



# Dimerix

(ASX:DXB)

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

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March 2024

## Investor Presentation



**ACTION3**  
FSGS CLINICAL STUDY

# 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)

## Lead Indication

- FSGS is a disease that causes scar tissue of kidneys, which leads to irreversible kidney damage<sup>1</sup>
- FSGS kidney damage can lead to dialysis, kidney transplants or death<sup>1</sup>

## Market Opportunity

- Estimated ~>200,000 people with FSGS in the 7 major markets (makes **FSGS a rare disease**)<sup>2</sup>
- Estimated 40,000<sup>1</sup> – 80,000<sup>2</sup> people in the US alone
- Drugs for rare kidney diseases can be priced at **~US\$120,000 per annum** in the US<sup>3</sup>
- There are currently **no approved treatments** available to treat FSGS

## Commercial Validation

- **Licensing deal already achieved** in October 2023 for EEA, UK, SUI, CA, AU and NZ<sup>4</sup>
- AUD\$10.8m received upfront, ~\$220m in potential milestone payments & mid-teen-20% tiered royalties

## Upcoming Milestones

- **Interim analysis expected imminently** from Company's Phase 3 clinical trial<sup>5</sup>
- **Execution of potential licensing deals** for available jurisdictions including the US & China<sup>6</sup>
- Announcements which relate to DXB's secondary assets

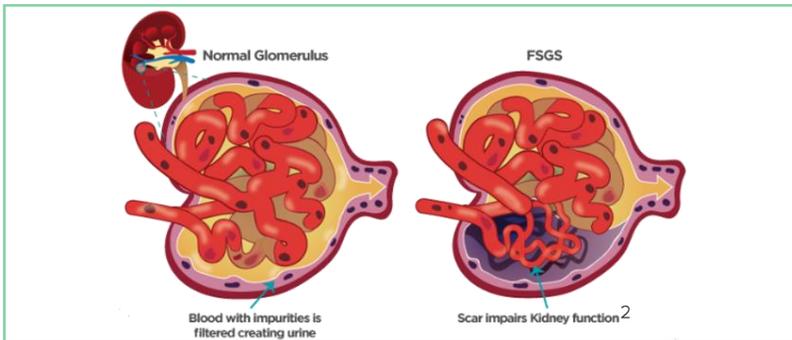
# Focal Segmental Glomerulosclerosis (FSGS)

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

## What is FSGS?

FSGS is a rare kidney disease that attacks part of the kidney filtering units, causing **inflammation** and irreversible scarring to the kidneys<sup>1</sup>

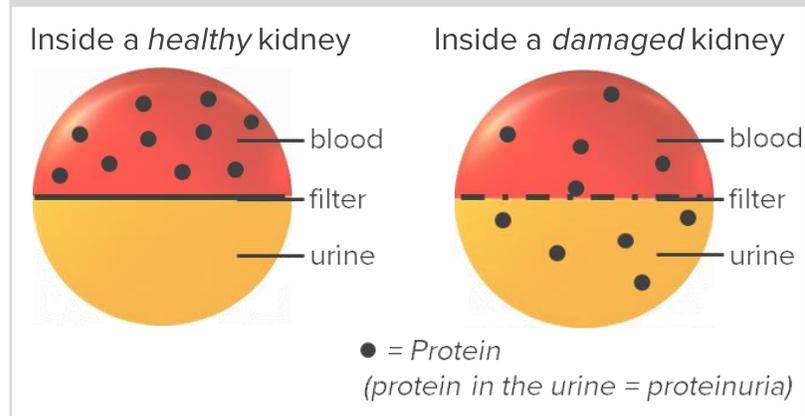
This inflammation and scarring leads to permanent kidney damage and eventually end-stage kidney failure, requiring dialysis or transplantation



## Why are kidneys important?

Kidneys are a special **filter system** for your body. Kidneys remove waste products from the blood and produce urine

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



## Why is proteinuria important?

When kidneys are damaged, protein can leak into the urine causing proteinuria, hence proteinuria can represent an important early marker of kidney function

↑ proteinuria suggests damaged kidney  
↓ little / no proteinuria suggests healthy kidney

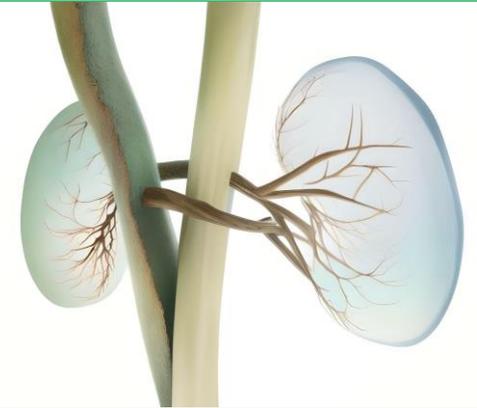
DMX-200 aims to reduce the inflammation of the kidneys: if DMX-200 reduces inflammation = the amount of proteinuria should decrease

Proteinuria: an important endpoint for DMX-200 study

# FSGS causes and prognosis

Focal segmental glomerulosclerosis (FSGS) is one of the most common forms of acquired glomerular disease leading to end stage kidney disease (ESKD), requiring dialysis or transplant

- ▶ Caused by a variety of conditions - primary FSGS, genetic FSGS, FSGS of unknown cause and secondary FSGS<sup>2</sup>
- ▶ Significant burden on global health systems
  - Patients end up on dialysis (est cost US\$90,000/patient/year)<sup>3</sup>
  - Patients requiring kidney transplant (est cost US\$442,500 per transplant + ongoing medication fees)<sup>4</sup>
  - 60% patients have reoccurring FSGS even after first kidney transplant<sup>5</sup>



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Approved drugs anywhere in the world

