

DIMERIX TO PRESENT AT BIO INTERNATIONAL CONVENTION

MELBOURNE, Australia, 6 June 2023: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical study in inflammatory disease, is pleased to advise that CEO & Managing Director, Dr Nina Webster, will be presenting the Dimerix opportunity to new potential partners, as well as meet with those potential partners who have already submitted non-binding offers, at the BIO International Convention in Boston, Massachusetts during the week commencing Monday 5 June 2023, US time. The one-on-one meetings are being scheduled via the BIO partnering system.

The presentation highlights the clear unmet need in kidney disease, the late-stage competitive pipeline and how Dimerix is overcoming the global challenges with its ACTION3 Phase 3 FSGS kidney study, currently recruiting across 70 sites in 11 different countries globally. The presentation also highlights those additional countries planned for Part 2 of the study following interim data from Part 1 of the study anticipated in Q1 2024.

BIO is the world's largest advocacy association representing member companies, state biotechnology groups, academic and research institutions, and related organizations across the United States and in 30+ countries. The BIO International Convention is the world's largest gathering of the biotechnology industry. It attracts more than 15,000 biotechnology and pharma leaders for one week of intensive networking to discover new opportunities and promising partnerships.

A copy of the presentation is attached.

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

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Authorised for lodgement by the Board of the Company

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About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company developing innovative new therapies in areas with unmet medical needs for global markets. Dimerix is currently developing its proprietary product DMX-200, for Focal Segmental Glomerulosclerosis (FSGS), respiratory complications associated with COVID-19 and Diabetic Kidney Disease, and is developing DMX-700 for Chronic Obstructive Pulmonary Disease (COPD). DMX-200 and DMX-700 were both identified using Dimerix' proprietary assay, Receptor Heteromer Investigation Technology (Receptor-HIT), which is a scalable and globally applicable technology platform enabling the understanding of receptor interactions to rapidly screen and identify new drug opportunities. Receptor-HIT is licensed non-exclusively to Excellerate Bioscience, a UK-based pharmacological assay service provider with a worldwide reputation for excellence in the field of molecular and cellular pharmacology.

About DMX-200

DMX-200 is the adjunct therapy of 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 2020, Dimerix completed two Phase 2 studies: one in FSGS and one in diabetic kidney disease, following a successful Phase 2a trial in patients with a range of chronic kidney diseases in 2017. No significant adverse safety events were reported in any trial, and all studies resulted in encouraging data that could provide meaningful clinical outcomes for patients with kidney disease. DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

FSGS

FSGS is a rare disease that attacks the kidney's filtering units, where blood is cleaned (called the 'glomeruli'), causing irreversible scarring. This leads to permanent kidney damage and eventual end-stage failure of the organ, requiring dialysis or transplantation. For those diagnosed with FSGS the prognosis is not good. The average time from a diagnosis of FSGS to the onset of complete kidney failure is only five years and it affects both adults and children as young as two years old.¹ For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.² At this time, there are no drugs specifically approved for FSGS anywhere in the world, so the treatment options and prognosis are poor.

The total global FSGS market was valued at US\$12.6 billion in 2022,³ with a CAGR of 8.2%, driven by approximately 220,000 FSGS sufferers across the 7 major markets⁴ and premium orphan drug pricing⁵. Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for FSGS.⁶ Orphan Drug Designation is granted to support the development of products for rare diseases and qualifies Dimerix for various development incentives including: seven years (FDA) and ten years (EMA) of market exclusivity if regulatory approval is received, exemption from certain application fees, and a fast-tracked regulatory pathway to approval. Dimerix reported positive Phase 2a data in FSGS patients in July 2020.⁷

References

- 1 Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: <https://www.ncbi.nlm.nih.gov/books/NBK532272/>
- 2 Front. Immunol., (July 2019) | <https://doi.org/10.3389/fimmu.2019.01669>
- 3 DataBridge Market Research (2022) Global Focal Segmental Glomerulosclerosis Drugs Market – Industry Trends and Forecast to 2030; <https://www.databridgemarketresearch.com/reports/global-focal-segmental-glomerulosclerosis-drugs-market>
- 4 Delve Insight Market Research Report (2022): Focal segmental glomerulosclerosis (FSGS) – Market Insight, Epidemiology and market forecast – 2032; <https://www.delveinsight.com/report-store/focal-segmental-glomerulosclerosis-fsgs-market>
- 5 IQVIA Report (2018), Orphan Drugs in the United States: Growth Trends in Rare Disease Treatments
- 6 ASX release 14Dec2015 and ASX release 21Nov2018
- 7 ASX release 29Jul2020



Dimerix

(ASX:DXB)

DMX-200

BIO 2023 Presentation

June 2023

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 profile¹ – no material adverse events in Phase 1/2



Proven efficacy¹ in Phase 2 studies – met primary and secondary endpoints



Completed toxicology studies² - expect no further work required by FDA



Completed commercial manufacturing scale-up³



Clear development pathway to market⁴



Orphan Drug designations⁵

Dimerix board



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 - Pharmaceutics
 - ✓ 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 drug development and registration worldwide in large and orphan indications
 - ✓ 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



