# Dimerix(ASX:DXB)

a Phase 2 biotech with a scalable, proprietary platform technology

# Trial Update Presentation

March 2019



# February 2019 investor update



New corporate branding
 & website launched:
 improved access to
 investor information



- •80% patients recruited into FSGS Phase 2 trial
- Patient enrolment on track for dosing completion in Q4CY19



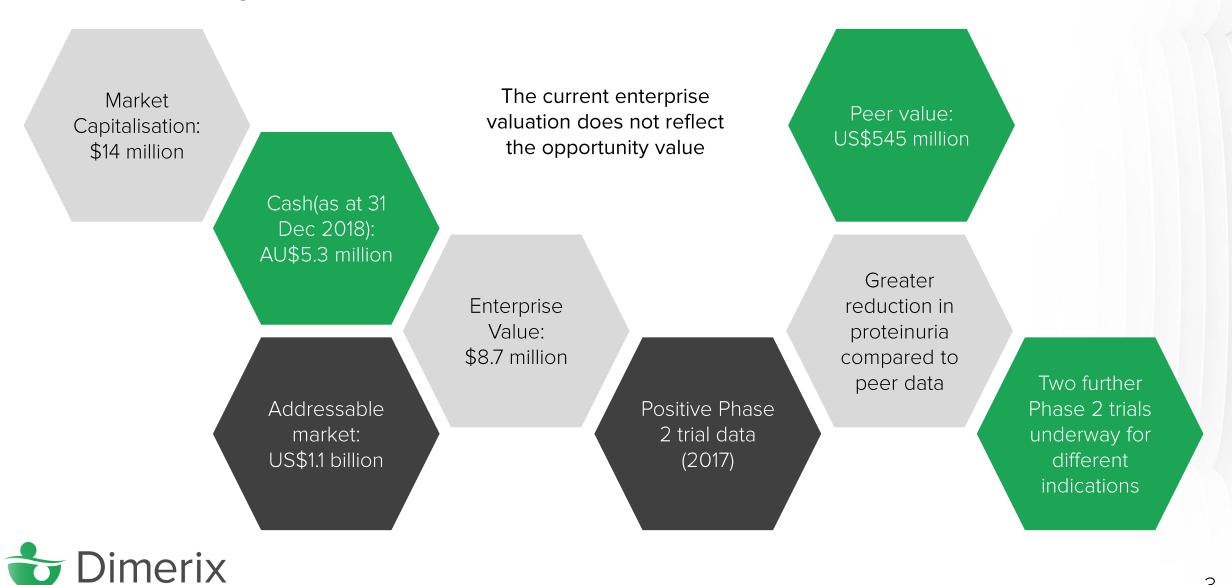
- •30% patients recruited into Diabetic Kidney Disease Phase 2 trial
- Patient enrolment on track for dosing completion in Q4CY19



 Multiple patients from 2017 Phase 2 trial continue on DMX-200 via TGA Special Access Scheme • Cash reserves at 31 December 2018: \$5.3 million



# Value Proposition



# Forward looking statements

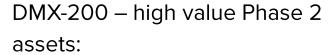
This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Dimerix to be materially different from the statements in this presentation.

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 (ASX:DXB)





- Diabetic Kidney Disease
- FSGS

Receptor-HIT GPCR screening assay

Assets wholly owned by Dimerix



Unique GPCR screening technology
Clear product differentiation
Comprehensive protection

- DMX-200 patents granted to 2033
- Receptor-HIT patents granted to 2029



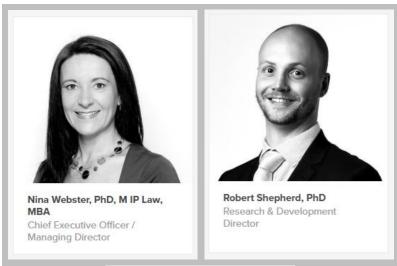
### People

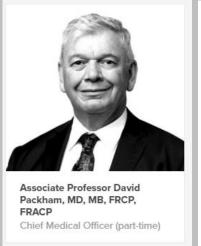
Proven Management and Board with international experience Diverse skill sets
Strategic alignment
Successfully commercialised pharma products globally



# Management & Board of Directors

#### Executive team





### Non-executive team



James Williams, PhD, MBA Non-Executive Chairman



David Franklyn, BEcon Non-Executive Director



Sonia Poli, PhD Non-Executive Director



Hugh Alsop BSc (Hons), MBA Non-Executive Director



## Strategic activities

### DMX-200 in Focal Segmental Glomerulosclerosis (FSGS)

- A serious and rare kidney disease: orphan indication
- Rapid progression to end-stage renal disease
- ~210,000 individuals affected globally
- Eventually require blood dialysis
- >93,000 patients on kidney transplant waiting list in US
- Kidney transplant costs >\$262,000 in the 1st year
- DMX-200 has US and EU Orphan Drug Designation for FSGS
- Faster path to market with set market exclusivity period

