



Immediate Release

DIMERIX PRESENTS AT EUROZ HARTLEY HEALTHCARE FORUM

MELBOURNE, Australia, 06 February 2024: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company with late-stage clinical assets, is pleased to advise that CEO and Managing Director, Dr Nina Webster, will be presenting at the Euroz Hartley Healthcare Forum in Perth, WA on 06 February 2024.

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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Dimerix is a biopharmaceutical company developing innovative new therapies in areas with unmet medical needs.

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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 study in patients with a range of chronic kidney diseases in 2017. No significant adverse safety events were reported in any study, 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 40% 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.

FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,³ and worldwide about 210,000. The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year³. Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for FSGS. 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.

References

- 1 Guruswamy Sangameswaran KD, Baradhi KM. *Focal Segmental Glomerulosclerosis* (July 2021), online: <https://www.ncbi.nlm.nih.gov/books/NBK532272/>
- 2 *DelveInsight Market Research Report (2020); Focal Segmental Glomerulosclerosis (FSGS)- Market Insight, Epidemiology and Market Forecast -2030*
- 3 *Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis*, online <https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/>



Dimerix

(ASX:DXB)

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

February 2024

Euroz Hartley Annual Conference



ACTION3
FSGS CLINICAL STUDY

Authorised for lodgement by the Board of the Company

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.

Phase 3 opportunity

1st outcome in March 2024

Lead Drug Candidate – DMX-200 in focal segmental glomerulosclerosis (FSGS)

Phase 2 **met primary** and secondary endpoints

Near term Phase 3 analysis outcome announced (**~15Mar24**)

Clear **commercialisation** pathway

Market Opportunity

Estimated >3b global market size p.a⁴ – 203,0004 patients across 7MM at example US pricing of US\$120,000 p.a.⁵



Intellectual Property

Orphan Drug status providing protection through **data exclusivity**³ for min 7-10 years, in addition to **comprehensive patent/IP strategy**

Commercialisation

Existing commercial **partnership** (EU, CA, AU, NZ) up to **\$230 million* + royalties**

Continued and progressed **partnering negotiations** with parties outside licensed territories²

Outlook

High unmet need, with no approved products, giving potential for **significant value**⁴ upside

Clear goals

1

Product development and commercialisation

- Complete Phase 3 clinical trial in FSGS (including clinical, non-clinical manufacturing, IP, quality and regulatory)
- Attract additional partners to:
 - Realise inherent value in existing assets
 - Provide early revenue and risk management to Dimerix via upfront/milestone payments and royalties






2

Next stage of growth

- Expand product portfolio
- Reach sound company valuation based on valuable product portfolio and commercialisation
- Expand talent pool



Corporate overview

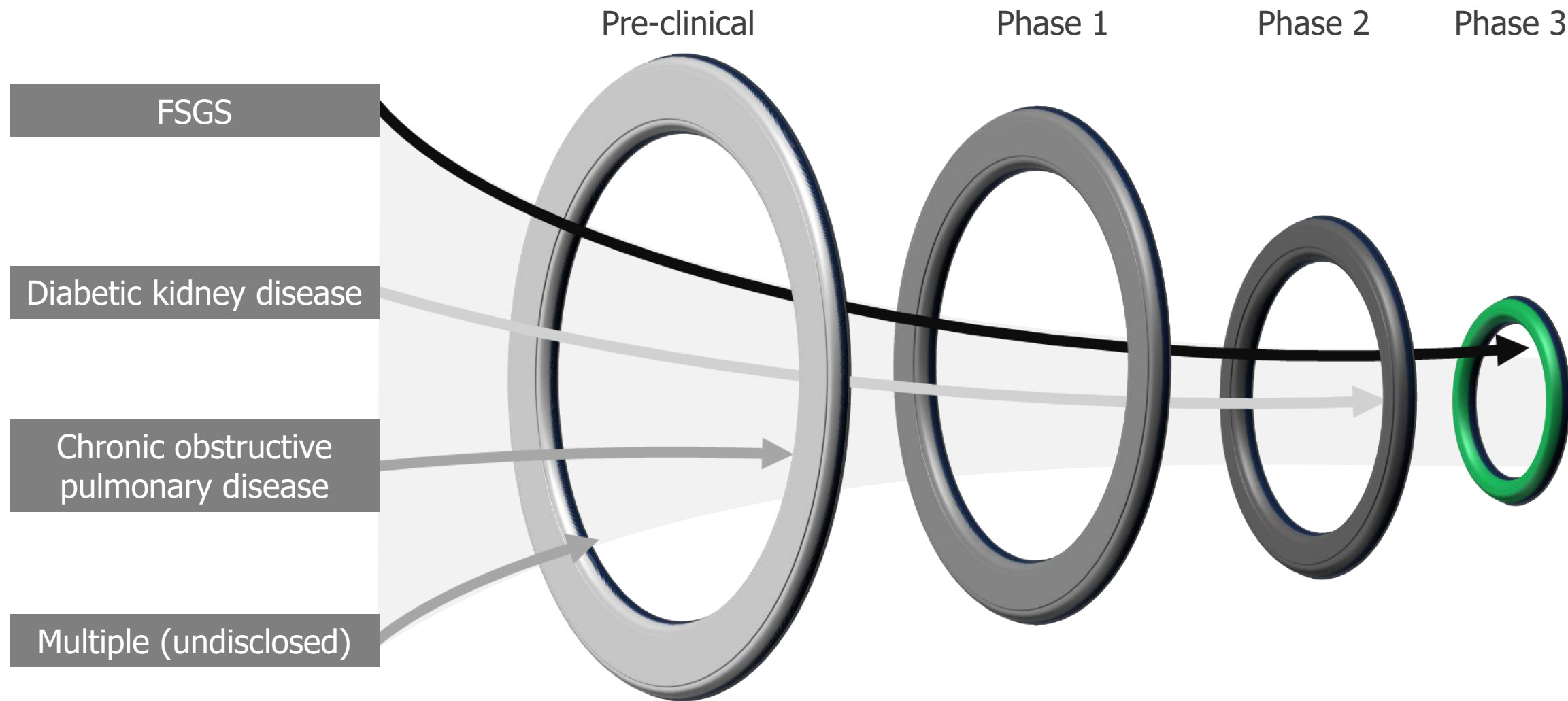
 ASX	Ticker Symbol	ASX:DXB
	Cash Balance (Dec23)	~A\$14.8 million
	Market Capitalisation	~A\$95 million
	Share price	~A\$0.22
	Total ordinary shares on issue	434,357,229



