

#### **INVESTOR BRIEFING NOTICE**

MELBOURNE, Australia, 23 November 2022: Dimerix Limited (ASX: DXB) ("Dimerix" or the "Company"), a clinical-stage biopharmaceutical company with multiple late-stage clinical assets, is pleased to invite investors to a live webinar with CEO & Managing Director, Dr Nina Webster, and hosted by Reach Markets, on Wednesday, 23 November 2022 at 12pm AEDT.

Date: Wednesday, 23 November 2022

• Time: 12pm AEDT

Topics for discussion include the progress of lead Phase 3 clinical asset, DMX-200 in focal segmental glomerulosclerosis (FSGS) and other pipeline programs. Dr Webster will also highlight the near-term milestones the Company is working towards and discuss recent progress towards partnering.

The briefing will be live and interactive, where investors will have the opportunity to ask questions directly and you will only need an internet connection to join.

The presentation which will be delivered is attached to this announcement.

The webcast will be hosted by Reach Markets so should you require any technical assistance, please contact them on 1300 805 795.

Investors can register to attend the briefing here: <a href="https://reachmarkets.com.au/the-insider-mtc/">https://reachmarkets.com.au/the-insider-mtc/</a>

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 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. For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney. 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>3</sup> 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 year<sup>3</sup>. Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for FSGS. This is a special status granted to a drug to treat a rare disease or condition; the designation means that DMX-200 can potentially be fast-tracked, and receive tax and other concessions to help it get to market.

DMX-200 for FSGS has been granted Orphan Drug Designation by the FDA and EMA. 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 an abbreviated regulatory pathway to approval.

Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

#### References

<sup>1</sup> Guruswamy Sangameswaran KD, Baradhi KM. Focal Segmental Glomerulosclerosis (July 2021), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/

<sup>3</sup> Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/

DelveInsight Market Research Report (2020); Focal Segmental Glomerulosclerosis (FSGS)- Market Insight, Epidemiology and Market Forecast -2030





## Investor Presentation

November 2022

## 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.



## **About Dimerix**

Dimerix is a biopharmaceutical company 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

Lead Drug Candidate Proven efficacy and DMX-200 safety

Proven efficacy and safety



Strong Pipeline

FSGS Phase 3 clinical study recruiting across ~70 sites globally<sup>1</sup>

Demonstrated clinical efficacy<sup>2</sup>; drug well understood, with strong safety profile<sup>2</sup> products with commercial manufacturing established

Strong outlook with potential for significant value<sup>3</sup> upside



ASX release: 01Feb2

<sup>3</sup> See slide i

# Corporate overview

<b>M</b> ASX	Ticker Symbol	ASX:DXB
<b>9</b>	Cash Balance (Sep22)*	~A\$12.1 million
<b>9</b>	Market Capitalisation	~A\$50 million
7004	Share price	~A\$0.16
	Total ordinary shares on issue	320,873,666

\*includes R&D Incentive Refund \$6m received post quarter end



Shareholders					
Position	Holder Name	Holding	% IC		
1	Mr Peter Meurs	44,179,309	13.8%		
2	Merchant Group & Nominees	17,925,000	5.6%		
3	Mr Andrew Coates & Mrs Melinda Coates	11,039,000	3.4%		
4	Bavaria Bay Pty Ltd	7,316,992	2.3%		
5	Yodambao Pty Ltd	6,362,603	2.0%		
TOTAL (TOP 5)		86,822,904	27.1%		



# Development pipeline

Program	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Key milestones
DMX-200	Focal Segmental Glomerulosclerosis (FSGS)					Phase 2a demonstrated encouraging efficacy & safety <sup>1</sup> ; Phase 3 underway across ~70 sites globally <sup>2</sup> , Part 1 completion anticipated mid-23 <sup>3</sup>
	Diabetic Kidney Disease					Phase 2 demonstrated promising efficacy and safety <sup>1</sup> , next study planned with support form Australian Centre for Diabetes Innovation; anticipated H123 <sup>4</sup>
	Late COVID pneumonia – REMAP-CAP					Study recruitment across Europe, recruitment closed pending analysis by REMAP-CAP, will update market upon receipt <sup>5</sup>
	Early COVID respiratory – CLARITY 2.0					Study recruitment across India, recruitment closed pending analysis by CLARITY, will update market upon receipt <sup>6</sup>
DMX-700	Chronic Obstructive Pulmonary Disease (COPD)					Pre-clinical studies reported 80% decrease in lung injury; clinical study design underway with study start anticipated H1 23 <sup>7</sup>
DMX-xxx	Undisclosed (multiple)					Additional target opportunities identified using Receptor-HIT; preliminary exploratory work underway



<sup>1.</sup> ASX release: 19Jul20;

