

# Dimerix

*Diabetic Kidney Disease Phase 2 Study  
Results Presentation*

14 September 2020



Dimerix

# 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.*

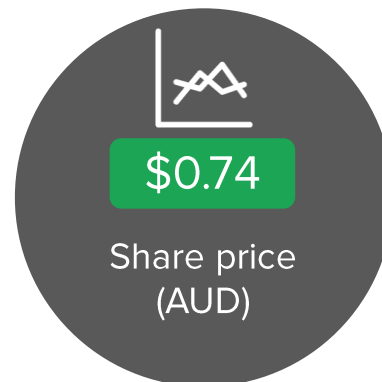
*Actual results could differ materially depending on factors such as the availability of resources, the results of clinical studies, the timing and effects of regulatory actions, the strength of competition, the outcome of legal proceedings and the effectiveness of patent protection.*

# Key Points

- Statistically significant difference in albuminuria reduction observed in patients receiving DMX 200 versus placebo with higher starting baseline albuminuria; consistent with prior studies:
  - 18% (p= .03) reduction in albuminuria in patients with >500mg/g (57mg/mmol) starting albuminuria (n=26) in addition to standard of care;
  - 64% of patients with the higher starting albuminuria level demonstrated a reduction in albuminuria versus placebo, with 56% achieving a clinically significant >25% reduction above that achieved by standard best therapy.
- No significant difference between treatment with DMX-200 and placebo across full patient cohort
- DMX-200 found to be generally safe and well-tolerated in diabetic kidney disease patients
- Growing body of consistent efficacy data in kidney diseases, all supportive of progression to the next stage of development in kidney disease



# Corporate Snapshot (ASX:DXB)



## Top 10 shareholders

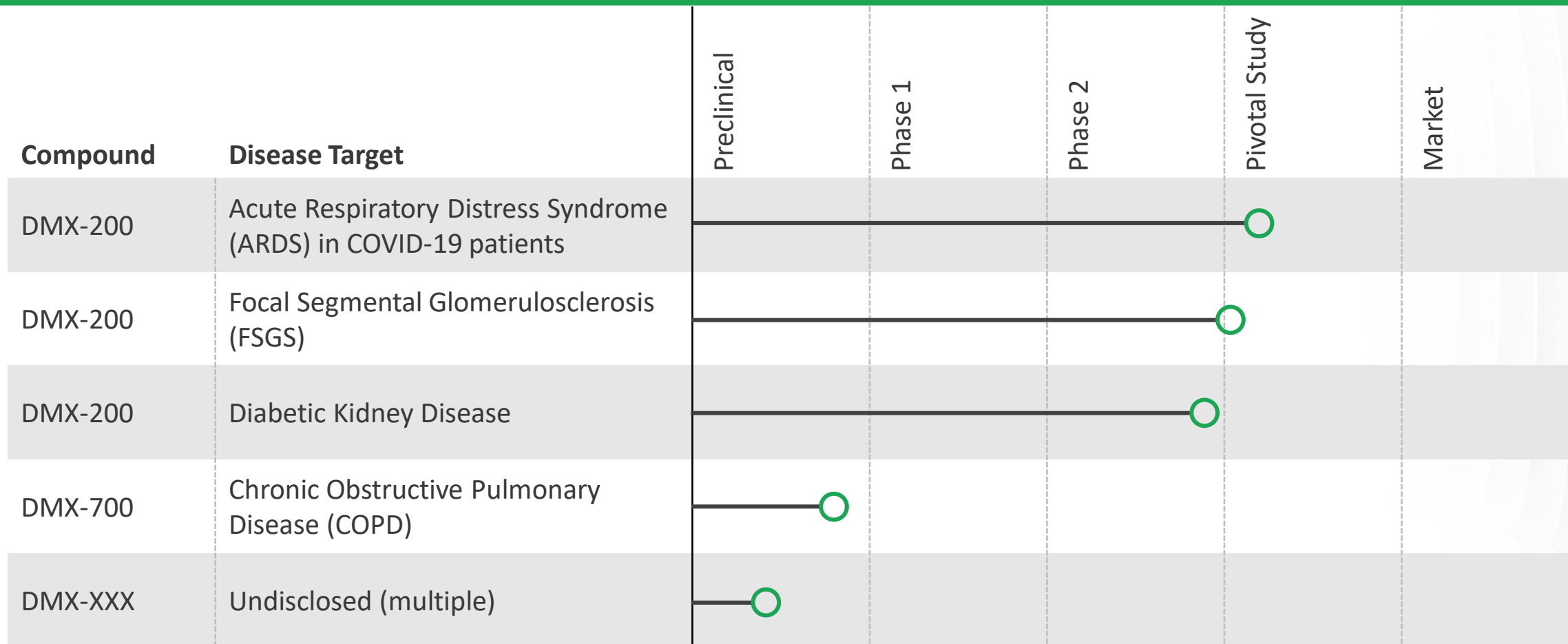
Position	Holder Name	Holding	% Holding
1	MR PETER FLETCHER MEURS	25,529,309	13%
2	BAVARIA BAY PTY LTD	7,316,992	4%
3	YODAMBAO PTY LTD	6,312,603	3%
4	CITICORP NOMINEES PTY LIMITED	2,275,640	1%
5	PFLEGER FAMILY A/C	2,105,988	1%
6	TOROHA PTY LTD	2,044,932	1%
7	TT NICHOLLS PTY LTD	1,816,667	1%
8	JAMPASO PTY LTD	1,778,742	1%
9	DR DAVID KENNETH PACKHAM	1,689,391	1%
10	DJEE SUPER PTY LTD	1,500,000	1%