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



Ash Soman
MBBS MRCP(UK) MBA
Chief Medical Officer



Robert Shepherd
PhD
VP R & D



Bronwyn Pollock
BSc (Hons), MBA
VP Product Development

Wyeth (Pfizer), Acrux, Immuron

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

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

Iqvia, AstraZeneca, Sanofi, Oncosil

- Experienced clinician spanning hospital clinical practice, clinical study design, medical affairs, compliance, patient safety & corporate strategy
- Clinical training in general and respiratory medicine
- ✓ Bachelor of Medicine and Surgery
- ✓ Member of the Royal College of Physicians
- ✓ MBA - Business

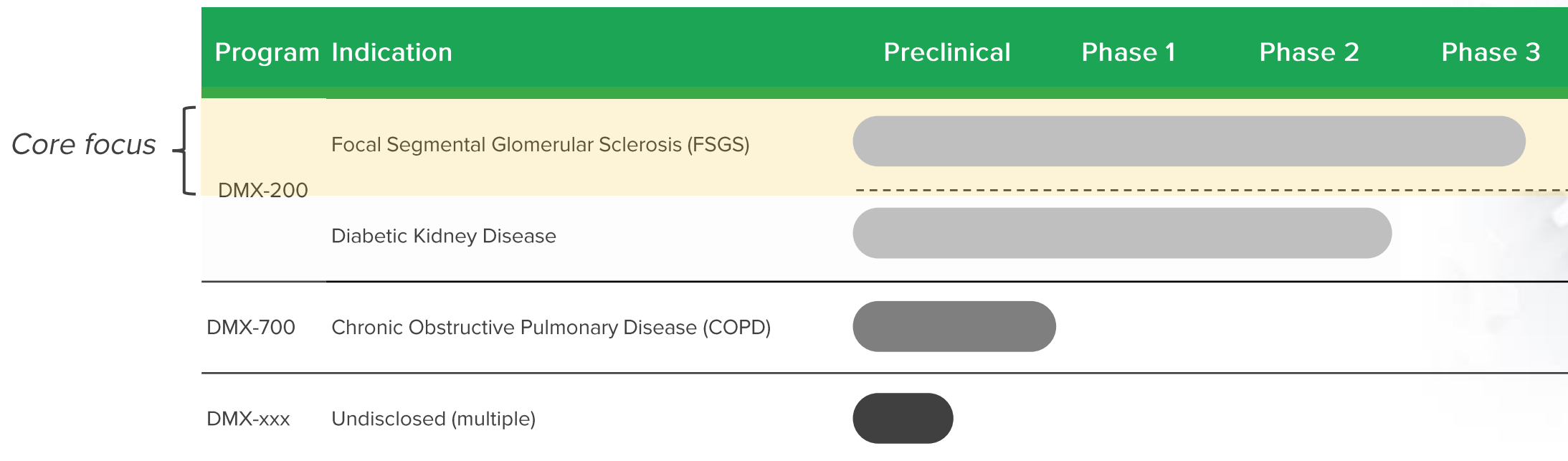
Monash, MDGH, Avecheo

- Experienced pharmaceutical executive in BD & corporate development, regulatory, project management, clinical & research development strategy
- Led multidisciplinary R&D teams for over 14 years
- ✓ BSc (Hons) – Genetics
- ✓ PhD – Molecular Immunology
- ✓ MBA – Business and leadership

Neuren, Prota, Acrux, Hospira, CSL

- 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

Development pipeline



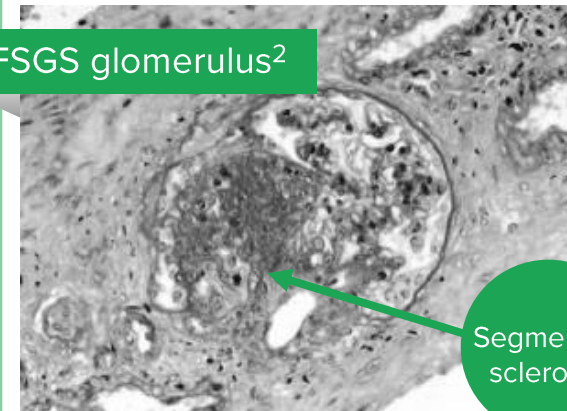
What is Focal Segmental Glomerulosclerosis (FSGS)?

- 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 diseases¹
- On average FSGS progresses to kidney failure within 5 years after onset of proteinuria¹
- Caused by a variety of conditions - primary FSGS, genetic FSGS, FSGS of unknown cause and secondary FSGS³
- 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)⁴
 - Patients requiring kidney transplant (est cost US\$442,500 per transplant + ongoing medication fees)⁵
 - 60% patients have reoccurring FSGS even after first kidney transplant⁶

Normal glomerulus²



FSGS glomerulus²



Segmental sclerosis

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

FSGS market size


 FSGS 7MM market size estimated to be **US3b** p.a¹

- ▶ Assuming US\$9,900k/month as example pricing in the US (same pricing as sparsentan in IgAN)²
- ▶ Current market specifically for FSGS does not exist

FSGS Market Size		
Region	Estimated diagnosed patients (2022)	\$US p.a (2032)
US	85,342 ¹	US\$2.05 billion ¹
EU/UK	85,014 ¹	US\$990 million ¹
Japan	32,644 ¹	US\$225 million ¹
China	>100,000 ⁴	US\$2.8 billion ³

7 major markets (MM)

