



Dimerix

(ASX:DXB)



ACTION3
FSGS CLINICAL STUDY

12 March 2024

Phase 3 Interim Analysis Investor Webinar

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

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

Successful interim analysis

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



ACTION3 Phase 3 trial **successfully passes first interim analysis** using proteinuria efficacy endpoint



DMX-200 is currently performing better than placebo in reducing proteinuria (using a statistical measure¹) in patients with FSGS in a significantly larger cohort than our prior Phase 2 study



Passing this early interim analysis suggests **a statistically significant and clinically meaningful result** in reducing proteinuria at the end of the study may be possible^{2,3}



IDMC has again noted **no safety concerns to date**, which is entirely consistent with the existing and growing strong safety profile of DMX-200



ACTION3 clinical trial will now **formally expand into Part 2** of the study



Study funded following successful Placement of \$20 million to Institutional and sophisticated investors to give **proforma cash balance of \$34.8⁴ million**

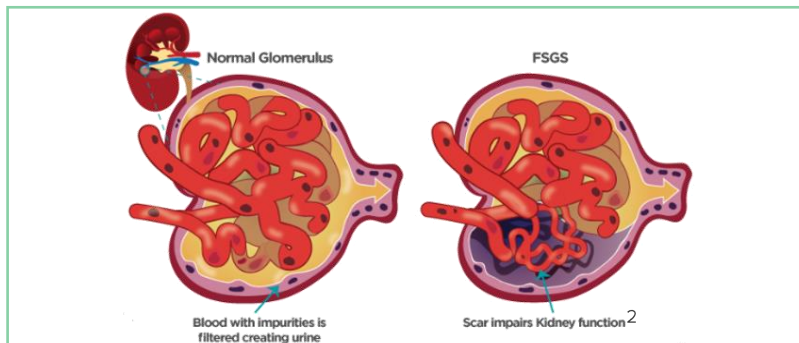
Focal Segmental Glomerulosclerosis (FSGS)

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

What is FSGS?

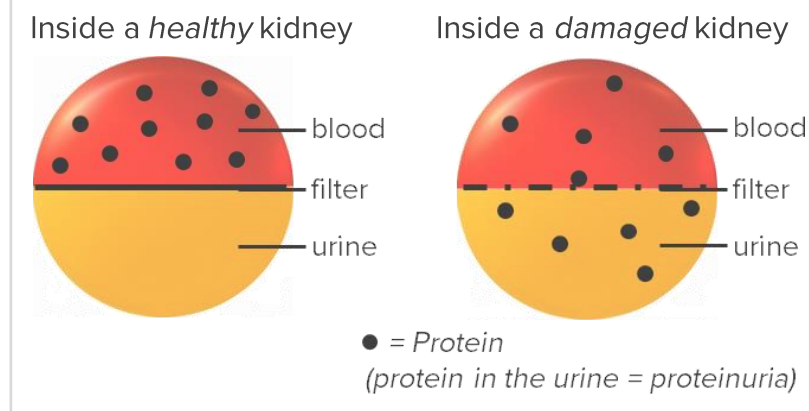
FSGS is a rare kidney disease that attacks part of the kidney filtering units, causing **inflammation** and irreversible scarring to the kidneys¹

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



Why are kidneys important?

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

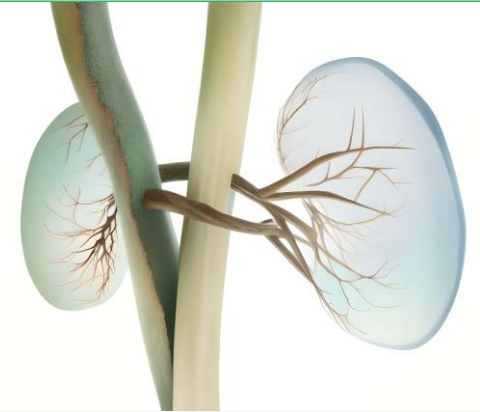
DMX-200 aims to reduce the inflammation of the kidneys: if DMX-200 reduces inflammation = the amount of proteinuria should decrease

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 FSGS²
- ▶ Significant burden on global health systems
 - Patients end up on dialysis (est cost US\$90,000/patient/year)³
 - Patients requiring kidney transplant (est cost US\$442,500 per transplant + ongoing medication fees)⁴
 - 60% patients have reoccurring FSGS even after first kidney transplant⁵



