# **Dimerix Limited**

a Phase 2 biotech with a scalable, proprietary platform technology

June 2019



### 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.



# Dimerix Corporate Overview

Financial information	
ASX Code	DXB
Share price (24 Jun 19)	\$0.085
52 week low / high	\$0.072 / \$0.15
Shares on issue	158.8m
<b>Market Capitalisation</b>	\$13.5 million
Cash (as at 31 Mar 19)	\$4.5 million
Debt	\$0
Enterprise value	\$9.0 million

Top shareholders:		
1	Mr Peter Meurs	15.63%
2	Yodambao Pty Ltd	3.98%
3	White Family A/C	1.38%
4	Pfleger Family A/C	1.33%
5	Jampaso Pty Ltd	1.12%

Automic Register as at 25Jun19 Note shareholders may have other holdings



#### **About Dimerix**



#### People

- Proven Management and Board with international experience
- Diverse skill sets
- Strategic alignment
- Successfully commercialised pharma products globally



#### **Patents**

- Unique GPCR screening technology
- Clear product differentiation
- Comprehensive protection
- ✓ DMX-200 patents granted to 2033
- ✓ Receptor-HIT patents granted to 2029



#### **Products**

- Receptor-HIT GPCR screening assay
- Positive successful Phase 2 data
- •DMX-200 high value Phase 2 assets:
- ✓ Diabetic Kidney Disease
- ✓ FSGS
- Assets wholly owned by Dimerix



## Corporate highlights



Special Access Scheme (SAS) available to patients completing Phase 2 trials

Multiple patients from 2017 study remain on SAS



Cash reserves of \$4.5 million sufficient to complete both trials



Receptor-HIT Assay licensed; Dimerix eligible for royalties on fee-forservice offering



Excellent results from Phase 2a trial in 2017

all trial endpoints met



R&D collaboration underway with University Western Australia



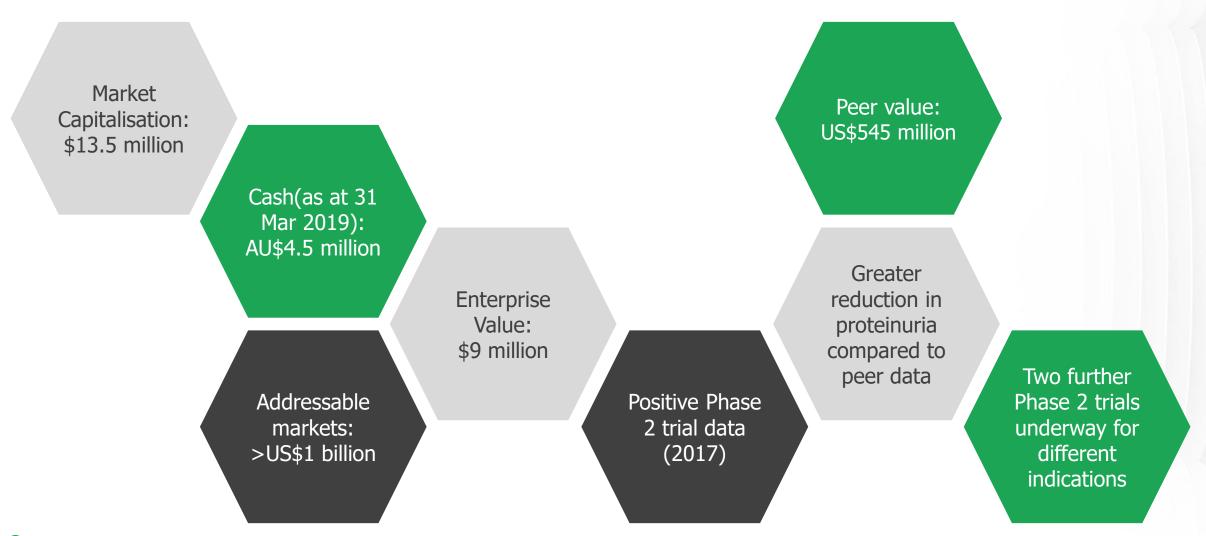
80% patients recruited in Diabetic Kidney Disease Phase 2 trial; data expected Q220