Only one therapy in phase 3 development

- Sparsentan failed phase 3 endpoint for use in FSGS – (01May2023 US time)
 - Sparsentan recently approved for Immunoglobulin A Nephropathy (IgAN), another rare form of kidney disease
 - Carries a black box safety warning for liver and foetal toxicity
- DMX-200 demonstrated clean safety profile in prior studies

Phase 3 drug candidates for FSGS treatment

Study	Drug candidate	Mode of action	Comparator	Primary interim (accelerated approval) endpoint	Patent /exclusivity	DMX-200 benefit
ACTION3 ¹	DMX-200	CCR2 inhibitor	Placebo	% change in uPCR and eGFR slope at week 35	Exclusivity 7-10 years ³ Granted method of use patents to 2032 ⁴	<ul style="list-style-type: none"> Strong safety profile Proven efficacy
DUPLEX ²	Sparsentan	AT ₁ R/ET _A R antagonist	Irbesartan	Proportion of patients achieving uPCR ≤ 1.5g/g and >40% reduction from baseline uPCR at week 36	Exclusivity 7-10 years ³ Granted method of use patents to March 2030	<ul style="list-style-type: none"> IgAN product label includes black box safety warning for liver and foetal toxicity Data suggests DMX-200 may be complementary

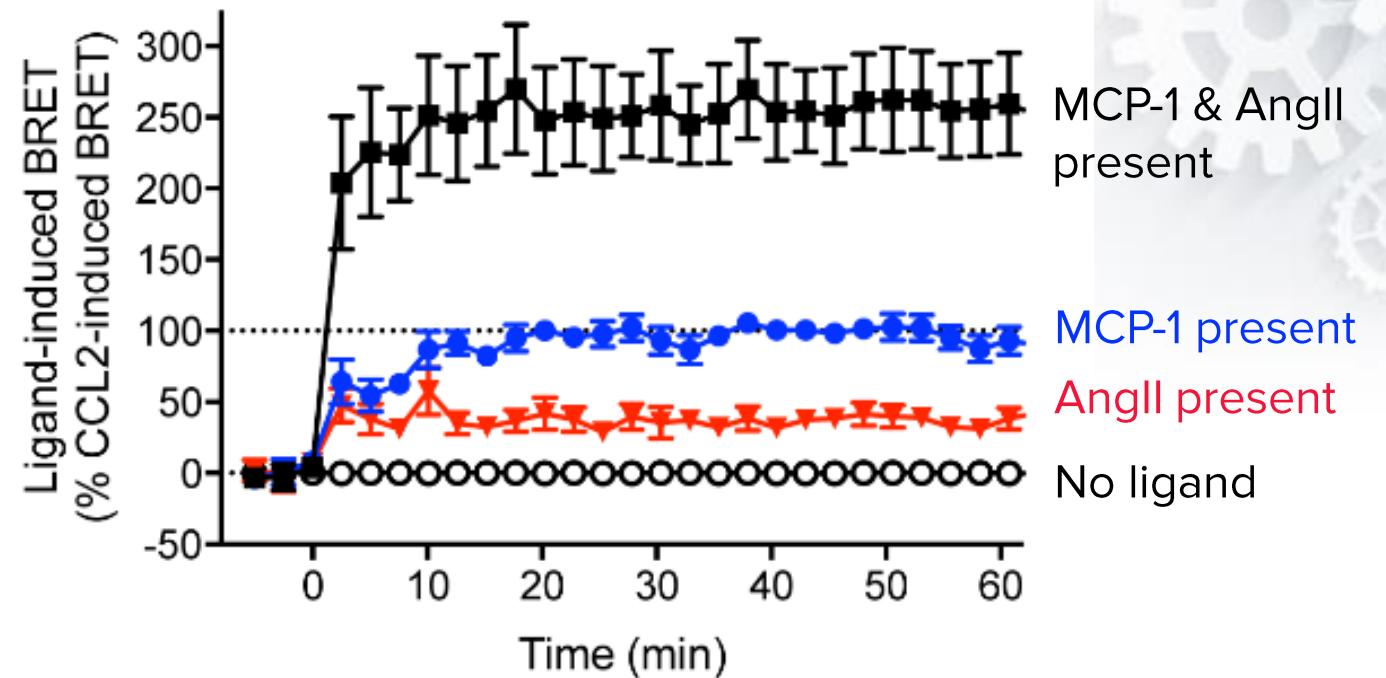
- Sparsentan failed phase 3 endpoint⁵ – noting different target, different mechanism of action, different study design