## Share price performance



# Development pipeline

4 product candidates in the pipeline, with 3 clinical opportunities



# Board & Management



**James Williams**  
PhD, MBA  
Non-Executive Chairman



**Nina Webster**  
PhD, MBA, M.IP.Law  
CEO & Managing Director



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



**Sonia Poli**  
PhD  
Non-Executive Director



**Robert Shepherd**  
PhD  
R & D Director



**Bronwyn Pollock**  
BSc (Hons), MBA  
Product Development Director

*iCeutica, Yuuwa, AdAlta (alternate), Polyactiva*  
Experienced Director of ASX-listed companies

- Co-founded Dimerix
- Co-founded Yuuwa Capital (\$40M venture fund)
- ✓ BSc (Hons) - Biochemistry
- ✓ PhD - Medicine
- ✓ MBA - Business

*Wyeth (Pfizer), Acrux, Immuron*

- Experienced in product development, commercial strategy development & execution
- Successfully commercialised multiple pharmaceutical products globally
- ✓ BSc (Hons) - Pharmacology
- ✓ PhD - Pharmaceuticals
- ✓ MBA - Business
- ✓ M.IP.Law - Intellectual Property Law

*Mayne Pharma, Acrux, Hatchtech, Kinosis*

- Extensive biotech drug development & commercial manufacturing experience
- Responsible for successful global commercialisation programs & NDA registrations
- ✓ BSc (Hons) - Chemistry
- ✓ MBA - Business

*Hoffman la Roche, Addex, AC Immune*

- Experienced executive in pharmaceutical operations
- Background in small molecules development and analytical development
- ✓ BSc (Hons) - Chemistry
- ✓ PhD - Industrial Chemistry

*Medicines Development, Avecheo*

- Experienced pharmaceutical executive in project management, clinical development and research programs
- Led multidisciplinary R&D teams for over 14 years
- ✓ BSc (Hons) - Genetics
- ✓ PhD - Molecular Immunology

*Neuren, Prota, Acrux, Hospira, CSL*

- Experienced pharmaceutical executive in Manufacturing (CMC)
- Successfully developed and submitted multiple dossiers to FDA, EMA, TGA
- Background in project management, technical transfer and product launch
- ✓ BSc (Hons) - Applied Biology
- ✓ MBA - Business

# DMX-200 overview

**New Chemical Entity**  
Never been FDA approved

DMX-200: a small molecule drug called propagermanium

- Known safety profile
- Administered to patients already on angiotensin receptor blockade
- Never been approved by a regulatory authority for clinical use in the US, Europe or Australia

Capsule administration

- 240mg oral delivery daily
  - 120mg capsule administered twice daily
  - transitioned from three times daily dose in prior study to a more convenient twice daily dose



# DMX-200 clinical experience



## Phase 1 study (DMX-200-101)

- Healthy volunteers
  - Pharmacokinetic, metabolism & safety clinical study



## Phase 2a study (DMX-200-201)

- Chronic Kidney Disease
  - Safety and tolerability study, with efficacy endpoints included



