# DIMERIX (ASX: DXB)

# **Investor Update**

October 2018



## 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.

## Investment highlights



#### a phase II biotech with a scalable, proprietary platform technology

#### **Excellent results from Phase 2 trials in CKD in 2017**

- DMX-200 phase 2a clinical trial in Chronic Kidney Disease completed
- No adverse safety events
- All trial endpoints achieved
- Sub group analysis shows statistically and clinically significant efficacy signals

#### Progress into two Phase 2 trials in high potential targets in 2018

- Two phase 2 clinical efficacy trials initiated in sub groups:
  - Phase 2b study in Diabetic Kidney Disease;
  - Phase 2a study in Focal Segmental Glomerulosclerosis (FSGS)

#### Partnering in a valuable & active market

- Estimated \$1.1 billion addressable market per year for DMX-200\*
- No current competitors on market
- Multiple pharma companies active in kidney disease licensing/M&A

Scalable, globally applicable, proprietary technology

- US patent covering DMX-200 granted providing protection to 2032
- HIT technology platform enables understanding of receptor interactions to rapidly screen and identify new drug opportunities

\*2017, IQVIA

### **Dimerix Corporate Overview**



Financial information	
Share price(01Oct18)	10.5 cents
52 week low / high	8 cents / 24 cents
Shares on issue	158.8m
Market Capitalisation	\$16.67m
Cash (as at 30Jun18)	\$6.28m
Debt (as at 30Jun18)	\$0
Enterprise value	\$10.39m



The current enterprise valuation does not reflect the opportunity value

FSGS + DKD = >\$1.1 billion/year addressable market\*

No competitors currently on market

+ HIT technology platform

### Market dynamics – two indications



#### **Focal Segmental Glomerulosclerosis (FSGS)**

- A serious and rare kidney disease: orphan indication
  - Rapid progression to end-stage renal disease
  - Eventually require blood dialysis
  - ~120,000 individuals in the US
  - >95,000 patients on kidney transplant waiting list in US‡
  - Kidney transplant costs >\$262,000 in the 1st year
- DMX-200 has US Orphan Drug Designation for **FSGS**

#### **Diabetic Kidney Disease (DKD)**

- Also known as Diabetic Nephropathy
- 23 million diagnosed diabetics in the US\*
  - Diabetes incidence estimated to grow 54% by 2040<sup>†</sup>
  - 36.5% of these had kidney disease\*
  - ~8.3 million with DKD
- 10% of diabetics develop kidney disease within 10 years of diagnosis#;
- Progressive disease, leading to kidney failure and blood dialysis
- Increased protein in the urine (proteinuria) = best clinical marker of rate of progression of kidney failure
- Deterioration in kidney function can be slowed with treatment DMX-200 could slow deterioration even further than the existing standard of care

<sup>‡</sup> Transplant Trends, United Network for Organ Sharing, 2018 [ONLINE] Available at: https://unos.org/data/transplant-trends/#waitlists\_by\_organ [Accessed 08Oct18]

Filabetic 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]

### What is DMX-200



Co-administration of 2 drugs to achieve a **synergistic** renal effect:

- Irbesartan 300mg angiotensin receptor blocker (ARB)
  - Small molecule
  - FDA (USA) approved for Diabetic Kidney Disease
- DMX-200 CCR2 antagonist
  - Small molecule
  - PDMA (Japan) approved for chronic hepatitis B



Proven drugs\* – abbreviated development with lower cost and less risk

## Product profile



- Product attributes deliver significant benefits for patients
- No approved competitor on the market strong patient need
- Co-administered with existing approved product
- Twice daily dose potential to maintain steady state pharmacokinetic profile
- Capsule administration
  - Enclosed in a tasteless shell
  - Easy to swallow capsule
  - Capsule shell dissolves in gastro-intestinal tract
- Long patent life granted to 2032

### Proposed mechanism of action



DMX-200 addresses the three most important mechanisms whereby chronic kidney damage progresses

hyperfiltration of and hypertension within blood vessels of the glomeruli inflammatory cell

infiltration of the

kidneys:

subsequent fibrosis

Irbesartan blocks cellular receptors responsible for hyperfiltration & glomerular hypertension

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

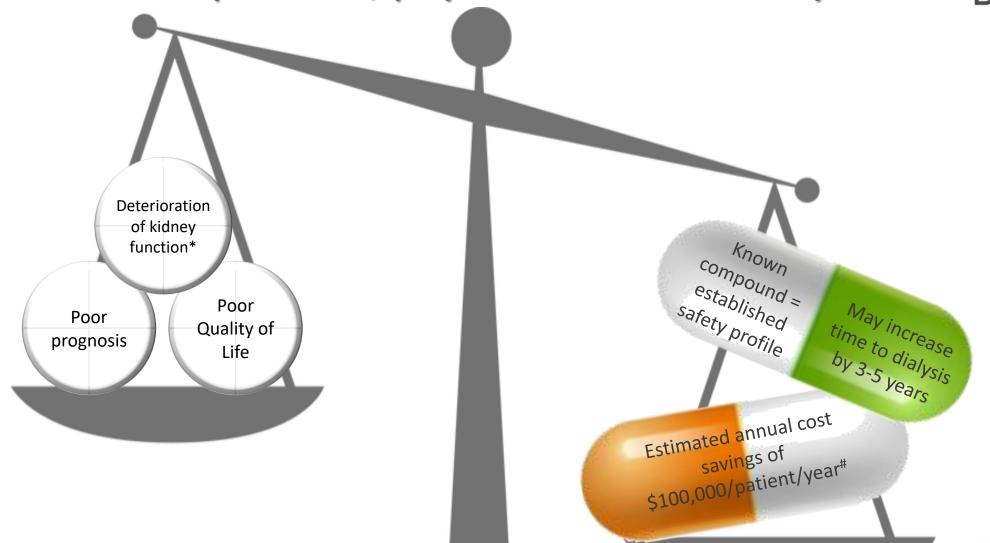
Certain kidney cells express both receptors, thus using only 1 compound does not block activation and results in only a partial response