0

Approved drugs anywhere in the world

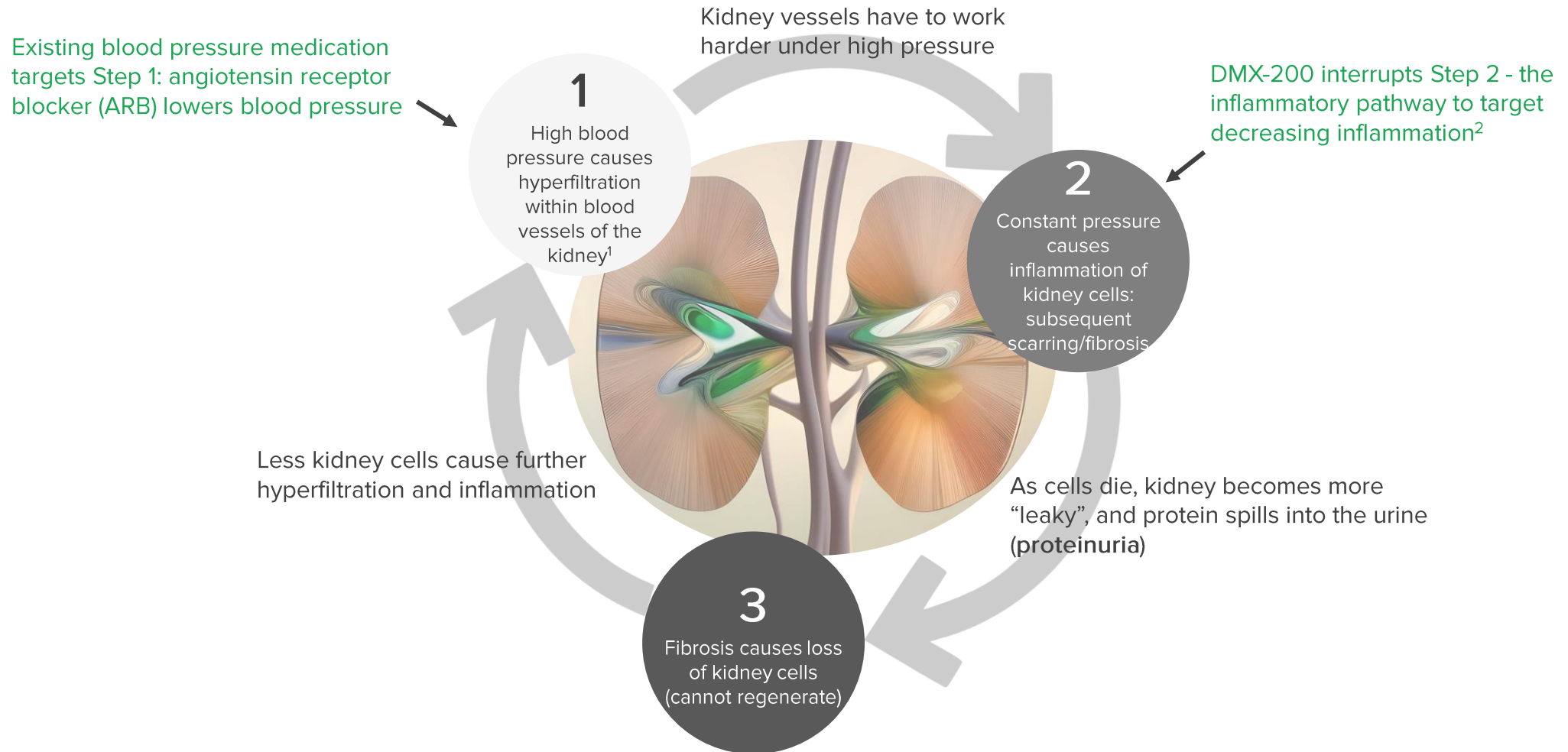
60%

Patients have reoccurring FSGS even after first kidney transplant⁶

5

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

Progression of FSGS kidney disease



PHASE 3 CLINICAL TRIAL



ACTION3 Part 1 interim analysis successful

FSGS CLINICAL STUDY



ACTION3 Phase 3 trial **successfully passes first interim analysis** (using a statistical measure¹) based on proteinuria efficacy endpoint²

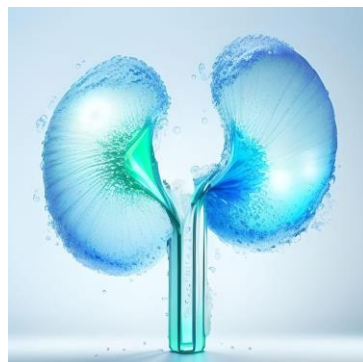
What does this interim analysis mean?

