



# Dimerix

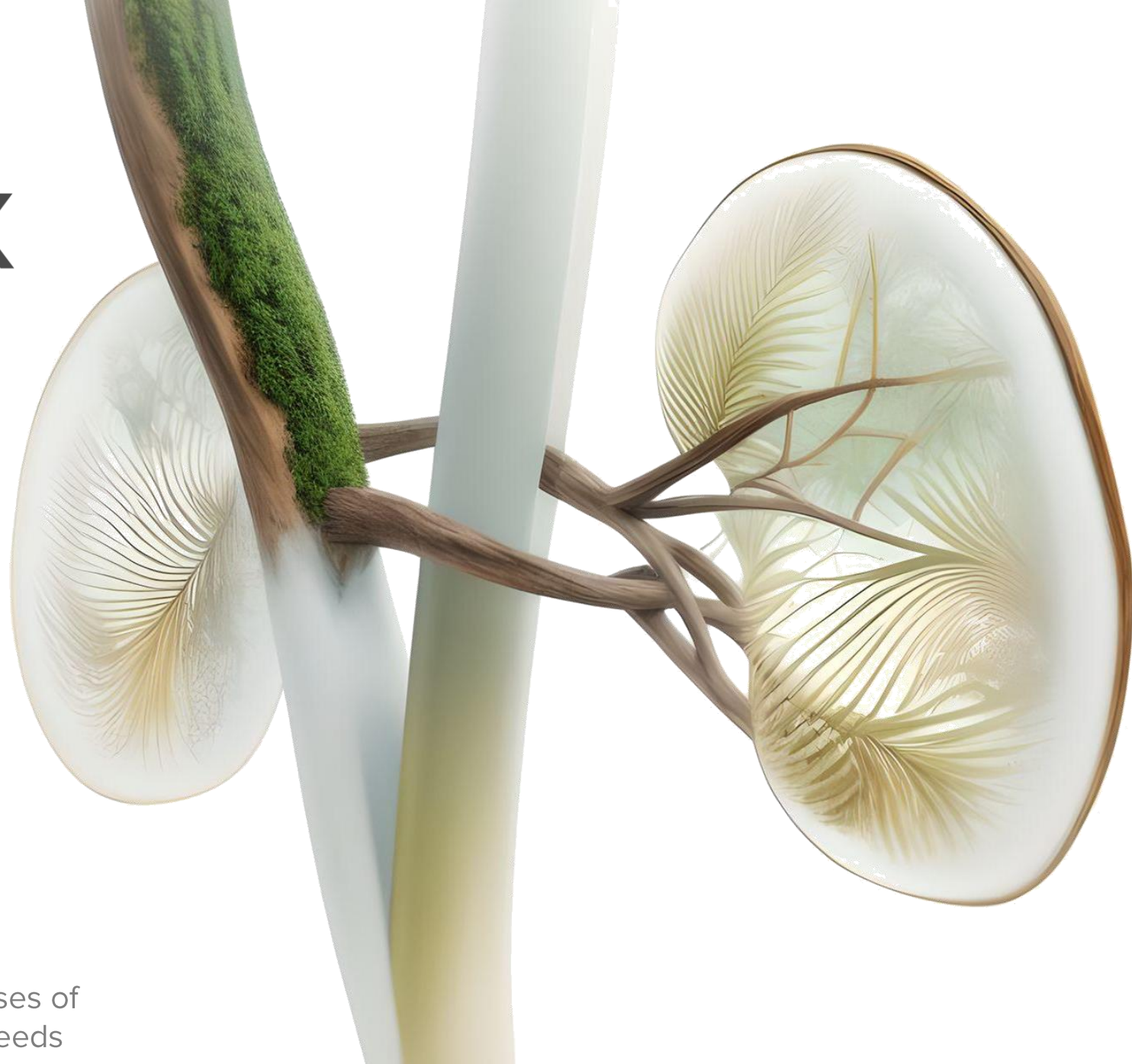
(ASX:DXB)

## DMX-200 for FSGS Non-confidential

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July 2024

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



# Significantly de-risked, late-stage development program



**Strong** safety profile – no material adverse events in Phase 1, 2 and 3



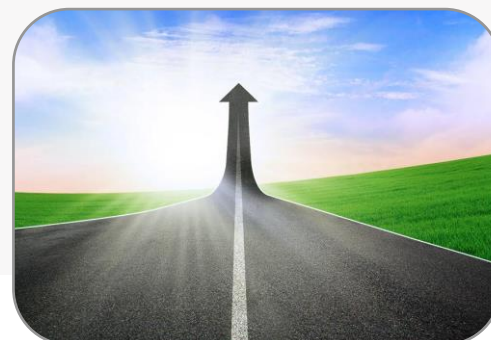
**Encouraging** efficacy in Phase 2 and successful interim analysis in Phase 3



**Completed** all non-clinical safety for FDA and EMA



**Completed** commercial manufacturing scale-up



**Clear** development and competitive pathway to market



**Orphan Drug** designations

# 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 - Chemistry
  - ✓ MBA - Business



**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



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

- Mayne Pharma, Acrux, Hatchtech, Kinosis*
- 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

- Hoffman la 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

- 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
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  - ✓ 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

# Medical Advisory Board



**Professor Hiddo Heerspink**  
PhD  
Chairman

Professor of Clinical Trials and Personalized Medicine: University Medical Center Groningen, the Netherlands. He specialises 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.