## Phase 2a study (DMX-200-202)

- Focal Segmental Glomerulosclerosis
  - Safety and efficacy endpoints



## Phase 2 study (DMX-200-203)

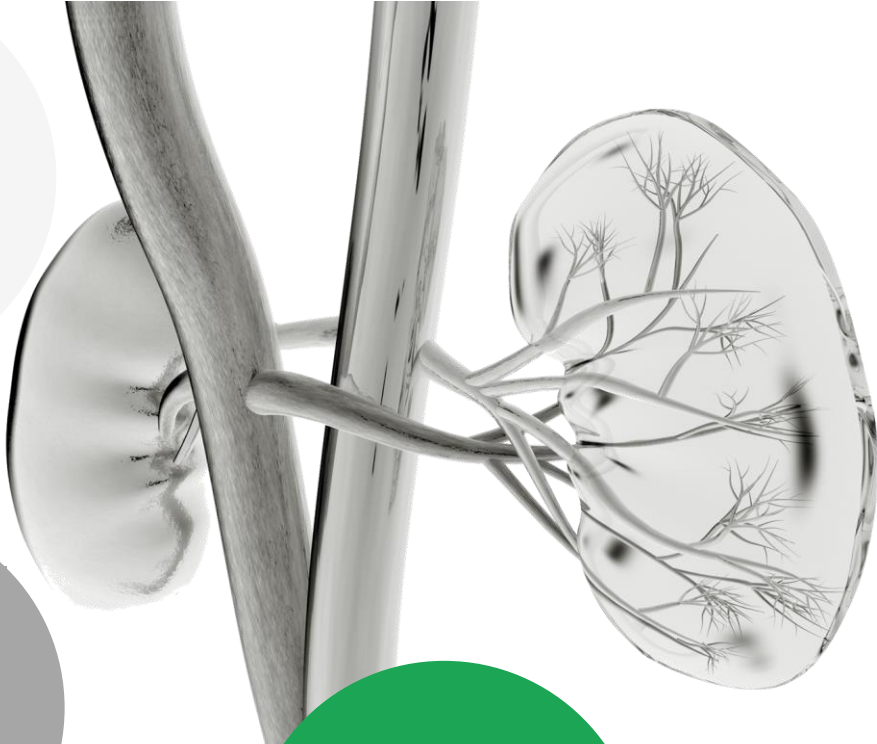
- Diabetic kidney disease
  - Efficacy and safety endpoints

- Positive efficacy signal across studies
- Safe and well tolerated in healthy volunteers and renal patients
- DMX-200 compares favourably to compounds currently in development
- Compelling data in all studies collectively leading to DMX-200 future development



# DMX-200 proposed mechanism of action

DMX-200 addresses three key mechanisms that cause renal damage and sclerotic kidney disease



Hyperfiltration of and hypertension within blood vessels of the glomeruli

Inflammatory cell infiltration of the kidneys: subsequent fibrosis

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

Irbesartan blocks cellular receptors responsible for hyperfiltration & glomerular hypertension

DMX-200 inhibits 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**

See Receptor-HIT on slide 24

# Current Phase 2 trial in diabetic kidney disease

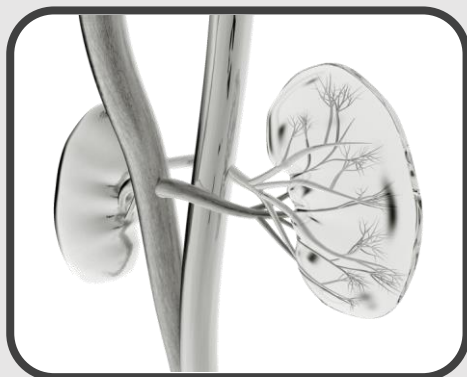
**Phase 2 DMX-200-203 (ACTION for diabetic kidney disease)** is a Phase 2, Double-blind, Randomised, Placebo-Controlled, Crossover Study Evaluating the Safety and Efficacy of DMX-200 in Patients with Diabetic Kidney Disease who are Receiving Irbesartan

