



Immediate Release

DIMERIX PRESENTS AT ASX SMALL & MID-CAP CONFERENCE 2024

MELBOURNE, Australia, 27 March 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 ASX Annual Small & Mid-Cap Conference in Sydney on 27 March 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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**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

27 March 2024

ASX

Small and Mid-Cap 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.

Summary | Phase 3 Global Opportunity



Lead Drug Candidate

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

FSGS Indication

- 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 $\sim >200,000$ 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 **\sim US\$120,000 per annum** in the US³
- There are currently **no approved treatments** available to treat FSGS

Commercial Validation

- Commercial licensing deal achieved** in October 2023 for EEA, UK, SUI, CA, AU and NZ⁴
- AUD\$10.8m received upfront, \sim \$220m in potential milestone payments & mid-teen-20% tiered royalties
- Phase 3 interim analysis: **DMX-200 is performing better than placebo** in reducing proteinuria (using a statistical measure⁵) in a significantly larger cohort than our prior Phase 2 study

Upcoming FSGS Milestones

- Execution of potential licensing deals** for available jurisdictions, including the US & China⁶
- Recruitment** and dosing of 144 patients for Part 2
- Part 2 – **second interim analysis** outcome estimated mid-2025

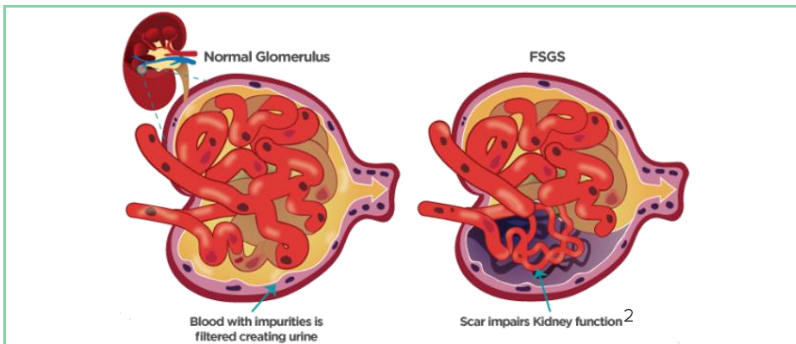
Focal Segmental Glomerulosclerosis (FSGS)

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

What is FSGS?

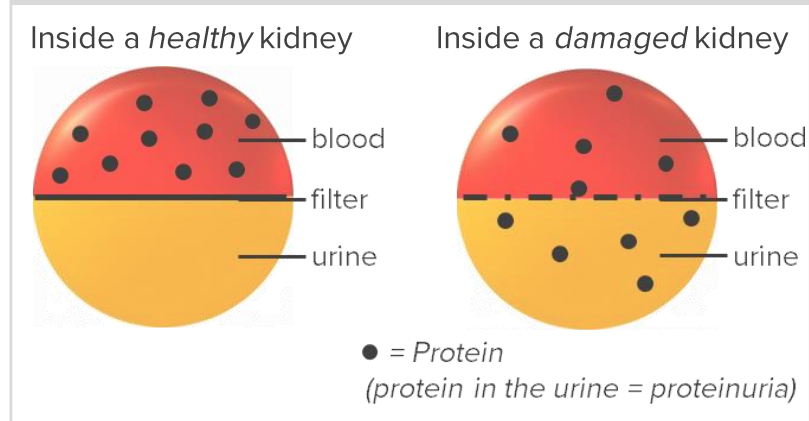
FSGS is a rare kidney disease that attacks part of the kidney filtering units, causing **inflammation** and **irreversible** scarring to the kidneys¹

This 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 urine¹



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

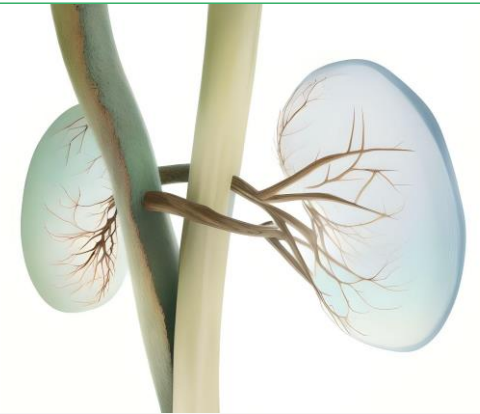
DMX-200 aims to reduce the inflammation of the kidneys: if DMX-200 reduces inflammation = the amount of proteinuria should decrease

