



# Dimerix

(ASX:DXB)

### **Investor Presentation**

February 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

> Advancing **three** Phase 3 clinical studies

Demonstrated clinical efficacy<sup>1</sup>; drug well understood, with strong safety profile1

Patent protected products with commercial manufacturing established Strong outlook with potential for significant value<sup>2</sup> upside



### Corporate overview



Ticker Symbol

**ASX:DXB** 



Cash Balance (31Dec21)

A\$16.3 million



Market Capitalisation

~A\$75 million



Share price

~A\$0.24



Total ordinary shares on issue

320,873,666



Average volume

1,177,054



Top 20 Shareholders own

35%





Top 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 & Mrs Melinda Coates	8,100,000	2.5%			
4	Bavaria Bay Pty Ltd	7,316,992	2.3%			
5	Yodambao Pty Ltd	6,362,603	2.0%			
6	Solequest Pty Ltd & Nominees	3,387,302	1.1%			
7	Pfleger Family A/C & Nominees	3,137,874	1.0%			
8	Tamer Yigit Property Group Pty Ltd	3,101,343	1.0%			
9	Rubi Holdings Pty Ltd	2,500,000	0.8%			
10	Jampaso Pty Ltd and Nominees	2,377,355	0.7%			
TOTAL (T	OP 10)	98,387,778	30.7%			

## Development pipeline

Program	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Key milestones
DMX-200	Focal Segmental Glomerular Sclerosis (FSGS)					Phase 2a demonstrated encouraging efficacy & safety <sup>1</sup> ; Phase 3 underway with regulatory &/or ethics authorisation in multiple countries <sup>2</sup> , recruitment of 1 <sup>st</sup> patients planned Q1 22, 1 <sup>st</sup> interim data anticipated H1 23 <sup>3</sup>
	Diabetic Kidney Disease					Phase 2 demonstrated promising efficacy and safety <sup>1</sup> , planning of next study design underway
	Late COVID pneumonia – REMAP-CAP					Recruitment underway across Europe <sup>4</sup> , initial data anticipated Q1 22 <sup>3</sup>
	Early COVID respiratory – CLARITY 2.0					Recruitment underway across India <sup>5</sup> , ethics approval in Australia <sup>6</sup> , interim data from India anticipated Q1 22 <sup>3</sup>
DMX-700	Chronic Obstructive Pulmonary Disease (COPD)					Pre-clinical studies underway to support entry into clinical studies; data anticipated Q2 22
DMX-xxx	Undisclosed (multiple)					Additional target opportunities identified using Receptor-HIT; preliminary exploratory work underway



<sup>&</sup>lt;sup>1</sup> ASX releases: 12Jul17, 18Oct17, 27Mar18, 29Jul20, 14Sep20, 27Oct20, 28Jan21, 24Mar21, 03Jun21, 07Jun21, 19Jul21

<sup>&</sup>lt;sup>2</sup> ASX releases: 21Oct21, 01Feb22 (Australia, Denmark); + Taiwan approved on 08Feb22