- 45 patients enrolled, 40 patients qualified for the evaluable population and final analysis
- Primary endpoint: % change from baseline in albuminuria compared to placebo
- Secondary endpoint: frequency of patients achieving >30% albuminuria reduction, other biomarker analysis & safety
- Indication: for the treatment of elevated serum creatinine and albuminuria in patients with diabetic kidney disease

n=40  
(45 patients  
dosed)

	Study period 1 12 weeks	Washout 6 weeks	Study Period 2 12 weeks	Results
Group 1 (n=20)	DMX-200		Placebo	
Group 2 (n=20)	Placebo		DMX-200	
Irbesartan 300mg				

# ACTION for DKD phase 2 study outcomes



Patients with diabetic kidney disease <sup>crossover</sup>  40

On stable ARB

12 week treatment

240mg DMX-200



Randomisation

DMX-200 versus baseline

DMX-200 versus placebo

Primary endpoint

% change from baseline in albuminuria (%ACR)

-14%\*

-2%\*

No statistical difference in primary endpoint

Secondary endpoint

Frequency of patients with >30% albuminuria reduction (ACR)

25%\*

Further investigation underway to explore relationship between treatment effect and other patient factors:

- inflammatory biomarkers
- concomitant medications
- patient demographics
- legacy effect

However, treatment effect appears to be related to baseline albuminuria

# Starting albuminuria >57mg/mmol (500mg/g)

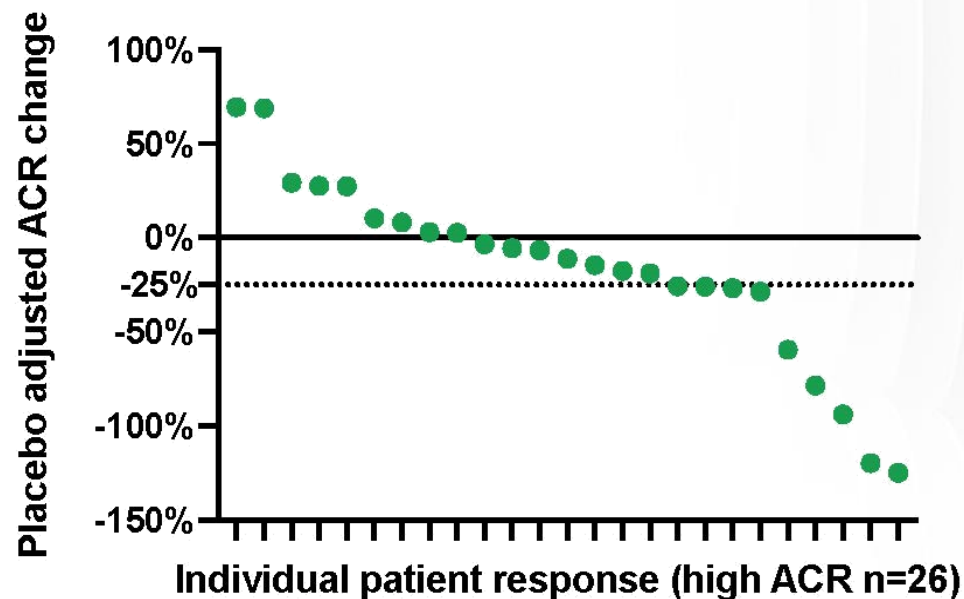
Placebo adjusted % change from baseline in albuminuria (%ACR)	No reduction from baseline compared to placebo in patients below 57mg/mmol	-18% ( $p = .03$ )
Frequency of patients with a albuminuria reduction (ACR)		64%
Frequency of patients with >25% albuminuria reduction (ACR)		56%

All prior studies:

- 30mg/mmol inclusion criteria

This is first exploratory study that enrolled patients with baseline albuminuria below 100mg/mmol

Regardless of any relationship between treatment effect and other factors:  
 DMX-200 resulted in statistically & clinically significant outcomes



# Phase 2 study secondary endpoint: safety data

## Safety

- As measured by the number and severity of adverse events and clinically significant changes in the patient safety profile with the use of DMX-200 compared to placebo in participants with diabetic kidney disease who are receiving irbesartan



DMX-200 was safe and well-tolerated



No variation in the incidence or severity of adverse events between treatment with DMX-200 or placebo



