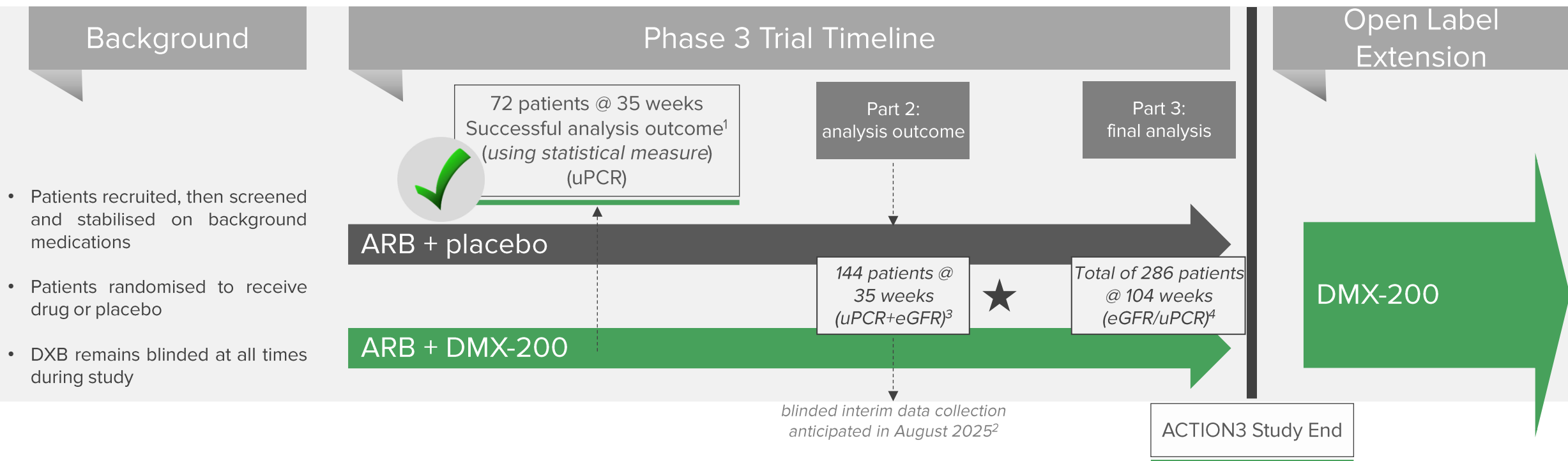
PHASE 3 CLINICAL TRIAL





Phase 3 clinical trial – next steps

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

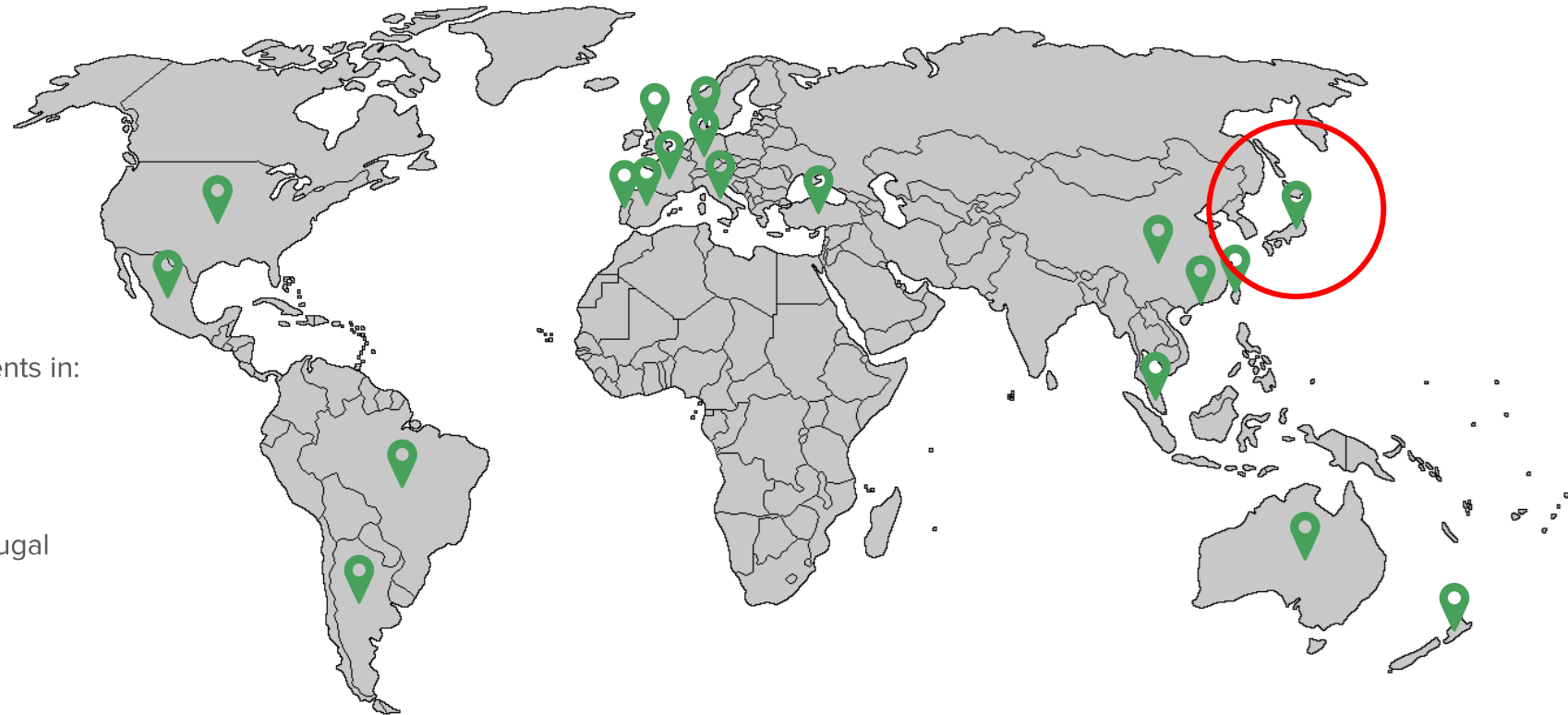


- 144 patients recruited, randomised and dosed in December 2024²
- Recruit, randomise and dose total of 286 patients - anticipated in Q3 2025²