FSGS Phase 2a trial recruitment expected to complete July19; data expected Q220



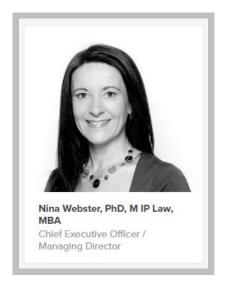
## Value proposition

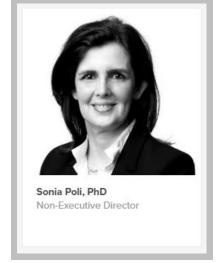


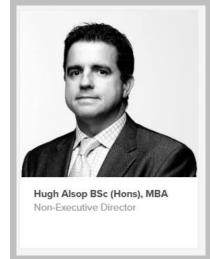


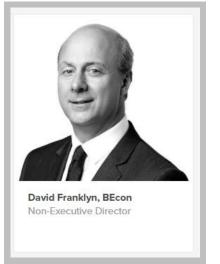
#### **Board of Directors**













#### Strategic activities

DMX-200 in Focal **Segmental Glomerulosclerosis** (FSGS) Faster path to market with set market exclusivity period

Serious and rare kidney disease: orphan indication

~210,000 individuals affected globally

>93,000 patients on kidney transplant waiting list in US

DMX-200 has US and **EU Orphan Drug** Designation for FSGS

**DMX-200** in Diabetic **Kidney Disease** (DKD)

> Progressive disease, leading to kidney failure and blood dialysis

23 million diagnosed diabetics in the US\*

Diabetes incidence estimated to grow 54% by 2040†

>20% of diabetics had kidney disease\*

**Receptor-HIT** technology platform

3

Licensed: fee-for-service Is available through licensee

Enables understanding of receptor interactions

Rapidly screen and identify new drug opportunities

Applied to multiple stages of drug development process **Pipeline Programs** 

4

Expand and build product pipeline

Business development focus

> Commercially attractive

Strategic fit within resource and funding capabilities



Diabetic Kidney Disease: Challenges, Progress, and Possibilities, American Journal of Nephrology, 2017. [ONLINE Available at https://cjasn.asnjournals.org/content/early/2017/07/12/CIN.11491116 [Accessed 01Oct18]<sup>†</sup>
US National Diabetes Statistics Report, 2017. [ONLINE] Available at https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf. [Accessed 01Oct18]
Kidney Health Australia. 2018. Diabetic Kidney Disease. [ONLINE] Available at https://kidney.org.au/cms\_uploads/docs/diabetic-kidney-disease--kidney-health-australia-fact-sheet.pdf [Accessed 11Sep18]

## Partnering strategy

- Identify partner(s) with the expertise and resources to advance products to market
- Build strategic alliances across commercial, clinical and manufacturing areas at the appropriate stage of development

Enhance potential success of product candidates

Mitigate capital obligations & commercial risk

#### **Current partners:**



2019 - Receptor-HIT Assay Technology license agreement with Excellerate Bioscience Limited



2018 - R&D collaboration on molecular pharmacology profiling of targets of interest to Dimerix with Harry Perkins Institute of Medical Research and University of Western Australia (UWA)

Professor Kevin Pfleger, Head of Molecular Endocrinology & Pharmacology at the Perkins and Chief Scientific Advisor to Dimerix



# Introduction to DMX-200





#### What is DMX-200

DMX-200: a small molecule also known as propagermanium

- Twice daily, capsule administration
- Administered to patients already on standard of care treatment (Irbesartan)
- Product attributes: deliver best-in-class benefits to patients
- Inhibits activity of a cellular receptor of inflammation: CCR2 (C-C Chemokine Receptor Type 2)
- Never been approved by a regulatory authority for clinical use in the US, Europe or Australia
- DMX-200 is not available as a generic drug and is considered a New Chemical Entity\* (NCE) in the US