DMX-200 inhibits AT1R and CCR2 heteromers

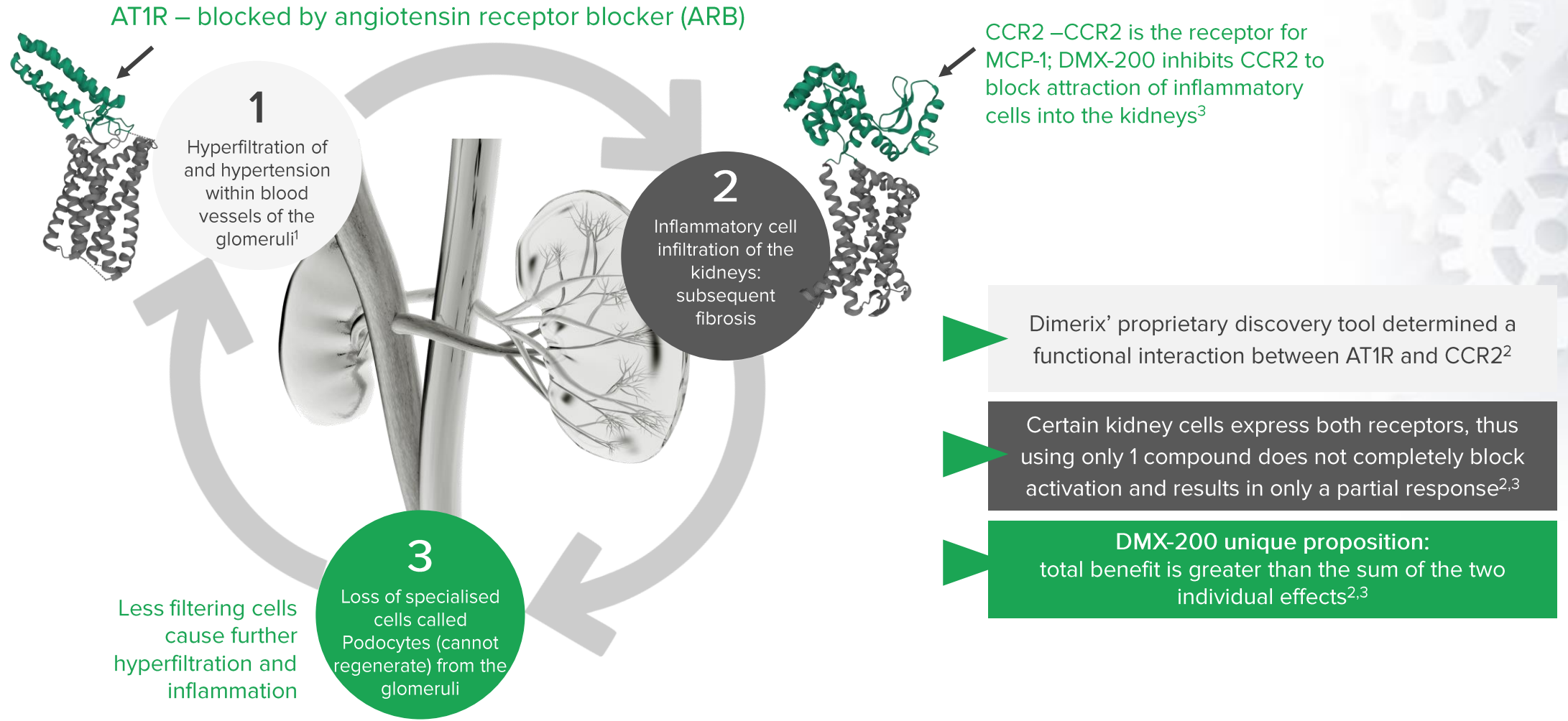
Unique pharmacology of AT1R/CCR2 heteromer

Proprietary discovery platform (Receptor-HIT) identified:

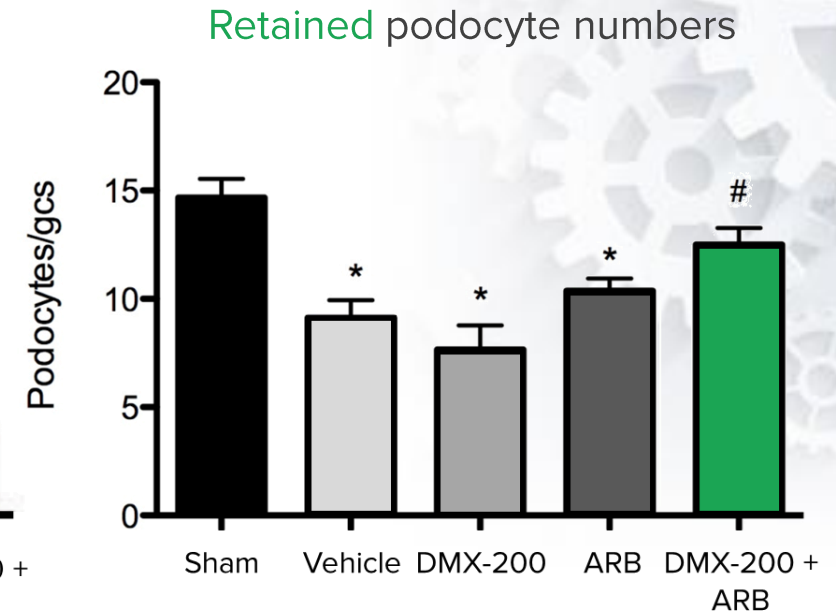
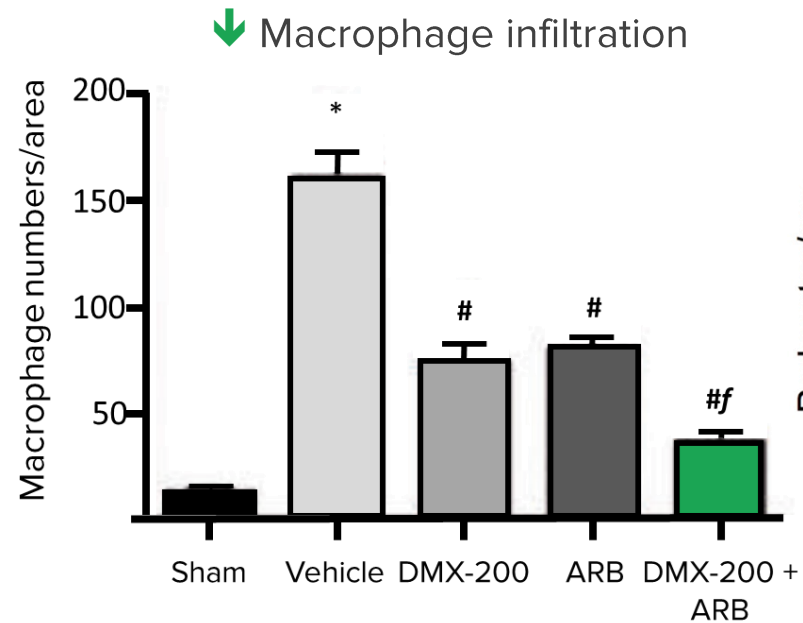
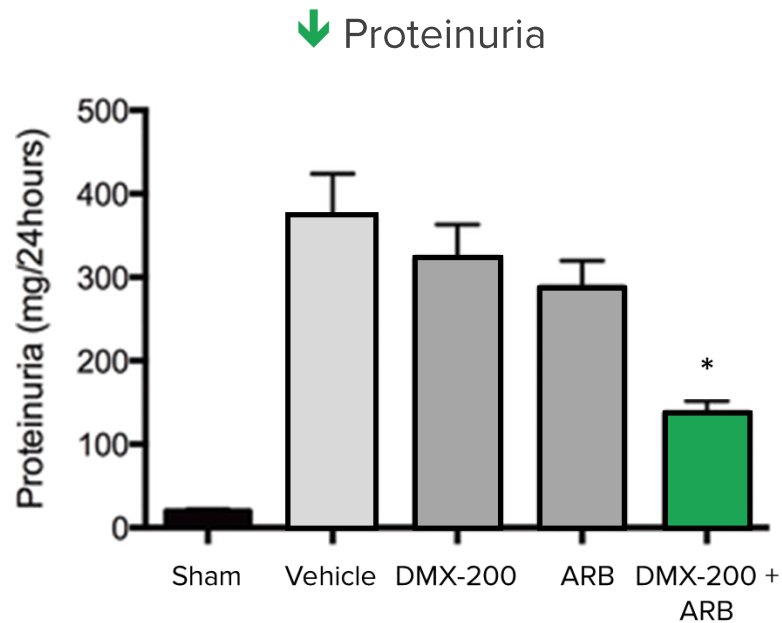
- Formation of AT1R and CCR2 heteromers;
- Novel pharmacology (potentiation of signaling)
- Dual antagonism required for completed inhibition



3 key mechanisms that cause sclerotic kidney disease



DMX-200 reduces proteinuria in an animal model



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

DMX-200 clinical experience



Phase 1 study (DMX-200-101)

- Healthy volunteers
- Pharmacokinetic, metabolism & safety clinical study



Phase 2a study (DMX-200-201)

- Chronic Kidney Disease
- Safety and tolerability study, with efficacy endpoints included



Phase 2 study (DMX-200-203)

- Diabetic kidney disease
- Efficacy and safety endpoints



Phase 2a study (DMX-200-202)

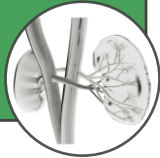
- Focal Segmental Glomerulosclerosis
- Safety and efficacy endpoints

- Positive efficacy signals across studies
- 240mg oral delivery daily (1 x 120mg capsule administered twice daily)
- Consistently safe and well tolerated in both healthy volunteers and renal patients (>100 patients dosed)
- Consistent data collectively leading to DMX-200 future development

DMX-200 FSGS Phase 2a met clinical study endpoints

- 6/7 patients demonstrated reduced proteinuria on DMX-200 versus placebo
- 2/7 of patients demonstrated >40% reduction in proteinuria

Efficacy



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

Safety



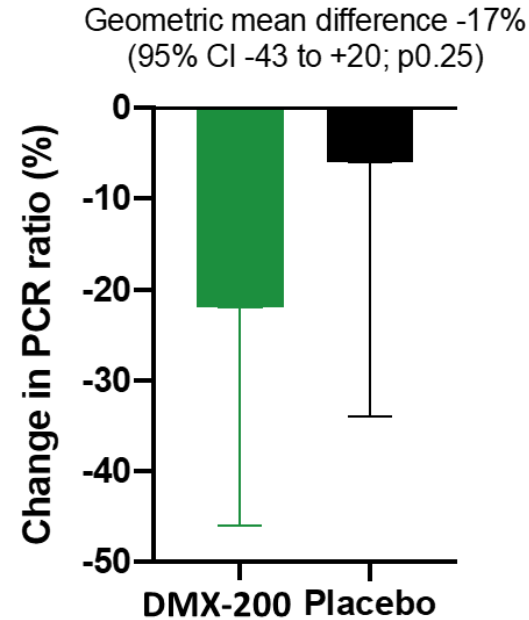
- 17% reduction of uPCR in addition to ARB: mixed model, repeat measures statistical test; (grouped analysis model shows a 25% drop in uPCR)