★ Potential to submit for conditional marketing approval³

Current and planned clinical sites

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



Recruitment planned at 170+ sites to recruit 286 patients in:

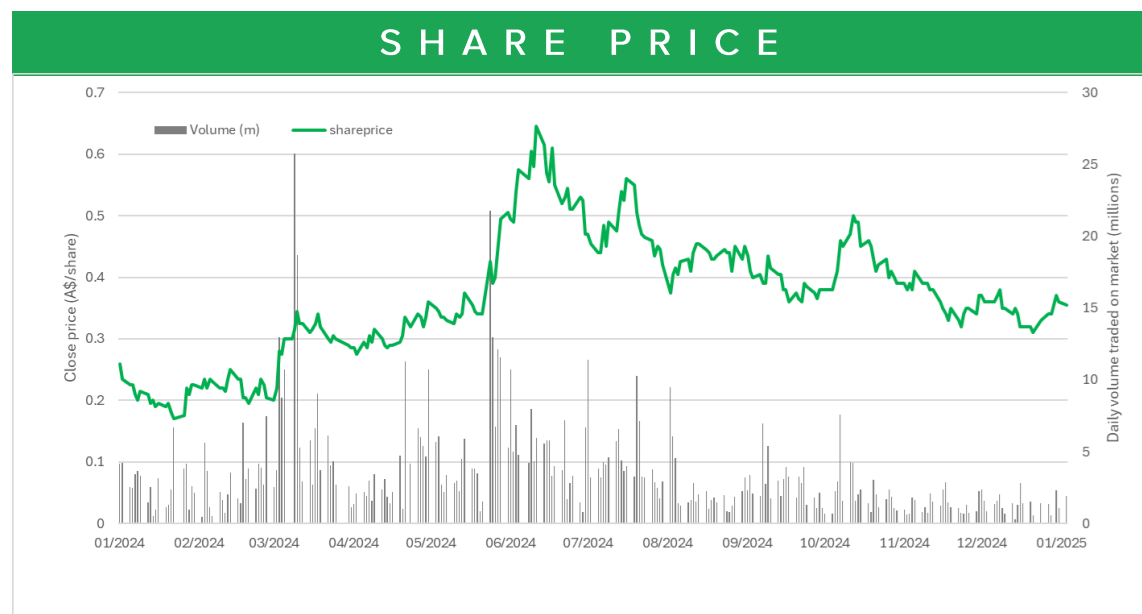
- Australia, New Zealand
- Taiwan, Hong Kong, Malaysia, Thailand
- Mainland China
- Japan
- France, Denmark, UK, Spain, Italy, Germany, Portugal
- Türkiye
- USA, Mexico
- Argentina, Brazil

Corporate overview

Ticker Symbol	ASX: DXB
Cash Balance (Sep24)*	\$19.2 million
Market Capitalisation ²	~A\$201 million
Share price ¹	~A\$0.36
Total ordinary shares on issue ²	557,866,917
Average Daily Liquidity by value for past 30 trading days ²	~A\$671,000

*Cash balance does not include:

- \$7.9 million - FY24 R&D tax incentive rebate received 15 November 2024
- ~\$3.1 million - upfront fee from Fuso development & licensing agreement, payable within 40 days of agreement execution
- ~\$4.1 million - payment on 1st clinical site opening in Japan from Fuso licensing agreement - anticipated first quarter 2025
- ~\$6.5 million - Anticipated conversion of 42,446,923 DXB options exercisable at 15.4c per share (expire 30 June 2025)



SUBSTANTIAL SHAREHOLDERS ³			
Position	Holder Name	Holding	% IC
1	Mr P Meurs	75,304,506	13.6%
TOTAL (TOP 5) Shareholders		128,860,138	22.8%

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A biopharmaceutical company developing innovative new therapies in areas with unmet medical needs, with a core focus on inflammatory kidney 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.

Dimerix HQ

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Victoria, Australia

T. 1300 813 321

E. investor@dimerix.com

Dimerix board



Mark Diamond
BSc, MBA
Non-Executive Chairman

Previous experience:



- 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:



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



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

Previous experience:



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

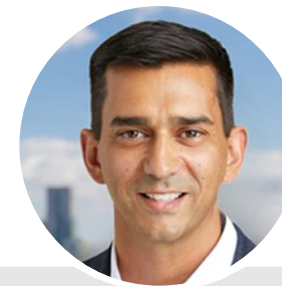


Sonia Poli
PhD
Non-Executive Director

Previous experience:



- 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:



- ~20 years experience as a leader with a focus in management, project delivery, risk management, & assurance
- Provides advisory services to a family office with multiple Australian biotech investments
 - ✓ BEng (Hons) – Chemical Engineering
 - ✓ BCom – Commerce

Dimerix management



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

Previous experience:



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



Hamish George
Bcom, CA, GIA (Cert)
CFO & Company Secretary

Previous experience:



- Experienced CFO & Co.Sec
- Expertise in Corporate Governance, financial reporting, cash flow management, taxation (including R&D Tax Incentive) & budgeting/forecasting
 - ✓ Bcomm – Commerce
 - ✓ G.Dip. - Financial Planning
 - ✓ M.Acc. – Accounting
 - ✓ GIA(Cert)
 - ✓ Chartered Accountant



David Fuller
B. Pharm (Hons), MBBS
CMO

Previous experience:



- 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,
CCO

Previous experience:



- 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



Bronwyn Pollock
BSc (Hons), MBA
VP, Product Development

Previous experience:



- Experienced pharmaceutical executive in Manufacturing (CMC)
- Successfully developed and submitted multiple dossiers to FDA, EMA, TGA
- Background in project management, technical transfer and product launch
 - ✓ BSc (Hons) – Applied Biology
 - ✓ MBA - Business

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

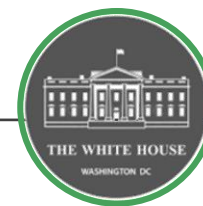
“A squeaky wheel waiting for grease: 50 years of kidney disease management in the US”¹



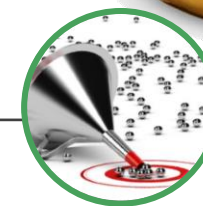
Historical lack of incentives and public policy have contributed to high costs and poor health outcomes for renal patients¹



2018: workshops and regulatory acceptance of surrogate end points in trials of kidney diseases²



2019 changes in US federal policy and rapid adoption of treatment guidelines have contributed to a sea change in the management of renal disease³

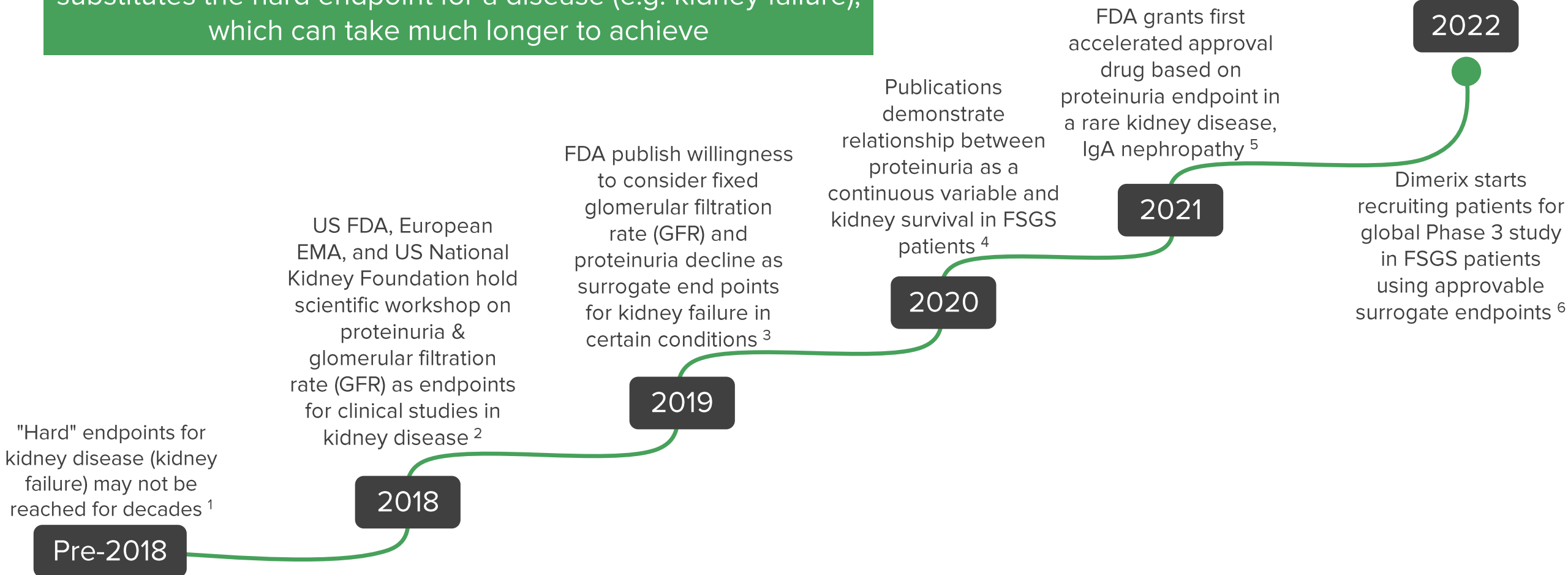


Public health policy, legislation and product innovation have converged to accelerate change in renal space today

“More change in the past 24 months than the past 24 years: The rapid evolution of [kidney disease] management”¹

Clinical study change: use of surrogate endpoints

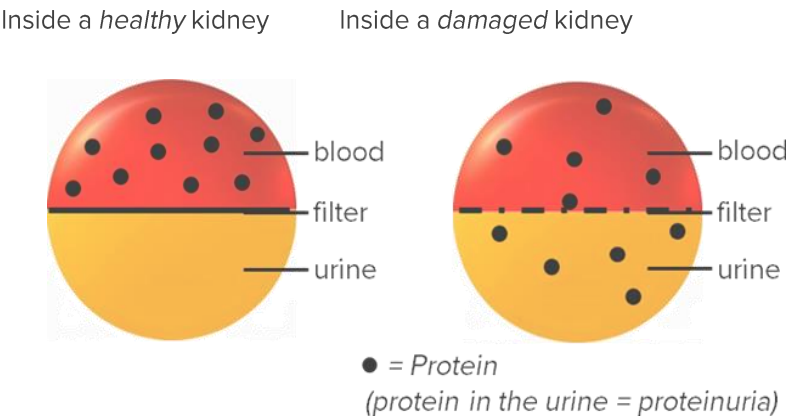
A surrogate endpoint is an intermediate outcome which substitutes the hard endpoint for a disease (e.g. kidney failure), which can take much longer to achieve