SHAREHOLDERS¹

	Holder Name	Holding	
1	Mr P Meurs	64,929,440	15.0%
2	Mr A & Mrs M Coates	11,606,500	2.7%
3	P & J Scott	8,000,000	1.8%
4	Mercer Street Global Opportunity Fund LLC	7,564,362	1.7%
5	Bavaria Bay Pty Ltd	7,316,992	1.7%
TOTAL (TOP 5)		99,417,294	22.9%

Development pipeline



Benefits of targeting orphan diseases



Orphan designation used by regulators to incentivise companies to develop new drugs for rare diseases

- Very little new drug development in rare kidney diseases over last 30 years

Commercially attractive pricing structure for orphan drugs

- ~US\$84,000p.a average orphan drug price in 2018¹
- ~US\$120,000p.a average price for other rare kidney treatments² (US\$9,900 for recently approved Sparsentan in treatment of IgAN)

Marketing exclusivity period without generic competition or challenge

- 7 years in US
- 10+ years in EU

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

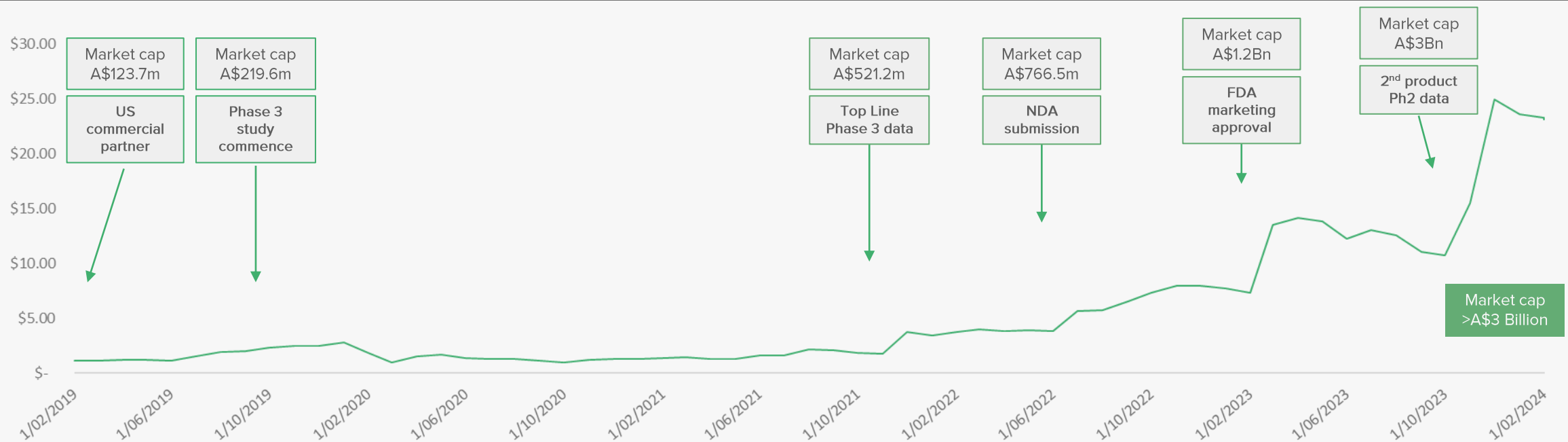
- Paediatric population to be included in Part 2 of Phase 3 trial³

Collaboration from global regulators including FDA

- Feedback and assistance designing Phase 3 trial⁴
- Design of overall 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\$375,000¹ and 5,000 diagnosed patients p.a¹



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), requiring dialysis or transplant

0

Approved drugs anywhere in the world

60%

Patients have reoccurring FSGS even after first kidney transplant⁶

5

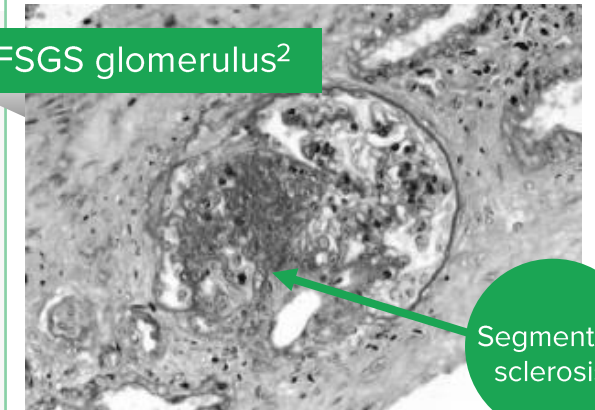
Average time (years) to kidney failure after onset of proteinuria¹

- ▶ Caused by a variety of conditions - primary FSGS, genetic FSGS, FSGS of unknown cause and secondary FSGS³
- ▶ Prevalence of FSGS³ growing due to increase in:
 - Diabetes
 - Obesity
 - Ageing population
- ▶ 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