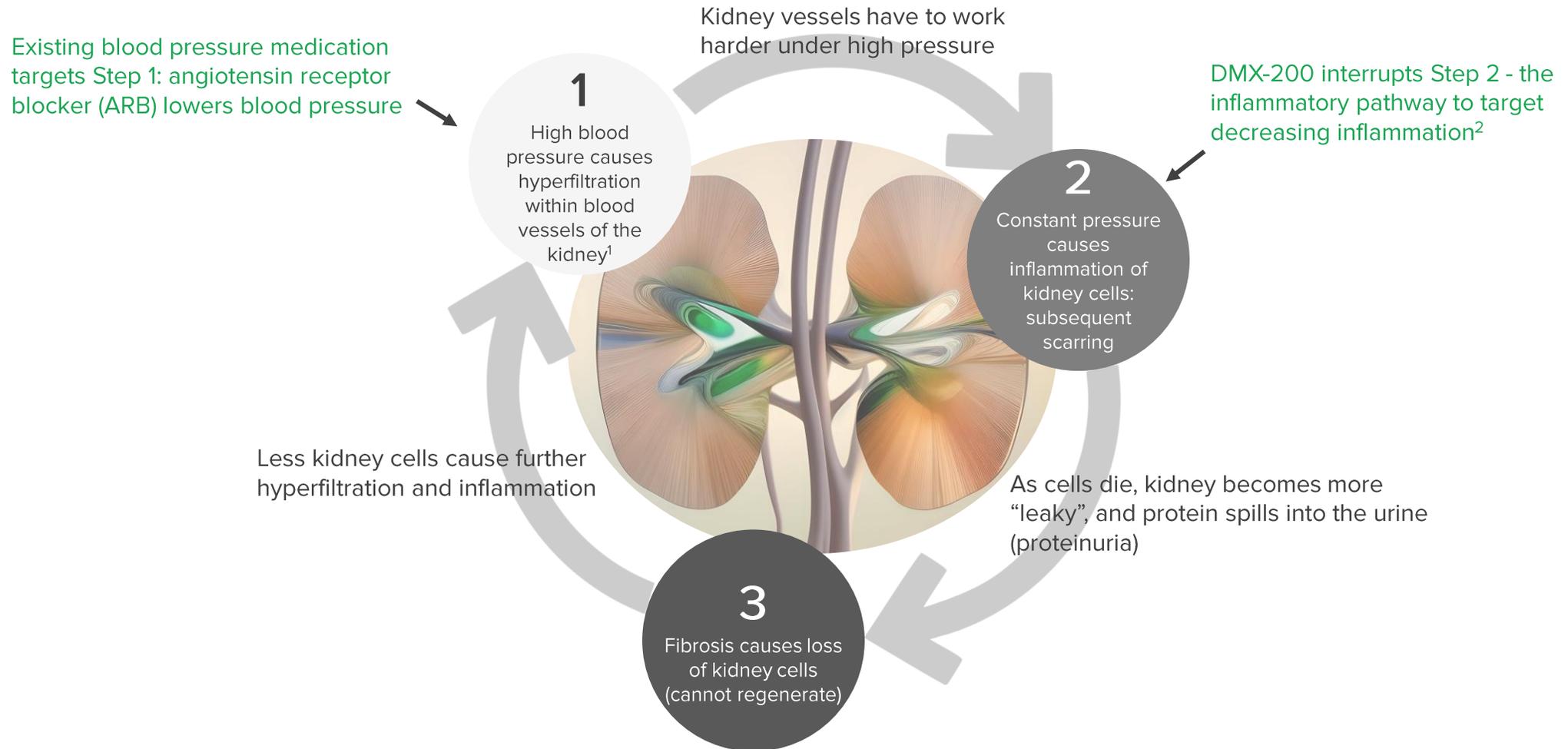
60%

Patients have reoccurring FSGS even after first kidney transplant<sup>5</sup>

5

Average time (years) to kidney failure after onset of proteinuria<sup>1</sup>

# Progression of FSGS kidney disease

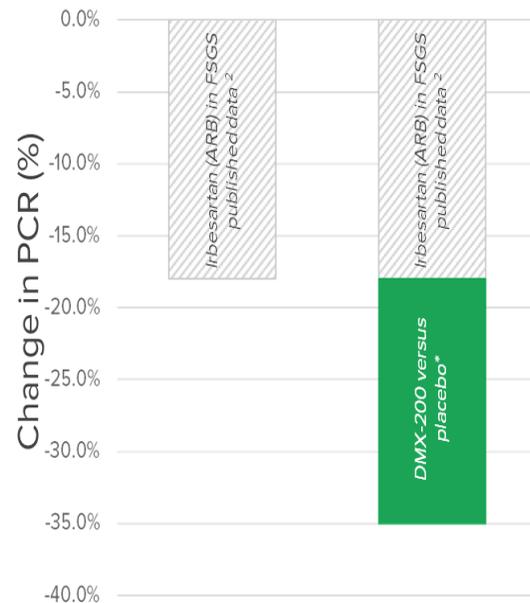


# DMX-200: Phase 2 met primary and secondary endpoints



 Clinically meaningful outcomes achieved for patients, with no safety issues

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



## EFFICACY

- 86% of patients demonstrated reduced proteinuria
- 29% of patients demonstrated >40% reduction in proteinuria



## SAFETY

- No safety concerns – reduced development risk
- DMX-200 compares favourably to compounds currently in development<sup>2,3</sup>

“Any reduction in proteinuria could yield years of preserved native kidney function and delay the onset of kidney failure and its attendant morbidity and mortality”  
*Kidney survival study – Troost et al, August 2020<sup>4</sup>*

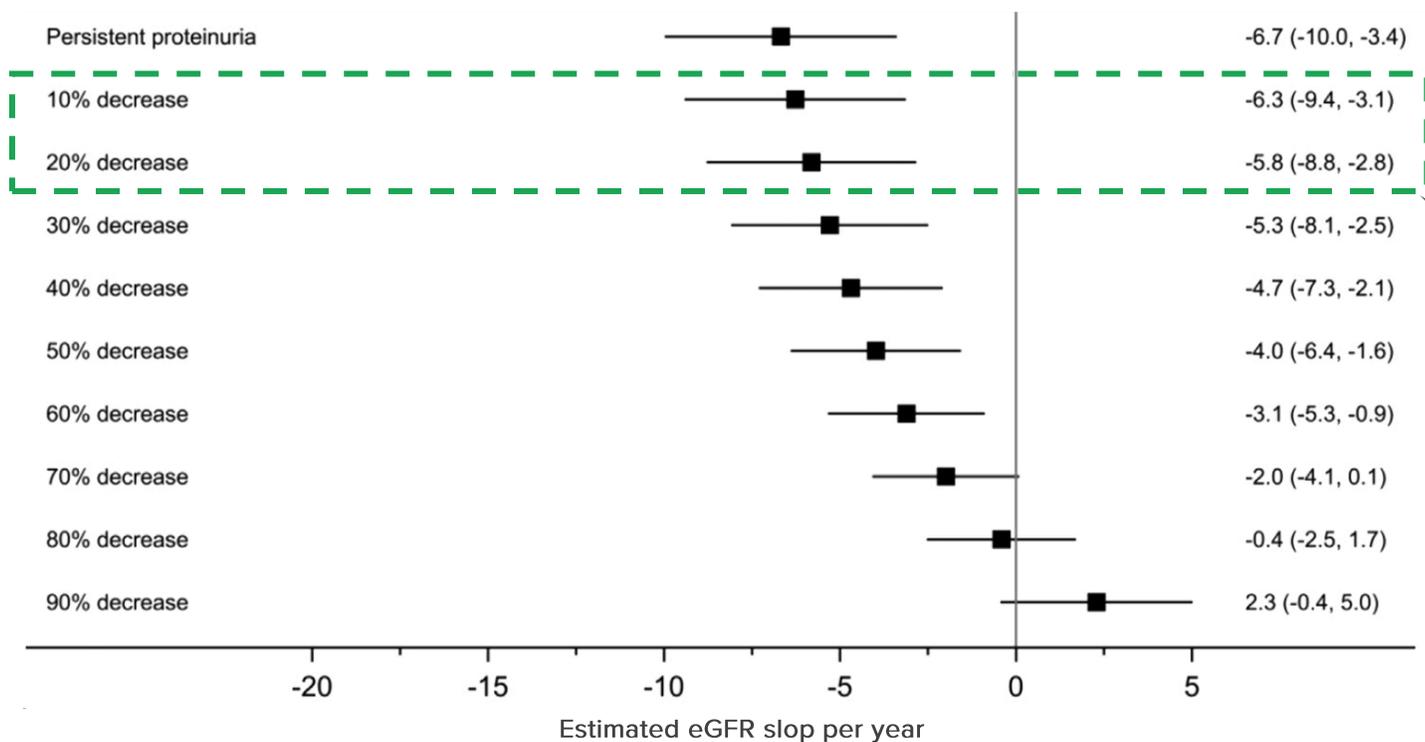
# DMX-200: Phase 2 met primary and secondary endpoints



17% average reduction of proteinuria in Phase 2 is clinically meaningful<sup>1</sup>

Adjusted models

uPCR reduction



FDA & EMA recognise surrogate markets, such as proteinuria & eGFR as registration endpoints in rare kidney disease

“reductions ~10% in proteinuria translated to clinically meaningful differences in eGFR”  
Kidney survival study – Troost et al, August 2020<sup>1</sup>

# PHASE 3 CLINICAL TRIAL

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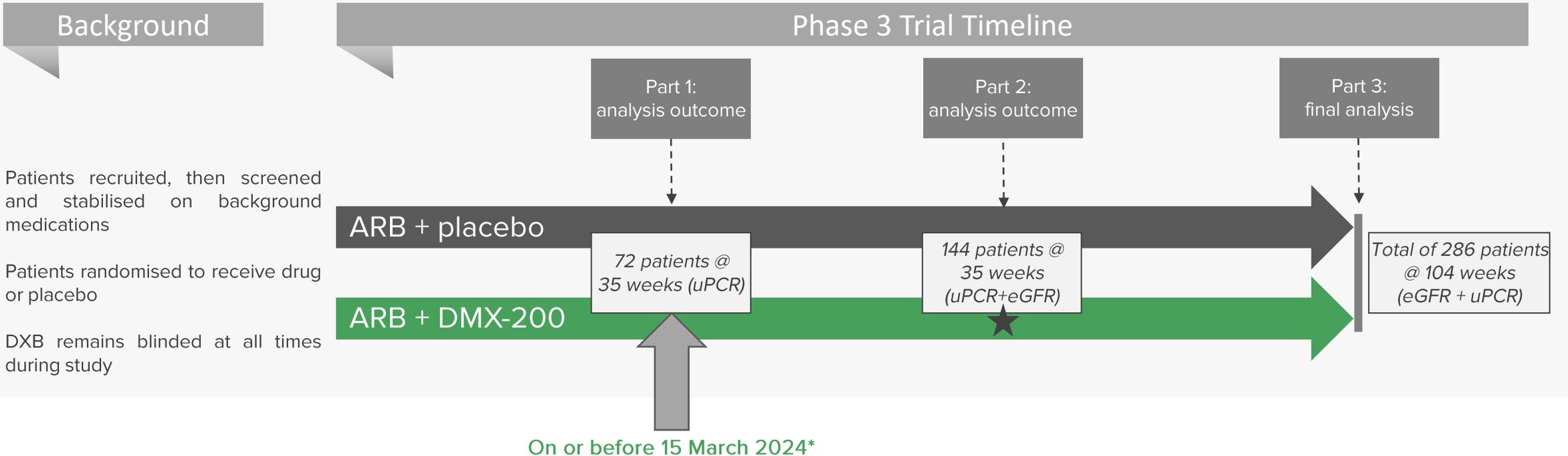