Not a generic Never been FDA approved





### Proposed mechanism of action

DMX-200 addresses three key mechanisms that causes renal damage and chronic kidney disease

hyperfiltration of and hypertension within blood vessels of the glomeruli

inflammatory cell infiltration of the loss of specialised cells called

> Podocytes (cannot regenerate) from the glomeruli

Irbesartan blocks cellular receptors responsible for hyperfiltration & glomerular hypertension

DMX-200 blocks chemokine receptor (CCR2) which initiates attraction of inflammatory cells into the kidneys

Certain kidney cells express both receptors, thus using only 1 compound does not block activation and results in only a partial response

DMX-200 unique proposition: total benefit is greater than the sum of the two individual effects

kidneys: subsequent

fibrosis

#### **Intellectual Property**



- Multiple granted patents in numerous territories
- New patent applications underway in line with commercialisation strategy
- Granted method of use patents in key territories strengthens the company's competitive position
- Granted patents may block some competitor product development plans
- Granted method of use patents expire ~2033



- New Chemical Entity can attract minimum 5 years exclusivity (more for orphan)
- DMX-200 advantage of submitting an NCE new drug application in the US & EU whilst simultaneously relying on existing safety data



- Exclusively owned IP & know-how associated with DMX-200 manufacturing processes & validated methodology
- Completed manufacture of demonstration batch



### DMX-200 Phase 2a 2017 results summary

An open label, Phase II, dose escalation and expansion study of DMX-200 in participants with proteinuria currently taking a stable Angiotensin Receptor Blocker therapy (Irbesartan): n=27

#### **Primary Endpoints ("safety")**

- Incidence and severity of Adverse Events
- Clinically significant changes in the safety profile of participants (biochemistry, hematology, urinalysis, physical examinations)

#### **Secondary Endpoints ("efficacy signals")**

 The proportion of responders, defined as those participants achieving normalisation of proteinuria or a 50% reduction in proteinuria





#### Diabetic sub-group ACR mean reduction (n=10)

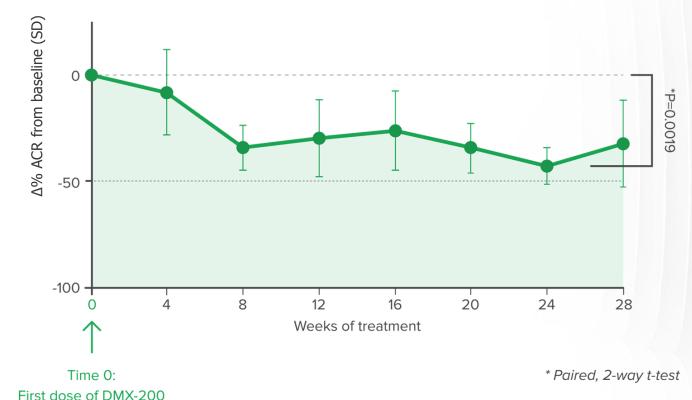
• In 2017 - DXB Phase 2a study: DMX-200 + Irbesartan

> Proteinuria levels reduced by a further 35.6% in diabetic sub-group

This reduction is <u>in addition</u> to the 24% reduction in proteinuria seen in patients taking Irbesartan

Reduction of proteinuria by >30% may increase time to dialysis by 3-5 years and reduce health costs by \$100,000 per patient per year