Clinically Meaningful

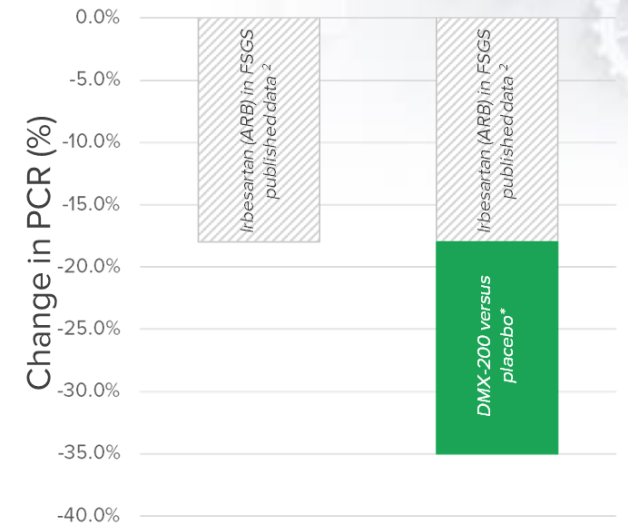


- Results comparable to other compounds in development
- DMX-200 may be complementary to other development compounds, such as sparsentan

Competitive

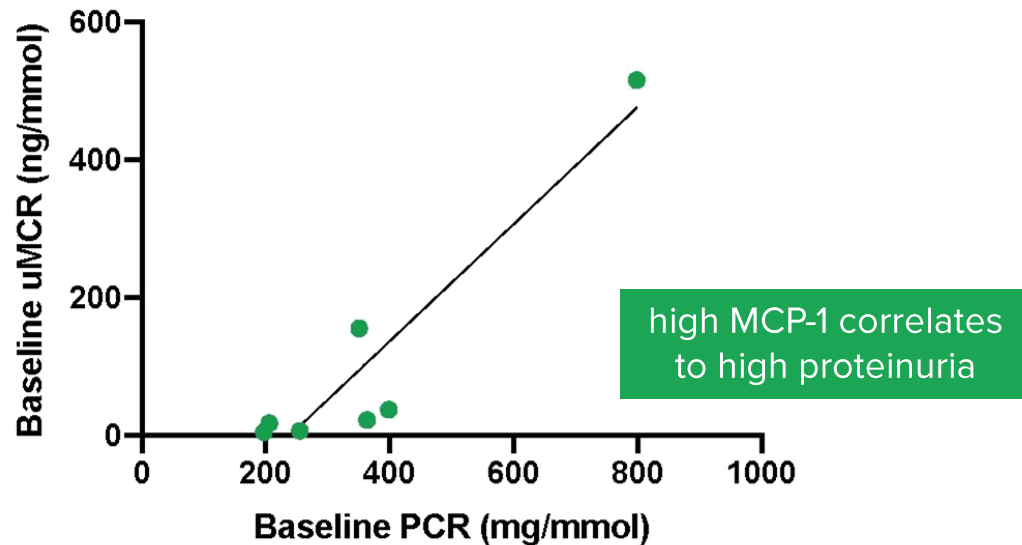


Average reduction in proteinuria after 16 weeks treatment on DMX-200 versus placebo compared to standard of care alone in FSGS patients¹