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 transplant¹

- ▶ Caused by a variety of conditions - primary FSGS, genetic FSGS, FSGS of unknown cause and secondary FSGS¹
- ▶ Significant burden on global health systems
 - Patients end up on dialysis (est cost US\$90,000/patient/year)²
 - Patients requiring kidney transplant (est cost US\$442,500 per transplant + ongoing medication fees)³
 - 60% patients have reoccurring FSGS even after first kidney transplant⁴



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Approved drugs anywhere in the world

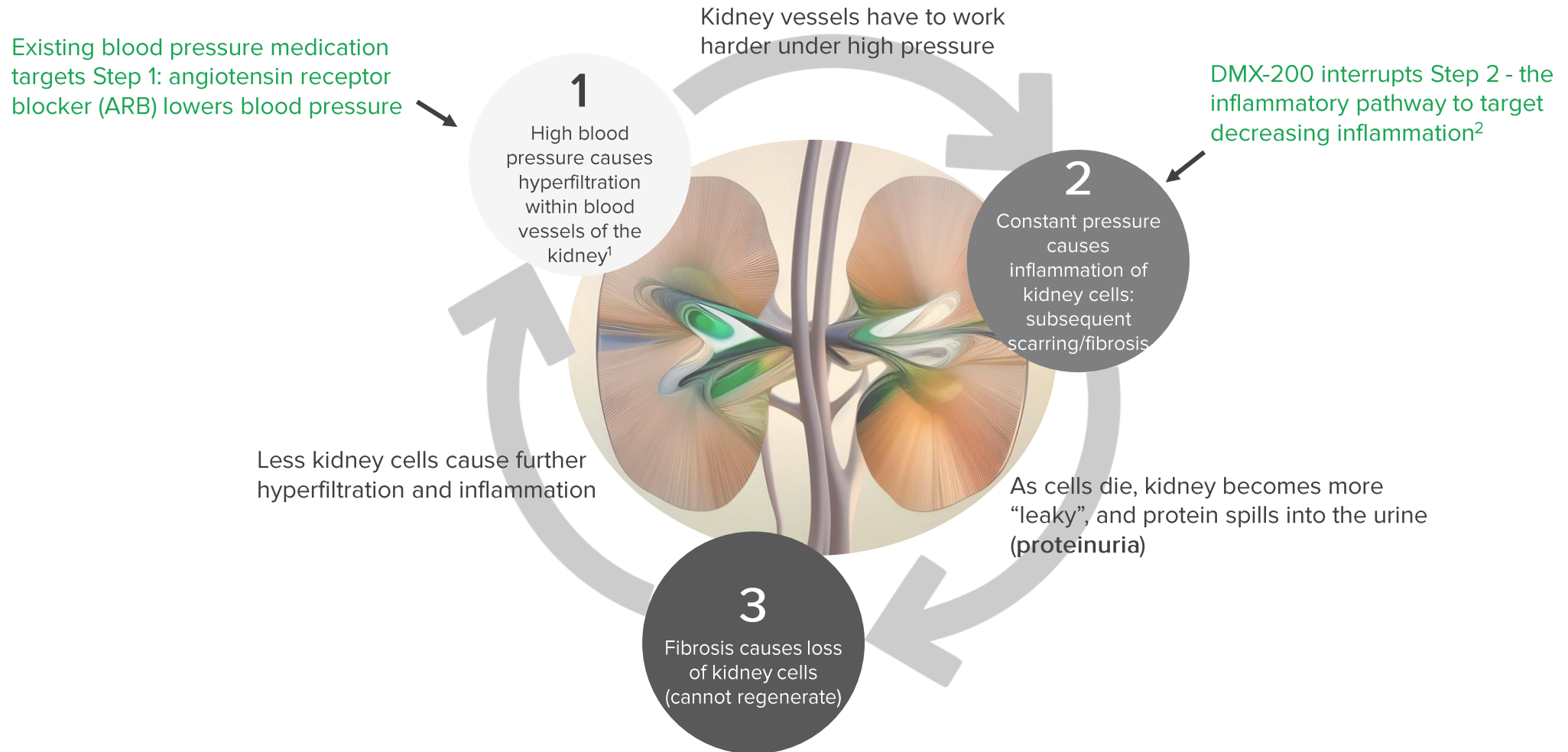
60%

Patients have reoccurring FSGS even after first kidney transplant⁶

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Average time (years) to kidney failure after onset of proteinuria⁵