### HIT technology platform

- Scalable, globally applicable, proprietary technology
- Enables understanding of receptor interactions to rapidly screen and identify new drug opportunities
- Can be applied to a number of stages of the drug development process

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

- Also known as Diabetic Nephropathy
- Progressive disease, leading to kidney failure and blood dialysis
- 23 million diagnosed diabetics in the US\*
- Diabetes incidence estimated to grow 54% by 2040<sup>t</sup>
- >20% of diabetics had kidney disease\*
- Progressive disease, leading to kidney failure and blood dialysis

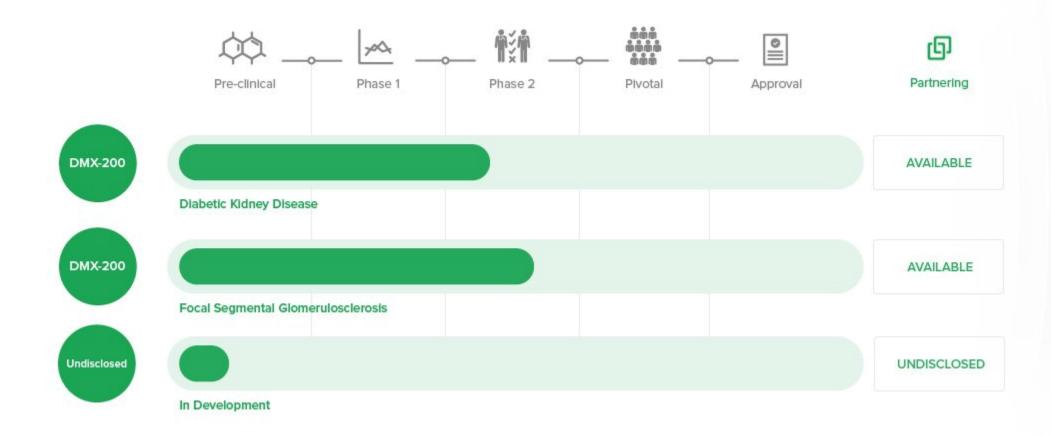
### Pipeline programs

- Expand and build product pipeline
- Business development focus
- All potential opportunities screened 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/CJN.11491116 [Accessed 01Oct18]
 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]

# Product pipeline





# Partnering strategy

Enhance potential success of product candidates and mitigate capital obligations & commercial risk

- 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

#### **Current collaborations**

Harry Perkins Institute of Medical Research and University of Western Australia (UWA) – 2018



- Molecular pharmacology profiling of targets of interest to Dimerix
- Overseen by: Associate Professor Kevin Pfleger
   Head of Molecular Endocrinology & Pharmacology at the Perkins and Chief Scientific Advisor to Dimerix



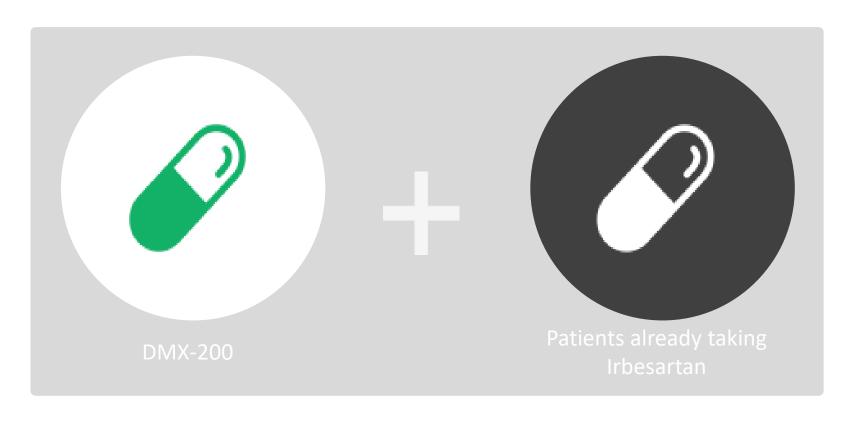


# Introduction to DMX-200





### What is DMX-200



- Irbesartan 300mg angiotensin receptor blocker (ARB)
  - Standard of care
  - FDA (USA) approved for Diabetic Kidney Disease
- DMX-200 CCR2 antagonist
  - Small molecule
  - PDMA (Japan) approved for chronic hepatitis B
  - Twice daily, capsule administration
  - Product attributes: deliver best-inclass benefits to patients

Administration of DMX-200 to achieve a synergistic effect in improving renal function