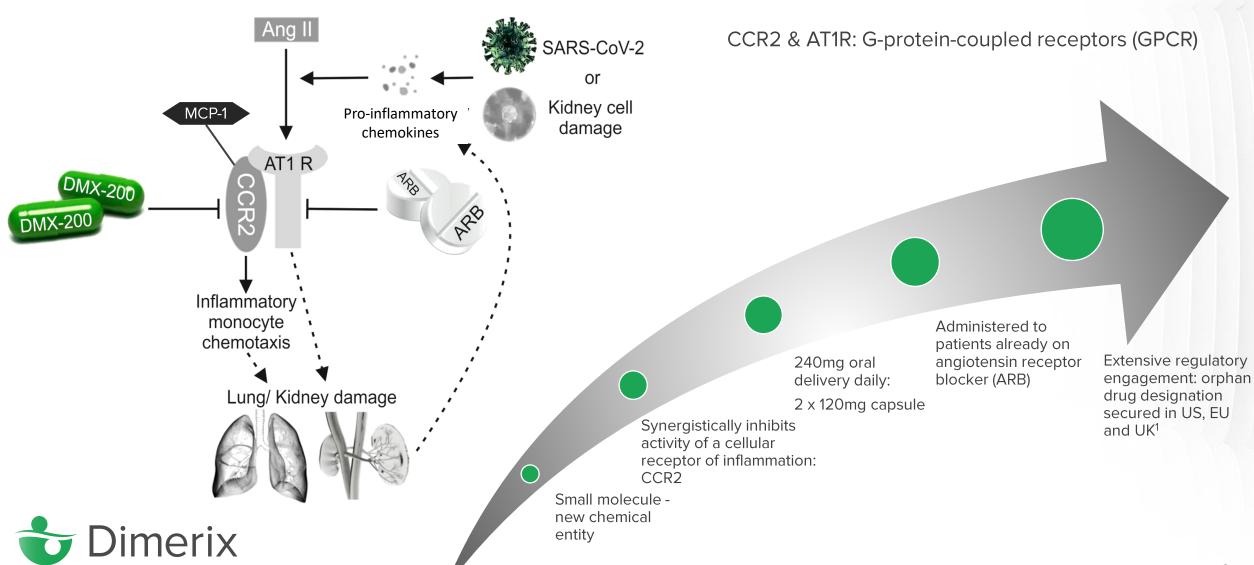
<sup>&</sup>lt;sup>3</sup> Subject to recruitment

<sup>&</sup>lt;sup>4</sup> ASX release: 23Apr21, 16Dec21

<sup>&</sup>lt;sup>5</sup> ASX release: 11Jan22

<sup>&</sup>lt;sup>6</sup> ASX release: 23Dec21

### DMX-200 – working on inflammatory signalling pathway



Kidney Disease Development Overview



FSGS: unmet need and market potential

Focal = some

Segmental = sections

Glomerulo = of the kidney filtering units

Sclerosis = are scarred

~40,000

people in the US are diagnosed with FSGS<sup>1</sup>

>US\$7,000

cost of average orphan drug per month in US<sup>5</sup> (US\$84,000/yr) >5,400

patients in the US are diagnosed with FSGS each year<sup>1</sup>/ 50%

of patients with FSGS will progress to kidney failure<sup>2</sup>

~1000

FSGS patients in

US receive a

kidney

transplant each

vear<sup>2</sup>

**20,000**SGS patients

FSGS patients in US have kidney failure<sup>2</sup>

60%

patients have reoccurring FSGS after first kidney

transplant<sup>3</sup>

20%

of child nephrotic

syndrome cases caused by FSGS<sup>2</sup>

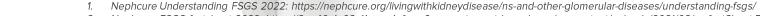
5x

more common

in males<sup>4</sup>

higher incidence in black patients<sup>4</sup>

No therapies yet approved for FSGS



<sup>2.</sup> Nephcure FSGS factsheet 2022: https://2eu46v1q93c11mayx1nfvwg6-wpengine.netdna-ssl.com/wp-content/uploads/2021/02/nc.factSheet.FSGS\_210106.pdf

**Dimerix** 

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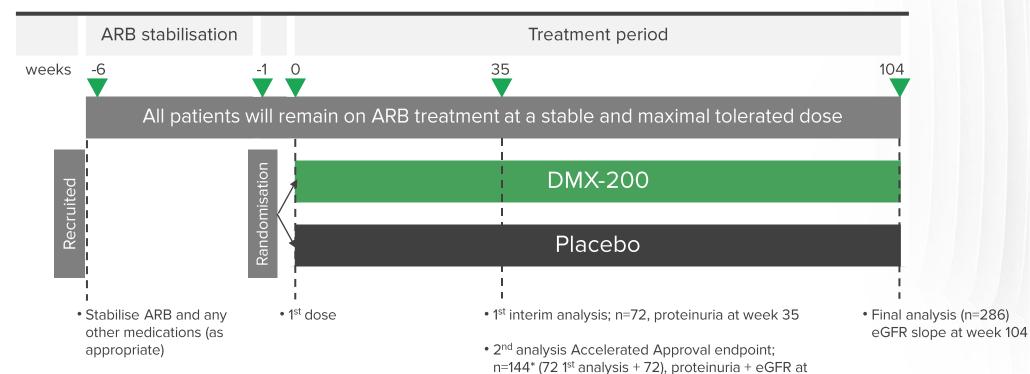
<sup>3.</sup> Front. Immunol., 17 July 2019 | https://doi.org/10.3389/fimmu.2019.01669