Progression of FSGS kidney disease

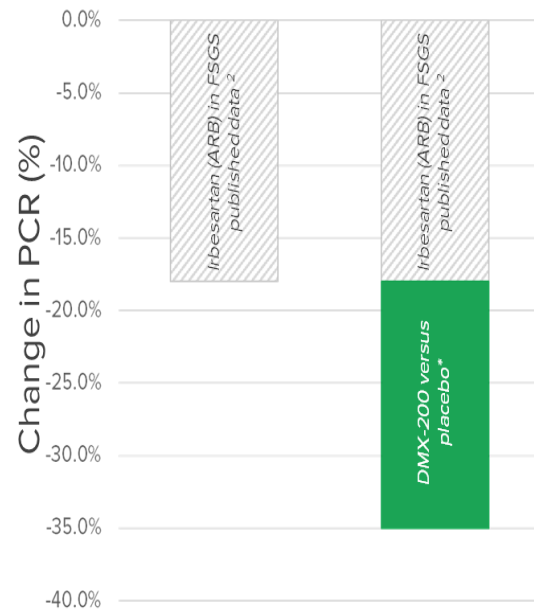


DMX-200: Phase 2 met primary and secondary endpoints



 Clinically meaningful outcomes achieved for patients, with no safety issues

Average reduction of 17% in proteinuria after 16 weeks treatment on DMX-200 versus placebo¹



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^{2,3}

“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 2020⁴

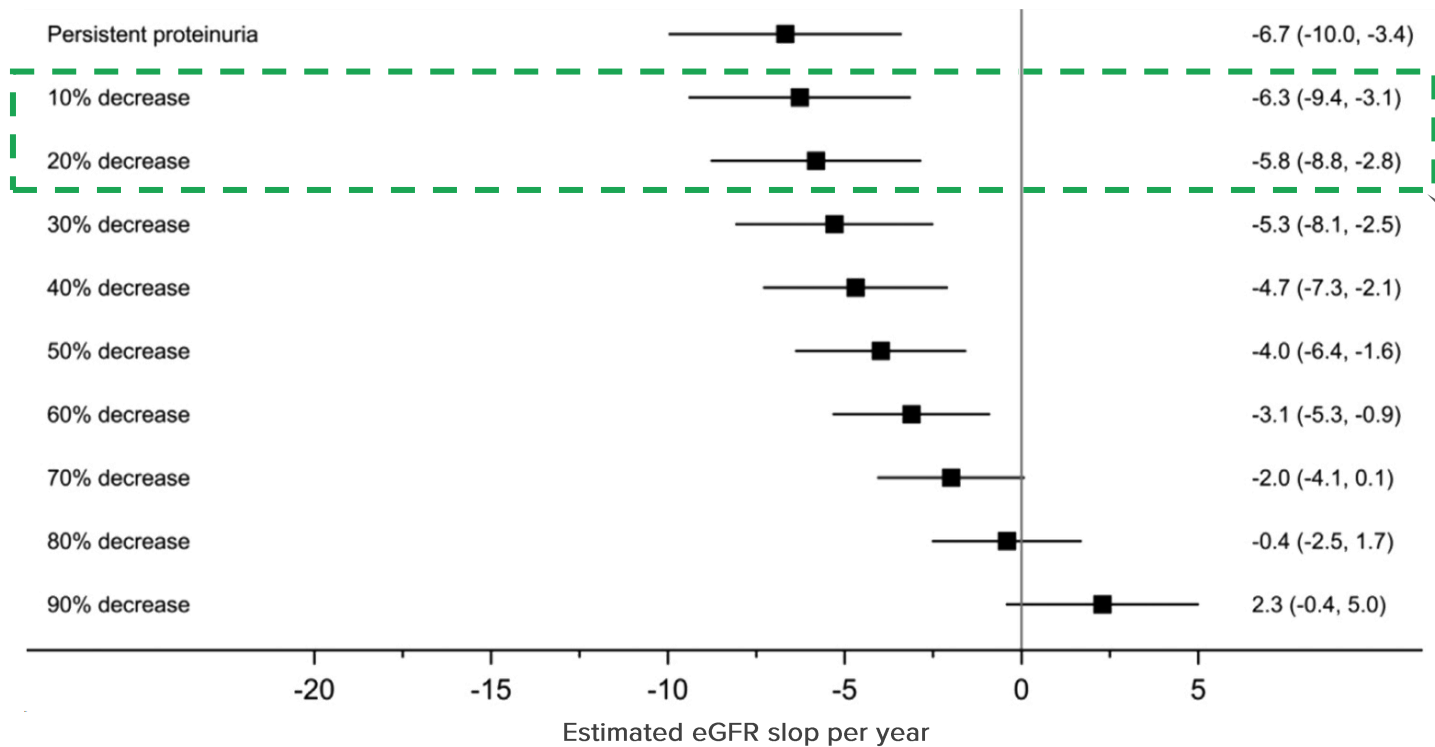
DMX-200: Phase 2 met primary and secondary endpoints