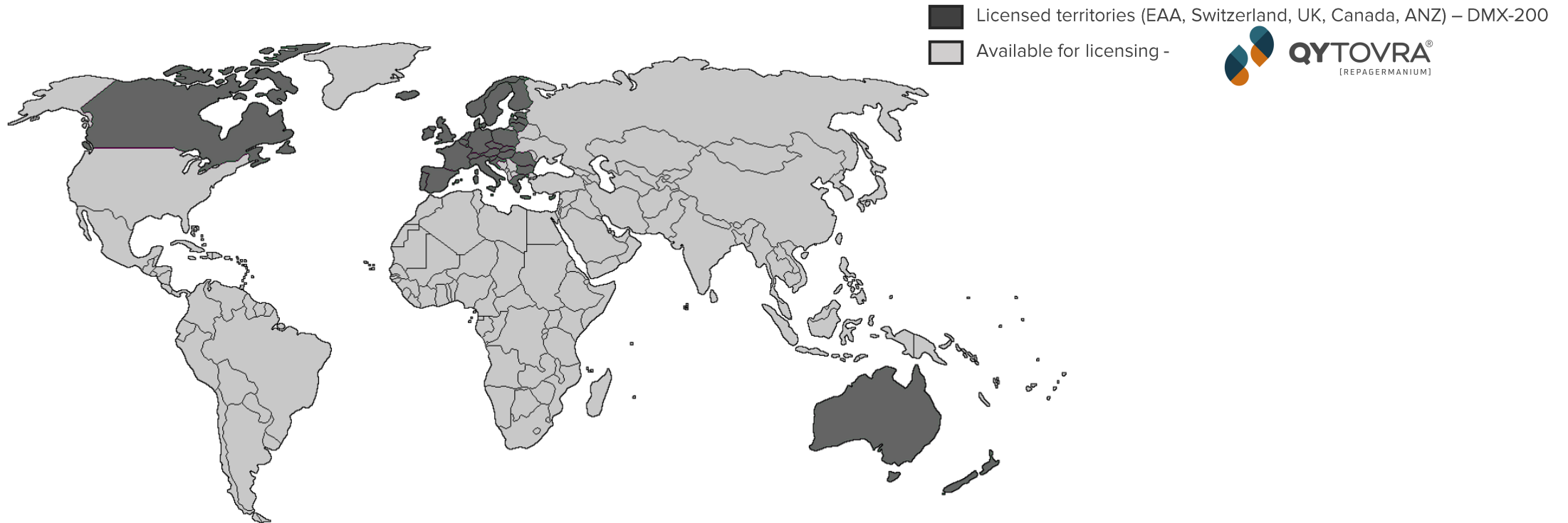


FSGS glomerulus²



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

Global partnering availability



• Licensing deal marks the first of potentially several agreements globally



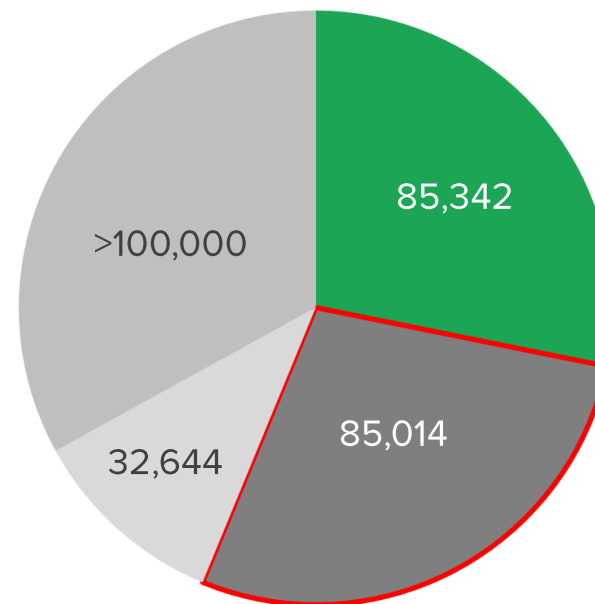
• Partnering discussion progressing in other territories

FSGS forecast market size

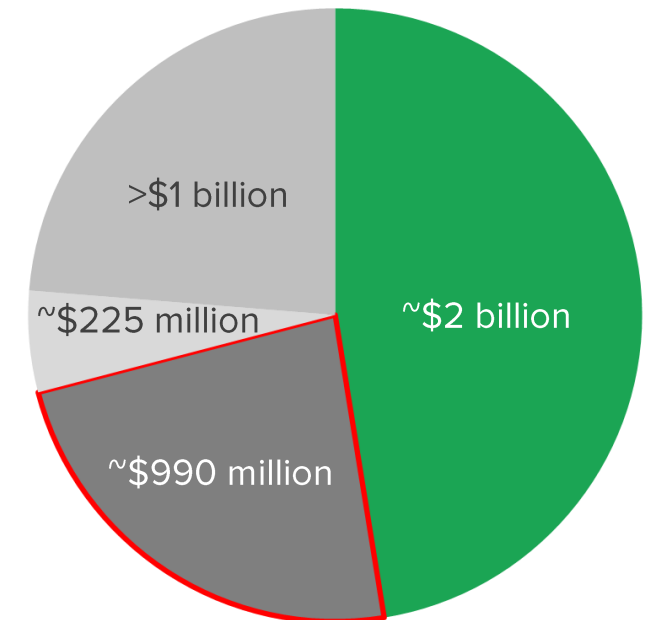


- ▶ Assuming US\$9,900k/month as example pricing in the US (same pricing as sparsentan in IgAN)²
- ▶ Current market specifically for FSGS does not exist