<sup>2.</sup> ASX release: 31May22

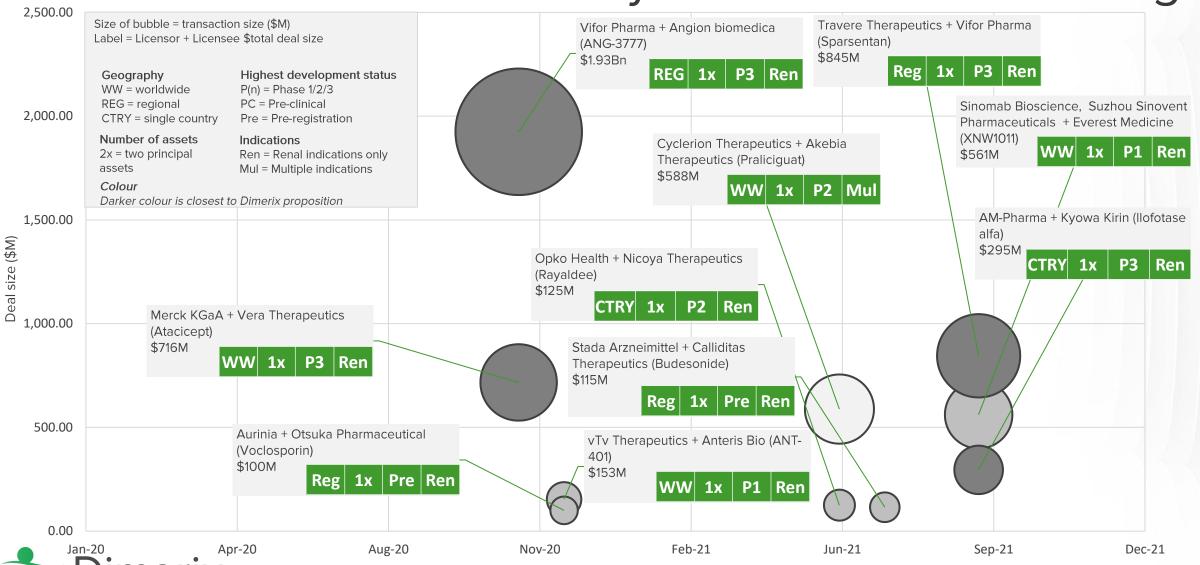
<sup>3.</sup> Subject to recruitment

<sup>4.</sup> ASX release: 07Jun22

<sup>5.</sup> ASX release 27Jun22 6. ASX release: 18Aug22 **5** 

<sup>7.</sup> ASX release: 04Jun22

# Increased interest in kidney transactions: licensing



## Renal disease landscape

"A squeaky wheel waiting for grease: 50 years of kidney disease management in the US"



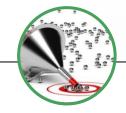
Historical lack of incentives and public policy have contributed to high costs and poor health outcomes for renal patients<sup>1</sup>



2018: workshops and regulatory acceptance of surrogate end points in trials of kidney diseases <sup>2</sup>



2019 changes in US federal policy and rapid adoption of treatment guidelines have contributed to a sea change in the management of renal disease 3



Public health policy, legislation and product innovation have converged to accelerate change in renal space today

"More change in the past 24 months than the past 24 years: The rapid evolution of [kidney disease] management"



## Policy change: renal disease healthcare economic burden

## ~40 million

adults have kidney disease (~15% of the adult population) in the US in 2021 1

## US\$88 billion

estimated total US Medicare expenses costs/year for renal patients in 2021 1,3

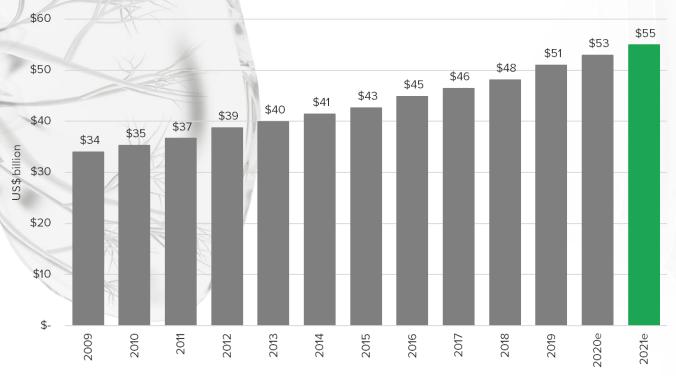
## 2019

White House executive order issued: incentives for providers to delay patient progression to renal failure <sup>2</sup>



## Economic cost of kidney failure in the US

Total Medicare expenses per year costs for kidney failure patients (2009-2021E) <sup>3</sup>