No serious adverse events related to the drug reported



3 patient withdrawals – none related to study drug

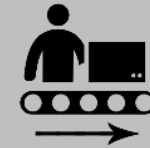
# Chemistry, Manufacturing and Control (CMC)



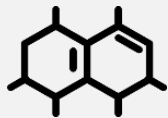
US based contract manufacturer appointed for commercial supply of API



FDA approved manufacturing facility



US based manufacturer engaged for finished product manufacture



Analytical methods validated



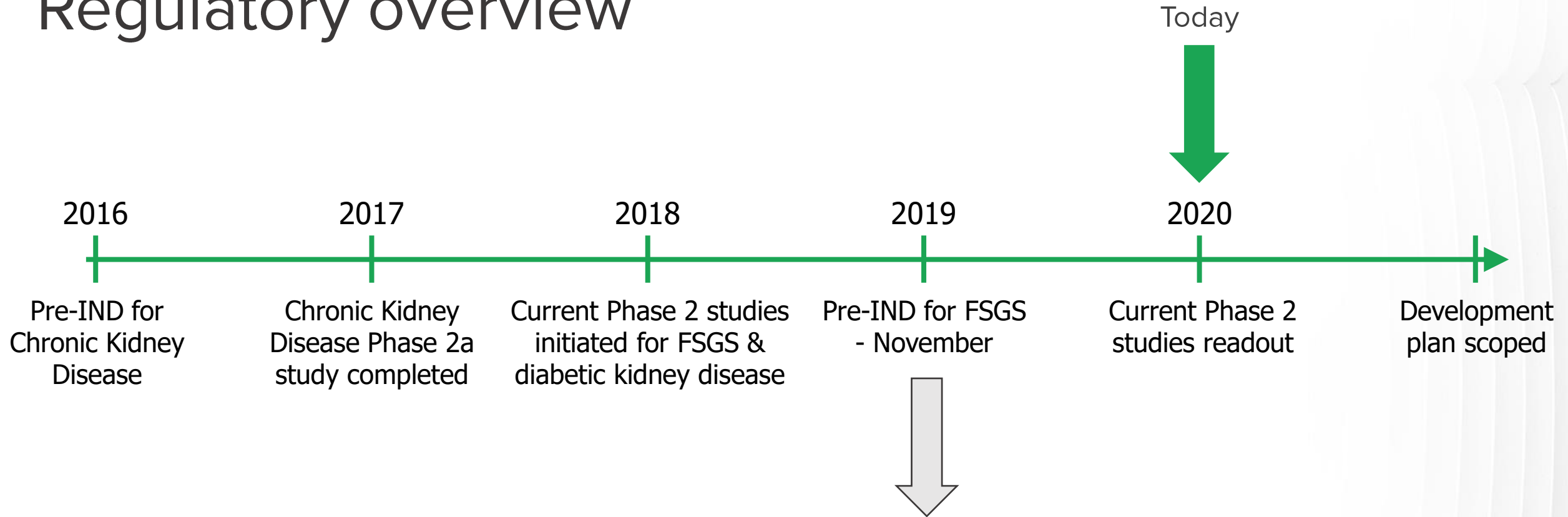
Commercial scale GMP batch manufacture completed



Exclusive development and methodology to manufacture API owned by Dimerix

CMC NDA package suitability confirmed with FDA

# Regulatory overview



- Non-clinical package appropriate for NDA and registration; and
- Proposed specifications for API manufactured by Dimerix are appropriate for registration

# DMX-200 Intellectual property and exclusivity

## Intellectual Property



Method of use:  
any CCR2 antagonist  
with any ARB for any  
kidney disease



Granted patents\*  
US 9,314,450  
US 10,058,555  
US 10,525,038

Patent applications with  
alternative claims filed



Method of use:  
DMX-200 with  
irbesartan



Granted patents\*  
EP 2663304

Patent applications with  
alternative claims filed

## Exclusivity



FSGS orphan  
exclusivity

7  
years



FSGS orphan  
exclusivity

10  
years

DMX-200 has potential benefit of exclusivity\*\* whilst  
relying on existing safety data



# Diabetic kidney disease market dynamics



US market size 2018<sup>^</sup>  
**US\$5.8 billion**



Market growth will **accelerate**  
at a CAGR (2019-2022)<sup>^</sup>  
**5.1%**



Addressable market  
**US\$1.1 billion**



Diabetic patients that  
have kidney disease\*  
**40%**



The market is highly  
concentrated, with few players  
occupying market share<sup>‡</sup>