Nephron 2020;144:413-427, https://doi.org/10.1159/000508099 2018, IQVIA , Orphan Drugs in the United States: Growth Trends in Rare Disease Treatments

# FSGS phase 3 study design



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



week 35



### FSGS phase 3 study locations



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

#### Global study with ~70 sites in 12 countries:

Country	Regulatory and/or ethics approval to proceed				
Australia	✓				
Argentina	✓				
Brazil					
Denmark	✓				
France	✓				
Hong Kong					
New Zealand	✓				
South Korea					
Spain					
Taiwan	✓				
UK					
USA					



# DMX-200 Intellectual property and exclusivity





- 1. If patent applications are granted: PCT/AU2022/050013;
- 2. DMX-200 is a New Chemical Entity (NCE): an active moiety not approved before which can attract exclusivity periods in various territories
- 3. Granted patents US9,314,450; US10,058,555; US10,525,038; CN2012800046165; CA2,821,985; EP12734251.7; HK 4104477.8; IL227414; JP2013-547780; SA203/5897; AU2012206945



# COVID-19 and pneumonia market potential

#### 3 million

deaths annually caused by lower respiratory tract infections pre-COVID\*



#### **US\$17** billion

pre-COVID: Pneumonia responsible for US\$17 billion in healthcare costs each year in the US<sup>1</sup>

#### US\$18.5 billion

market forecast expected by 2029, growing at 10%/year<sup>3</sup>

#### 4.5 million:

covident counting cou



of all patients with pneumonia require admission to Intensive Care Units<sup>1</sup>



#### \$ 2,300-4,600

The cost of treatment with Tocilizumab (IL-6 receptor antagonist used for COVID-19): IV single dose<sup>4</sup>



- . REMAP-CAP background: https://www.remapcap.org/background
- 2. WHO COVID dashboard: https://covid19.who.int/
- Data Bridge Market Research 2022, https://www.databridgemarketresearch.com/reports/global-acute-respiratory-distress-syndrome-ards-market 12
- Dose and therefore cost varies with patient weight; PharmacoEconomics & Outcomes News 2021; volume 879, p.28

### Potential benefits of DMX-200





Antiviral medications:

Typically effective at preventing damage caused by a virus when administered

within 3-5 days of infection<sup>1</sup>

when many are asymptomatic





Does not rely on early inhibition of viral replication

DMX-200 aims to prevent damaging immune response regardless of vaccination or antiviral treatment



#### DMX-200:

May be beneficial for patients with a wide range of respiratory diseases in addition to COVID<sup>2</sup>

specific for a virus and sometimes even the



### Two Phase 3 studies in COVID-19 patients





#### **REMAP-CAP:** COVID-19 pneumonia in ICU

- >750 patients recruited to the study domain
- WHO endorsed study
- Primary endpoint = 21 day mortality



Funded by European Union through H2020 "Rapid European COVID-19 Emergency Research response" (RECOVER) project

#### **CLARITY 2.0:** COVID-19 respiratory complications

- Recruiting >600 patients in India and Australia
- Primary endpoint = 14 day WHO Clinical Health Score

Run through the NHMRC Clinical trials centre and the University of Sydney

Secondary endpoint: recovery and quality of life post hospitalisation (long-COVID assessment)