<sup>1.</sup> Garibaldi A, et al (2021) The Evolution of Kidney Health Management and the Next Frontier; https://www.lek.com/insights/ei/evolution-kidney-health-management-and-next-frontier 2. https://www.federalregister.gov/documents/2019/07/15/2019-15159/advancing-american-kidney-health;

<sup>3.</sup> The United States Renal Data System (USRDS) Annual Report 2021; (2020 & 2021 estimates based on CAGR 2014-2019)

# Focal Segmental Glomerulosclerosis

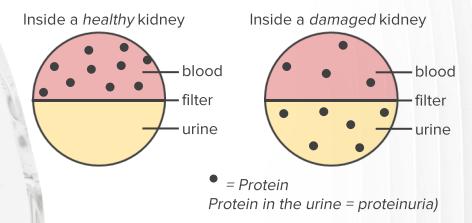
Focal = some

Segmental = sections

Glomerulo = of the kidney filtering units

Sclerosis = are scarred

### A healthy kidney has little to no protein in the urine



- A rare disease that attacks part of the kidney, causing inflammation and irreversible scarring<sup>1</sup>;
- Leads to permanent kidney damage and eventual end-stage kidney failure, requiring dialysis or transplantation
- US orphan indication: ~40,000 with FSGS and >5,400 diagnosed annually²
- Average orphan drug retails for US\$7,000/month in US<sup>3</sup>

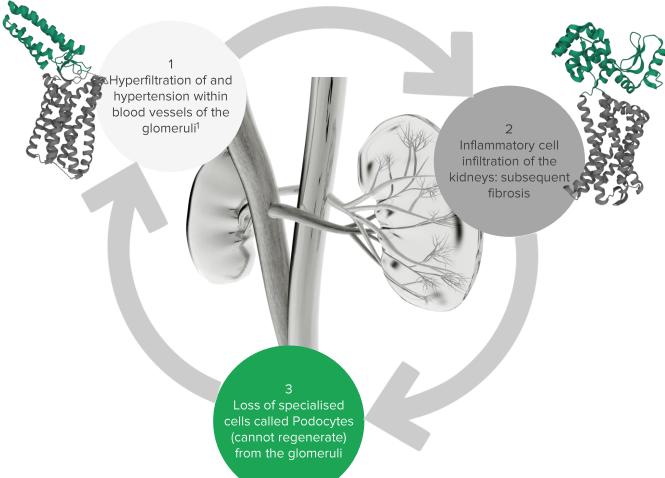


<sup>1.</sup> Guruswamy Sangameswaran KD, Baradhi KM. Focal Segmental Glomerulosclerosis (July 2021), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/

<sup>2.</sup> Nephcure Understanding FSGS 2022: https://nephcure.org/livingwithkidneydisease/ns-and-other-glomerular-diseases/understanding-fsgs/3.2018, IQVIA, Orphan Drugs in the United States: Growth Trends in Rare Disease Treatments

## 3 key mechanisms that cause sclerotic kidney disease

AT1R – blocked by angiotensin receptor blocker (ARB)



CCR2 –CCR2 is the receptor for MCP-1; DMX-200 inhibits CCR2 to block attraction of inflammatory cells into the kidneys<sup>3</sup>

Dimerix' proprietary discovery tool determined a functional interaction between AT1R and CCR2<sup>2</sup>

Certain kidney cells express both receptors, thus using only 1 compound does not completely block activation and results in only a partial response<sup>2,3</sup>

DMX-200 unique proposition: total benefit is greater than the sum of the two individual effects<sup>2,3</sup>



Less filtering cells cause further hyperfiltration and inflammation

## Phase 3 studies investigating FSGS treatments

No therapies yet approved specifically for FSGS

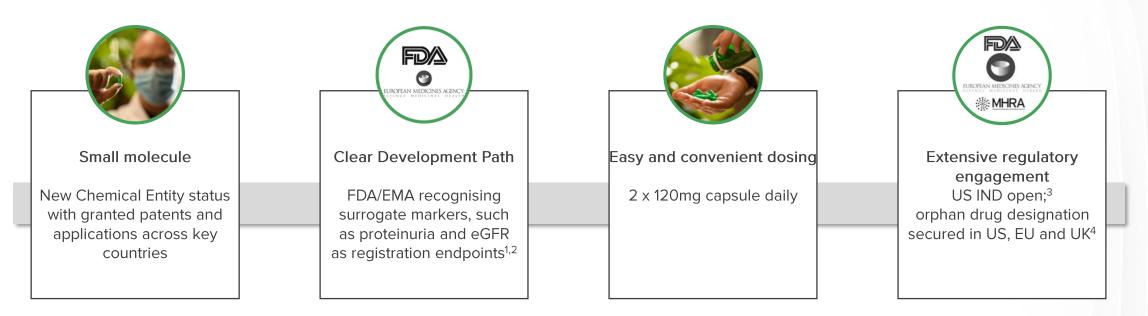
Study	Drug candidate	Mode of action	Comparator	Primary interim (accelerated approval) endpoint
ACTION3 <sup>1</sup>	DMX-200	CCR2 inhibitor	Placebo	Percent change in uPCR and eGFR slope at week 35
DUPLEX <sup>2</sup>	Sparsentan	Dual angiotensin/endothelin A receptor antagonist	Irbesartan	Proportion of patients achieving uPCR ≤ 1.5g/g and >40% reduction from baseline uPCR at week 36