Estimated diagnosed patients (2022)^{1,3}



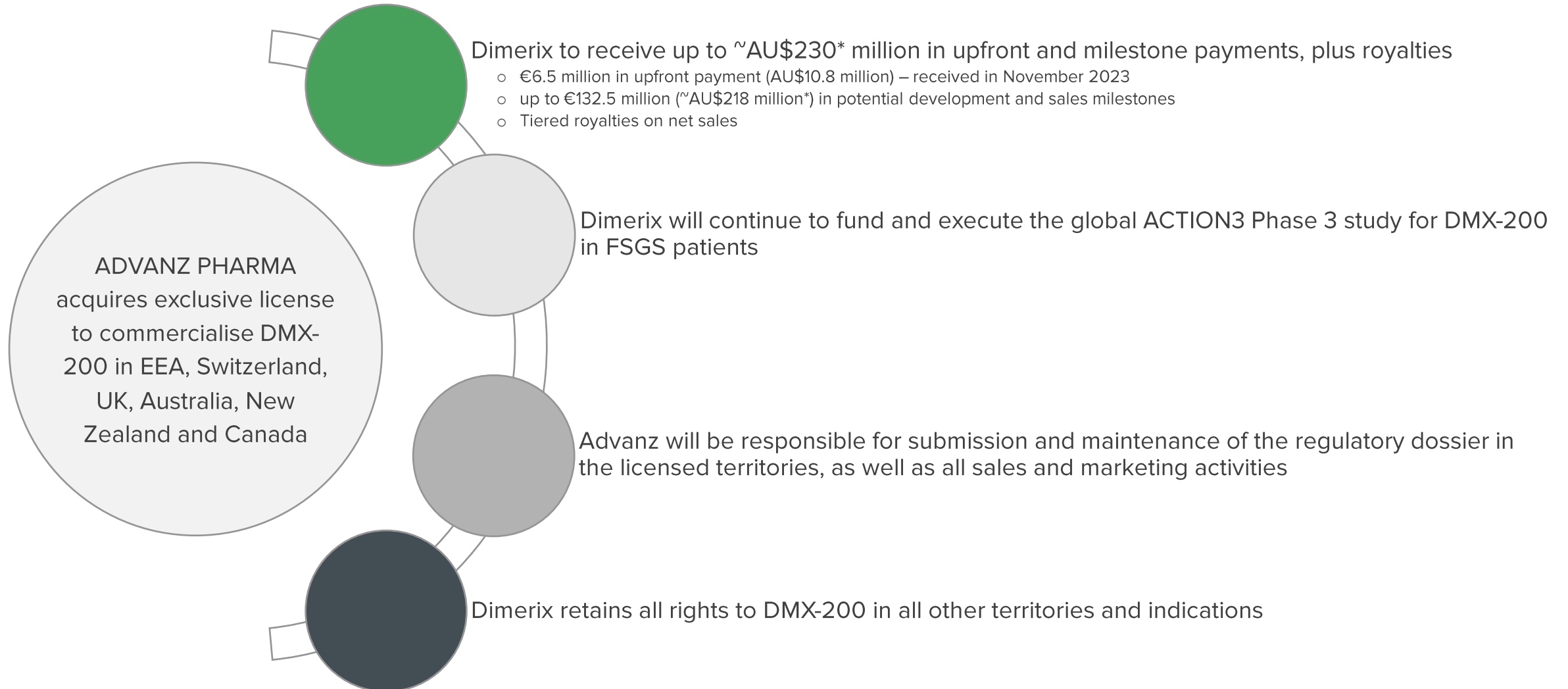
\$US p.a (e2032)^{1,4}



7 Major Markets

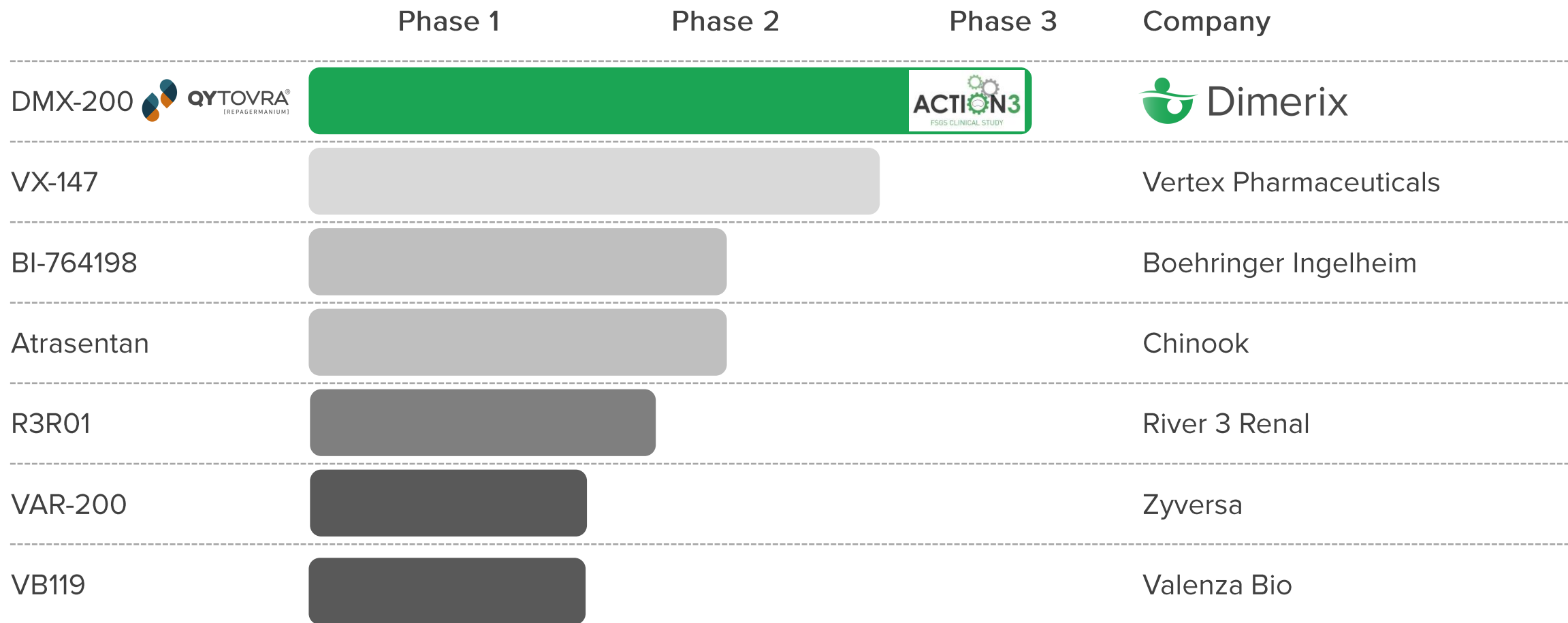


Key elements of **ADVANZ PHARMA** partnership



Competitive landscape in FSGS

DMX-200 is the only therapy in phase 3 development

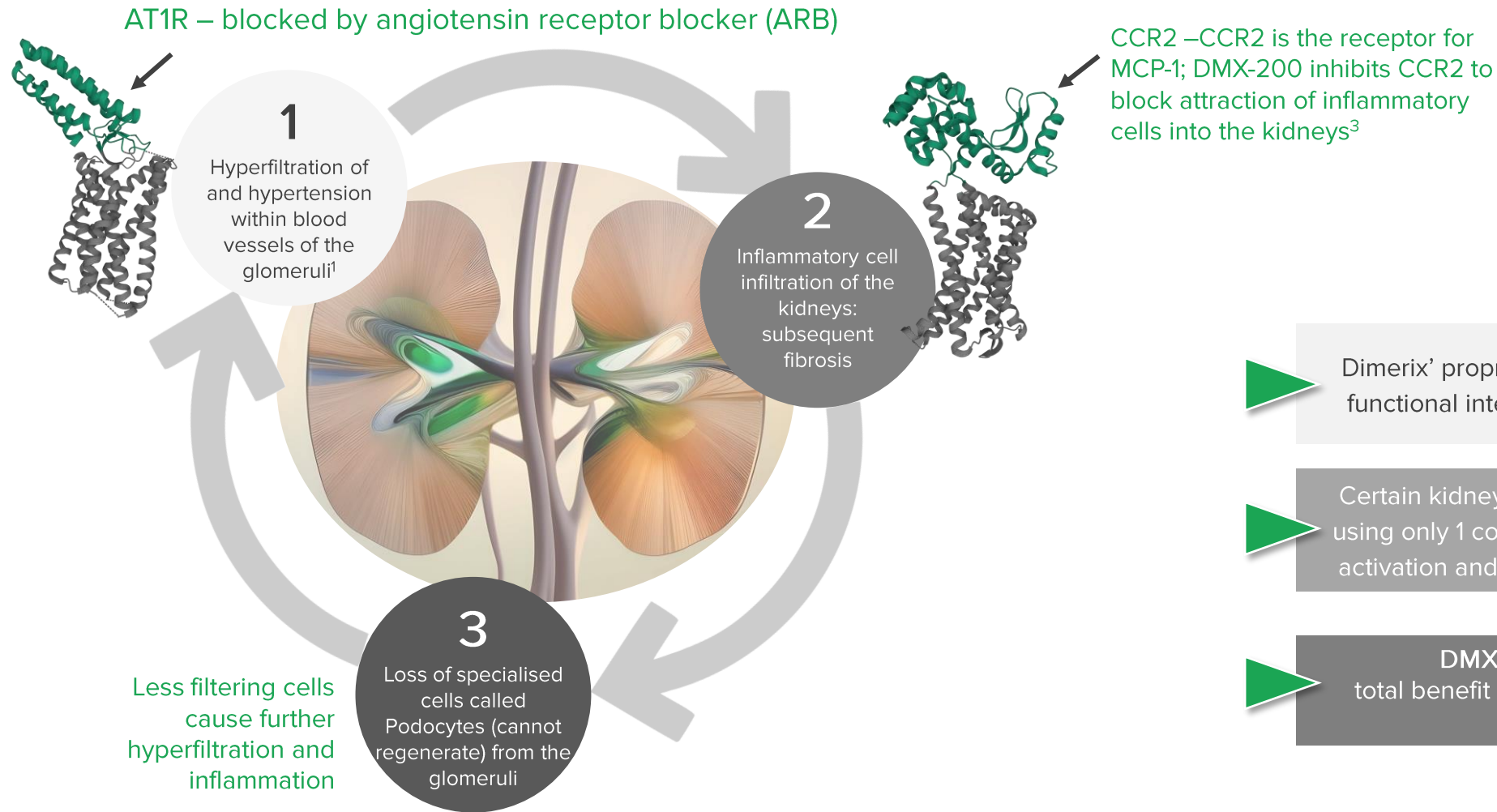


PHASE 3 CLINICAL TRIAL

ACTION3
FSGS CLINICAL STUDY



3 key mechanisms that cause sclerotic kidney disease



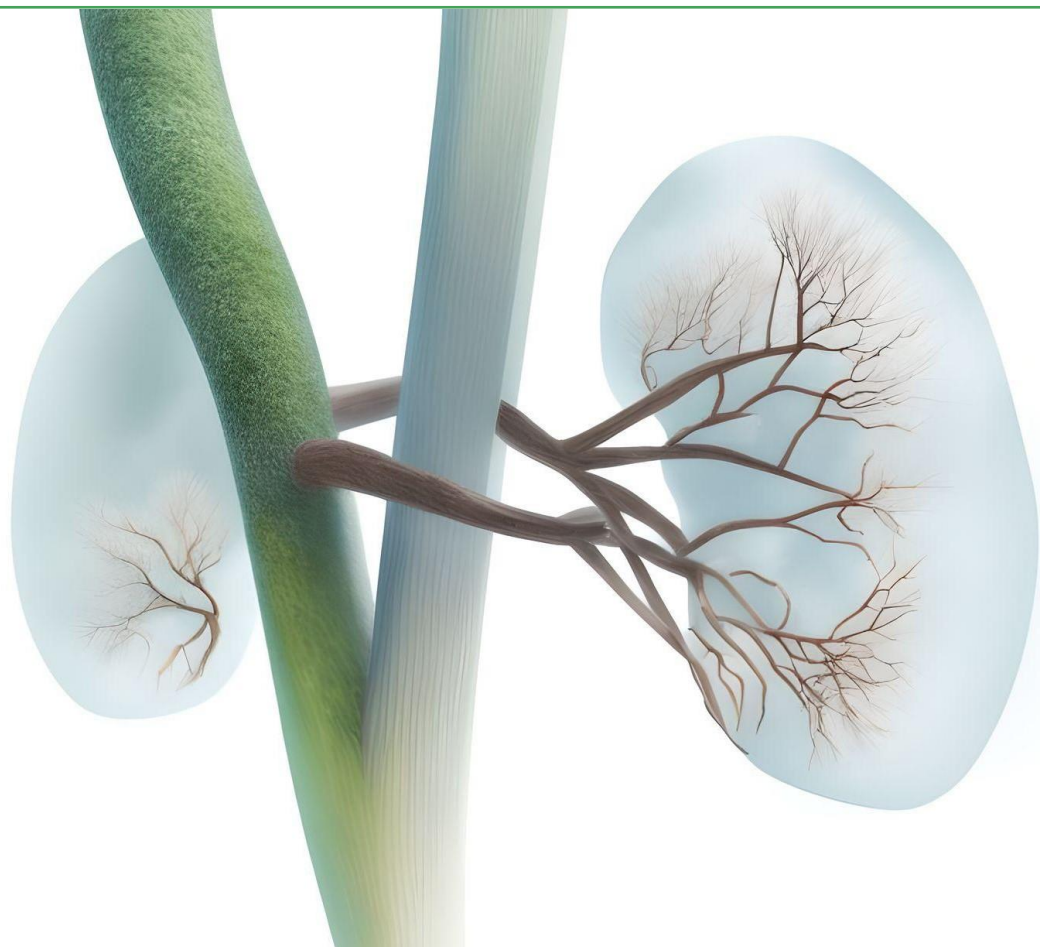
Dimerix' proprietary discovery tool determined a functional interaction between AT1R and CCR2²