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

loss of specialised cells called Podocytes (cannot regenerate) from the glomeruli

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





<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]

**DMX-200** 

<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:

- Co-administration with Irbesartan 300mg, therefore valuation model based on Irbesartan 300 mg sales
  - Hypertensive patients maintenance dose ~150 mg daily<sup>†</sup>
  - Kidney Disease patients maintenance dose ~300 mg daily<sup>†</sup>
- Therefore assume >50% of Irbesartan 300 mg scripts due to kidney disease
- As diabetes rates rise, sales will continue to grow

Addressable market: \$1.1 billion/year with no current marketed competitors

<sup>#</sup> pre-genericization;

<sup>\*</sup>adjusted by 50% of 300mg data (total = 4.05 million); 2017, IQVIA

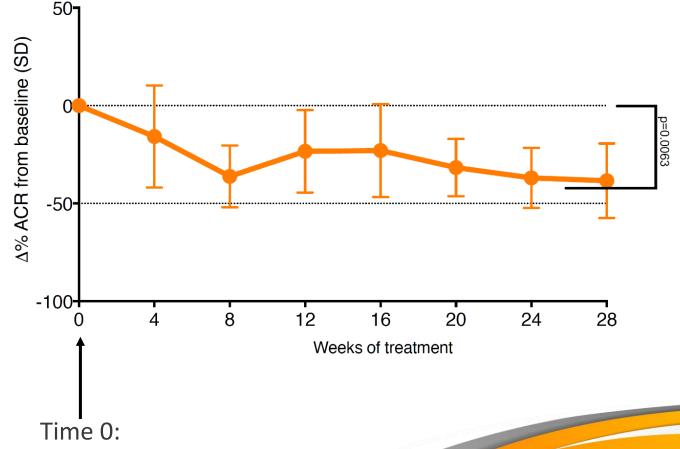
<sup>†</sup> Avapro prescribing information

### Phase 2a results - 2017



- 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 subgroup

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 Reduction in ACR (24-hr) of diabetic nephropathy patient cohort (n=10) during combined treatment with irbesartan and propagermanium.



Two-tailed.

paired t-test

### Current clinical trial design - Diabetic Kidney Disease



Double-blind, randomised, placebo-controlled, crossover study evaluating the safety and efficacy of DMX-200 in patients with diabetic kidney disease who are receiving irbesartan

- Number of patients: 40
- Must be on 300 mg/daily of irbesartan for >3months prior to screening
- All patients will receive DMX-200 and be followed for:
  - Safety;
  - Reduction in protein in patient's urine; and
  - Improvement in kidney function

- Subject to patient recruitment rates, efficacy analysis is anticipated in calendar year Q4 2019
- Interim efficacy results not planned as the study is designed to support validity of endpoint analysis

### Current clinical trial design – FSGS



Double-blind, randomised, placebo-controlled, crossover study evaluating the safety and efficacy of DMX-200 in patients with focal segmental glomerulosclerosis who are receiving irbesartan

- Number of patients: 10
- Must be on 300 mg/daily of irbesartan for >3months prior to screening
- All patients will receive DMX-200 and be followed for:
  - Safety;
  - Reduction in protein in patient's urine; and
  - Improvement in kidney function

- Subject to patient recruitment rates, efficacy analysis is anticipated in calendar year Q4 2019
- Interim efficacy results not planned as the study is designed to support validity of endpoint analysis

## Value driving events



#### **Complete upcoming clinical milestones - 2019**

- ✓ Ethics approvals for both clinical studies was achieved in July
- ✓ Clinical trial sites were opened and patient recruitment commenced in September
- EU orphan drug application outcome for FSGS anticipated in current quarter
- Preliminary DKD data anticipated in CY19Q4
- Preliminary FSGS data anticipated in CY19Q4

#### Secure a licensing agreement – 2020

 Dimerix plans to seek a commercial partner(s) who will assist development, then market and sell the product

#### **Generate ongoing revenue stream**

- development, then market and sell Estimated \$1.1 billion addressable the product market per year for DMX-200
  - No current competitors on market
  - Multiple pharma companies active in kidney disease licensing/M&A with:
    - Upfront/milestones >\$200million#
    - + royalties

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

# Dimerix (ASX: DXB)

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