- DMX-200 given to patients already taking an angiotensin receptor blocker, such as irbesartan (current standard of care)
- Data suggests DMX-200 may be complementary to other development compounds, such as sparsentan<sup>3</sup>



## 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)



- 4 clinical studies completed to date: positive efficacy signals across studies
- Consistently safe and well tolerated in both healthy volunteers and renal patients (total of 95 patients dosed)
- DMX-200 safety profile and efficacy outcomes compares favourably to compounds currently in development



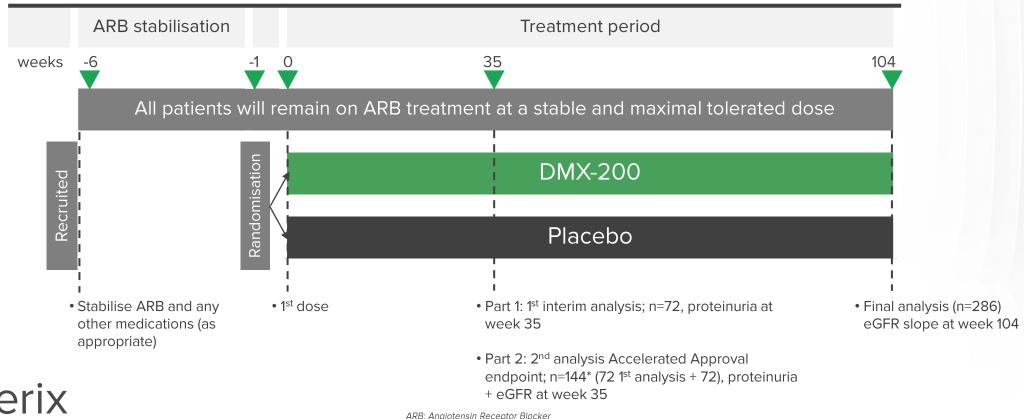
<sup>1.</sup> Thompson et al., (2019) CJASN, 14 (3) 469-481; https://doi.org/10.2215/CJN.08600718

<sup>2.</sup> FDA pulication, (2021); FDA approves first drug to decrease urine protein in IgA nephropathy, a rare kidney disease https://www.fda.gov/drugs/fda-approves-first-drug-decrease-urine-protein-iga-nephropathy-rare-kidney-disease

<sup>3.</sup> ASX release: 09May2022

<sup>4.</sup> ASX releases: 14Dec15, 21Nov18, 07Jun21

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





# ACTION3 - FSGS phase 3 study locations — Part 1

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



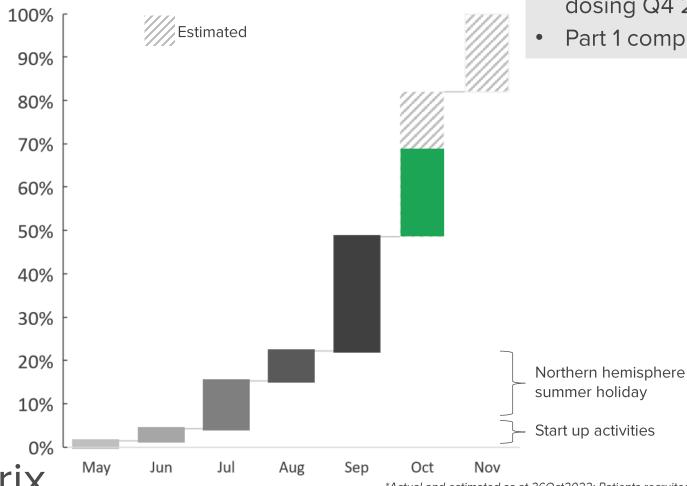




# ACTION3 Study part 1 recruitment status

FSGS CLINICAL STUDY





- On track to complete Part 1 recruitment and dosing Q4 2022
- Part 1 completion anticipated mid-2023\*\*

\*Actual and estimated as at 26Oct2022; Patients recruited undergo ~6 weeks background medication stabilisation period \*\* Subject to recruitment



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.

Lead phase 3 program to report mid 2023

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#### ESG Statement