Current standard of care  
control blood pressure levels:  
Angiotensin receptor blockers  
(ARBs)\*



Diabetic kidney disease is the  
**leading cause** of Chronic  
Kidney Disease Worldwide\*



Key driver is the rise in diabetes  
global incidence<sup>^</sup>

# Dimerix well-positioned to deliver



Existing long-term safety data available & approved for compassionate use



Demonstrated efficacy in FSGS and diabetic kidney disease



High unmet need, with little marketed competition



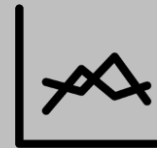
Scientific rationale compares favourably to compounds currently in development



Pharmaceutical grade (GMP) drug process developed and validated



Full capability in place to scale up for commercial supply

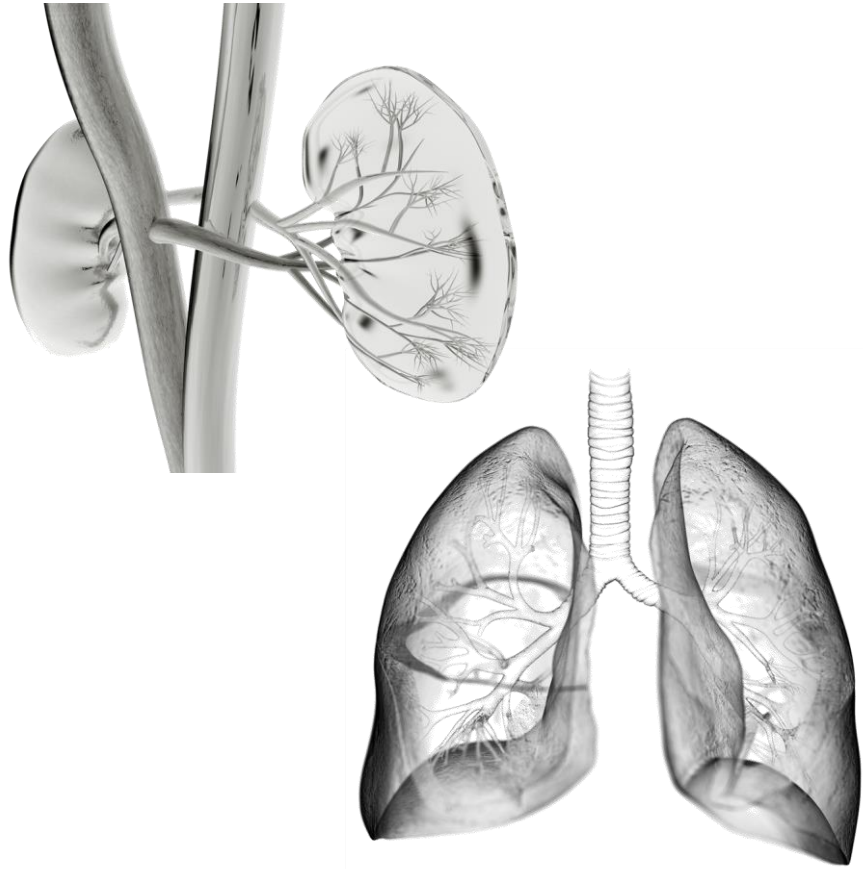


Planning continues for proposed global Phase 3 pivotal program in FSGS



Patents granted and pending, 100% owned by company

Assets 100% owned by Dimerix



Additional Assets

# Phase 2a trial in FSGS – positive data

*A double-blind, Randomised, Placebo-Controlled, Crossover Study*

	Study period 1 16 weeks	Washout 6 weeks	Study Period 2 16 weeks	Results
Group 1 (n=5)	DMX-200		Placebo	
Group 2 (n=5)	Placebo		DMX-200	
Irbesartan 300mg				

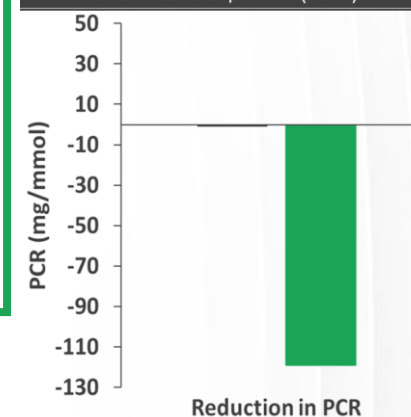
DMX-200 has US and EU Orphan Drug Designation for FSGS