**Dr Muh Geot Wong**  
MBBS, PhD, FRCP  
Member

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.



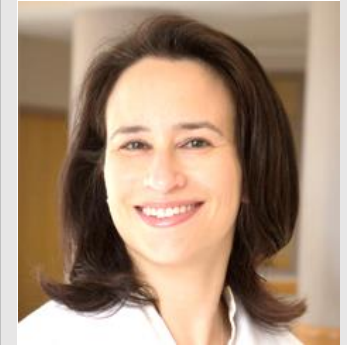
**Professor Alessia Fornoni**  
MD, PhD, FASN  
Member

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  
Member

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.

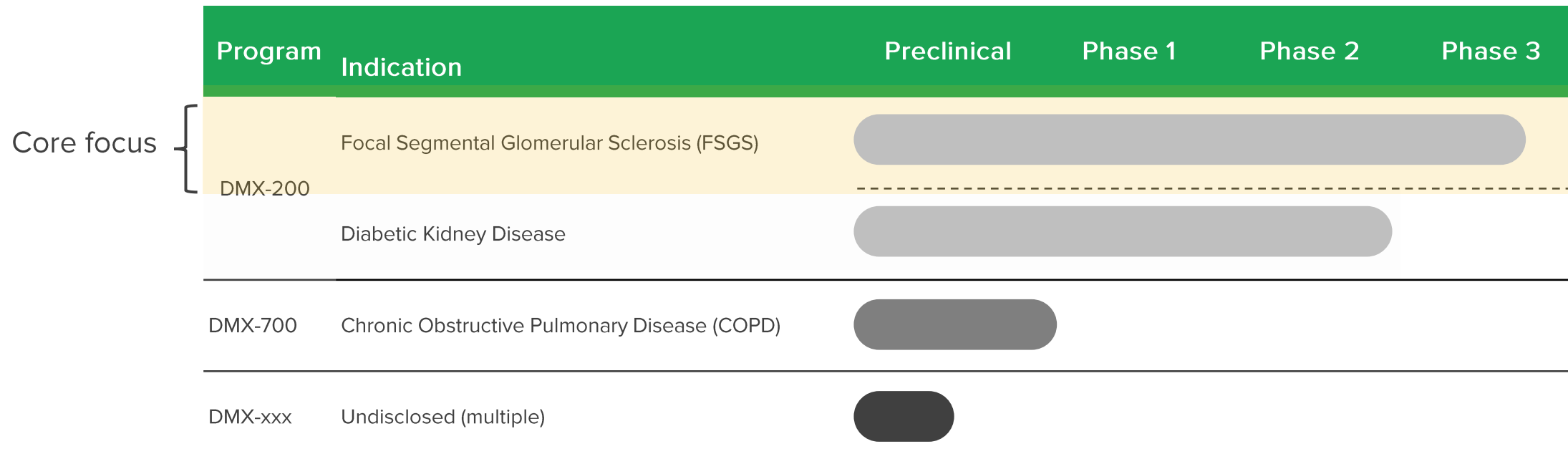


**Associate Professor Lesley Inker**  
MD, MS, FRCPC  
Member

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.

China Lead Investigator: **Professor Hong Zhang, MD PhD**  
Deputy Director of Renal division at Peking University First Hospital

# Development pipeline



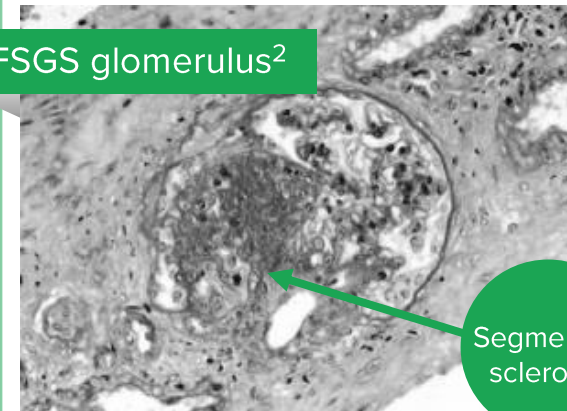
# What is the patient journey of Focal Segmental Glomerulosclerosis (FSGS)?