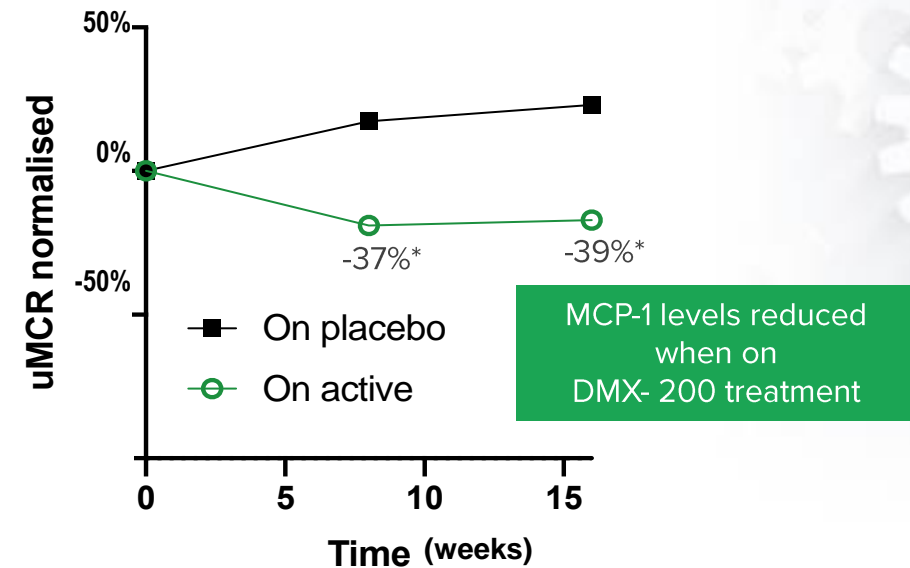


DMX-200 Phase 2a effect on inflammatory biomarker

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

ACTION3 Phase 3 clinical trial status

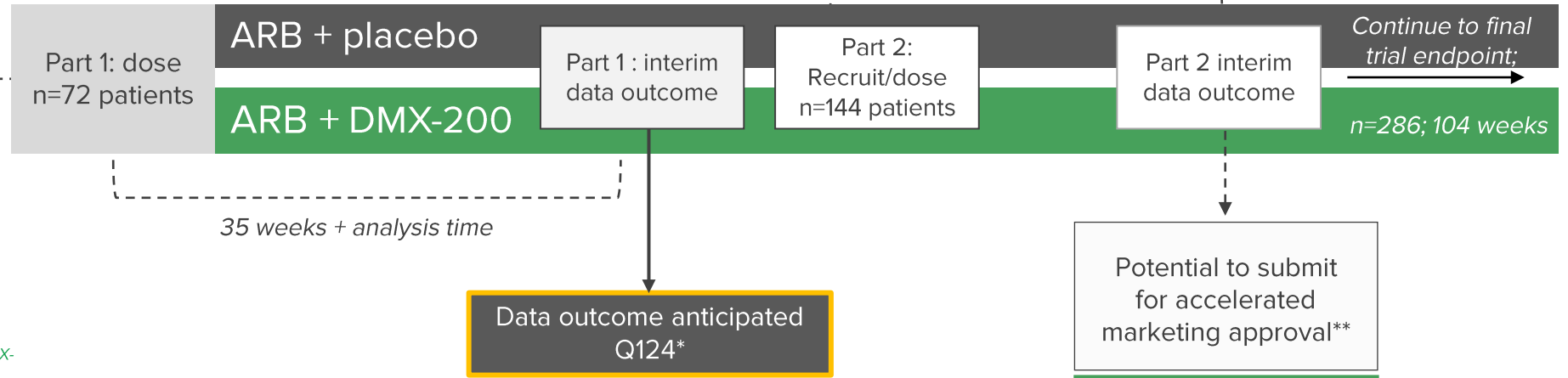
FSGS CLINICAL STUDY

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

Initiate clinical sites Part 1

Recruit 72 patients Part 1

Screening (2-4 wks) and stabilisation (4-6 wks) of background medication



Part 1: global study recruiting across ~70 sites in 11 countries:

- Geographically diverse to meet differing regulatory requirements;



Part 2: additional countries and sites will open following Part 1 outcome

- Increases recruitment potential
- Increases commercial opportunity in each territory