Certain kidney cells express both receptors, thus using only 1 compound does not completely block activation and results in only a partial response^{2,3}

DMX-200 unique proposition:
total benefit is greater than the sum of the two individual effects^{2,3}

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)¹; open IND in US¹ and China², and granted patents/applications across key countries

Small molecule

2 x 120mg capsule daily



Easy & convenient dosing

Consistently safe and well tolerated in both healthy volunteers and renal patients (total of 95 patients dosed)³



Strong safety profile⁴

4 clinical studies completed to date: positive efficacy signals across studies³



Proven efficacy⁴

DMX-200: Phase 2 met primary and secondary endpoints



Clinically meaningful outcomes for patients



EFFICACY

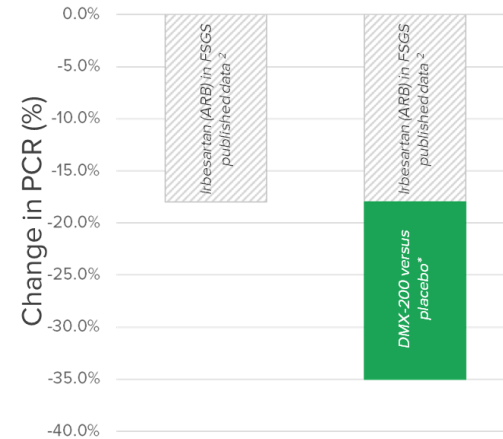
- 86% of patients demonstrated reduced proteinuria on DMX-200 versus placebo
- 29% of patients demonstrated >40% reduction in proteinuria
- MCP-1 levels reduced by 39% when on DMX-200 treatment



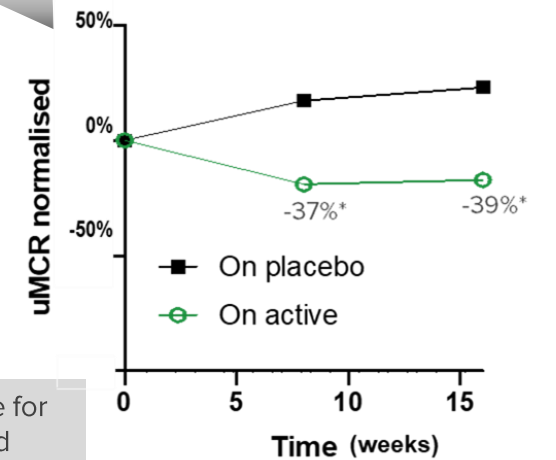
SAFETY

- No safety concerns – reduced development risk
- DMX-200 compares favourably to compounds currently in development^{2,3}