17% average reduction of proteinuria in Phase 2 is clinically meaningful¹

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 2020¹

PHASE 3 CLINICAL TRIAL



ACTION3 Phase 3 clinical trial

FSGS CLINICAL STUDY

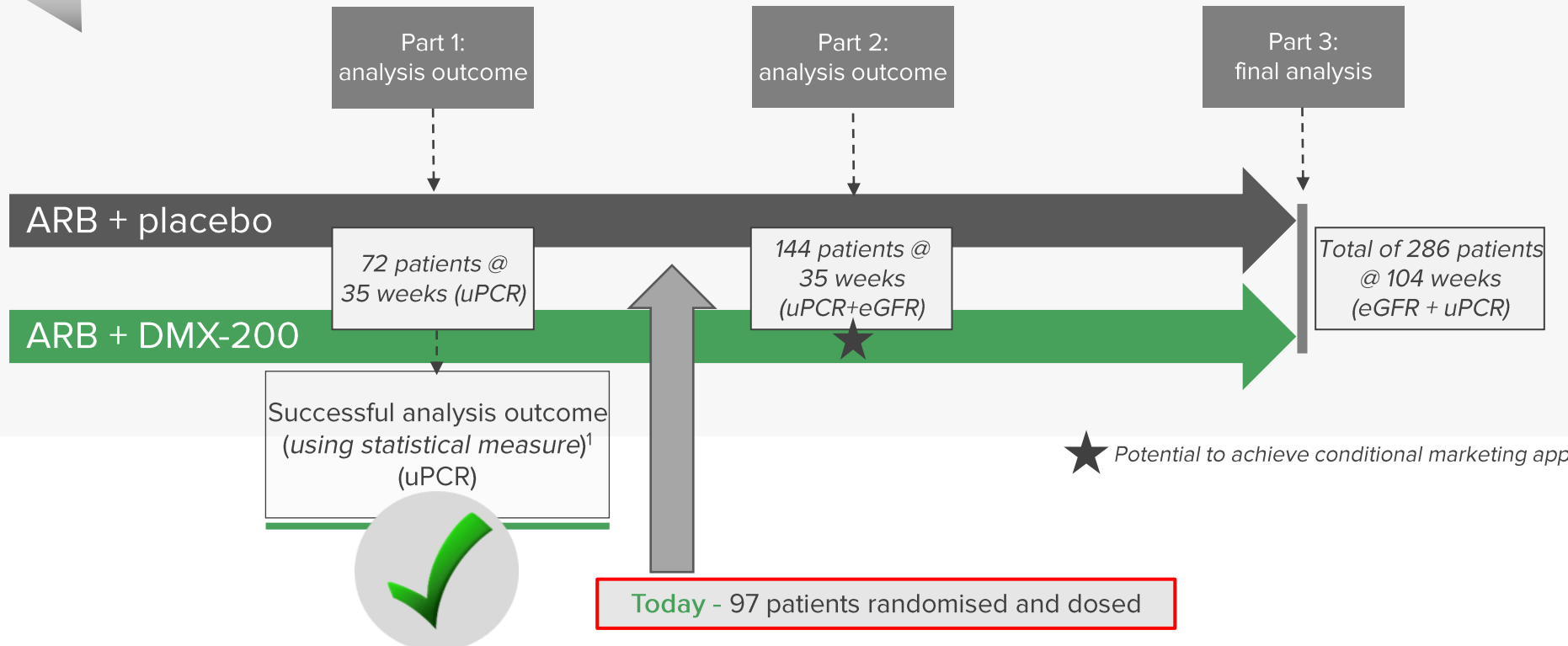


A randomised, double-blind, multi-centre, placebo-controlled study of renal outcomes of DMX-200 in patients with FSGS receiving an ARB