- Focal segmental glomerulosclerosis (FSGS) is one of the most common forms of acquired glomerular disease leading to end stage kidney disease (ESKD)
- FSGS makes up approximately 10% of all kidney diseases<sup>1</sup>
- On average FSGS progresses to kidney failure within 5 years after onset of proteinuria<sup>1</sup>
- Caused by a variety of conditions - primary FSGS, genetic FSGS, FSGS of unknown cause and secondary FSGS<sup>3</sup>
- Prevalence of FSGS growing due to increase in:
  - Diabetes
  - Obesity
  - Ageing population
- Currently no approved drugs for FSGS
  - patients are treated with medications off-label, including angiotensin receptor blockers
- Significant burden on global health systems to support healthcare economics / drug pricing
  - Patients end up on dialysis (est cost US\$90,000/patient/year)<sup>4</sup>
  - Patients requiring kidney transplant (est cost US\$442,500 per transplant + ongoing medication fees)<sup>5</sup>
  - 60% patients have reoccurring FSGS even after first kidney transplant<sup>6</sup>

Normal glomerulus<sup>2</sup>



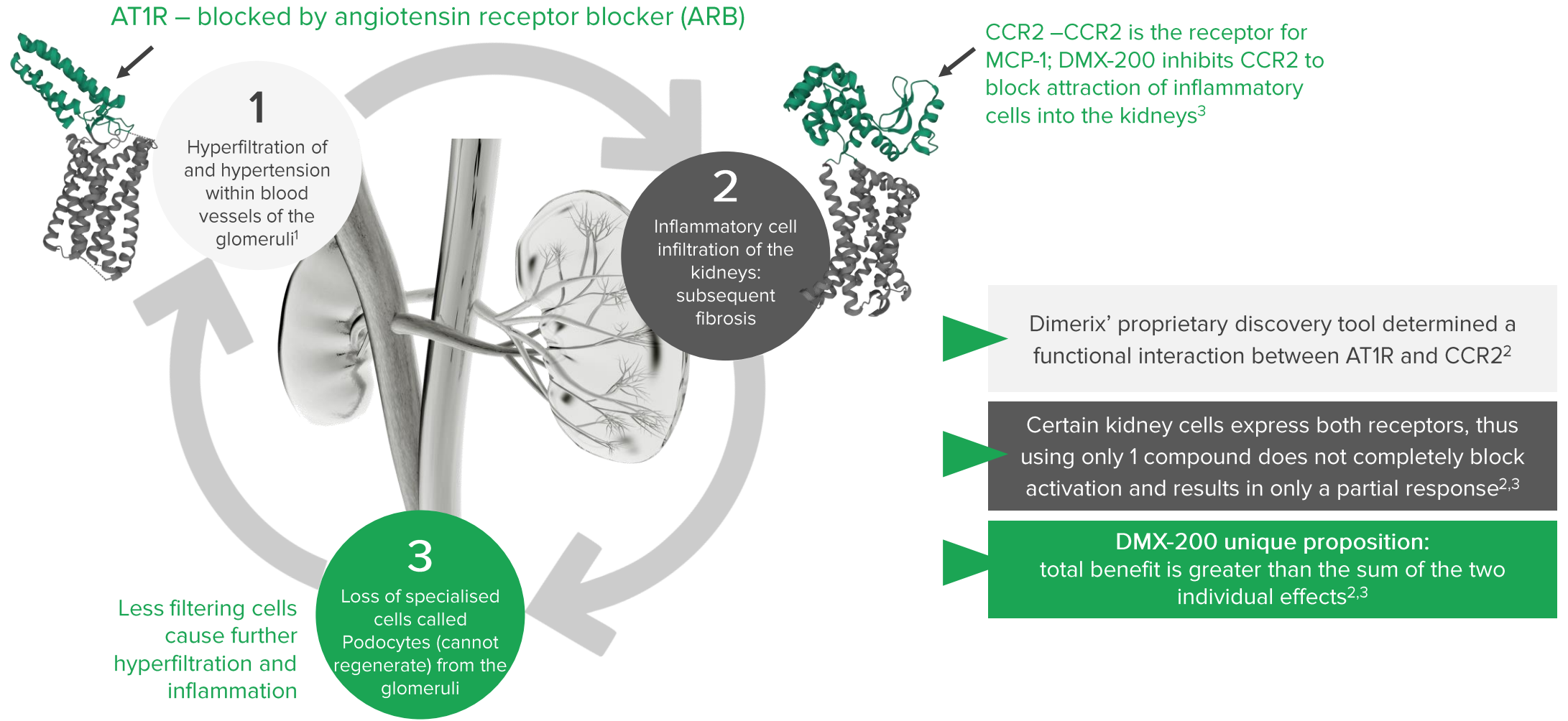
FSGS glomerulus<sup>2</sup>



Segmental sclerosis

Glomeruli are the tiny network of blood vessels that are the “cleaning units” of the kidney