- An interim analysis incorporating a futility assessment is designed to assess whether a trial is having the **desired effect** and whether it is likely to meet its objectives if continued to completion³
- Passing this early interim analysis suggests that it is possible DMX-200 may achieve a **statistically significant and clinically meaningful** result at the end of the study.^{1,2,3}
- Interim analysis outcome is important = based on a **significantly larger cohort** than the Dimerix Phase 2 study

ACTION3 Part 1 analysis interpretation

FSGS CLINICAL STUDY

- ACTION3 Phase 3 trial **successfully passes** first interim analysis using proteinuria efficacy endpoint¹
- This means that:
 - DMX-200 is currently **performing better than placebo** in reducing proteinuria in patients with FSGS (using a statistical measure²)
 - IDMC noted **no safety concerns** to date - consistent with existing & growing strong safety profile of DMX-200



In line with best practice for blinded Phase 3 clinical trials, the interim analysis data are only reviewed by the IDMC

Dimerix, the regulatory authorities including the United States Food and Drug Administration (FDA), and the trial investigators are blinded to treatment allocations, grouped safety and efficacy data for the ongoing trial and the data inputs into this interim analysis

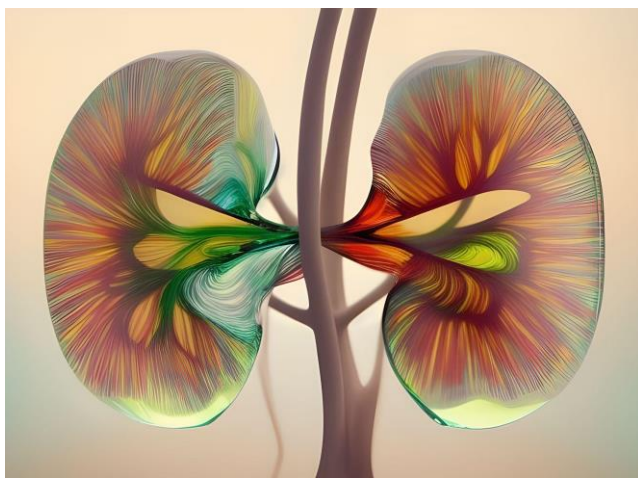
ACTION3 Part 1 analysis observations

FSGS CLINICAL STUDY

“It is very pleasing to see that the Phase 3 clinical trial of DMX-200 was successful in the pre-specified interim futility analysis for efficacy in the first 72 patients. The positive signal suggests that treatment with DMX-200 may indeed result in a clinically meaningful improvement in kidney function when added to the standard of care in patients with FSGS. With limited treatment options currently available, there remains a significant unmet need for more efficacious and durable therapies for FSGS.”

Professor Jonathan Barratt, Nephrologist, Mayer Professor of Renal Medicine:

University of Leicester, Co-Chair UK Glomerulonephritis Clinical Study Group, Dimerix Medical Advisory Board Member



“Passing this first interim analysis for DMX-200 is a key milestone for Dimerix and our FSGS program. It demonstrates that DMX-200 is performing better than placebo in reducing proteinuria in a much larger cohort than our prior 8-patient Phase 2 study, and this validates our strategy and our prioritisation of this potentially valuable program in a disease where there are no FDA approved therapies. We now look forward to rapidly expanding this study, which will include recruiting children down to 12 years old as well as adults.”