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

Phase 3 Trial Timeline




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

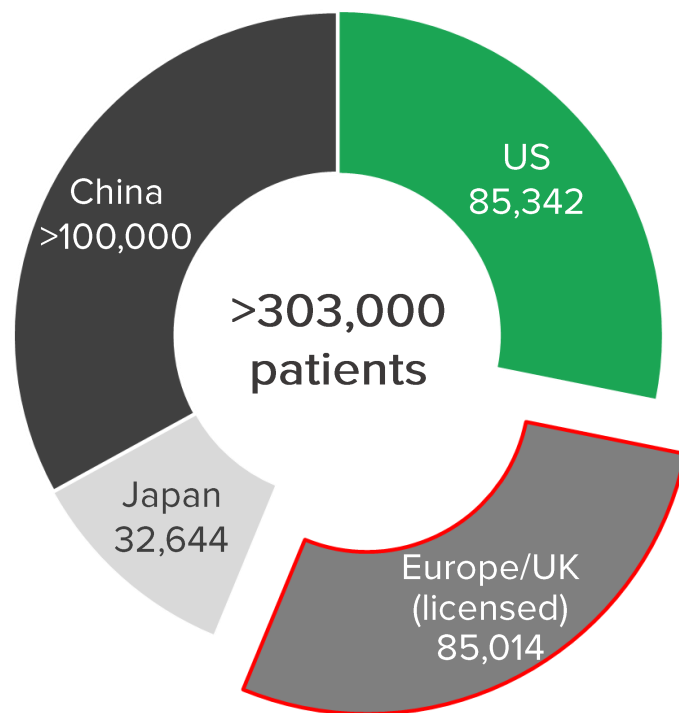
 ACTION3 clinical trial will now **formally expand into Part 2** of the study

FSGS MARKET OPPORTUNITY



Potential FSGS market size

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



No approved therapies for FSGS

DMX-200 is the only therapy in phase 3 development

Multi-billion dollar market potential¹



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 in rare kidney disease^{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

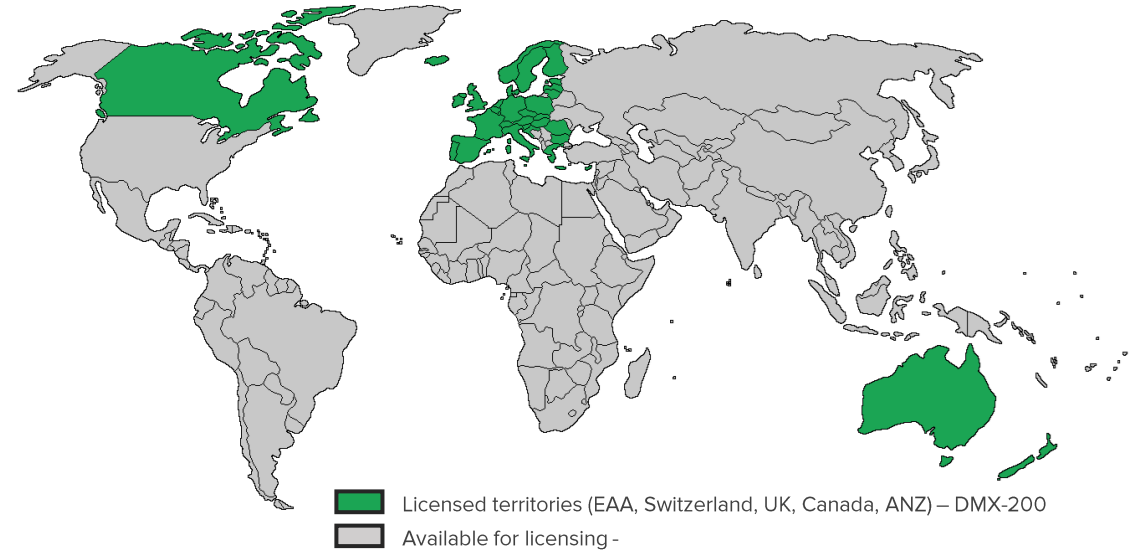
Dimerix - strategic partners in nephrology

Significant amount of partnering interest received from pharma companies

- 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 established infrastructure for desired territories:
 - regulatory,
 - sales; and
 - marketing



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\$219 million*) in potential development and sales milestones
- Tiered royalties on net sales