# 3 key mechanisms that cause sclerotic kidney disease

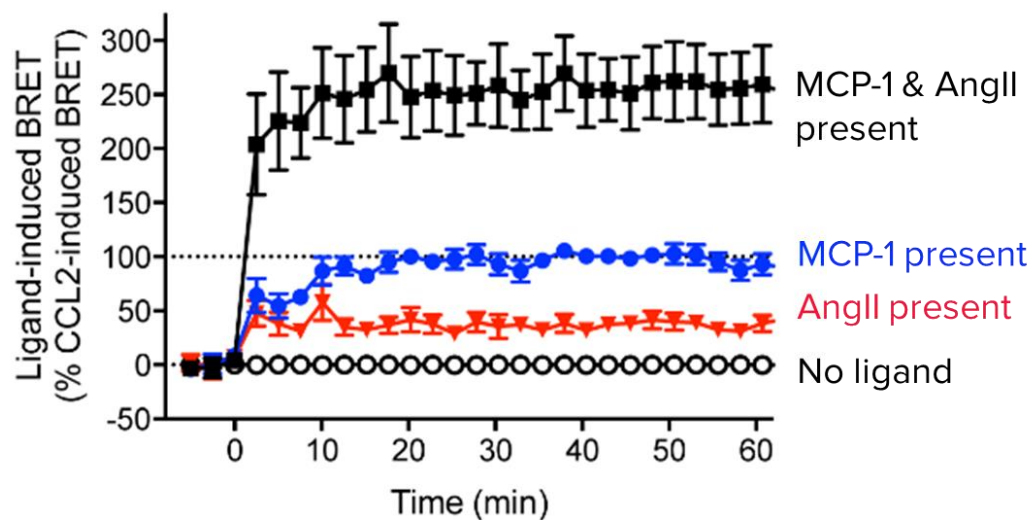




# DMX-200 unique heteromer pharmacology

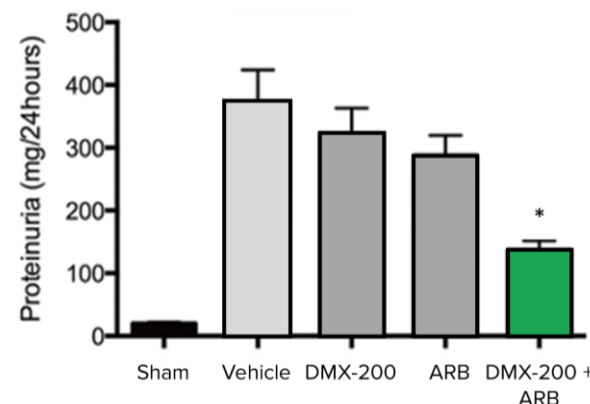
Proprietary discovery platform (Receptor-HIT) identified:

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

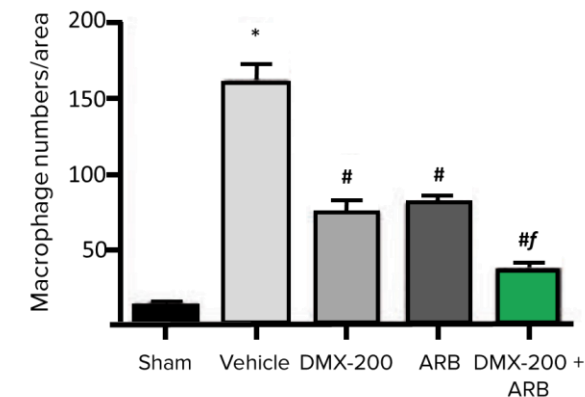


Proposed non-clinical safety package suitability for NDA confirmed with FDA

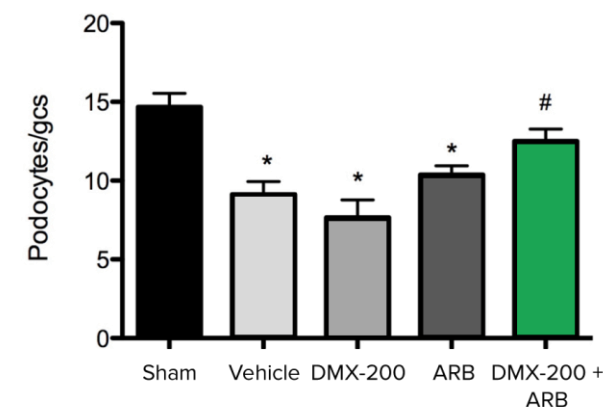
↓ Proteinuria



↓ Macrophage infiltration

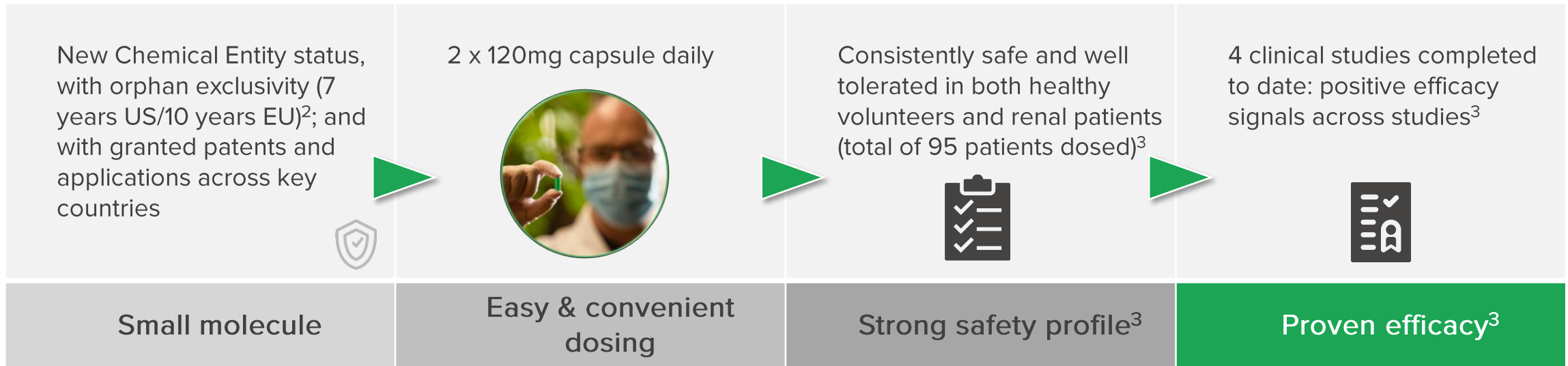


Retained podocyte numbers



# DMX-200 is a strong product candidate

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



# DMX-200 met Phase 2a clinical study endpoints



Clinically meaningful outcomes for patients



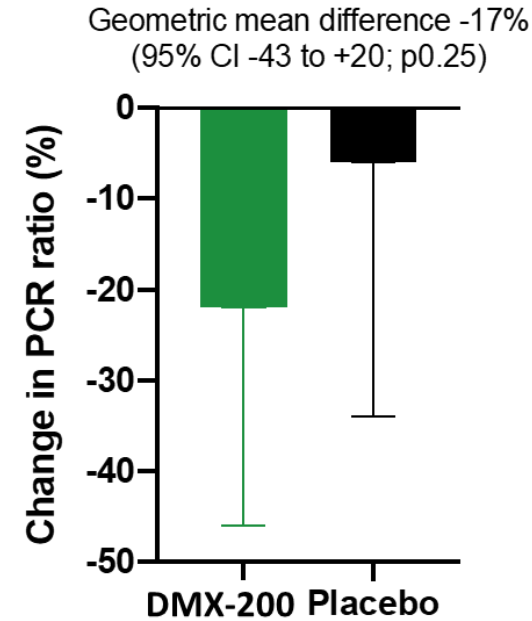
## EFFICACY

- 86% of patients demonstrated reduced proteinuria on DMX-200 versus placebo
- 29% of patients demonstrated >40% reduction in proteinuria

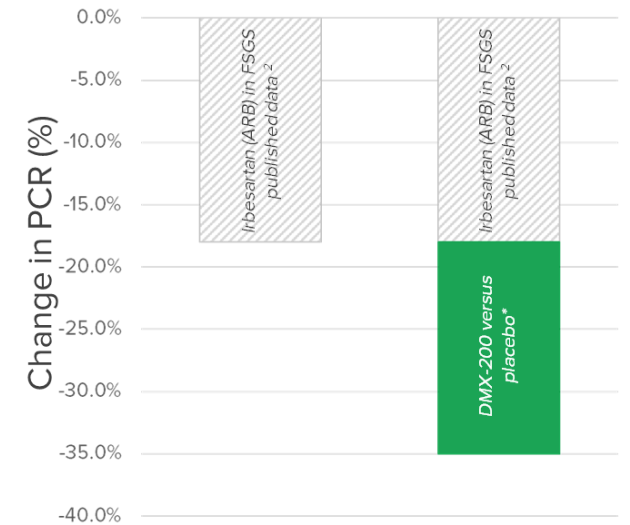


## SAFETY

- No safety concerns – reduced development risk
- DMX-200 compares favourably to compounds currently in development

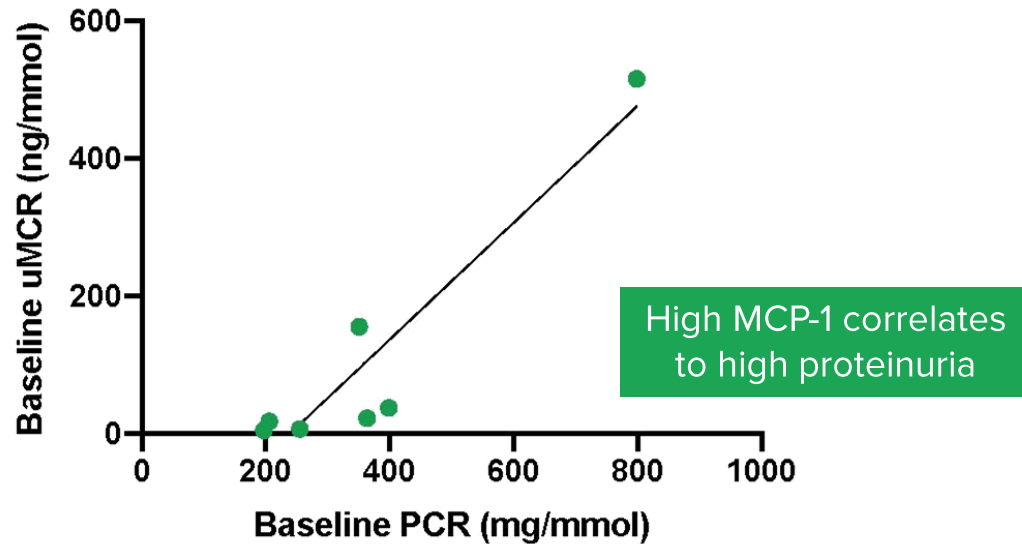


Average reduction in proteinuria after 16 weeks treatment on DMX-200 versus placebo compared to standard of care alone in FSGS patients<sup>1</sup>