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>

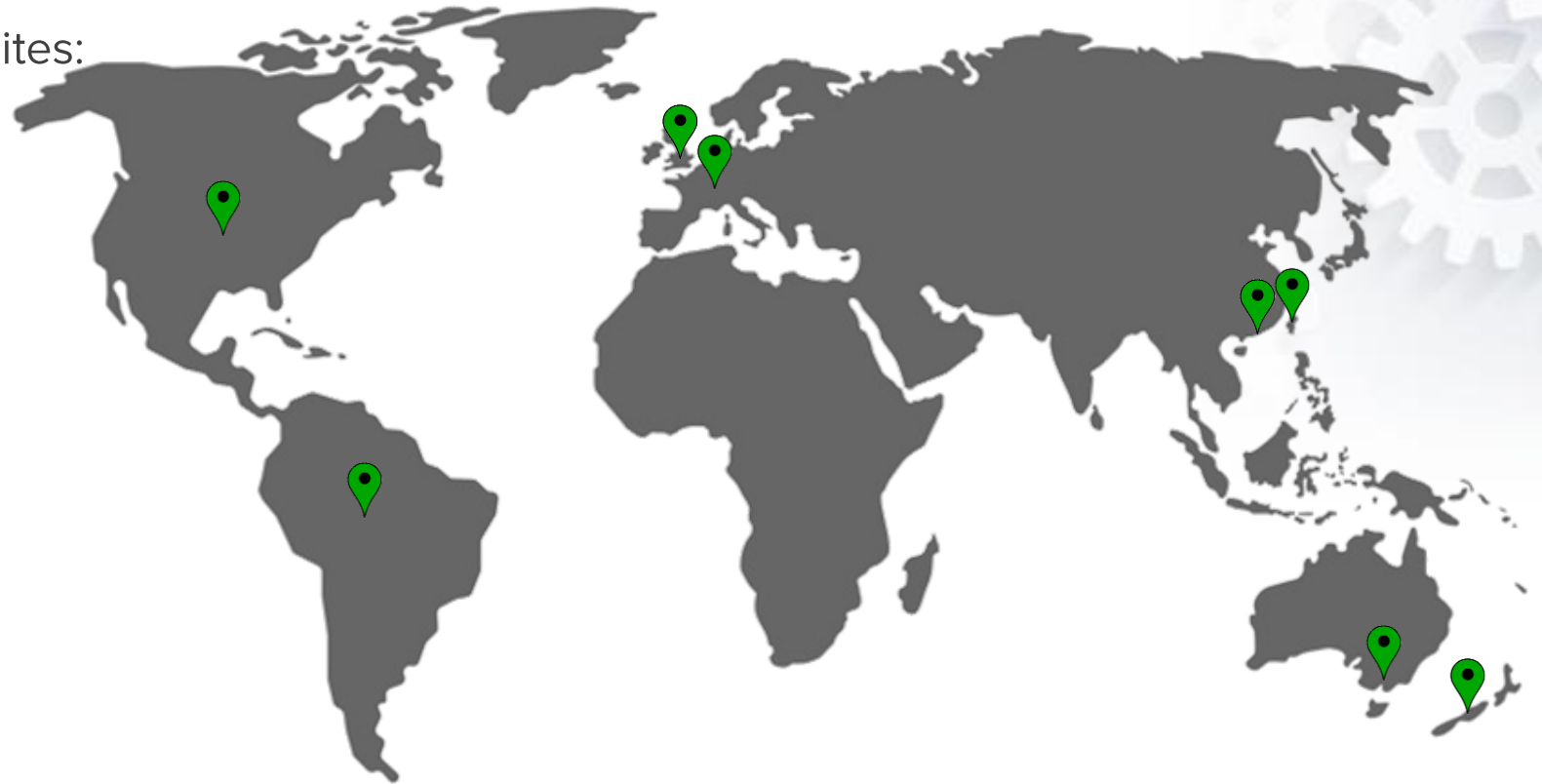
ACTION3 Existing Part 1 site locations

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

Global study recruiting across ~70 sites:

- Australasia: 9 sites
- Asia: 9 sites
- Europe: 18 sites
- Latin America: 11 sites
- UK: 6 sites
- USA: 20 sites

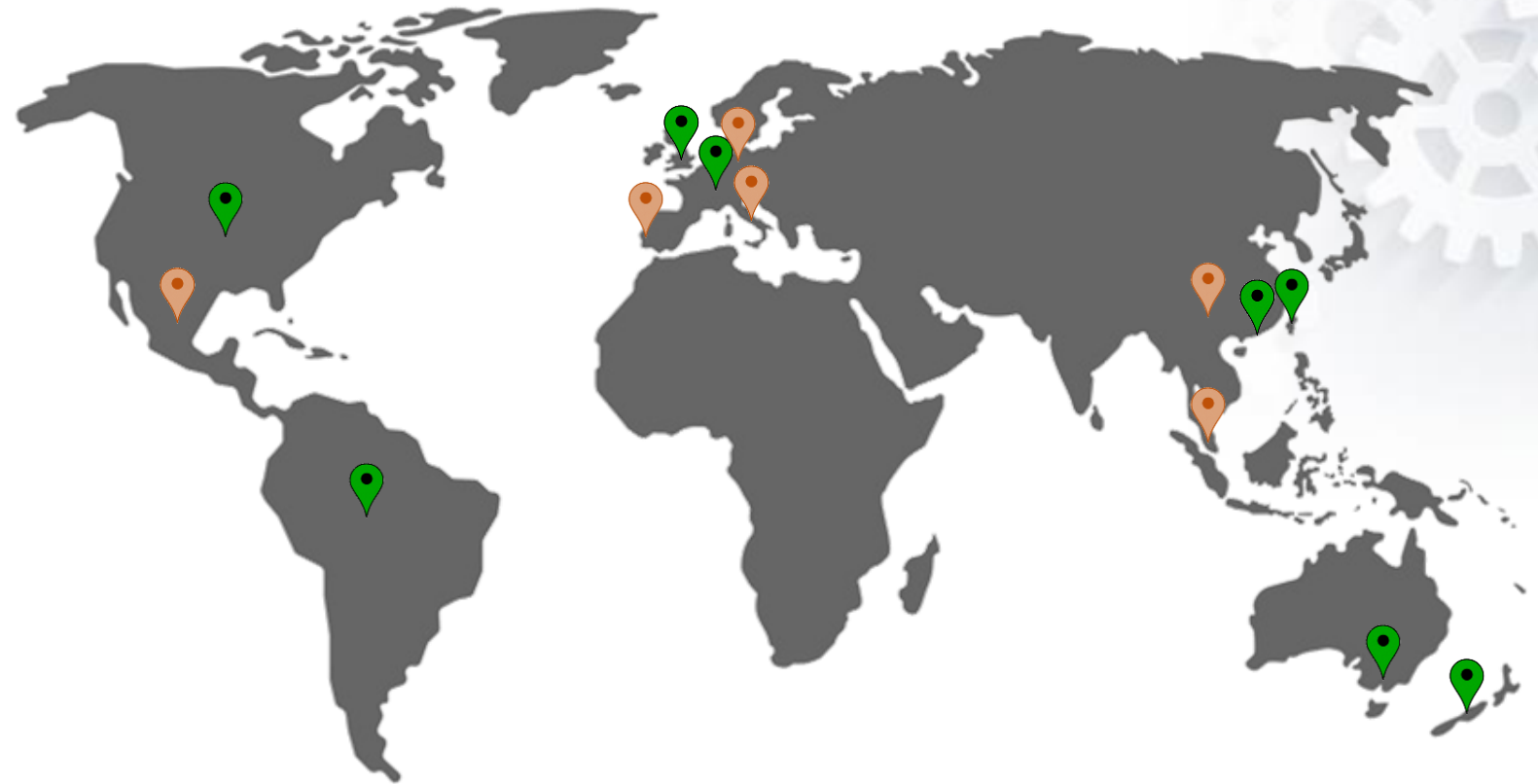


Planned Part 2 additional site locations

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

New countries planned for Part 2:

- China
- Malaysia
- Mexico
- Portugal
- Germany
- Italy



Intellectual property and exclusivity