# ACTION3 Phase 3 clinical trial

FSGS CLINICAL STUDY



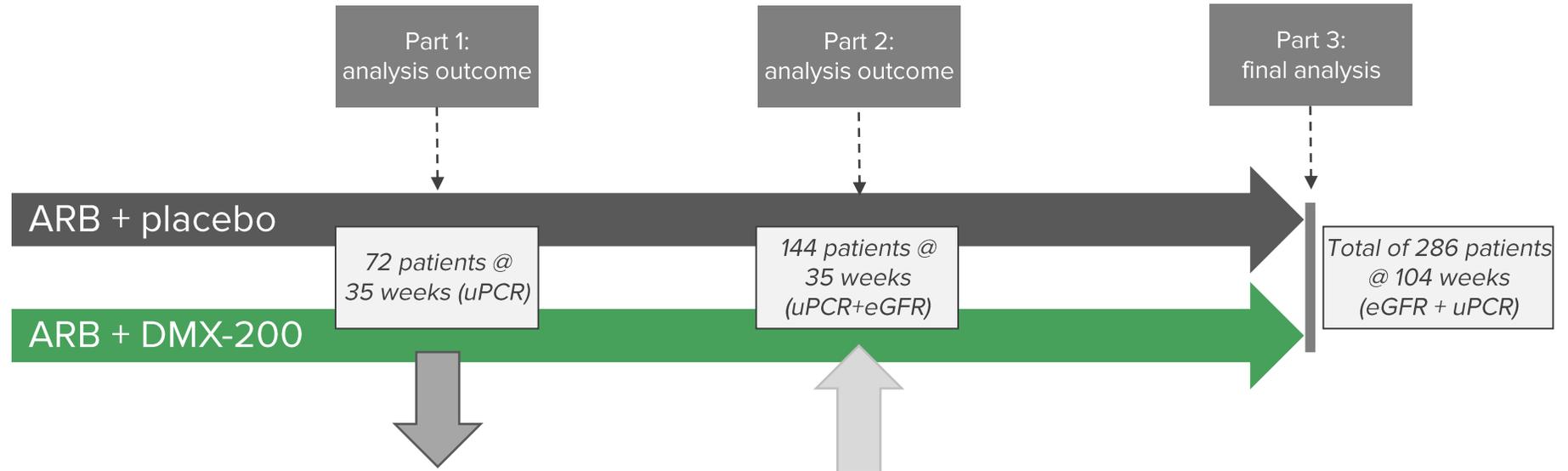
A randomised, double-blind, multi-centre, placebo-controlled study of renal outcomes of DMX-200 in patients with FSGS receiving an ARB



★ Potential to achieve conditional marketing approval\*\*

# ACTION3 Phase 3 clinical trial

FSGS CLINICAL STUDY



Data outcome expected imminently\*



If Part 1 shows DMX-200 is performing better than placebo in **proteinuria reduction** (using statistical measure)

→ Trial proceeds to Part 2

If data does not show improvement in proteinuria, review additional data and

→ Trial may halt



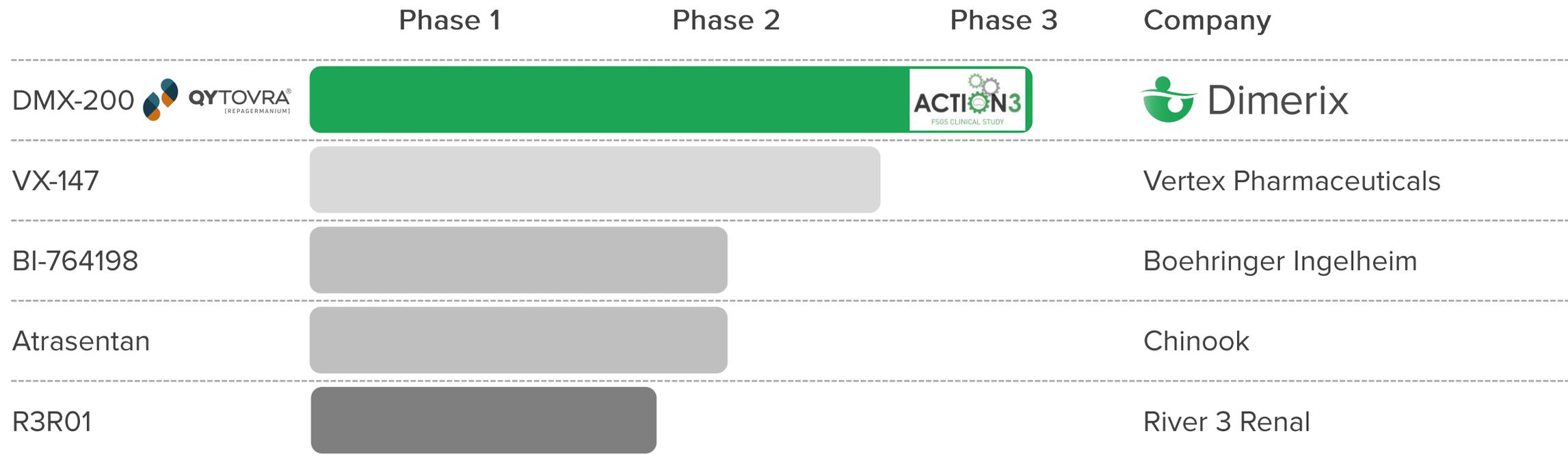
Part 1 successful outcome will demonstrate DMX-200 is performing better than placebo in a much larger population than Phase 2 study

# Competitive landscape in FSGS

No approved therapies for FSGS



DMX-200 is the only therapy in phase 3 development



# Benefits of targeting orphan diseases

DXB has been granted Orphan Drug Designation Status for DMX-200



Orphan designation used by regulators to incentivise companies to develop new drugs for rare diseases - granted to DMX-200 in US, EU and UK

## Benefits of Targeting Orphan Diseases



### Commercially attractive pricing

- ~US\$84,000p.a average orphan drug price in 2018<sup>1</sup>
- ~US\$120,000p.a average price for other rare kidney treatments<sup>2</sup> (US\$9,900 for recently approved Sparsentan in treatment of IgAN)



### Marketing exclusivity period without generic competition or challenge

- 7 years in the United States
- 10+ years in European Union



### Opportunity to extend exclusivity for another ~2 years on paediatric indication

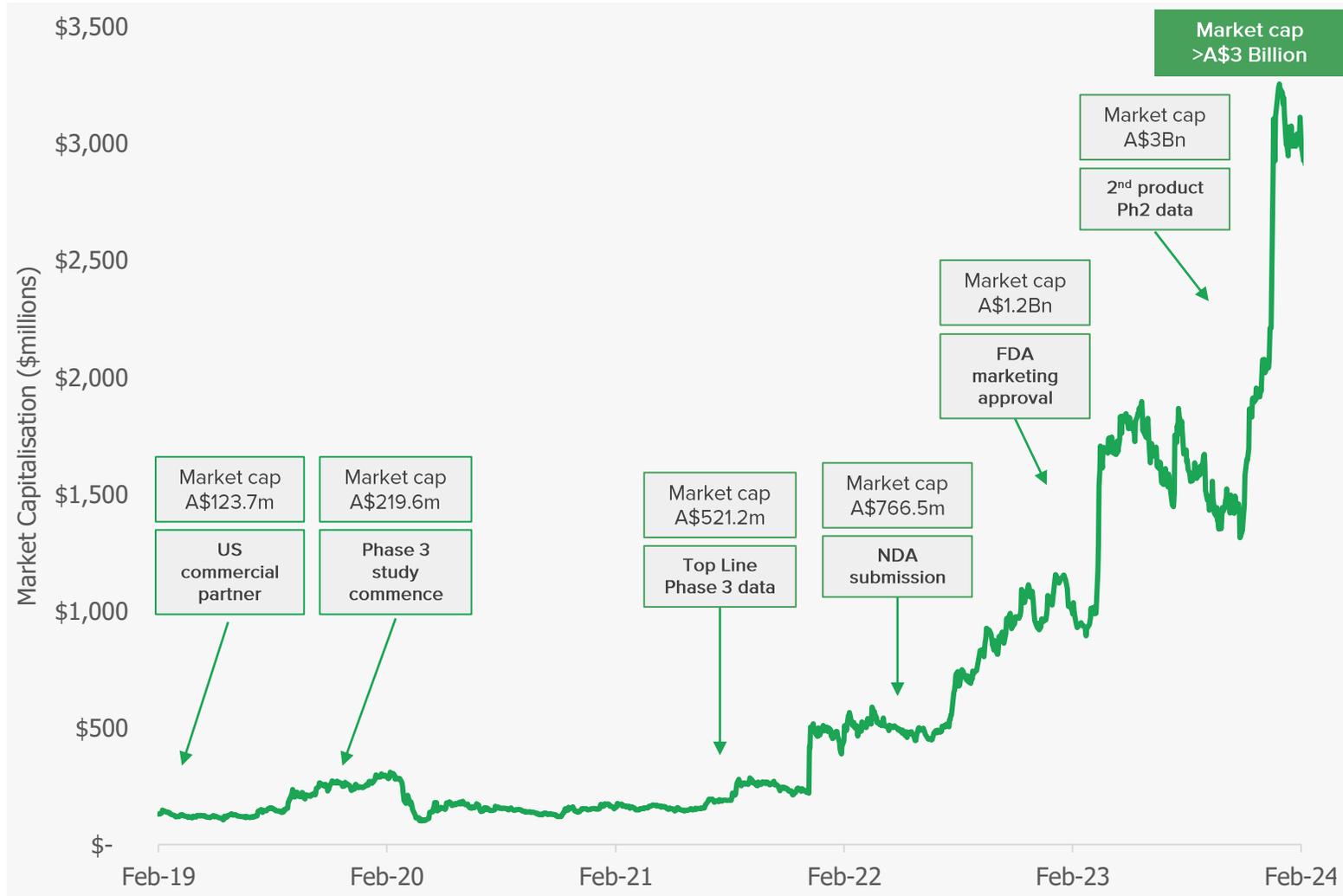
- Paediatric population to be included in Part 2 of Phase 3 trial<sup>3</sup>