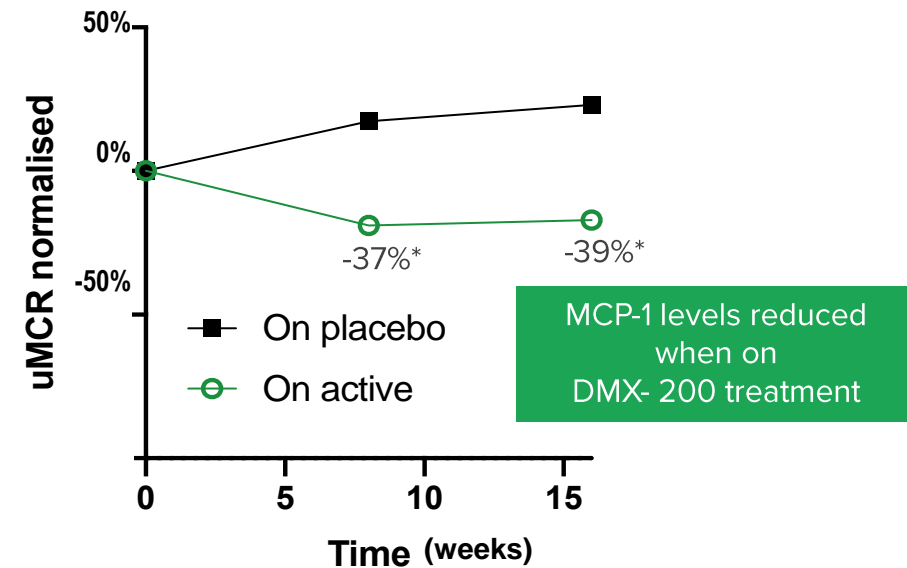


# DMX-200 targets key inflammatory biomarker

FSGS patients with high proteinuria present with high urine MCP-1 concentration



Unlike other clinical-stage CCR2 antagonists, DMX-200 reduces MCP-1 concentration

