

**INVESTOR BRIEFING NOTICE**

MELBOURNE, Australia, 22 March 2023: Dimerix Limited (ASX: DXB) a biopharmaceutical company with late-stage clinical assets in inflammatory diseases, is pleased to advise that CEO & Managing Director, Dr Nina Webster, will be presenting at the Emergence23 Wholesale Investor conference in Sydney on 24 March 2023.

**Key points that will be covered:**

- Phase 3 global clinical trial in FSGS kidney disease patients status and update
- Advanced partnering negotiations with material offers received from multiple parties for various territories<sup>1</sup>
- Commercial opportunity and addressable market value

The 8 minute presentation will be live and online, and investors can register ahead to attend the presentation here: <https://www.emergence.wholesaleinvestor.com/attend-sydney>

The presentation is attached to this announcement.

For further information, please visit our website at [www.dimerix.com](http://www.dimerix.com) or contact:

Dr Nina Webster  
Dimerix Limited  
Chief Executive Officer & Managing Director  
Tel: +61 1300 813 321  
E: [investor@dimerix.com](mailto:investor@dimerix.com)

Rudi Michelson  
Monsoon Communications  
Tel: +61 3 9620 3333  
Mob: +61 (0)411 402 737  
E: [rudim@monsoon.com.au](mailto:rudim@monsoon.com.au)

Follow us on [LinkedIn](#) and [Twitter](#)

*Authorised for lodgement by the Board of the Company*

—END—

For personal use only

## 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.<sup>2</sup> For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.<sup>3</sup> 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,<sup>2</sup> and worldwide about 220,000.<sup>4</sup> The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.<sup>5</sup> 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

- <sup>1</sup> *Offers are non-binding and subject to due diligence, a definitive agreement and board approval*
- <sup>2</sup> Guruswamy Sangameswaran KD, Baradhi KM. (2021) *Focal Segmental Glomerulosclerosis*, online: <https://www.ncbi.nlm.nih.gov/books/NBK532272/>
- <sup>3</sup> *Front. Immunol.*, (July 2019) | <https://doi.org/10.3389/fimmu.2019.01669>
- <sup>4</sup> *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>
- <sup>5</sup> *Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis*, online <https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/>

For personal use only



FSGS CLINICAL STUDY



Developing innovative new therapies in areas with unmet medical needs, with a core focus on developing new therapies to treat inflammatory causes of kidney and respiratory disease

(ASX:DXB)

# Wholesale Investor Presentation

March 2023

For personal use only



# 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.*

# Late stage, phase 3 clinical development asset

For personal use only



DMX-200  
in focal segmental  
glomerulosclerosis  
(FSGS) kidney  
disease



Near term **Phase 3 interim analysis**, and potential accelerated approval pathway



Advanced **partnering negotiations** with offers received from multiple parties for various territories<sup>1</sup>



Comprehensive development plan to ensure **commercial ready** product



**Orphan Drug** status providing protection through data exclusivity<sup>2</sup>



Growing **global market** forecasted to exceed \$3b by 2032<sup>3</sup>



**Strong progress** to date in recruitment, managed by an experienced team and global CRO



# Significantly de-risked, late-stage development program

For personal use only



**Strong** safety profile<sup>1</sup>



**Proven** efficacy<sup>1</sup>



**Completed** toxicology studies<sup>2</sup>



**Completed** commercial manufacturing scale-up<sup>3</sup>



**Clear** development pathway to market<sup>4</sup>



**Orphan Drug** designations<sup>5</sup>

# Targeting orphan disease

For personal use only

Orphan designation created incentives for companies to develop new drugs for rare diseases



Commercially attractive pricing structure

(~US\$120,000 potential cost per year based on rare kidney treatments<sup>1</sup>, average US orphan drug price of \$84,000/year in 2018<sup>2</sup>)



Opportunity for accelerated approval on compelling interim data with rapid incorporation into KDIGO treatment guidelines



Marketing exclusivity period without generic competition or challenge – 7 years in US, 10 years in EU, with opportunity to extend on paediatric indication – in addition to comprehensive patent/IP strategy