## Proposed mechanism of action

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

1 hyperfiltration of and hypertension within blood vessels of the glomeruli

2
inflammatory cell
infiltration of the
kidneys:
subsequent
fibrosis

imerix

3
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

# Intellectual Property



- Multiple granted patents in numerous territories
- New patent applications underway
- Covers the use of CCR2 antagonists (e.g. DMX-200) in patients receiving angiotensin receptor blockers (e.g. Irbesartan), for various indications including kidney disease
- Granted therapeutic use patents expire ~2033



- Assay based technology for receptor interactions, e.g. G-protein coupled receptors (GPCRs)
- Can be applied to a number of stages of the drug development process
- Allows identification of pairs of different receptors that interact when ligands, small molecule drugs, peptides or antibodies, bind to them
- Granted method patents expire ~2029



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

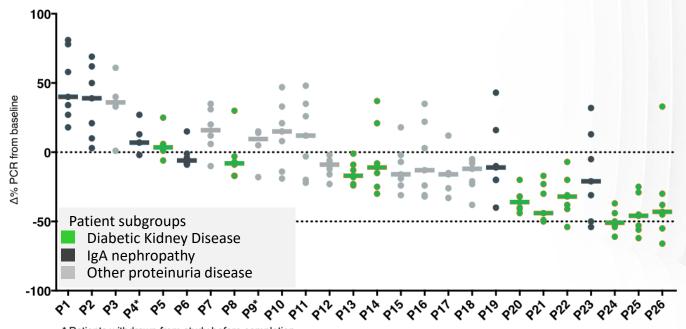
### All endpoints met:

safe and well tolerated

### Responders

6/24 patients had a 50% decrease in PCR





<sup>\*</sup> Patients withdrawn from study before completion



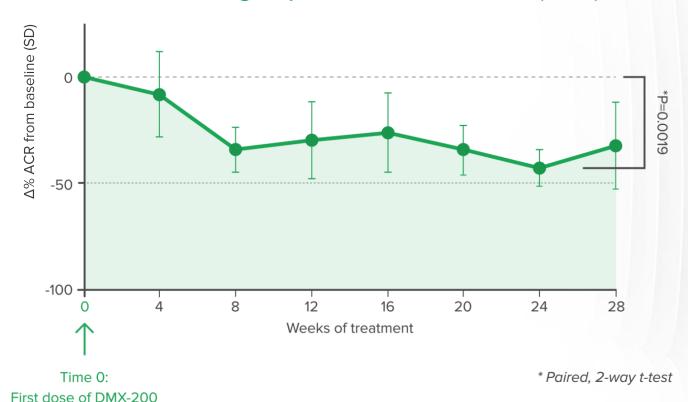
## Diabetic sub-group ACR mean reduction (n=10)

- In 2001 Irbesartan studied in a large group of type 2 diabetics
  - Proteinuria levels reduced by 24%
- In 2017 DXB Phase 2a study: DMX-200
  + Irbesartan

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

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)





### Two current clinical trials

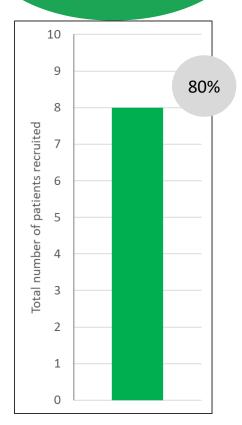
#### Both studies:

- Double-blind, randomised, placebo-controlled, crossover study evaluating the safety and efficacy of DMX-200 in patients with diabetic kidney disease or FSGS who are receiving Irbesartan
- Must be on 300 mg/daily of Irbesartan for >3months prior to screening
- All patients will receive DMX-200 and be followed for:
  - Safety
  - o Reduction in protein in patient's urine
  - Improvement in kidney function
- Interim efficacy results not planned as the study is designed to support validity of endpoint analysis

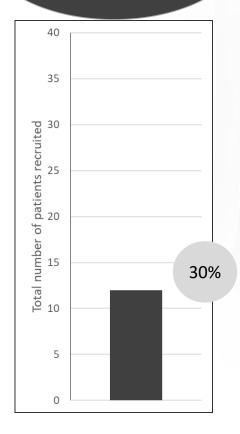
# **b** Dimerix

#### FSGS

- Number of patients to be enrolled: 10
- Enrolment is on track for dosing completion in CY Q4'2019

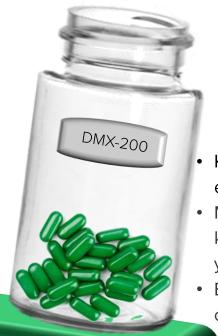


- <u>Diabetic Kidney Disease</u>
- Number of patients to be enrolled: 40
- Enrolment is on track for dosing completion in CY Q4'2019



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





- Known compound = established safety profile
- May increase life of the kidneys (time to dialysis) by 3-5 years
- Estimated annual cost savings of \$100,000/patient/year#