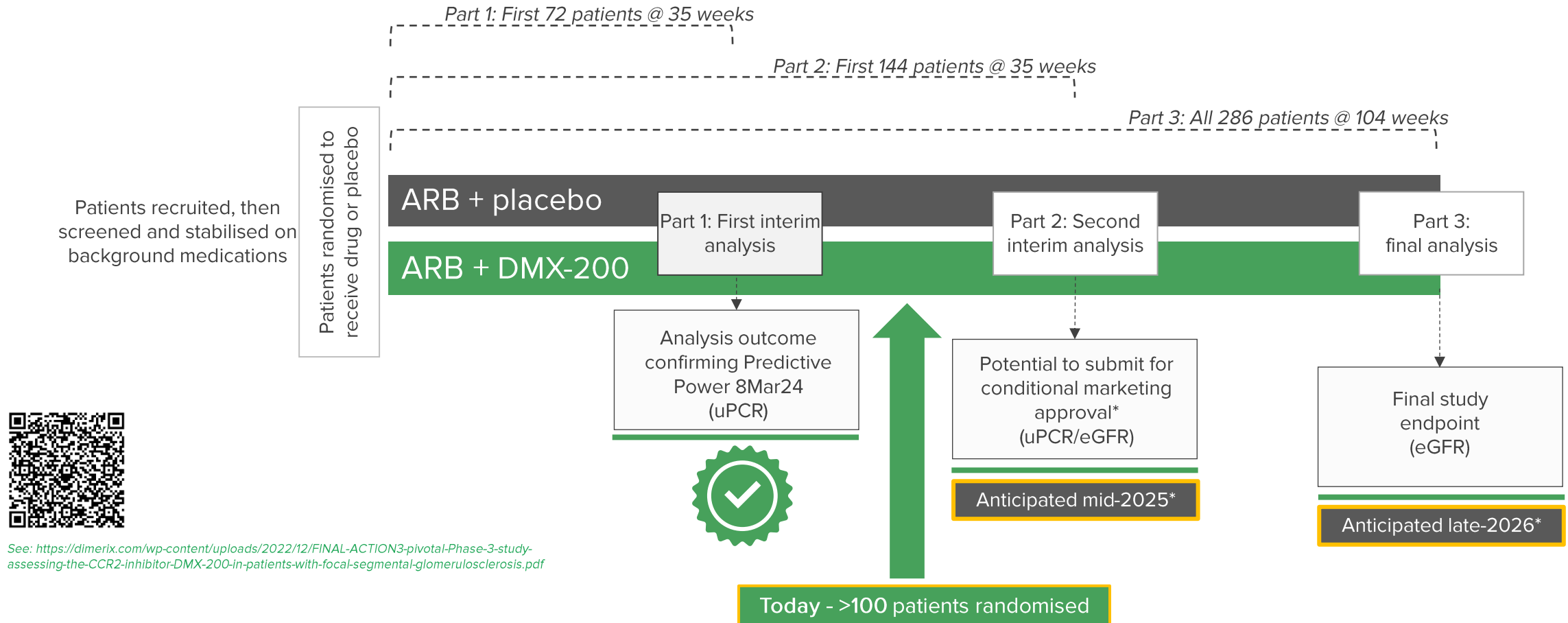


- 16 weeks treatment with DMX-200 vs placebo reduced MCP-1 biomarker by 39%:
  - Reduced immune cell recruitment to the kidney is highly correlated with reduced inflammation and subsequent fibrosis (scarring) in animal models and clinical studies

# ACTION3 Global 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



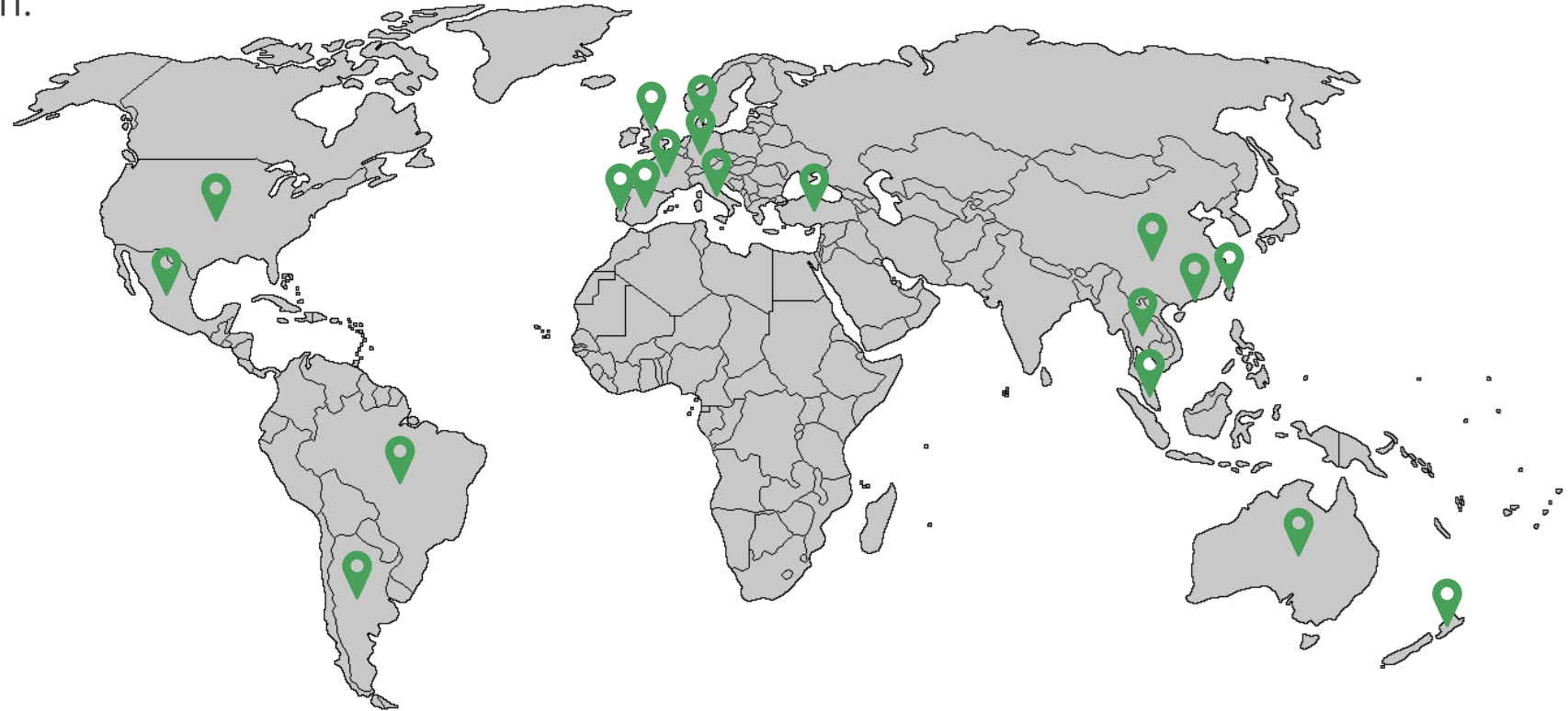
See: <https://dimerix.com/wp-content/uploads/2022/12/FINAL-ACTION3-pivotal-Phase-3-study-assessing-the-CCR2-inhibitor-DMX-200-in-patients-with-focal-segmental-glomerulosclerosis.pdf>