Mean reduction in proteinuria


(%PCR grouped analysis):


- 29% from baseline on DMX-200 compared to placebo


Average change in proteinuria from baseline on DMX-200 or placebo (mean)



  
DMX-200 was generally safe and well-tolerated

  
No variation in the incidence or severity of adverse events between treatment with DMX-200 or placebo

  
No serious adverse events related to the drug reported

  
No patient withdrawals from the study

Proportion of patients demonstrating a reduction versus placebo:

- 86% of patients demonstrated reduced proteinuria on DMX-200 versus placebo
- 29% of patients demonstrated >40% reduction in proteinuria

# Acute Respiratory Distress Syndrome (ARDS)

in COVID-19 patients – awarded \$1 million from AUS Government



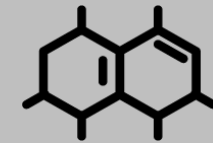
REMAP-CAP: global WHO endorsed clinical study; >200 clinical sites in 16 countries\*



Study targets patients with Acute Respiratory Distress Syndrome (ARDS) as a result of a pandemic\*



REMAP-CAP/COVID-19 study protocol to include DMX-200



New renin-angiotensin system study domain approved by International Steering Committee



REMAP-CAP has been designated by the WHO as a Pandemic Special Study\*  
translation of clinical trial results occur directly with policymakers & public health officials for rapid implementation globally



REMAP-CAP is supported and funded by a consortium of government and non-government organisations\*



Results generated from REMAP-CAP during a declared pandemic can provide a collaborative pathway to global clinical practice\*



DMX-200 selected based on overwhelming scientific rationale & unique potential to treat COVID-19 related issues  
(supported by multiple peer-reviewed publications over the past month^)

# Pre-Clinical: DMX-700 in COPD

- DMX-700 for the treatment of COPD by blocking heteromer signalling in receptors active in COPD
- Initial studies shown interaction of key receptors in pathogenic biased signalling
- In vitro program to identify existing clinical-stage compounds capable of altering signalling pathways
- Provisional patent application filed; additional applications anticipated



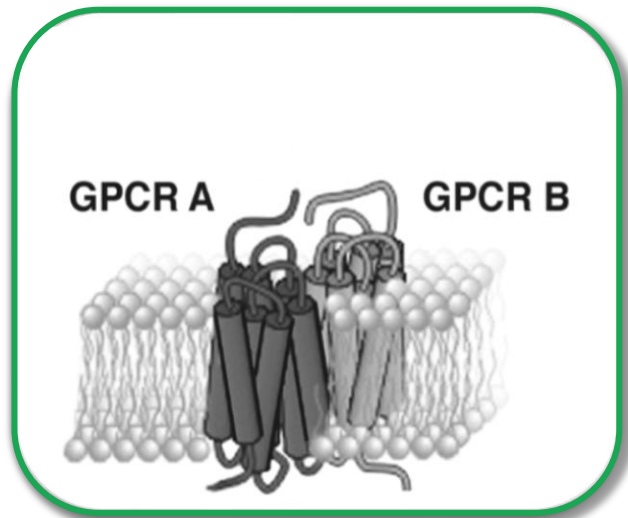
Actual molecules & receptor targets remain confidential pending stage 1 data & additional patent submissions

Timeline to clinic  
~2 years

New Chemical Entity

# Dimerix technology platform – Receptor-HIT

- Patented multiple configurations of a Bioluminescence Resonance Energy Transfer (BRET) assay that enables understanding of real-time receptor heteromer interactions
- Particularly suited to GPCRs
- Can identify **new uses** for existing drugs, deorphanize receptors, and drive the **discovery** of new drugs and research programs



**Receptor Heteromer:** Macromolecular complex composed of at least two (functional) receptor units with biochemical properties that are demonstrably different from those of its individual components.\*