### Global regulators provide greater feedback

- DXB received feedback and assistance designing Phase 3 trial<sup>4</sup>
- DXB has received assistance with its drug development plan

# Orphan drug case study - Neuren (NEU.ASX)



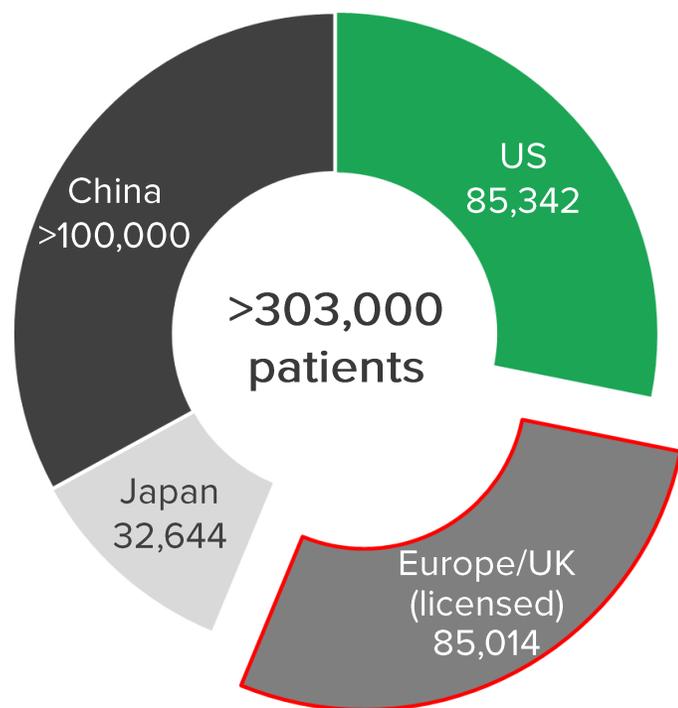
- Neuren are focussed on **orphan disease treatment** with a pipeline of rare neurodevelopmental disorders
- Lead program/drug, DAYBUE™ (trofinetide) has **orphan designation** and received significant valuation uplifts during and after its **Phase 3** program
  - \$220m market cap at commencement of Phase 3
  - \$520m market cap at read out of Phase 3 results (240% uplift)
  - \$767m market cap prior to New Drug Application (NDA) to FDA (further 150% uplift)
  - \$1.6b market cap post FDA approval of first candidate (further 200% uplift)
- US market assumes pricing of ~US\$375,000<sup>1</sup> and 5,000 diagnosed patients p.a<sup>1</sup>

# Potential FSGS market size

DXB is targeting multi-billion dollar markets with **no approved treatments**

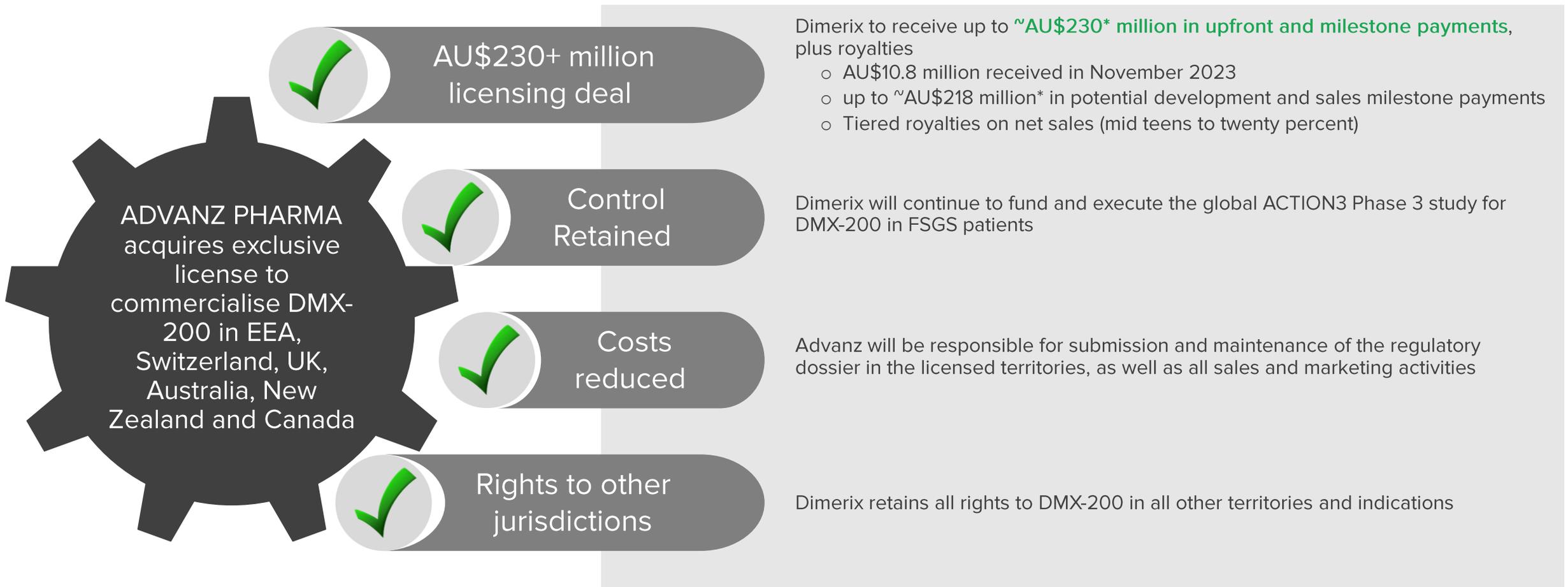


Estimated 7MM (+China)  
diagnosed patients (2022)<sup>1,4</sup>

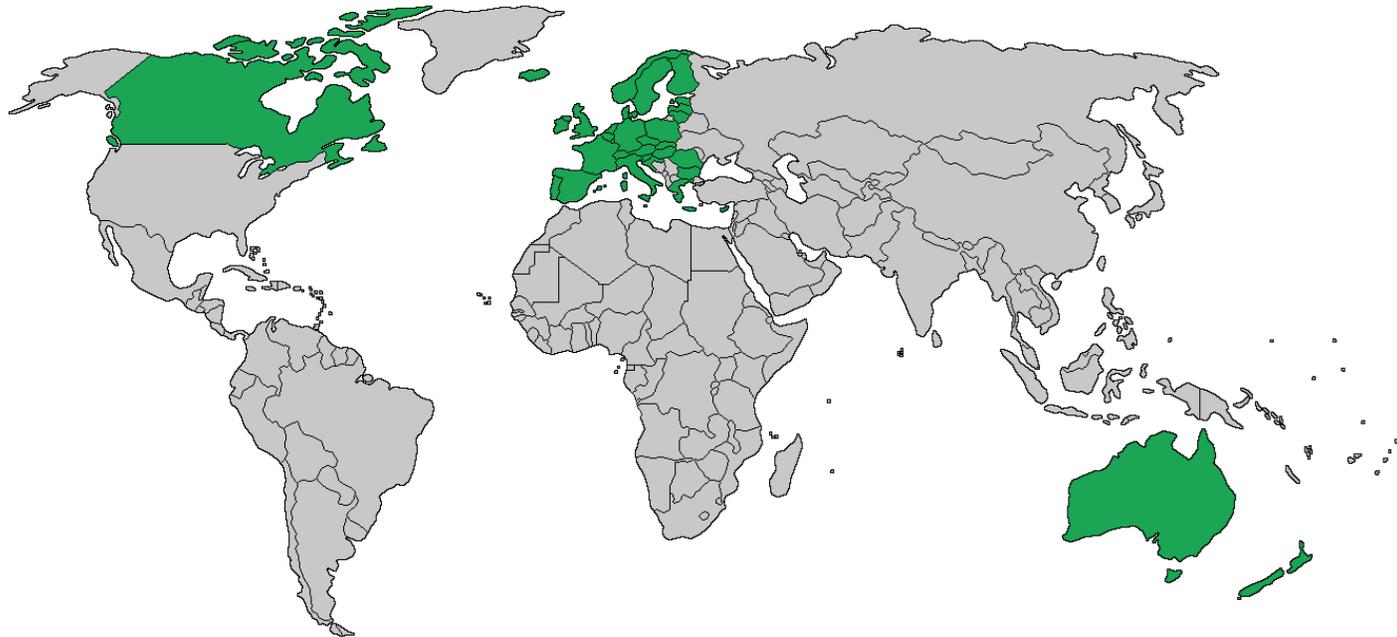


- ▶ Example pricing for other rare kidney disease drugs :
  - in the US (i.e. Filspari in IgAN)<sup>2</sup> is **US\$9,900 p/month**
  - in Europe/UK (i.e. Kinpeygo/Tarpeyo)<sup>3</sup> is **US\$8,267 p/month (€7,630)**
- ▶ Potential for:
  - **~US\$120k per annum per patient for FSGS drug in US**
  - **~€91,560 per annum per patient for FSGS drug in Europe**
- ▶ **Next major targets for DXB are US & China, with partnering discussions already underway**