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



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

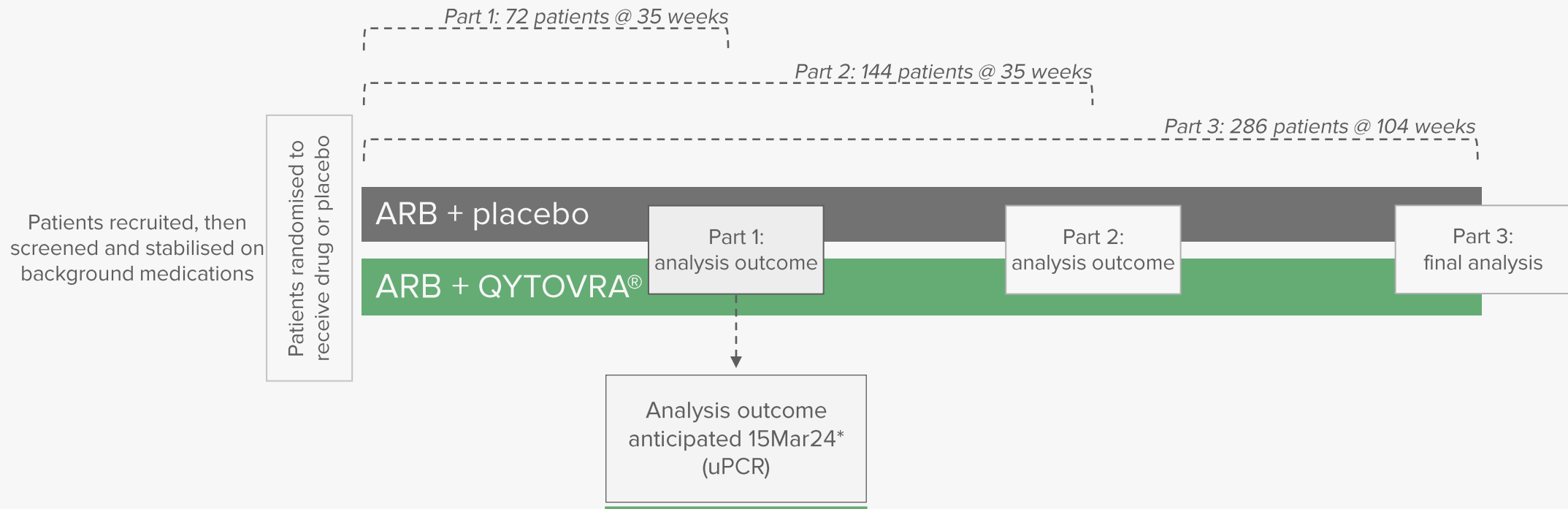


DMX-200 blocks receptor responsible for inflammation - translates to reduced inflammation and subsequent fibrosis (scarring) in the kidney

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



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



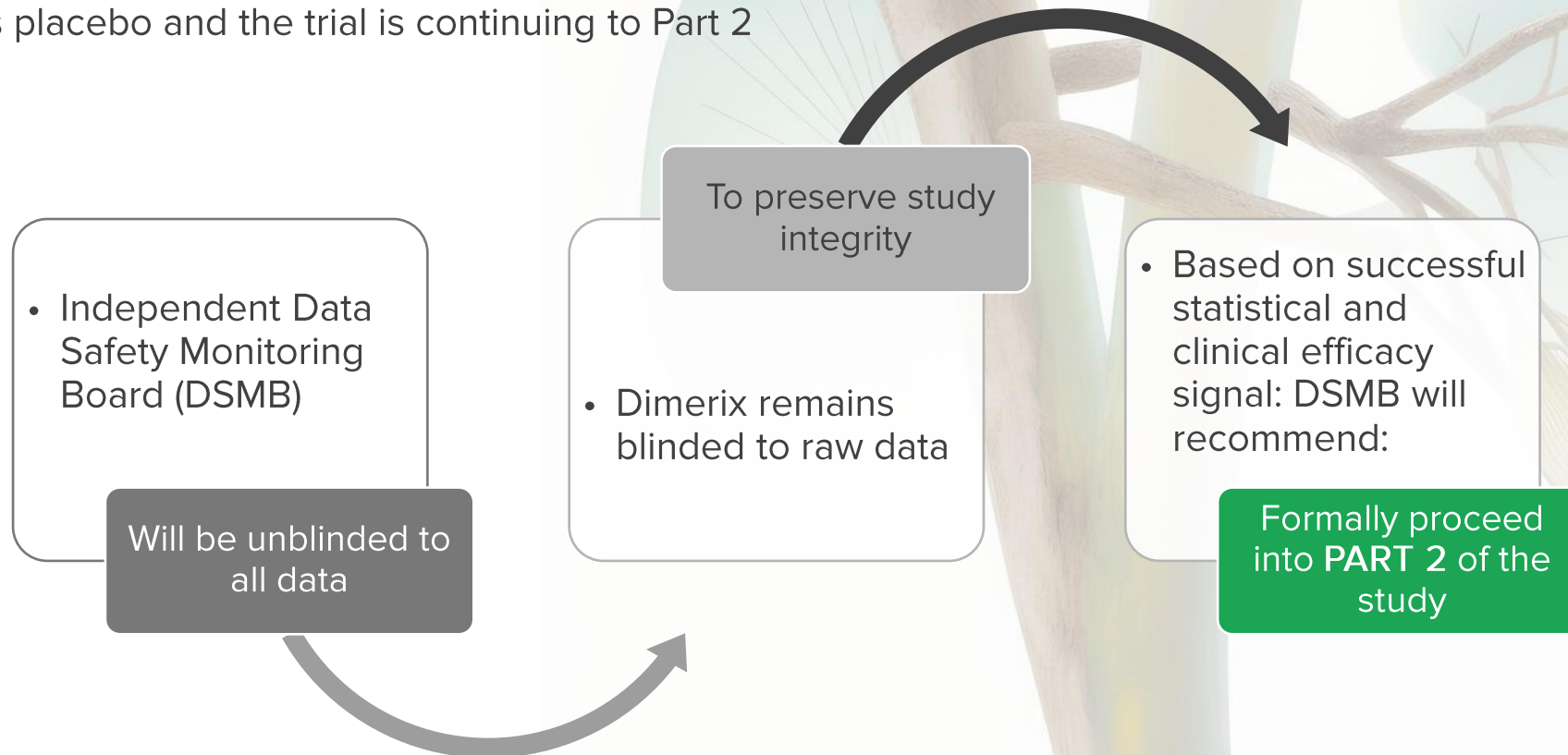
- Part 1 recruiting at 70 sites:
 - Australia, New Zealand
 - Taiwan, Hong Kong
 - France, Denmark, UK, Spain
 - Argentina, Brazil
 - USA
- Part 2 new countries:
 - China
 - Malaysia
 - Italy, Germany, Portugal
 - Mexico