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 urine¹



- When kidneys are damaged, protein can leak into the urine causing proteinuria
- Proteinuria represents an important early marker of kidney function²

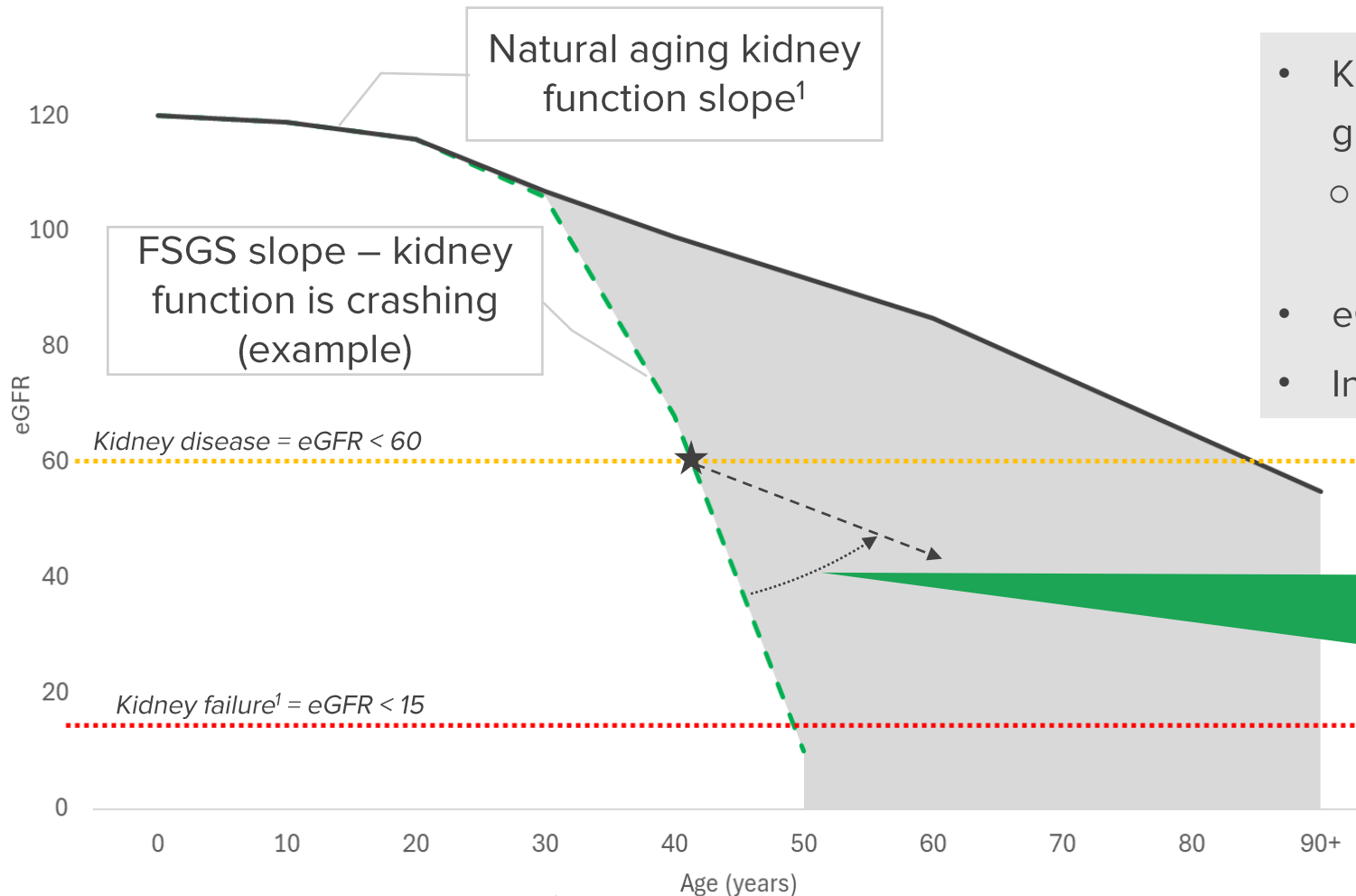
Symptoms of proteinuria

	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

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 age¹
- 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

PARASOL: proteinuria as an endpoint for full FDA approval

① Ongoing progress: PARASOL



➤ PARASOL was formed in Dec-23 to address the need to **validate alternative surrogate endpoints** for FSGS, and is a coalition of nonprofit organizations, academia, registries, trials and Sponsors to share data to support analysis⁽¹⁾

- PARASOL confirmed that eGFR slope is a valid endpoint for predicting progression of kidney disease, and ACTION3 is powered based on expected trial variance
- It is recognised FSGS patients see higher proteinuria, even in remission, due to residual scarring of the glomeruli
- PARASOL data demonstrated the strong relationship between a reduction in proteinuria and a reduction in the progression of kidney disease in FSGS patients
- Subject to FDA confirmation, a reduction in proteinuria may also become a validated endpoint for full FDA approval for FSGS

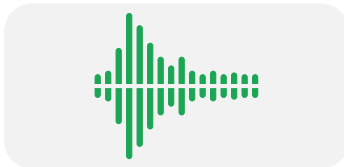
② Biological Plausibility



➤ The FDA has emphasised the need for programs wishing to use proteinuria endpoints to be able to justify the biological plausibility (scientific rationale of why or how the drug candidate is having the desired effect) of the drug on the endpoint chosen