#### Diabetic sub-group ACR mean reduction (n=10)

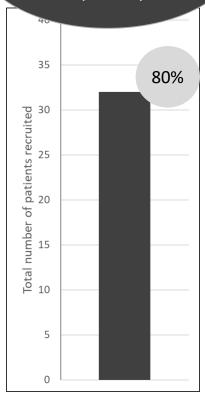




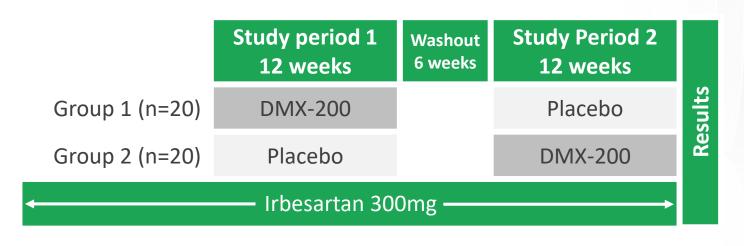
## Phase 2 trial in Diabetic Kidney Disease

#### **Diabetic Kidney Disease**

- Number of patients to be enrolled: 40
- Recruitment expected to complete Sept 2019



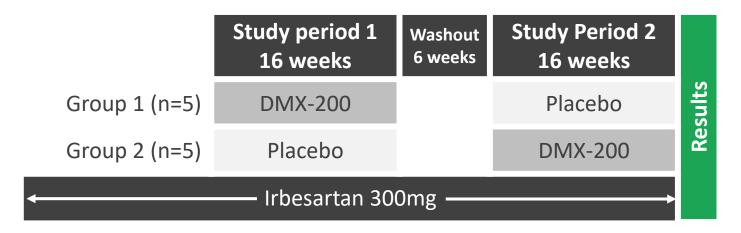
- Double-blind, randomised, placebo-controlled, crossover study evaluating the safety and efficacy of DMX-200 in patients with diabetic kidney disease who are receiving a stable dose of Irbesartan
- 12 weeks propagermanium and 12 weeks placebo separated by a 6 week washout period (ANZCTR website for details)





#### Phase 2 trial in FSGS

- Double-blind, randomised, placebo-controlled, crossover study evaluating the safety and efficacy of DMX-200 in patients with FSGS who are receiving a stable dose of Irbesartan
- 16 weeks propagermanium and 16 weeks placebo separated by a 6 week washout period (ANZCTR website for details)

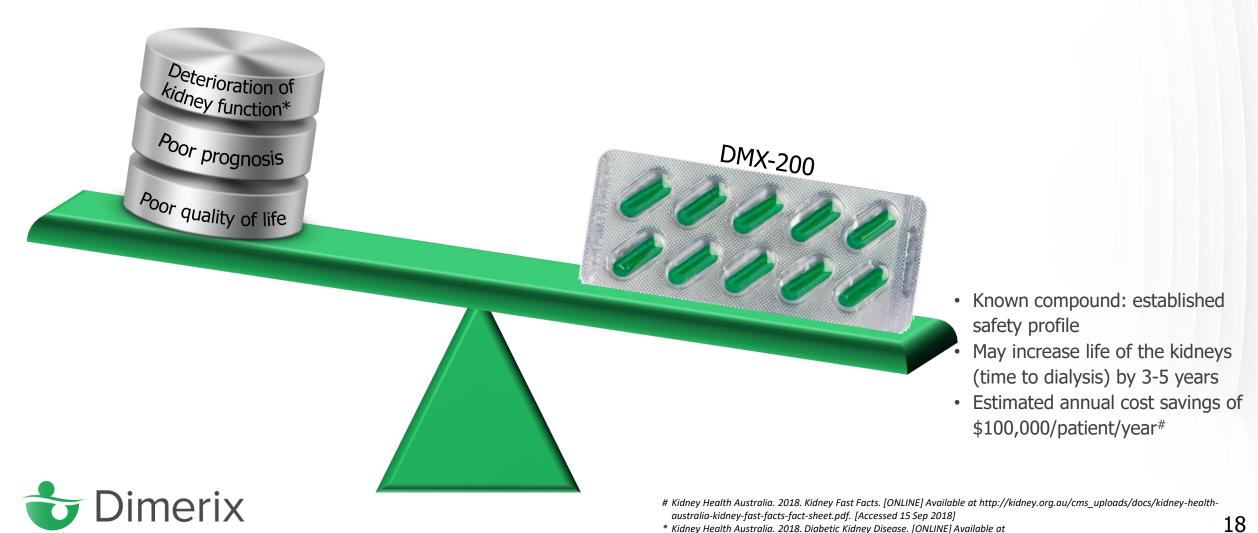


Study results anticipated Q2 2020 (calendar year)