<sup>#</sup> Kidney Health Australia. 2018. Kidney Fast Facts. [ONLINE] Available at http://kidney.org.au/cms\_uploads/docs/kidney-health-australia-kidney-fast-facts-fact-sheet.pdf. [Accessed 15 Sep 2018]

<sup>\*</sup> 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]

### DMX-200 value: large market with low competition

### Assumptions:

- Administered to patients receiving Irbesartan 300mg for kidney disease
- 4.05 million scripts for irbesartan 300mg in 2017\*
- Assume >50% of Irbesartan 300mg scripts due to kidney disease
- As diabetes rates rise, sales will continue to grow

Addressable market: \$1.1 billion/year

Multiple pharma companies active in kidney disease licensing/M&A with:

- Upfront/milestones >\$200million\*\*
- + royalties





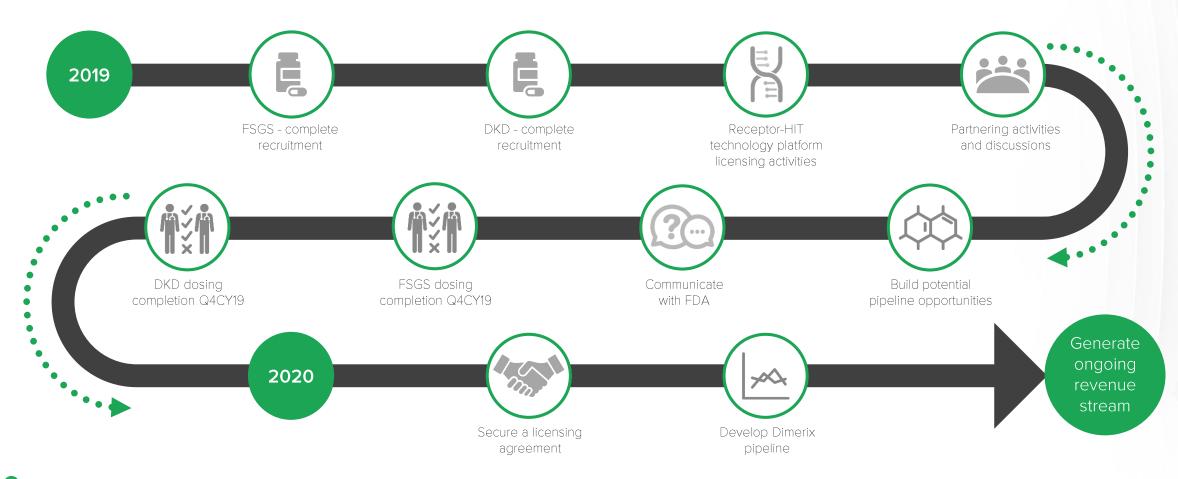
<sup>#</sup> pre-genericization

<sup>\*2017,</sup> IQVIA, (total = 4.05 million -adjusted by 50%)

<sup>†</sup> Avapro prescribing information

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

# Value driving events





# DIMERIX

**End of Presentation** 

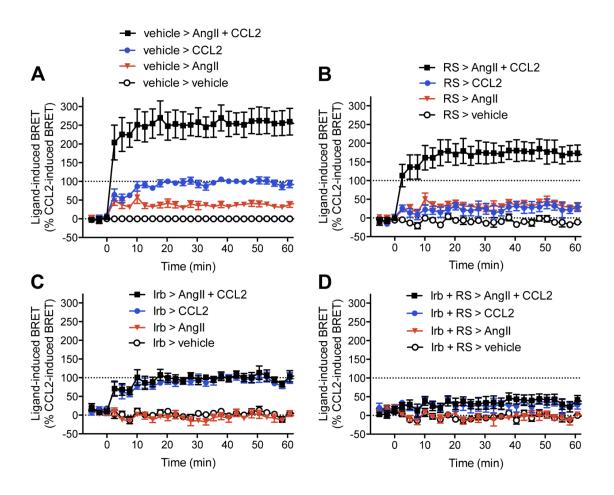


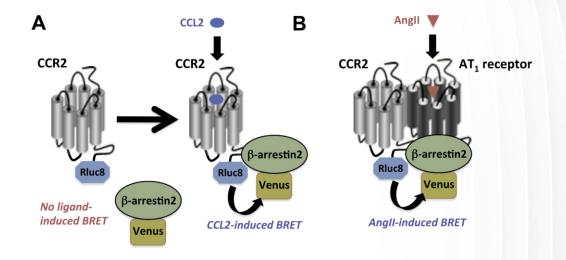
#### **Dimerix HQ** St, Fitzroy 3065

# Appendices



# Discovery of DMX-200 – Receptor-HIT at work





Dual blockade of AT1 receptor and CCR2 is required for total inhibition of  $\beta$ -arrestin 2 recruitment