Dr David Fuller; Chief Medical Officer, Dimerix

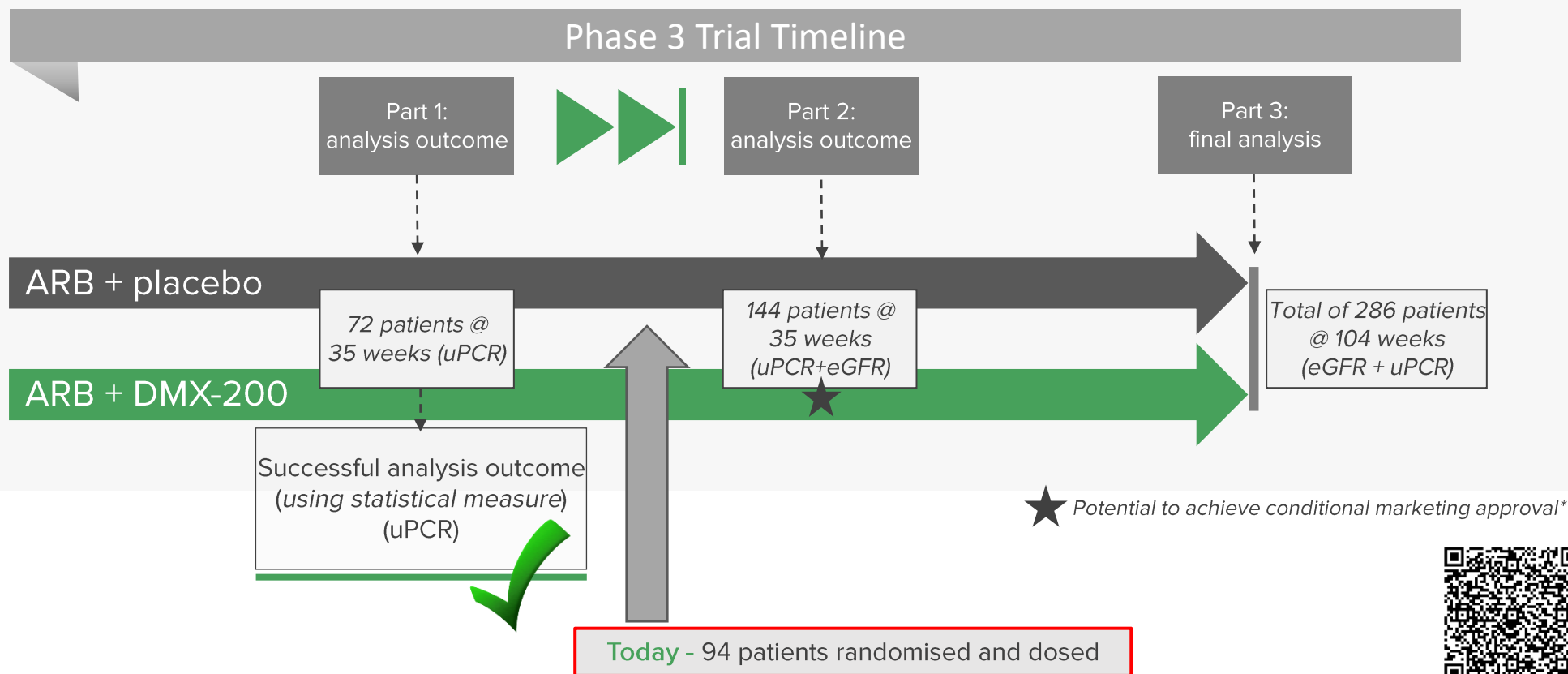
ACTION3 Phase 3 clinical trial – next steps