***Assay has granted patents in key territories, protection until 2029***

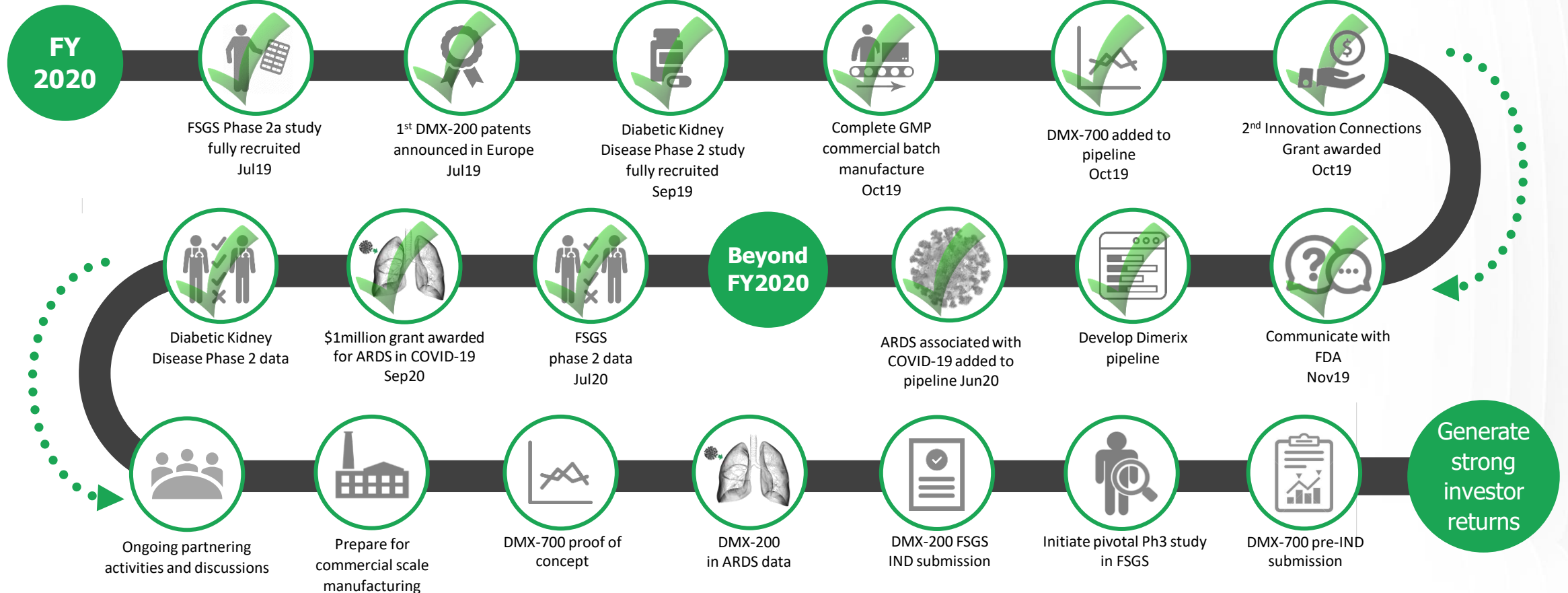


Dimerix

Summary



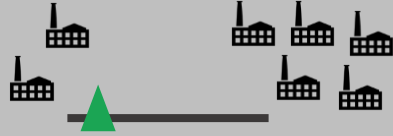
# Financial Year 2020/2021 value driving events



# DMX-200 summary



Commercially attractive and growing markets



Unmet need, with little or no current competition



DMX-200 compares favourably to compounds currently in development



Positive efficacy data in 3 different kidney studies



Product supply secured with FDA approved manufacturing facility



Orphan status for FSGS in both US & EU



New chemical entity with granted patents and additional patents pending



Existing long-term safety data available: lower development risk



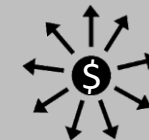
Approved by TGA for compassionate use in Australia



Diabetic kidney disease Phase 2 clinical study results anticipated 4-6 weeks



FDA confirmed non-clinical & CMC NDA package suitability + Ph3 FSGS study design principles



Additional assets to diversify risk and potential sources of revenue

Assets 100% owned by Dimerix



# DIMERIX

End of Presentation



Dimerix

**Dimerix HQ**  
425 Smith St, Fitzroy 3065  
Victoria, Australia  
T. 1300 813 321  
E. [bd@dimerix.com](mailto:bd@dimerix.com)