# Licensing deal - **ADVANZ** PHARMA partnership



# Global partnering availability



• Advanz Partnership marked the first of many potential agreements globally



• Partnering negotiations remain on-going in other territories



• Potential multi-billion dollar markets yet to be licensed (incl. the US & China)

■ Licensed territories (EAA, Switzerland, UK, Canada, ANZ) – DMX-200

■ Available for licensing -  **QYTOVRA**<sup>®</sup>  
[REPAGERMANIUM]

# Summary | Phase 3 Global Opportunity



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# Appendices

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## WELL POSITIONED TO DELIVER AGAINST STRATEGIC PLAN



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Victoria, Australia

T. 1300 813 321

E. [investor@dimerix.com](mailto:investor@dimerix.com)

**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.*

# Corporate overview

Ticker Symbol	ASX: DXB
Cash Balance (Dec23)	~A\$14.8 million
Market Capitalisation	~A\$100 million
Share price	~A\$0.20
Total ordinary shares on issue	437,526,482
Average daily liquidity for past 30 days*	4.76 million



SUBSTANTIAL SHAREHOLDERS <sup>1</sup>			
	Holder Name	Holding	% IC
1	Mr P Meurs	64,929,440	15.0%
TOTAL (TOP 5)		97,359,869	22.25%

# Dimerix board



**Mark Diamond**  
BSc, MBA  
Non-Executive Chairman

- Antisense, Faulding (Pfizer)*
- 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 – Microbiology/immunology
  - ✓ MBA - Business



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

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



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

- Kinosis, Hatchtech, Acrux, Mayne Pharma*
- Extensive biotech drug development & commercial manufacturing experience
  - Responsible for successful global commercialisation programs & NDA registrations
  - ✓ BSc (Hons) - Chemistry
  - ✓ MBA - Business



**Sonia Poli**  
PhD  
Non-Executive Director

- Minoryx, AC Immune, Addex, Hoffman la Roche*
- 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

- Woodside Energy, iCetana*
- ~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

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



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

- Bio101, Pitcher Partners*
- 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

- Race Oncology, Syneos, 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  
CCO

- Medicines Development, Avecheo*
- Experienced pharmaceutical executive in project management, clinical development and research programs
  - BD and strategic alliance leader
  - Led multidisciplinary R&D&C teams for over 14 years
  - ✓ BSc (Hons) – Genetics
  - ✓ PhD – Molecular Immunology
  - ✓ MBA - Business



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

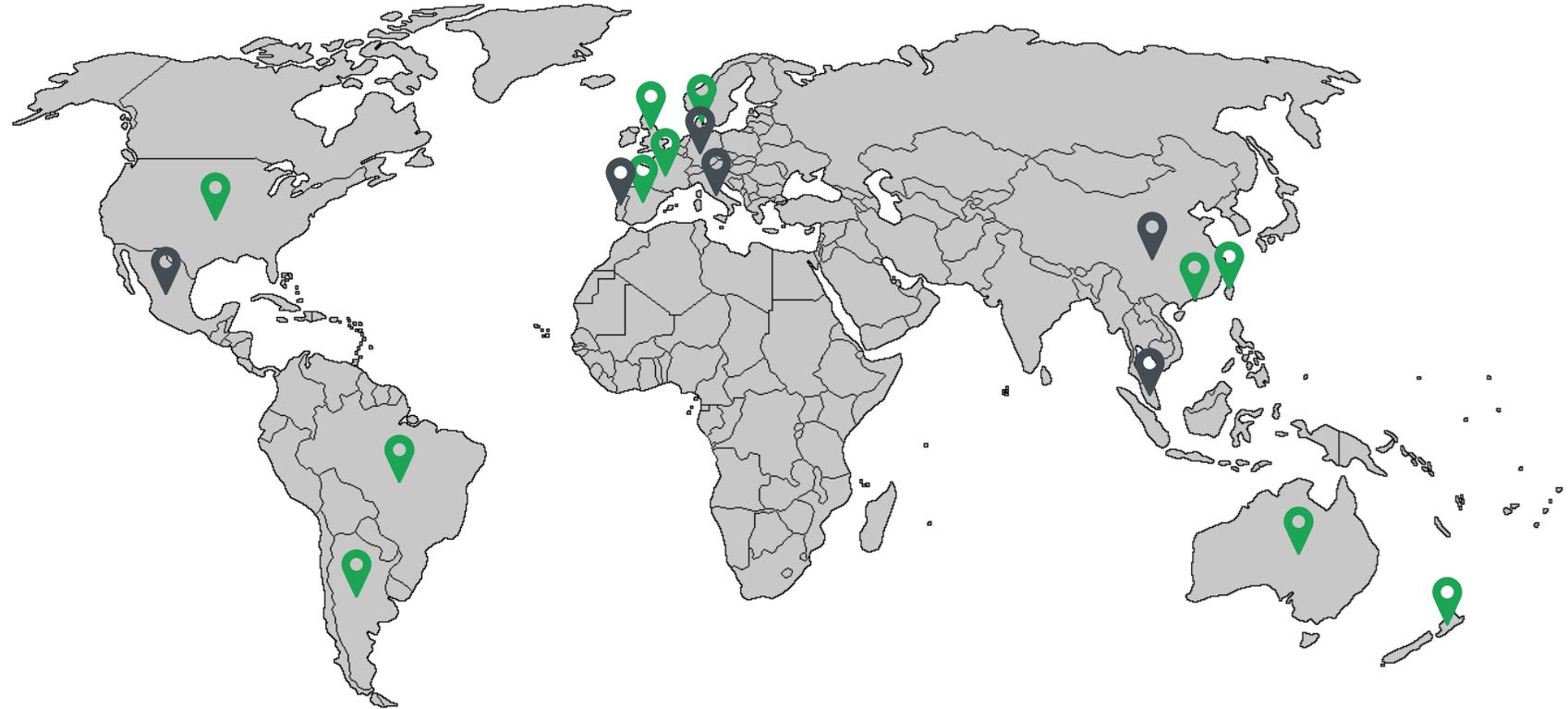
- Neuren, Prota, Acrux, CSL*
- Experienced pharmaceutical executive in Manufacturing (CMC)
  - Successfully developed and submitted multiple dossiers to FDA, EMA, TGA
  - Background in technical transfer and product launch
  - ✓ BSc (Hons) – Applied Biology
  - ✓ MBA - Business

# Current and planned clinical site locations

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



- Part 1 recruiting at 70 sites:
  - Australia, New Zealand
  - Taiwan, Hong Kong
  - France, Denmark, UK, Spain
  - Argentina, Brazil
  - USA
- Part 2 new countries:
  - China
  - Malaysia
  - Italy, Germany, Portugal
  - Mexico



# Renal disease landscape



*“A squeaky wheel waiting for grease: 50 years of kidney disease management in the US”<sup>1</sup>*



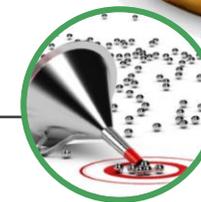
Historical lack of incentives and public policy have contributed to high costs and poor health outcomes for renal patients<sup>1</sup>



2018: workshops and regulatory acceptance of surrogate end points in trials of kidney diseases<sup>2</sup>



2019 changes in US federal policy and rapid adoption of treatment guidelines have contributed to a sea change in the management of renal disease<sup>3</sup>

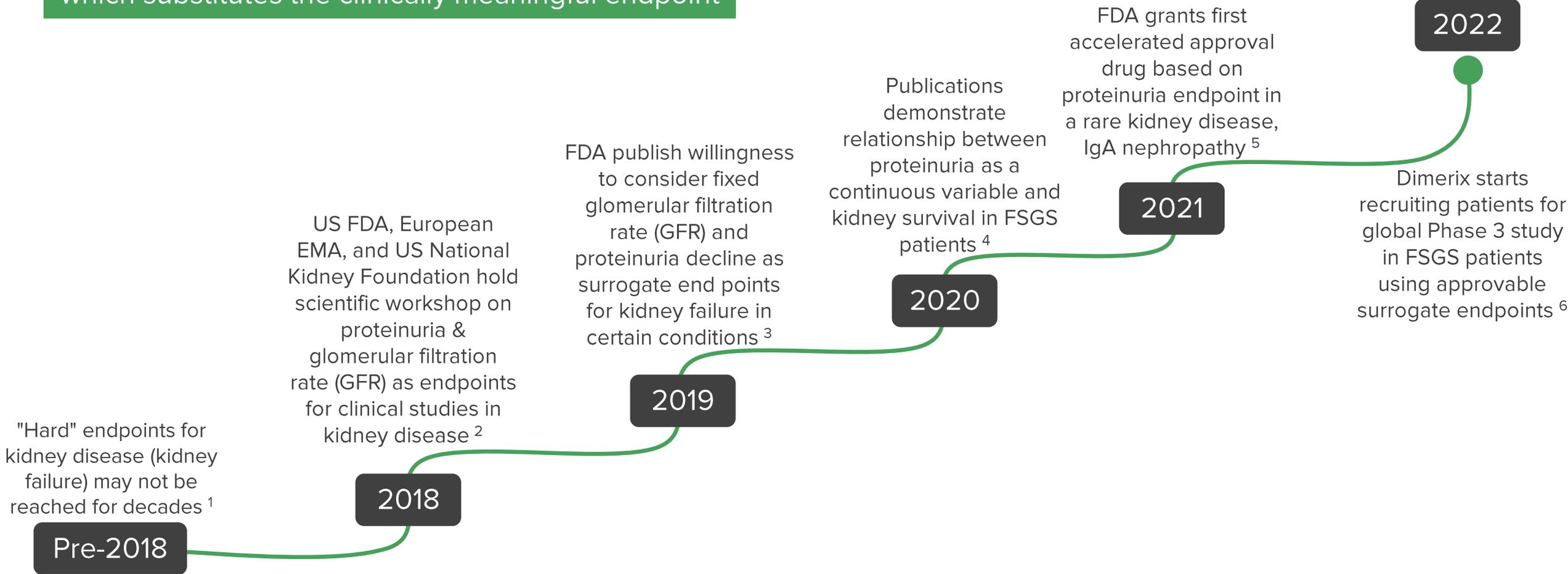


Public health policy, legislation and product innovation have converged to accelerate change in renal space today