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

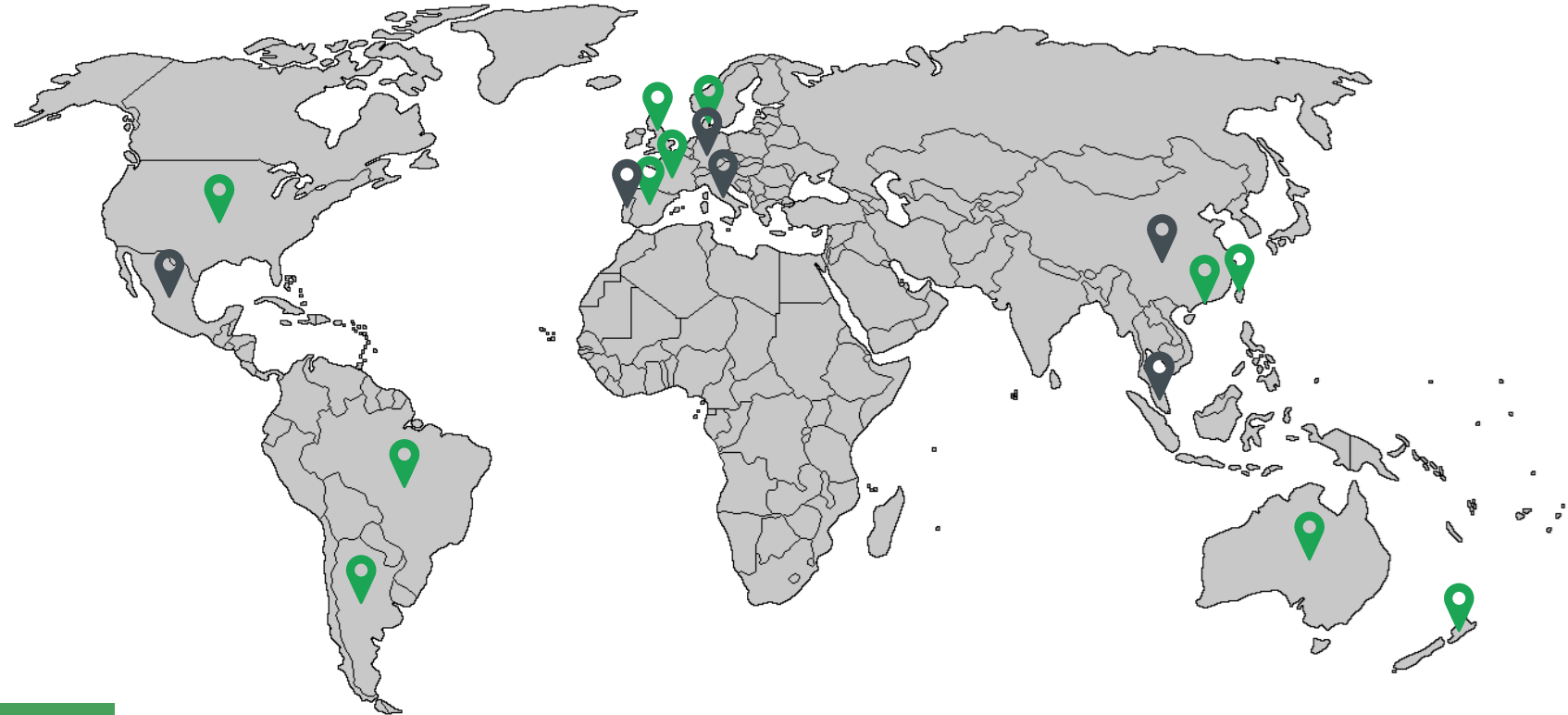
Background

- Patients recruited, then screened and stabilised on background medications
- Patients randomised to receive drug or placebo
- DXB remains blinded at all times during study



- Existing recruitment sites:
- Australia, New Zealand
 - Taiwan, Hong Kong
 - France, Denmark, UK, Spain
 - Argentina, Brazil
 - USA

- New recruitment sites planned:
- China
 - Malaysia
 - Italy, Germany, Portugal
 - Mexico



Recruitment to include children 12+

FSGS MARKET OPPORTUNITY



Potential FSGS market size

No approved therapies for FSGS

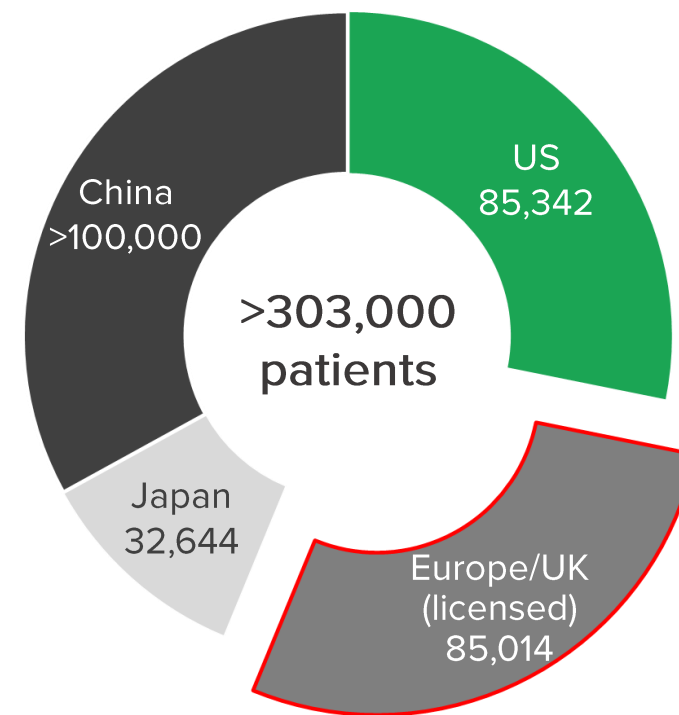
DMX-200 is the only therapy in phase 3 development