### Additional asset value propositions

Longer term opportunities



DMX-200 Diabetic Kidney Disease Diversifying risk and potential sources of revenue

DMX-700 Chronic Obstructive Pulmonary Disease



Addressable market

US\$1.1 billion\*

Key driver is the rise in diabetes global incidence

Global COPD treatment market (2017)

US\$14 billion\*\*



<sup>2017</sup> IQVIA ARB prescription and pricing data;

https://www.marketwatch.com/press-release/chronic-obstructive-pulmonary-disease-copd-therapeutics-market-global-industry-analysis-trends-market-size-and-forecasts-up-to-2030-2021-11-10?tesla=v



# Corporate Outlook

### Potential value driving events

2021

2022

- ✓ DMX-200 demonstrated **encouraging clinical efficacy** and **strong safety profile** across multiple Phase 2 renal clinical studies
- ✓ Consistent advice received from FDA, EMA and UK MHRA on FSGS Phase 3 study design
- Orphan Drug Designation/accelerated approval pathway granted by US FDA, EU EMA and UK MHRA for FSGS
- ✓ Two independent Phase 3 clinical studies underway in patients with COVID-19 respiratory complications
- ✓ DMX-200 manufacturing process optimised to improve commercial scalability and global logistics
- ✓ DMX-700 in COPD progressed further towards clinical development
- ✓ Expansion of IP portfolio
- ✓ Strong financial position

FSGS ethics approval and clinical site initiations				
FSGS Phase 3 study recruitment and first patient first dose				
REMAP-CAP Phase 3 COVID-19 study recruitment and top line data				
CLARITY 2.0 Phase 3 COVID-19 study recruitment and top line data				
DMX-700 for Chronic Obstructive Pulmonary Disease progression towards <b>clinical study</b>				
Diabetic kidney disease <b>clinical study</b> design and next steps				
✓ Further expansion of <b>IP portfolio</b>				
FSGS Phase 3 study Part 1 analysis and progression to Part 2				





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.

**Advancing three Phase 3 opportunities** 

Well positioned to deliver against strategic plan

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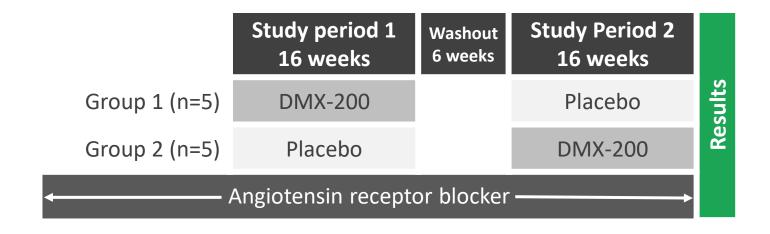
#### ESG Statement



### Phase 2a trial in FSGS completed

Phase 2a DMX-200-202 (ACTION for FSGS): Phase 2a, Double-blind, Randomised, Placebo-Controlled, <u>Crossover</u> Study Evaluating the Safety and Efficacy of DMX-200 in Patients with Primary Focal Segmental Glomerulosclerosis who are Receiving Irbesartan

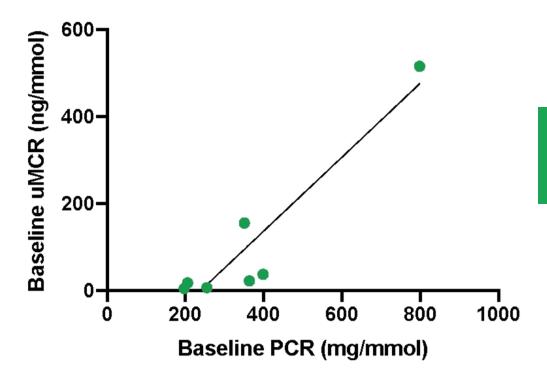
- Primary endpoint: safety. Secondary endpoint: proteinuria and biomarker analysis.
- Patient population: Patients with primary FSGS who are receiving irbesartan