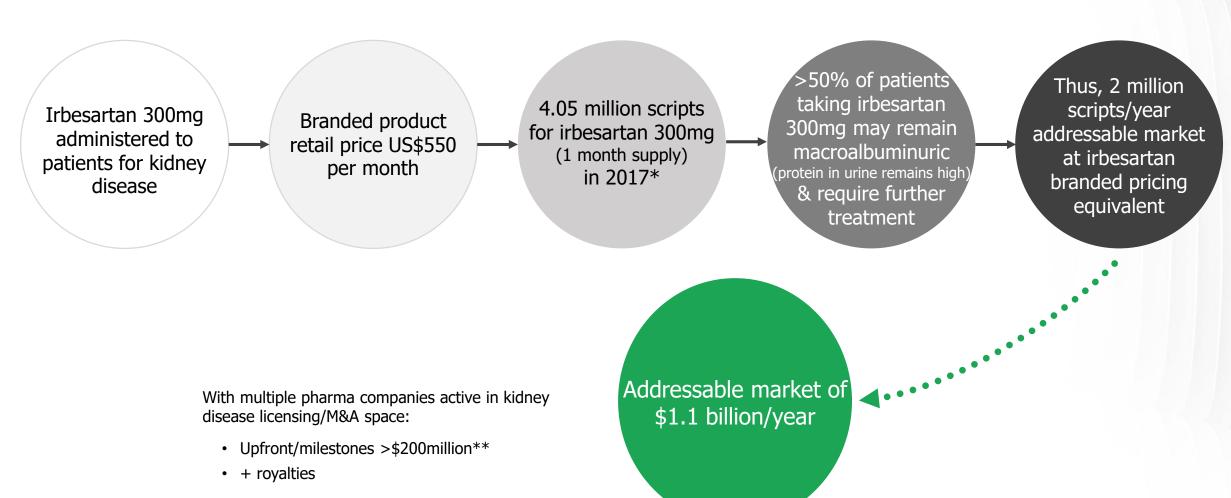




#### DMX-200 value: patients, payers & healthcare system



# DMX-200 for Diabetic Kidney Disease value in US: large market with low competition





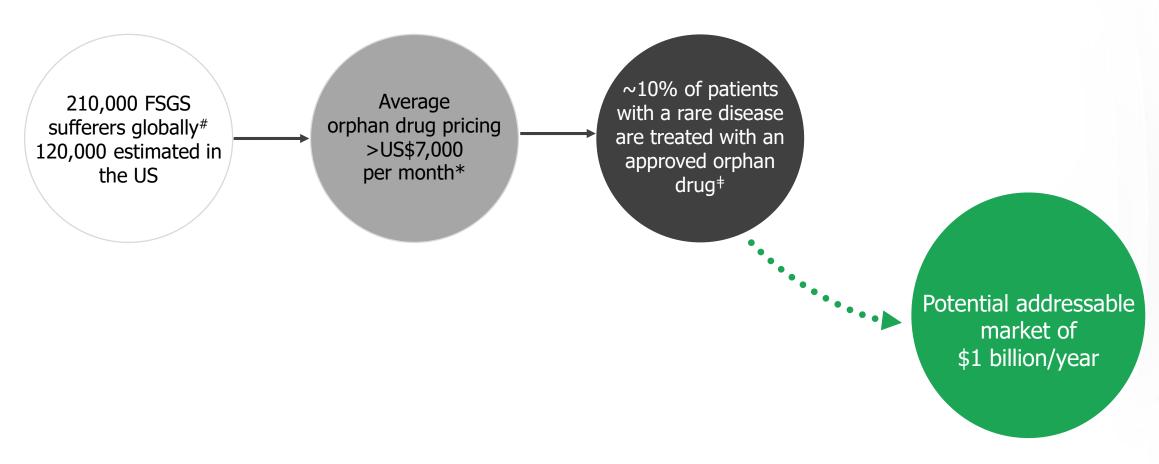
# pre-genericization

<sup>\*2017,</sup> IQVIA

<sup>†</sup> Avapro prescribing information

<sup>\*\*</sup> Ionis, Vifor, Epigen deals in 2018

# DMX-200 for FSGS value in US: orphan drug status with low competition

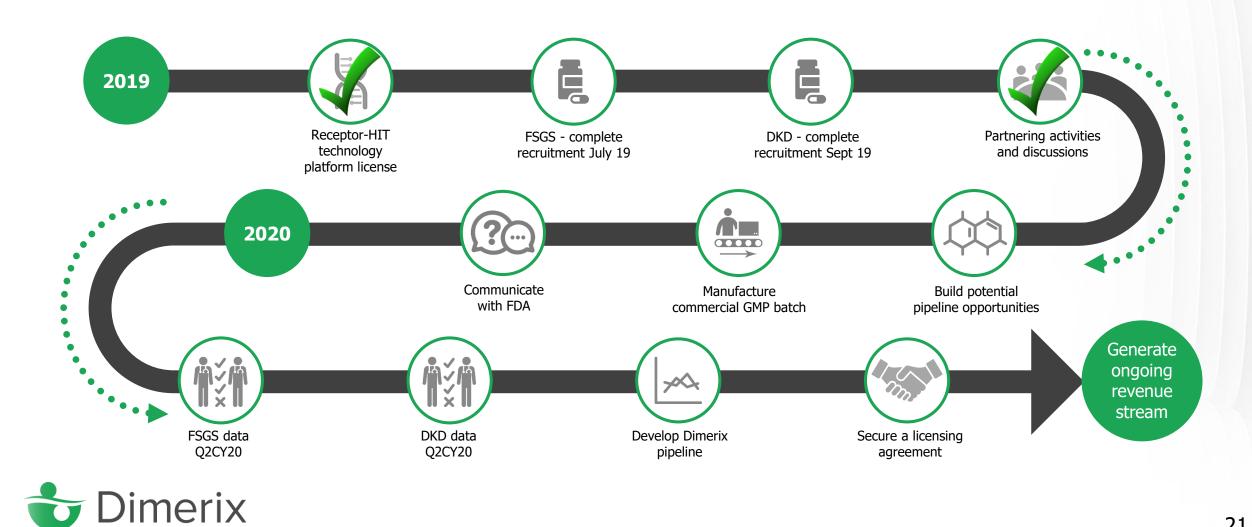


<sup>\*</sup>Transparency Market Research, 2018, Focal Segmental Glomerulosclerosis (FSGS) Market, Global Industry Analysis, Size, Share, Growth, Trends, & Forecast 2017-2025, [ONLINE] Available at: <a href="https://www.transparencymarketresearch.com/focal-segmental-glomerulosclerosis-market.html">https://www.transparencymarketresearch.com/focal-segmental-glomerulosclerosis-market.html</a> [accessed 21Nov18)



<sup>\*2018,</sup> IQVIA, Orphan Drugs in the United States: Growth Trends in Rare Disease Treatments, [ONLINE] Available at: <a href="https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/orphan-drugs-in-the-united-states-growth-trends-in-rare-disease-treatments.pdf">https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/orphan-drugs-in-the-united-states-exclusivity, Pricing and Treated Populations, [ONLINE] Available at: <a href="https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/orphan-drugs-in-the-united-states-exclusivity-pricing-and-treated-populations.pdf">https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/orphan-drugs-in-the-united-states-exclusivity-pricing-and-treated-populations.pdf</a> [accessed 19Jun19]

# Value driving events



## DIMERIX

**End of Presentation** 