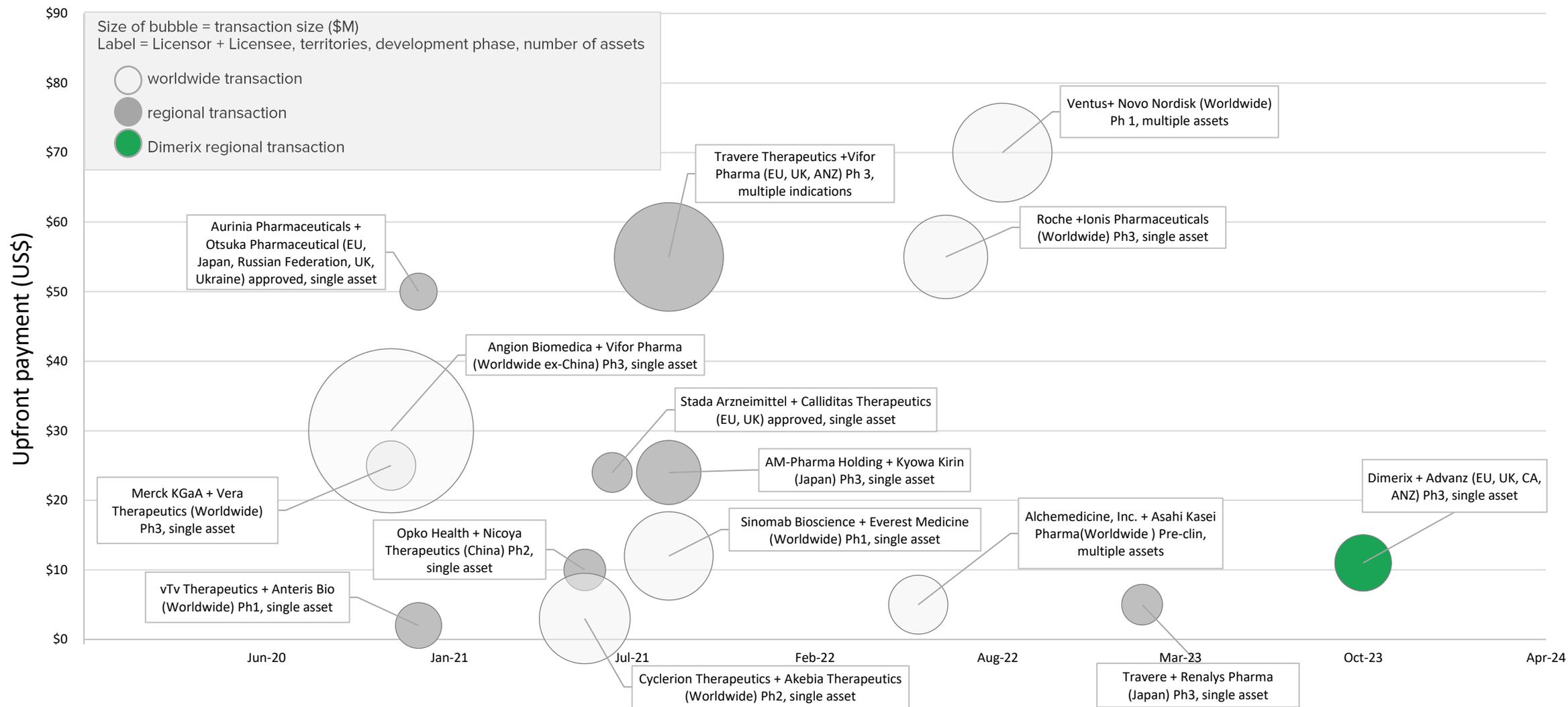
*“More change in the past 24 months than the past 24 years: The rapid evolution of [kidney disease] management”<sup>1</sup>*

# Clinical study change: use of surrogate endpoints

A surrogate endpoint is an intermediate outcome which substitutes the clinically meaningful endpoint



# Renal licensing deals details



# Policy change: renal disease healthcare economic burden

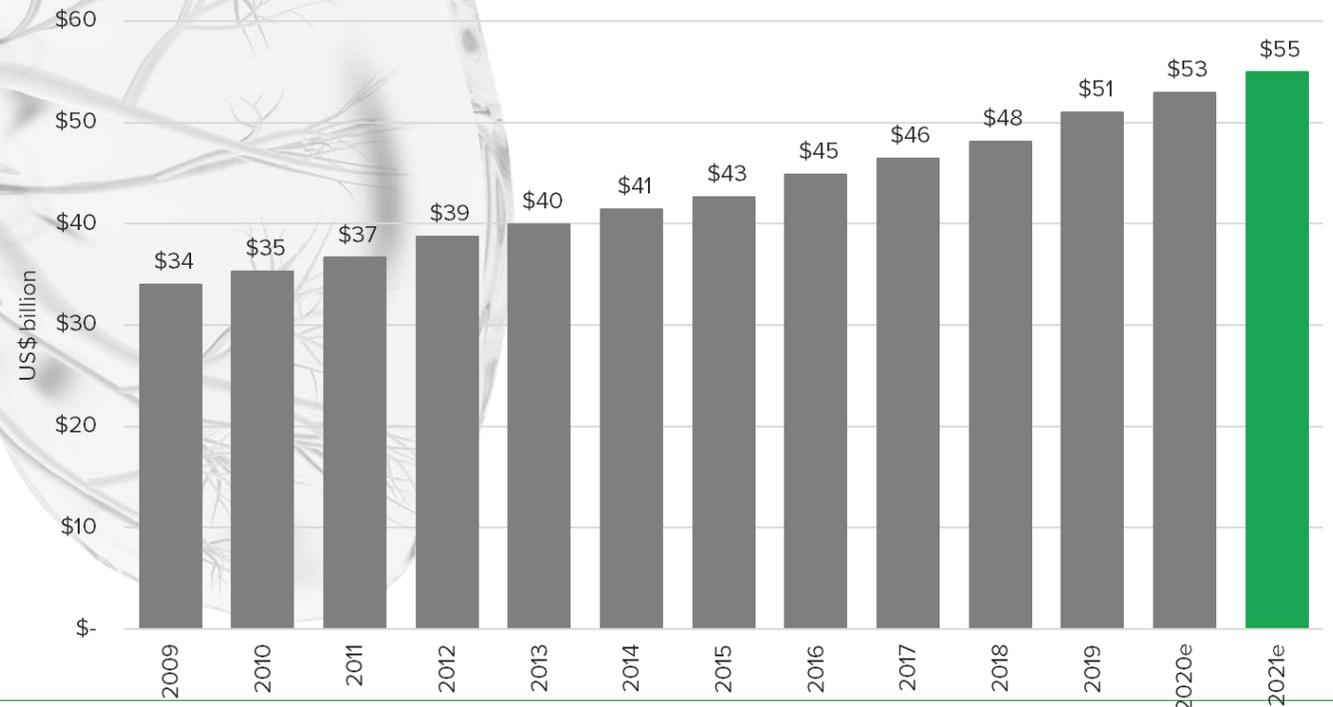
**~40 million**  
adults have kidney  
disease (~15% of the  
adult population) in the  
US in 2021<sup>1</sup>

**US\$88 billion**  
estimated total US  
Medicare expenses  
costs/year for renal  
patients in 2021<sup>1,3</sup>

**2019**  
White House executive  
order issued: incentives  
for providers to delay  
patient progression to  
renal failure<sup>2</sup>