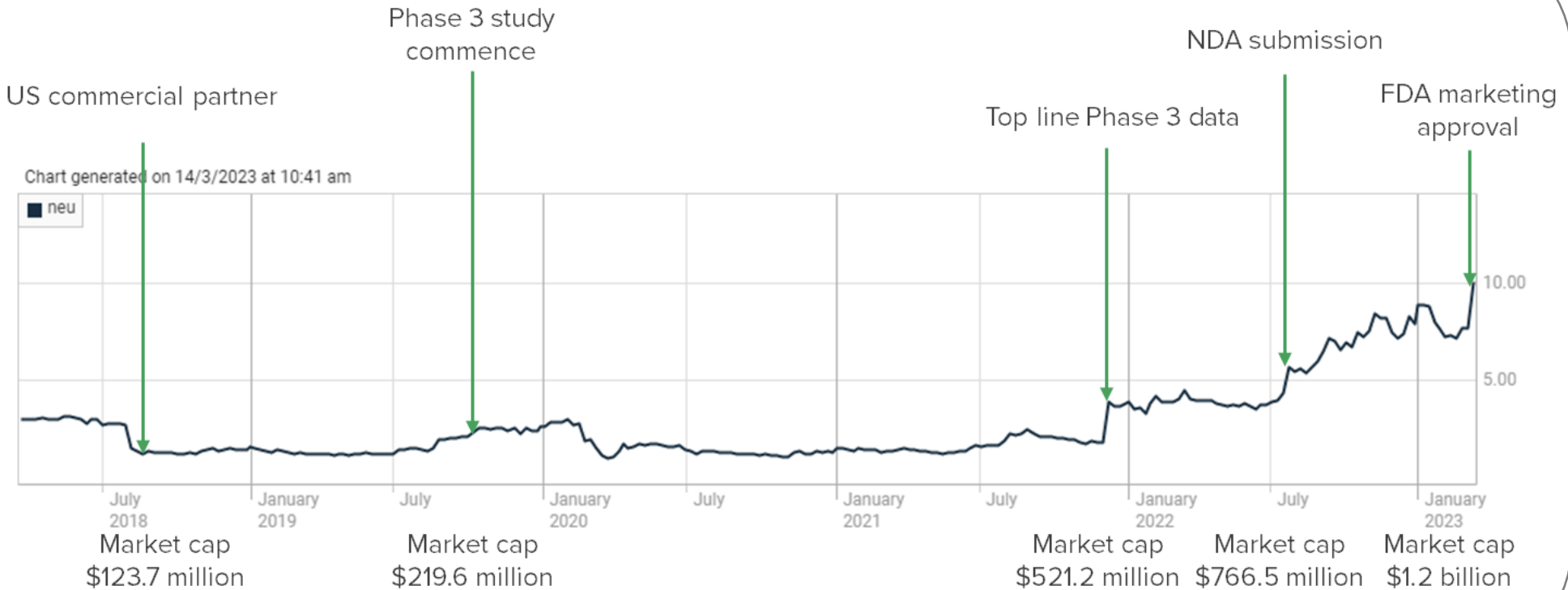
Regulatory assistance and guidance from regulators in the design of an overall drug development plan

# Orphan disease treatment – case study

neuren

Pipeline focus on rare neurodevelopmental disorders

pharmaceuticals





# FSGS has large unmet medical need

With no therapies approved for the treatment of FSGS:

- patients are treated with other medications off-label, including angiotensin receptor blockers
- patients likely end up on dialysis and/or kidney transplant
- current market specifically for FSGS does not exist

21% forecast global market growth year on year<sup>1</sup>

220,000 diagnosed patients (7MM)<sup>1</sup>

US\$9,900 cost per month<sup>2</sup>  
*Example only\*\* Final market price TBD*

Estimated US\$3.27 billion by 2032 (7MM)<sup>1</sup>

## Market drivers



Increased prevalence of FSGS



Potential increase in therapeutic options



Growing elderly population



Increase in diagnostic tests

# 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)

For personal use only

New Chemical Entity status, with orphan exclusivity (7 years US/10 years EU)<sup>1</sup>; and with granted patents and 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)<sup>2</sup>

Strong safety profile<sup>2</sup>

4 clinical studies completed to date: positive efficacy signals across studies<sup>2</sup>

Proven efficacy<sup>2</sup>

# ACTION3 Clinical trial status

FSGS CLINICAL STUDY

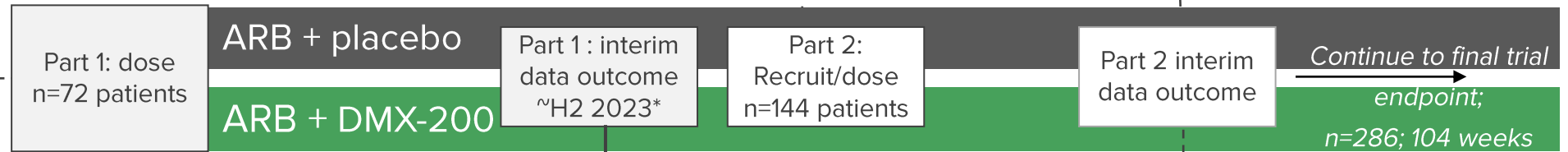
A randomised, double-blind, multi-centre, placebo-controlled study of renal outcomes of DMX-200 in patients with FSGS receiving an ARB

- 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

Initiate clinical sites Part 1

Recruit 72 patients Part 1

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



Data outcome anticipated end 2023\*

Potential to submit for accelerated marketing approval\*\*



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>



\*Subject to recruitment, screening and randomisation  
 \*\*Subject to data outcome and regulatory feedback in each territory

# Late stage, phase 3 clinical development asset

For personal use only



DMX-200  
in focal segmental  
glomerulosclerosis  
(FSGS) kidney  
disease



Near term **Phase 3 interim analysis**, and potential accelerated approval pathway



Advanced **partnering negotiations** with offers received from multiple parties for various territories<sup>1</sup>



Comprehensive development plan to ensure **commercial ready** product



**Orphan Drug** status providing protection through data exclusivity<sup>2</sup>



Growing **global market** forecasted to exceed \$3b by 2032<sup>3</sup>



**Strong progress** to date in recruitment, managed by an experienced team and global CRO





# Dimerix

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

ASX:DXB

Dimerix HQ  
425 Smith St, Fitzroy 3065  
Victoria, Australia  
T. 1300 813 321  
E. [investor@dimerix.com](mailto:investor@dimerix.com)

#### 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.