Further licencing opportunities

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

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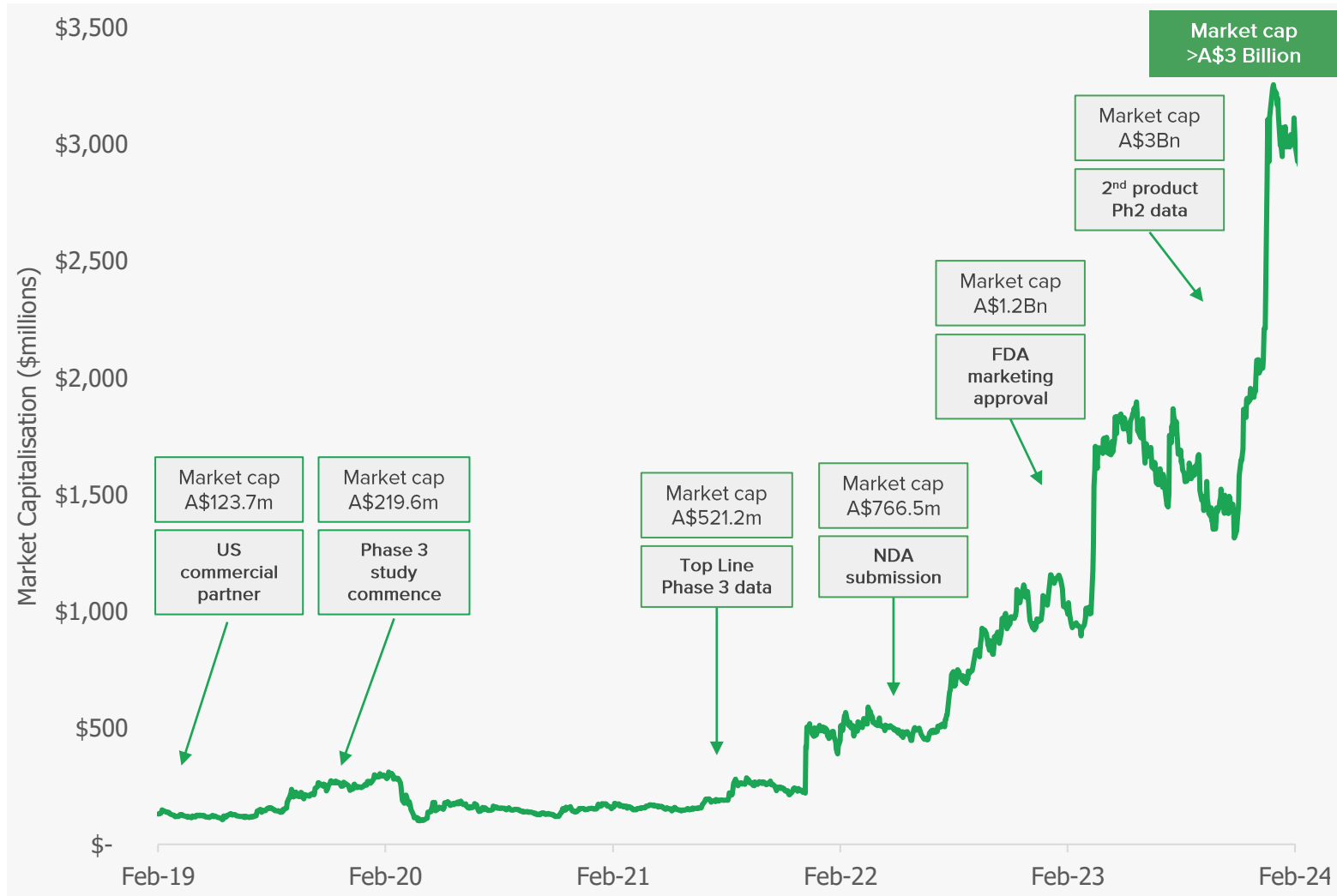
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Orphan drug case study - Neuren (NEU.ASX)



- 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

Corporate overview

Ticker Symbol	ASX: DXB
Proforma Cash Balance (Dec23) ¹	~A\$34.8 million
Market Capitalisation	~A\$165 million
Share price	~A\$0.3
Total ordinary shares on issue	548,602,359
Average daily liquidity for past 10 days ²	8.75 million



SUBSTANTIAL SHAREHOLDERS³

	Holder Name	Holding	
1	Mr P Meurs	75,304,506	13.8%
TOTAL (TOP 5)		133,940,200	24.4%



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



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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.