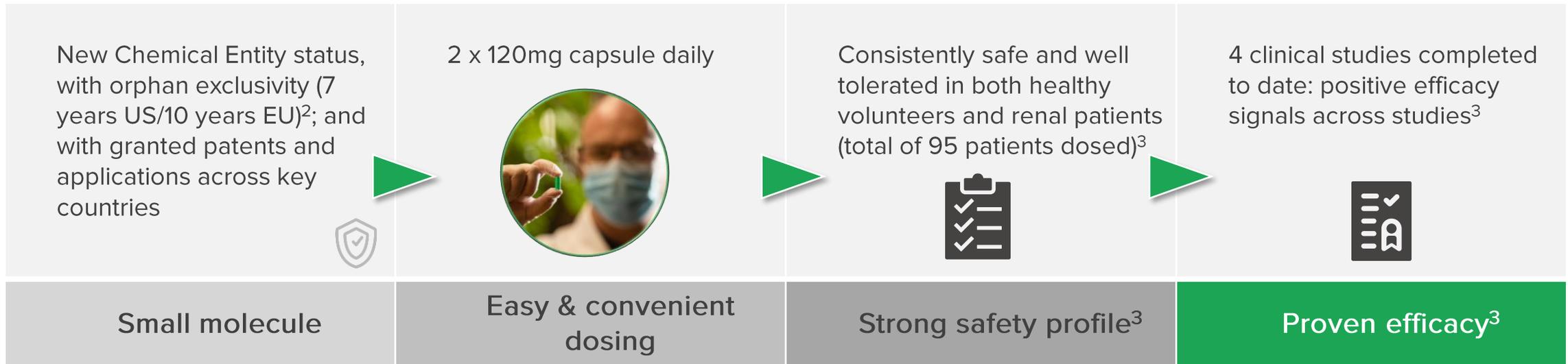
## Economic cost of kidney failure in the US

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



# DMX-200 – working on inflammatory signalling pathway

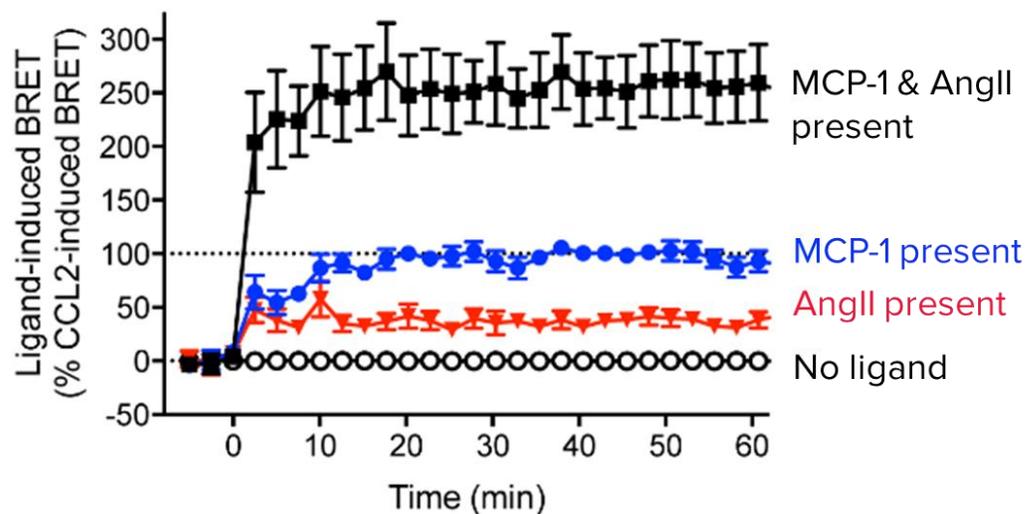
A CCR2 inhibitor working synergistically alongside the current standard of care (AT1R blocker): G protein-coupled receptor (GPCR)



# DMX-200 unique heteromer pharmacology

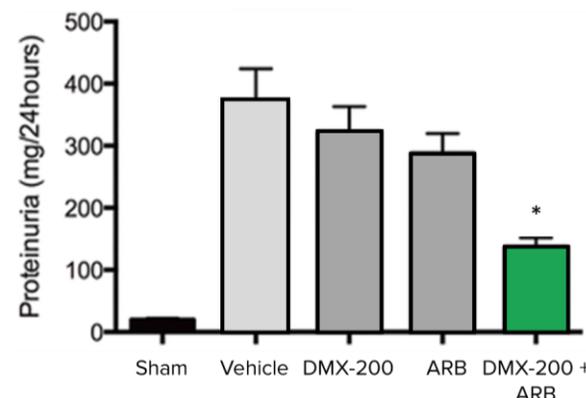
Proprietary discovery platform (Receptor-HIT) identified:

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

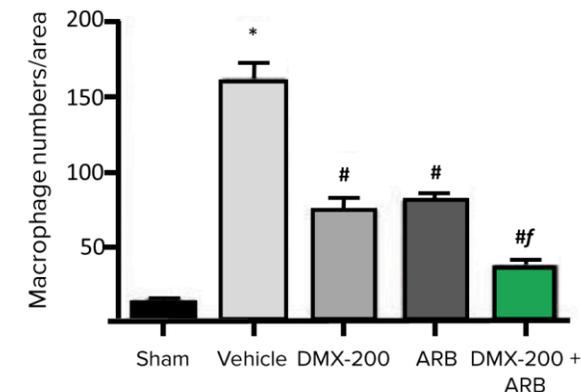


Proposed non-clinical safety package suitability for NDA confirmed with FDA

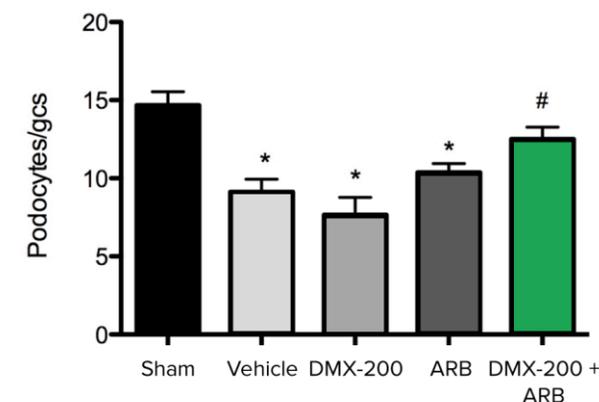
↓ Proteinuria



↓ Macrophage infiltration

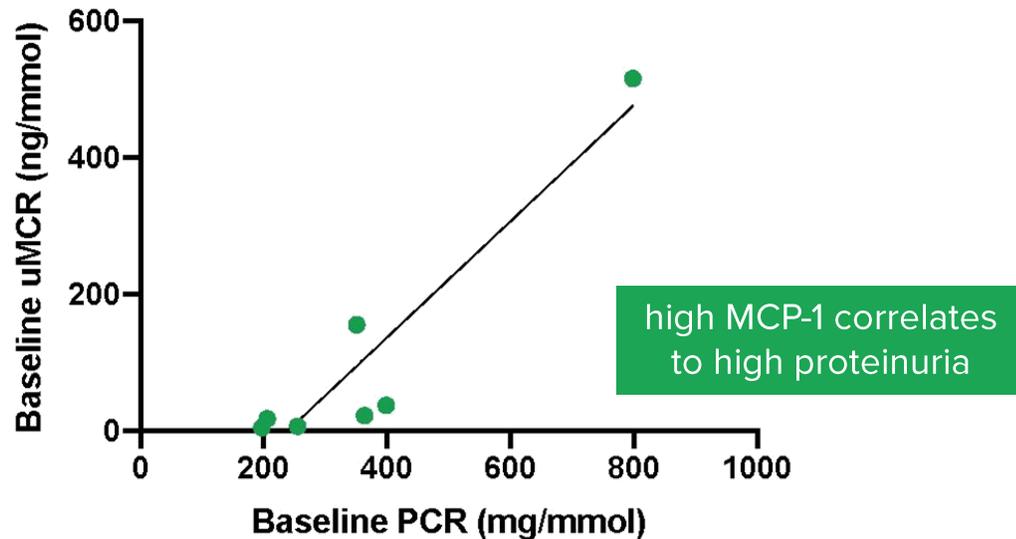


Retained podocyte numbers

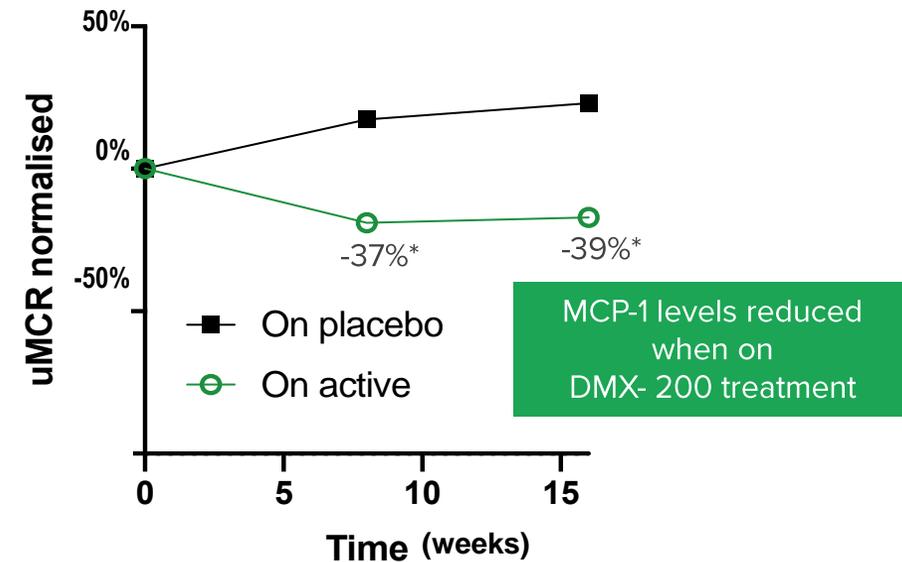


# DMX-200 Phase 2a effect on inflammatory biomarker

Average baseline MCP-1 versus average baseline proteinuria

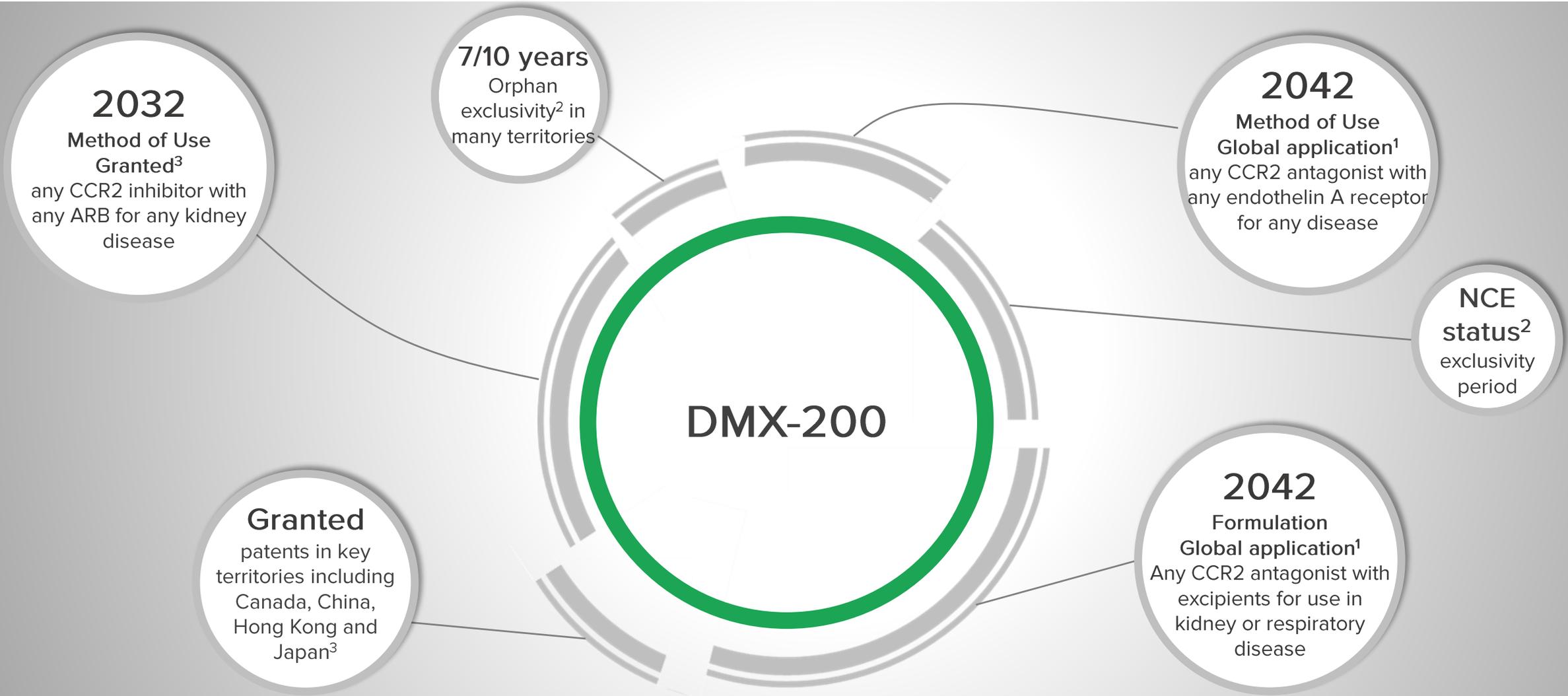


Change in MCP-1 over time on DMX-200 versus placebo

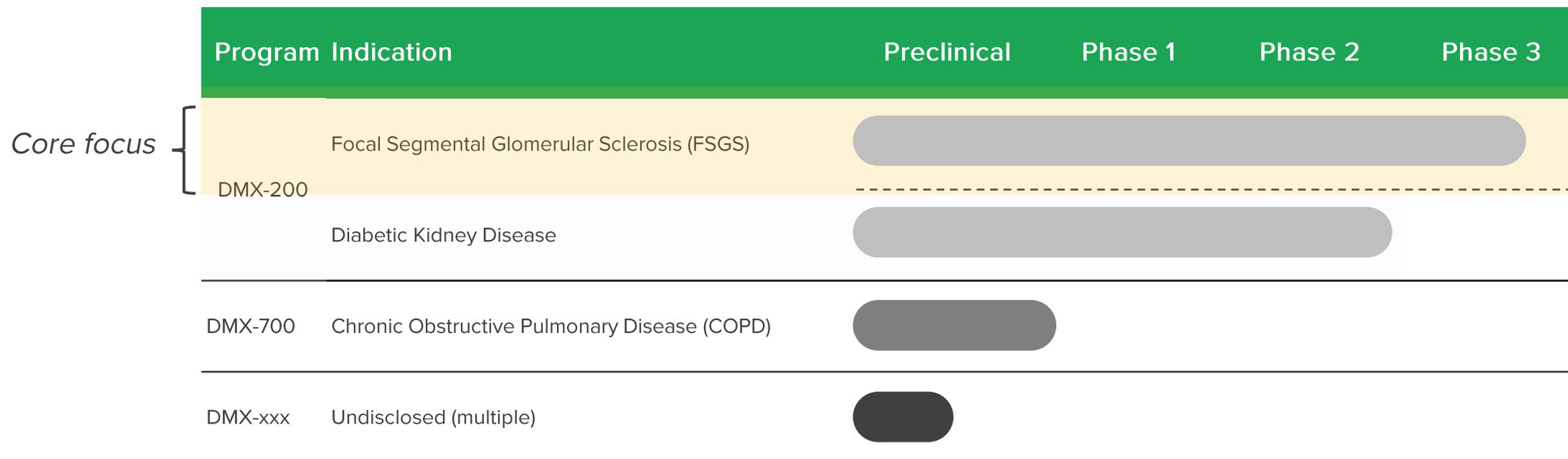


- 16 weeks treatment with DMX-200 vs placebo reduced inflammatory biomarker by 39%:
  - DMX-200 blocks receptor responsible for inflammation
  - Translates to reduced inflammation and subsequent fibrosis (scarring) in the kidney

# Intellectual property and exclusivity



# Development pipeline

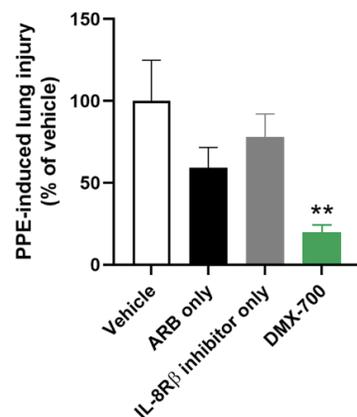


# Advancing the broader pipeline

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

## DMX-700 for Chronic Obstructive Pulmonary Disease (COPD)

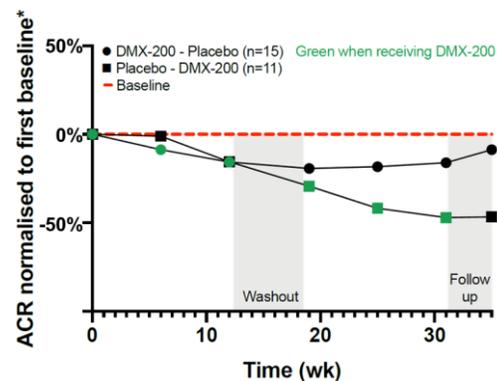
Preclinical studies show that DMX-700 significantly reduced lung injury by 80% ( $p < 0.01$ ) after 21 days treatment<sup>1</sup>



Pre-clinical asset

## DMX-200 for Diabetic Kidney Disease

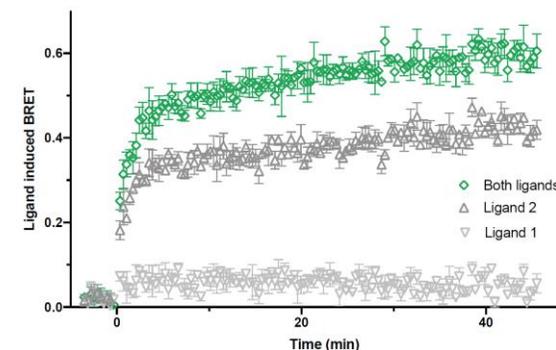
Phase 2 demonstrated promising efficacy & safety<sup>2</sup>, proteinuria declined after treatment with DMX-200 in both treatment periods<sup>2</sup>



Phase 2 asset

## Undisclosed Opportunities

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



Pre-clinical identified opportunities