Multi-billion dollar market potential



- ▶ Example pricing for other rare kidney disease drugs :
 - in the US (i.e. Filispari in IgAN)² is **US\$9,900 p/month**
 - in Europe/UK (i.e. Kinpeygo/Tarpeyo)³ is **US\$8,267 p/month (€7,630)**
- ▶ Example annual pricing^{2,3}:
 - **~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

Estimated 7MM (+China)
diagnosed patients (2022)^{1,4}





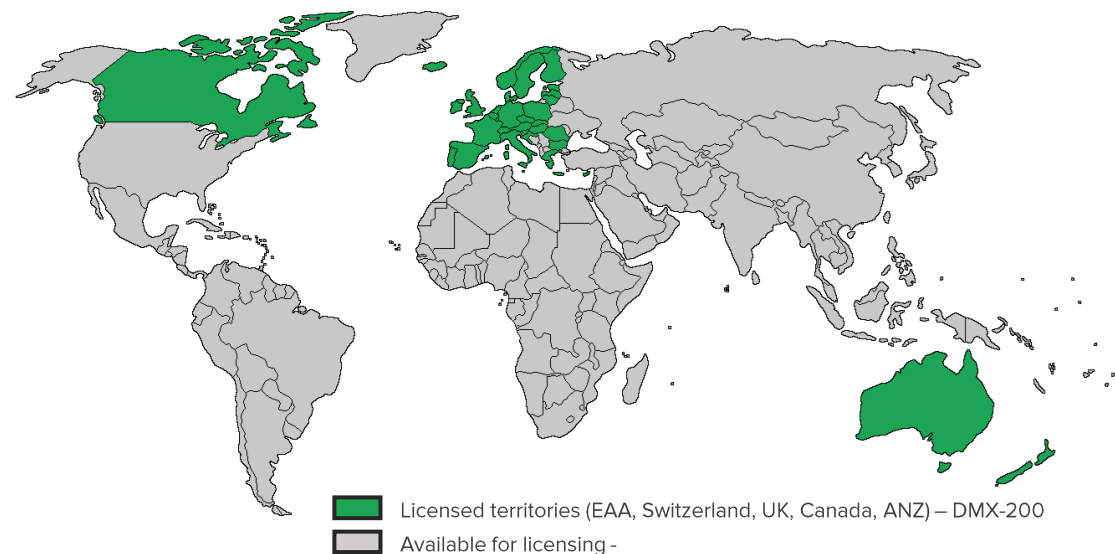
Dimerix - strategic partners in nephrology

Dimerix has received a significant amount of partnering interest from pharma companies globally

- Received multiple non-binding term sheets for global deals and regional deals¹
- Multiple parties in data room conducting due diligence and negotiating for various territories¹

Preference is to work with experienced, capable partners

- Partners with regulatory, sales and marketing infrastructure and experience for desired territories



Existing partnerships



Dimerix to receive up to ~AU\$230* million in upfront and milestone payments, plus royalties

- €6.5 million in upfront payment (AU\$10.8 million) – received in November 2023
- up to €132.5 million (~AU\$218 million*) in potential development and sales milestones
- Tiered royalties on net sales



Significant potential upside

Partnering still available for other potential multi-billion dollar markets (incl. the US & China)

Summary | Phase 3 Global Opportunity



Lead Drug Candidate

- DMX-200 is currently in a **Phase 3 clinical trial** for focal segmental glomerulosclerosis (FSGS)

FSGS

- FSGS is a disease that causes scar tissue of kidneys, which leads to irreversible kidney damage¹
- FSGS kidney damage can lead to dialysis, kidney transplants or death¹

Market Opportunity

- Estimated ~>200,000 people with FSGS in the 7 major markets (makes **FSGS a rare disease**)²
- Estimated 40,000¹ – 80,000² people in the US alone
- Drugs for rare kidney diseases can be priced at **~US\$120,000 per annum** in the US³
- 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 NZ⁴
- AUD\$10.8m received upfront, ~\$220m in potential milestone payments & mid-teen-20% tiered royalties

Upcoming Milestones

- Execution of potential licensing deals** for available jurisdictions, including the US & China⁵
- Recruitment** and dosing of 144 patients for Part 2
- Part 2 – **second interim analysis** outcome estimated mid-2025
- Announcements which relate to DXB's secondary assets

CAPITAL RAISING DETAILS



Details of the Offer

Entitlement Offer

- **Placement:** to institutional and sophisticated investors to raise \$20 million, via the issue of 66,666,667 million shares, utilising the company's existing placement capacity under ASX Listing Rules 7.1.