- Dimerix has existing preclinical evidence on the preservation effect of DMX-200 on the specialist cells on the kidney – the podocytes
- Next steps: agree with FDA appropriate proteinuria endpoints, and potential for accelerated approval, for DMX-200 in the ACTION3 Phase 3 clinical trial
- PARASOL has increased the range of potential endpoints that may best show the treatment effect of DMX-200

③ ACTION3 capturing all proposed endpoint data: eGFR and proteinuria



Proteinuria

- Randomised, double blind PCR values over 24 months
- PCR captured across 4-week washout
- PCR measured over additional 24 month open-label period



eGFR slope

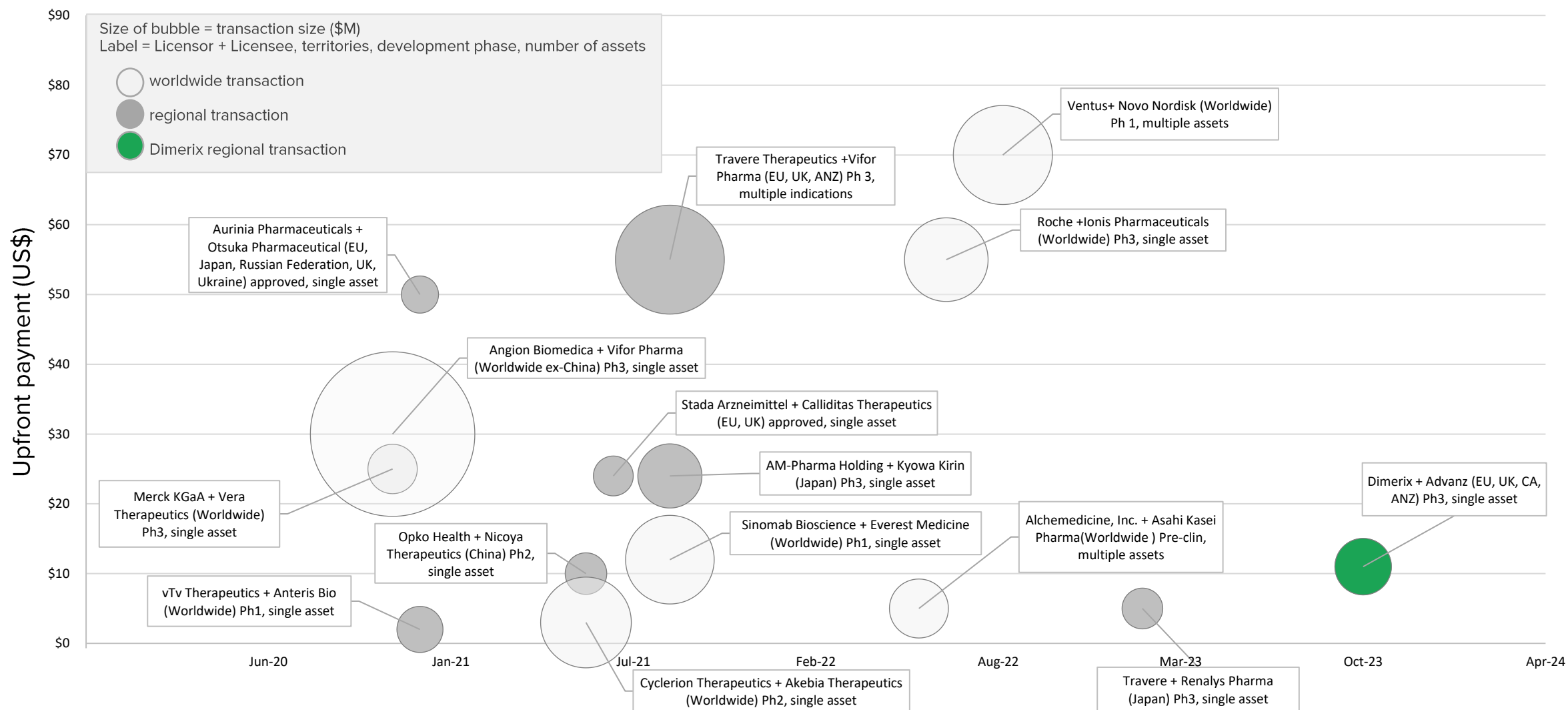
- Randomised, double blind eGFR values captured over 24 months, including raw values and total eGFR slope



Other endpoints

- Classical definitions of complete and partial remission
- PARASOL-informed response endpoints
- Hard-renal endpoints (where available)