# Current and planned clinical sites

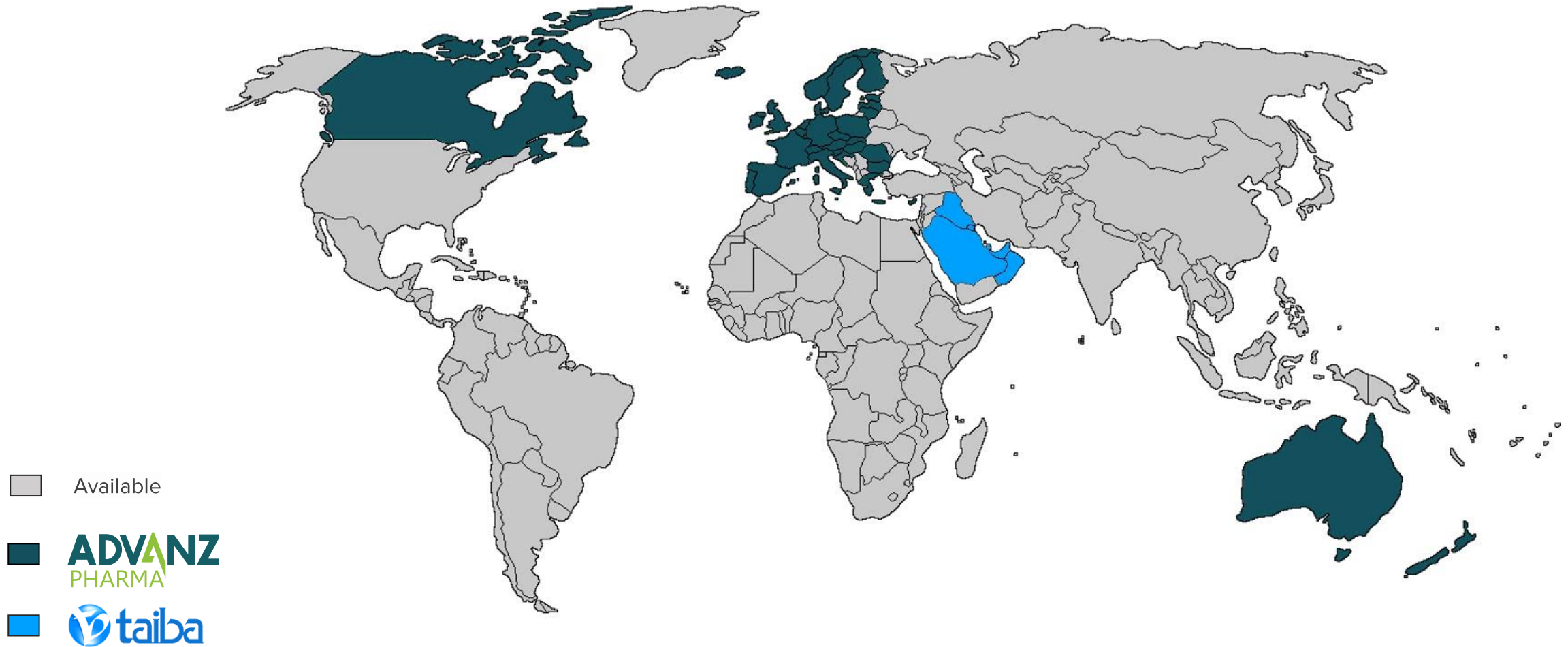
A randomised, double-blind, multi-centre, placebo-controlled study of renal outcomes of DMX-200 in patients with FSGS receiving an ARB

Recruitment planned at 170+ sites in:

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



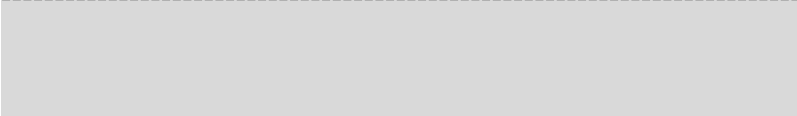
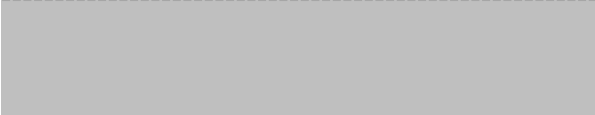
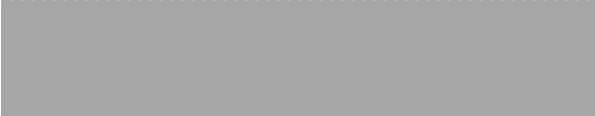



# Global partnering availability



# Low competitive landscape in FSGS

DMX-200 is the leading therapy in phase 3 development for FSGS

	Phase 1	Phase 2	Phase 3	Company
DMX-200 (AT1R&CCR2)				 Dimerix
VX-147 (APOL1)				Vertex Pharmaceuticals
BI-764198 (TRPC6)				Boehringer Ingelheim
Atrasentan (ETAR)				Chinook/Novartis
R3R01 (OSBPL7/ABCA1)				River3Renal



# Strong exclusivity and intellectual property