Offer Price

- Offer Price of \$0.30 per share represents a:
 - 52 week high
 - 0% discount to the last close of \$0.30 on 08 March 2024;
 - 14.5% premium to the 5-day VWAP of \$0.262 up to and including 08 March 2024
 - 29.2% premium to the 30-day VWAP of \$0.232 up to and including 08 March 2024

Ranking

- The New Shares to be issued pursuant to the Placement are fully paid ordinary Shares in the Company and rank pari passu with existing Shares on issue

Lead Manager

- Euroz Hartleys are sole Lead Manager.

Use of funds

Pro forma capital structure	
Ordinary shares on issue prior to the Capital Raise	454,741,433
Undiluted market capitalisation pre-Capital Raising ¹	\$136.4M
Gross proceeds to be raise from Capital Raising	\$20M
Share on issue post Capital Raising	521,408,100
Offer price	\$0.30
Implied market capitalisation (at offer price)	\$156.4M
Pro-forma cash ²	\$34.8 million
Convertible notes	0
Options (inc. listed options)	151,457,328

Intended use of funds	A\$ Million
Clinical studies, including: • ACTION3 Phase 3 clinical trial in patients with FSGS • Preparation and submission of appropriate regulatory applications to continue FSGS Phase 3 clinical study; and • Continued manufacturing distribution and logistics of the required clinical trial material	\$17.00
Transaction/partnering activities	\$0.50
Working capital and offer costs	\$2.50
Total	\$20.00

Offer timetable*

Trading halt

Monday, 11 March 2024

Placement announced, trading halt lifted

Tuesday, 12 March 2024

Allotment and trading of New Shares under the Placement

Wednesday, 20 March 2024

Risk summary*

- Clinical trial risk: Dimerix is currently undertaking a phase 3 clinical trial for its proprietary product, DMX-200. Drug development is a high risk endeavour with a significant failure rate, and no assurance can be given that required regulatory approvals for commercial activities will be received on commercial terms, or at all.
- Competition risk: Dimerix faces competition as new and existing companies enter the market and advances in research and technology become available. The size and financial positions of the competitors to Dimerix may make it difficult for Dimerix to maintain a competitive position.
- Commercialisation risk: There is no certainty that the drug candidates will be of interest to a third party or that an agreement will be able to be negotiated on commercially acceptable terms for Dimerix to adequately realise the value of a drug candidate.
- Intellectual property risks: Obtaining, securing and maintaining the intellectual property rights of Dimerix is an integral part of securing potential value arising from conduct of its business. The patent position in biotech and pharmaceutical companies can be highly uncertain and frequently involves complex legal and factual questions.
- Regulatory and governmental risks: Changes in matters over which Dimerix has limited control such as laws, regulations, standards and practices applicable to the industry in which Dimerix operates may increase costs and limit the proposed scope of the activities of Dimerix.
- Human resource risk: Dimerix is reliant upon the skills and experience of its personnel and the loss of existing personnel, or the inability to identify suitable replacements, may have a negative impact on Dimerix.
- Risks associated with collaboration arrangements with third parties: There is no guarantee that Dimerix will attract and retain appropriate strategic partners or that any such collaborators will perform and meeting commercialisation goals.
- Future capital requirements: Pharmaceutical R&D activities require a high level of funding over a protracted period of time. Additional development costs may arise that are required to be funded for Dimerix to meet its stated objectives.
- Value of securities and share market conditions including liquidity risk: No assurance can be given by Dimerix with respect to market factors, including with respect to the liquidity or price of the securities of Dimerix.
- Speculative investment: An investment in securities of Dimerix carries risk. While the Directors of Dimerix seek where possible to manage potential risks with careful planning, some risks are highly unpredictable or are outside the control of Dimerix.

Corporate overview

Ticker Symbol	ASX: DXB
Proforma Cash Balance (Dec23) ¹	~A\$34.8 million
Market Capitalisation	~A\$136 million
Share price	~A\$0.30
Total ordinary shares on issue	454,741,433
Average daily liquidity for past 30 days*	5.88 million





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 OUR 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.



SCAN ME

Dimerix HQ

425 Smith St, Fitzroy 3065

Victoria, Australia

T. 1300 813 321

E. investor@dimerix.com