Renal licensing deals details



Policy change: renal disease healthcare economic burden

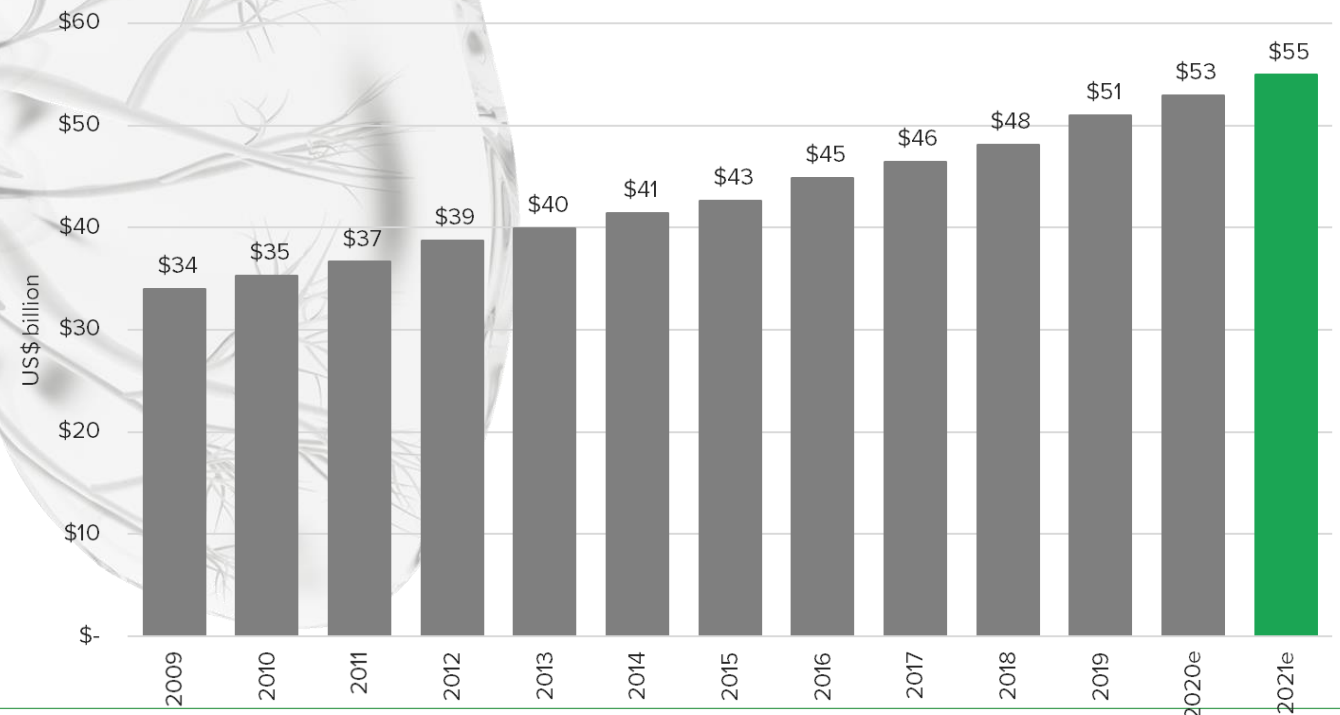
~40 million
adults have kidney
disease (~15% of the
adult population) in the
US in 2021¹

US\$88 billion
estimated total US
Medicare expenses
costs/year for renal
patients in 2021^{1,3}

2019
White House executive
order issued: incentives
for providers to delay
patient progression to
renal failure²

Economic cost of kidney failure in the US

Total Medicare expenses per year costs for kidney failure patients (2009-2021E)³



FSGS market

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

>2,600

New diagnosed cases per year in US²

47%

Of all diagnosed FSGS cases globally are in US³

0

Drugs specifically approved anywhere in the world



Multi-billion dollar market potential



Strong licensing potential upside



Attractive reimbursement/pricing potential



- Example pricing for other rare kidney disease drugs :
- in the US (i.e. Filspari in IgAN)⁴ is **US\$9,900 p/month**
 - in Europe/UK (i.e. Kinpeygo/Tarpeyo)⁵ is **US\$8,267 p/month (€7,630)**

DMX-200 – working on inflammatory signalling pathway

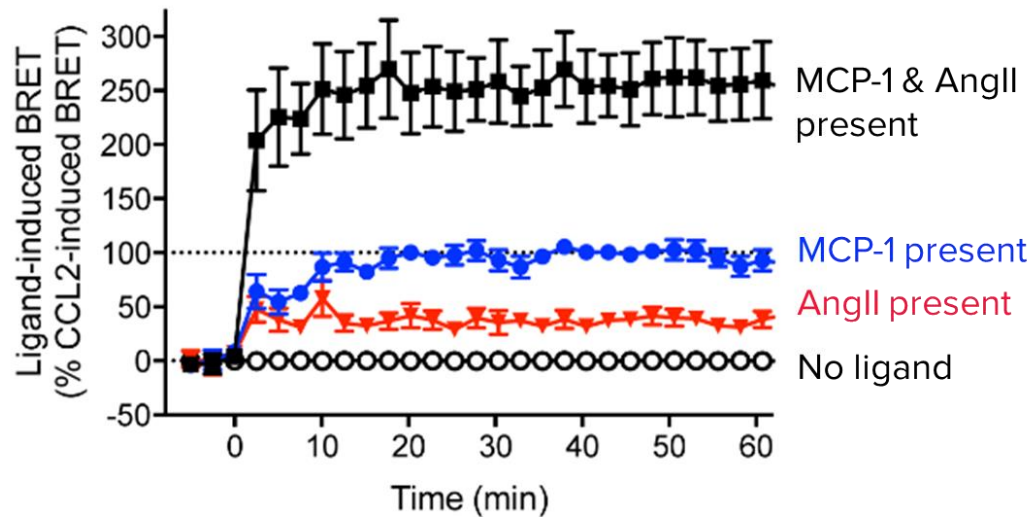
A CCR2 inhibitor working synergistically alongside the current standard of care (AT1R blocker): G protein-coupled receptor (GPCR)



DMX-200 unique heteromer pharmacology

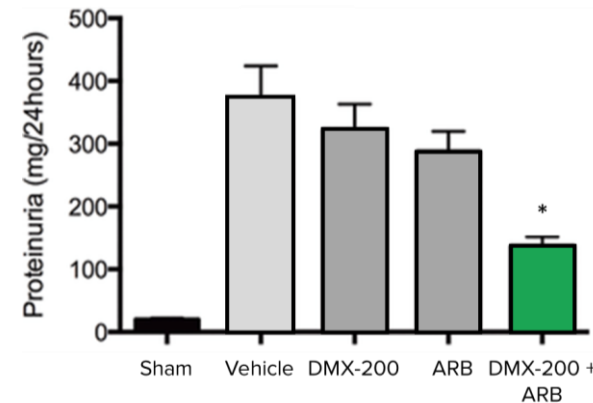
Proprietary discovery platform (Receptor-HIT) identified:

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

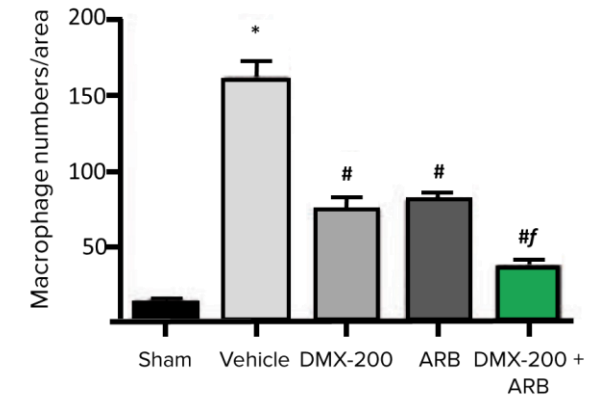


Proposed non-clinical safety package suitability for NDA confirmed with FDA¹

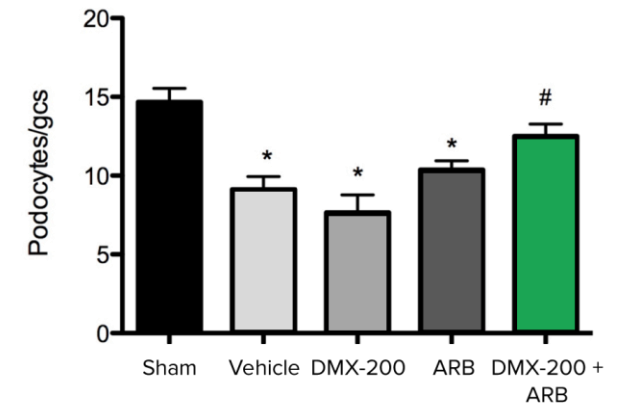
↓ Proteinuria



↓ Macrophage infiltration



Retained podocyte numbers



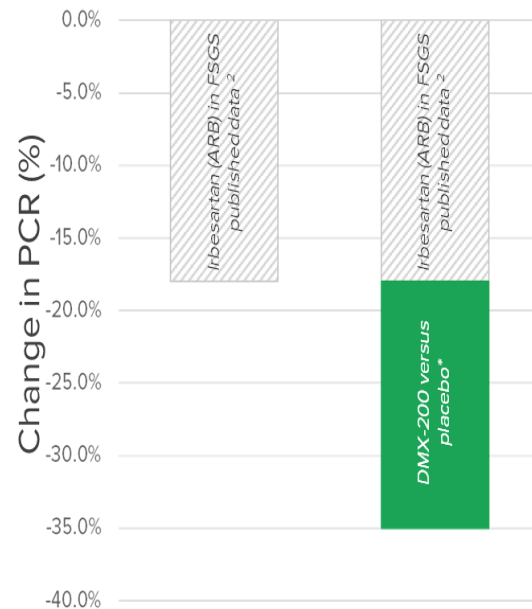
DMX-200: Phase 2 met primary and secondary endpoints



Clinically meaningful outcomes achieved for patients,³ with no safety issues

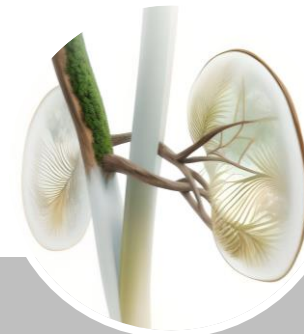


Average reduction of **17%** in proteinuria after 16 weeks treatment on DMX-200 versus placebo¹