ACTION3 Part 1 analysis set for March 2024

FSGS CLINICAL STUDY

- Announcement of Part 1 analysis of Phase 3 trial expected on, or around, 15 March 2024*
- A successful outcome of the first analysis would represent a clinically and statistical meaningful improvement in proteinuria vs placebo and the trial is continuing to Part 2



Late stage, phase 3 clinical development asset

Lead Drug Candidate – DMX-200 in focal segmental glomerulosclerosis (FSGS)

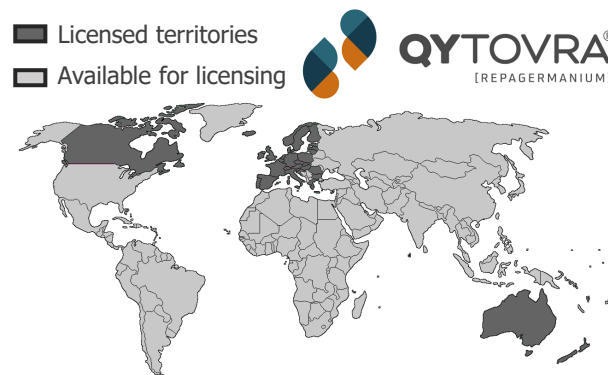
Phase 2 **met primary** and secondary endpoints

Near term Phase 3 analysis outcome announced (~15Mar24¹)

Clear **commercialisation** pathway

Market Opportunity

Estimated >3b global market size p.a.³ – 203,0004 patients across 7MM at example US pricing of US\$120,000 p.a.⁵



Intellectual Property

Orphan Drug status providing protection through **data exclusivity**³ for min 7-10 years, in addition to **comprehensive patent/IP strategy**

Commercialisation

Existing commercial **partnership** (EU, CA, AU, NZ) up to **\$230 million* + royalties**

Continued and progressed **partnering negotiations** with parties outside licensed territories²

Outlook

Strong outlook with **potential for significant value**³ upside



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.



WELL POSITIONED TO DELIVER AGAINST STRATEGIC PLAN



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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.



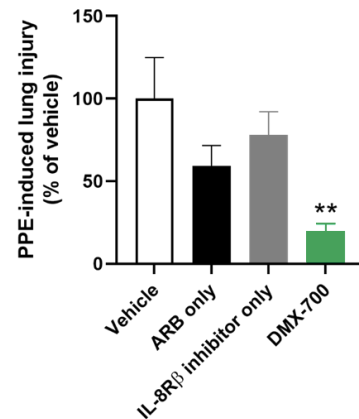
APPENDIX

Advancing the broader pipeline

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

DMX-700 for Chronic Obstructive Pulmonary Disease (COPD)

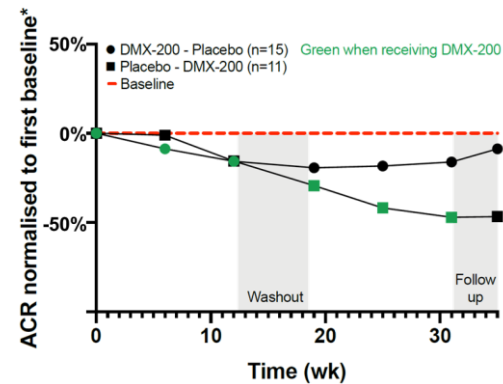
Preclinical studies show that DMX-700 significantly reduced lung injury by 80% ($p < 0.01$) after 21 days treatment¹



Pre-clinical asset

DMX-200 for Diabetic Kidney Disease

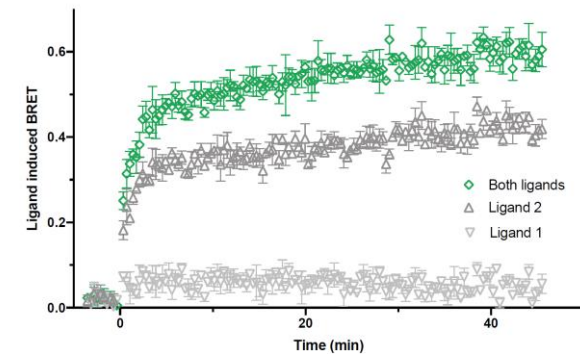
Phase 2 demonstrated promising efficacy & safety², proteinuria declined after treatment with DMX-200 in both treatment periods²



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

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