### DMX-200 inflammatory biomarker

Average baseline MCP-1 versus average baseline proteinuria



DMX-200 Phase 2 study confirmed high MCP-1 correlates to high proteinuria in FSGS patients

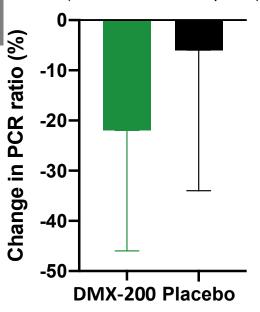


### DMX-200 PCR summary

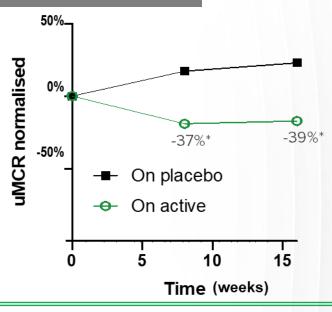
Change in uPCR over time on DMX-200 versus placebo

(repeat measures mixed model)

Geometric mean difference -17% (95% CI -43 to +20; p0.25)



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



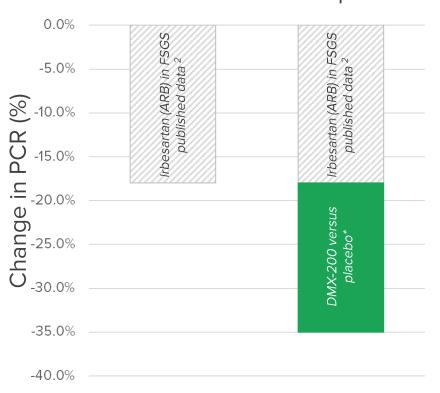
16 weeks treatment with DMX-200 vs placebo:

- 17% reduction of uPCR: mixed model, repeat measures statistical test; (grouped analysis model shows a 25% drop in uPCR)
- 39% reduction inflammatory biomarker MCP-1:
  - DMX-200 blocks receptor responsible for inflammation
  - translates to reduced inflammation and subsequent fibrosis (scarring) in the kidney



### DMX-200 treatment group met primary and secondary endpoints

Average reduction in proteinuria after 16 weeks treatment on DMX-200 versus placebo compared to standard of care alone in FSGS patients<sup>1</sup>



- DMX-200 demonstrated clear benefit to patients with FSGS
  - o 86% of patients demonstrated reduced proteinuria on DMX-200 versus placebo
  - o 29% of patients demonstrated >40% reduction in proteinuria
  - o Results comparable to other compounds in development<sup>2</sup>
- DMX-200 was safe and well-tolerated
- DMX-200 may be complementary to other development compounds, such as sparsentan<sup>3</sup>

No safety concerns – reduced development risk DMX-200 compares favourably to compounds currently in development<sup>2,4</sup>



PCR = protein creatinine ratio

ARB = angiotensin receptor blocker

<sup>1.</sup> Repeated measures mixed model analysis; top line data was reported as grouped analysis

<sup>2.</sup>Trachtman, et al., 2018. J Amer Soc Nephrology 29(11):2745-2754

<sup>3.</sup>ASX release 24Mar21

<sup>4.</sup>Based on: a) https://lupkynispro.com/safety/; b) https://www.reatapharma.com/investors/news/news-details/2021/Reata-Pharmaceuticals-Announces-Outcome-of-FDA-Advisory-Committee-Meeting-of-Bardoxolone-for-the-Treatment-of-Patients-with-Chronic-Kidney-Disease-Caused-by-Alport-Syndrome/default.aspx; c) https://pubmed.ncbi.nlm.nih.gov/31343124/; https://www.goldfinchbio.com/news-features/goldfinch-bio-presents-clinical-data-from-phase-1-trial-supporting-advancement-of-gfb-887-as-a-precision-medicine-for-patients-with-kidney-diseases/