“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 2020³



EFFICACY

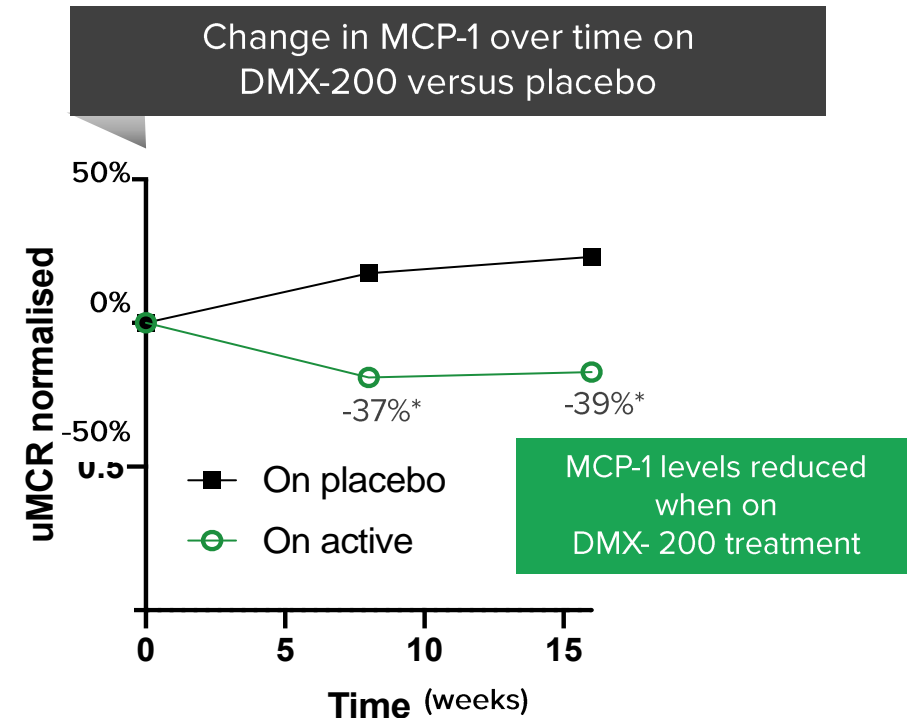
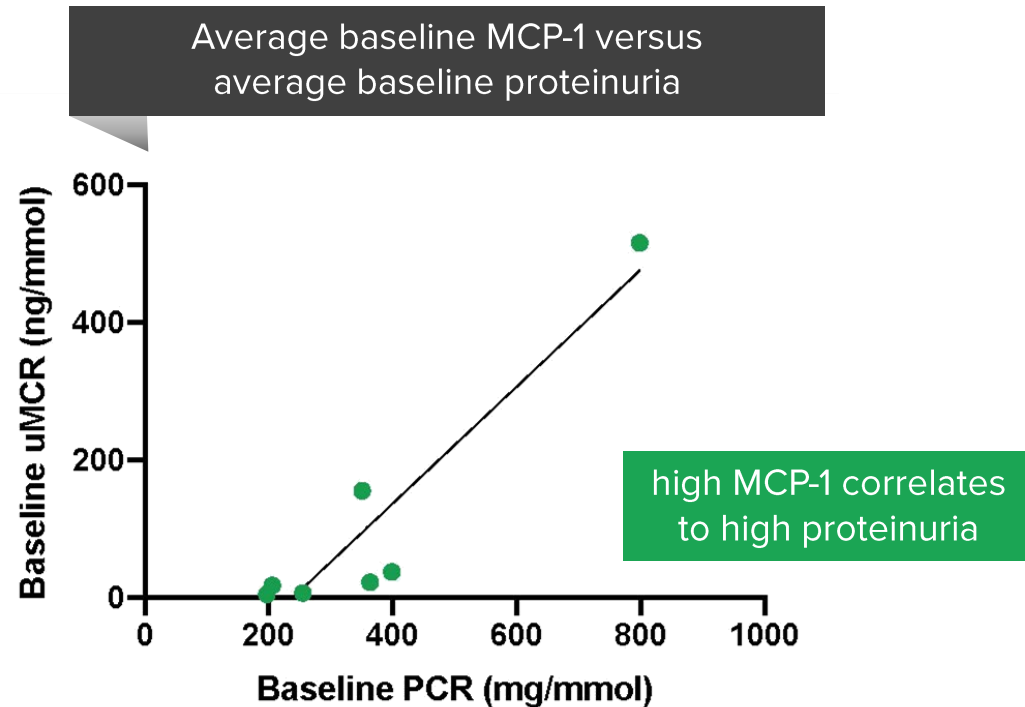
- **86%** of patients demonstrated reduced proteinuria
- DMX-200 reduced inflammatory biomarker by **39%** vs placebo



SAFETY

- No safety concerns – reduced development risk

DMX-200 Phase 2 effect on inflammatory biomarker



- 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 kidney¹

Intellectual property and exclusivity

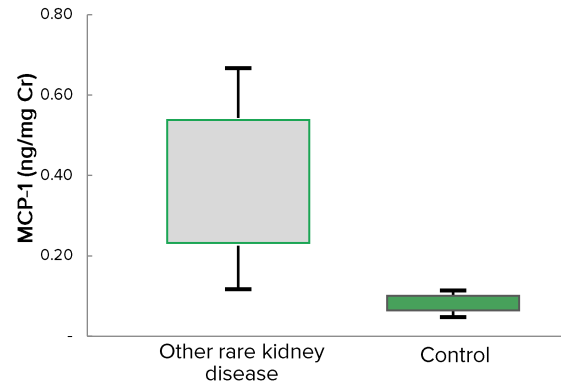


Advancing the broader pipeline

Additional longer term pipeline opportunities diversify risk and potential sources of revenue

DMX-200 potential label expansion

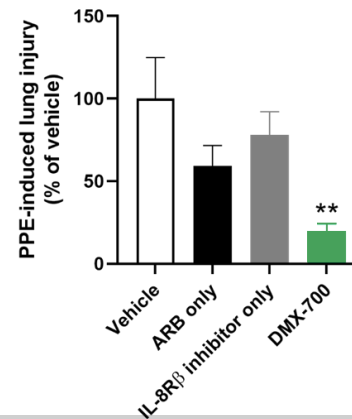
Potential to expand DMX-200 into other rare kidney diseases where inflammation is a key driver of the disease



Phase 2/3 potential

DMX-700 for respiratory/renal fibrosis

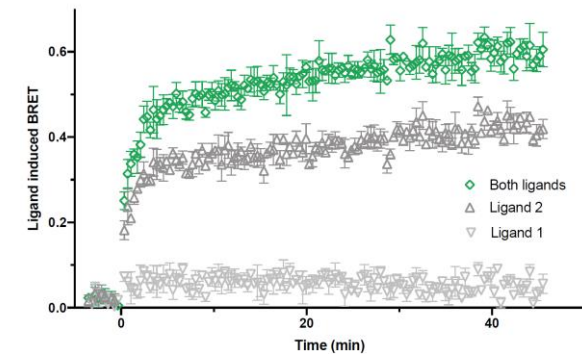
Preclinical studies show that DMX-700 significantly reduced lung injury by 80% ($p < 0.01$) after 21 days treatment¹



Pre-clinical asset

Undisclosed Opportunities

Commercially attractive pipeline of G Protein-Coupled Receptors (GPCR) targets of inflammatory diseases with an unmet need



Pre-clinical identified opportunities