

Dimerix

Investor Presentation

May 2021



Dimerix

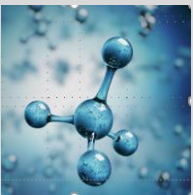
Forward looking statements

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.

About Dimerix

Dimerix Limited (ASX:DXB) is 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 multiple near-term Phase 3 clinical studies	• Renal: lead Phase 3 program in orphan renal condition with Accelerated Approval end point; >US\$1 billion market opportunity • Respiratory COVID-19: Two late stage (Phase 3) studies with near term readouts; Potential for Emergency Use Approval
	Drug well understood	Favourable drug attributes (very strong safety profile, self-administered daily capsule or via nasogastric tube, granted patents in all key territories, applicable across multiple indications)
	Commercial manufacturing established for DMX-200	• US based contract manufacturer for commercial supply of finished product • FDA approved manufacturing facilities • Analytical methods validated
	Strong outlook with significant value upside	• Strong cash balance of \$8.51 million* with two COVID studies fully funded • FSGS Phase 3 clinical study to commence 2021 • Additional longer-term opportunities also in development

Corporate overview



Top shareholders

Position	Holder Name	Holding	% IC
1	MR PETER FLETCHER MEURS	26,529,309	13.4%
2	BAVARIA BAY PTY LTD	7,316,992	3.7%
3	YODAMBAO PTY LTD	6,312,603	3.2%
4	HSBC CUSTODY NOMINEES	2,302,301	1.2%
5	MR RICHARD STANLEY DE RAVIN	2,200,000	1.1%



Ticker Symbol

ASX:DXB



Share price

~A\$0.25



Total ordinary shares on issue

197,999,297



Market Capitalisation

~A\$50 million



Average volume

1,877,843



Cash Balance (31Mar21)

A\$8.5 million



Top 20 Shareholders own

33.5%

Key achievements – FY2021



- ✓ DMX-200 demonstrates favourable clinical efficacy and strong safety profile across multiple Phase 2 renal clinical studies



- ✓ Orphan Drug Designation/accelerated approval pathway granted by US FDA and EU EMA 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

Next
steps

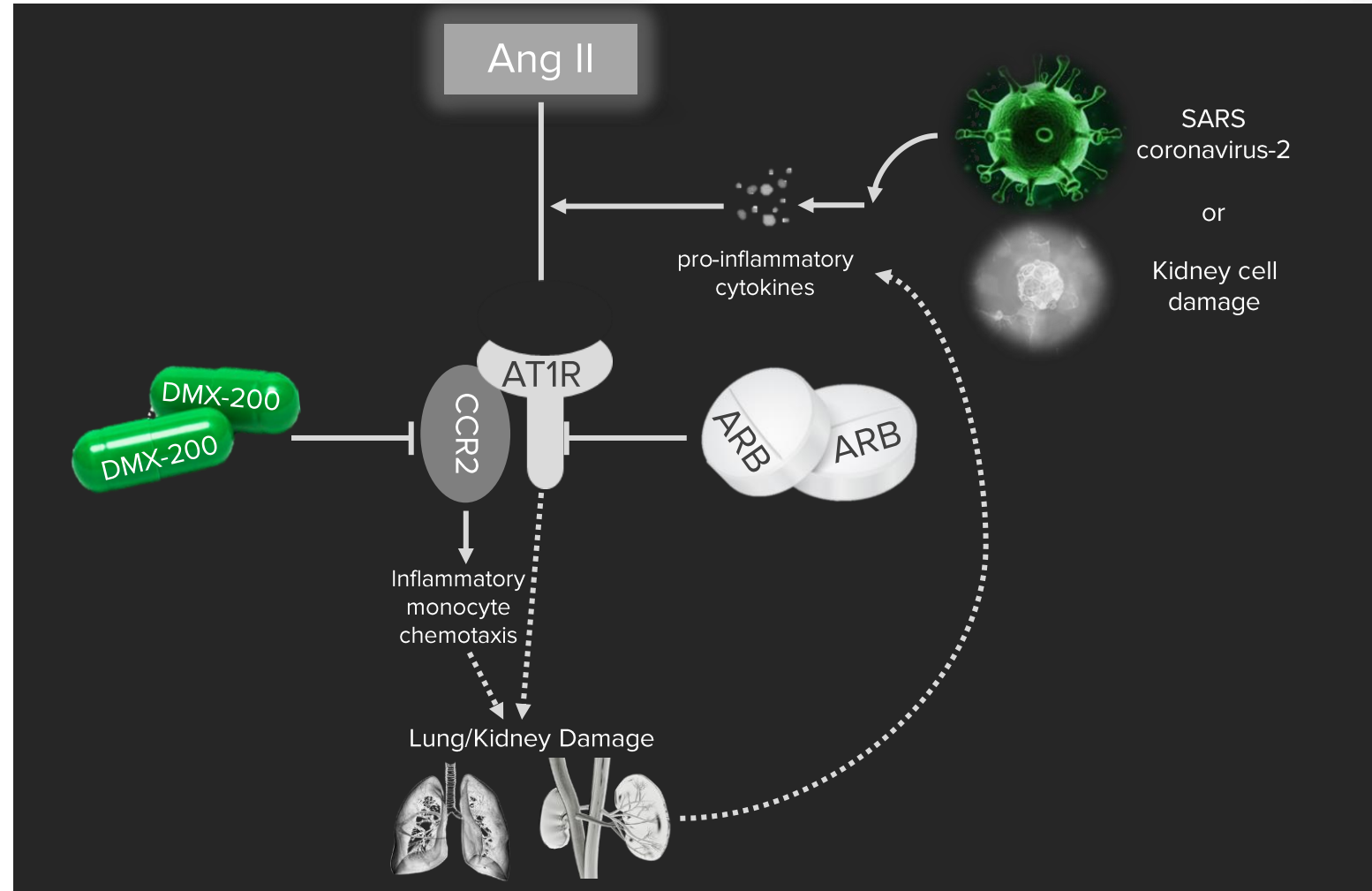
Dimerix well placed to deliver three near term propositions

- ☐ Global FSGS Phase 3 clinical study initiation
- ☐ REMAP-CAP Phase 3 study in intensive care COVID-19 patients conclusion
- ☐ CLARITY 2.0 Phase 3 study in hospitalised COVID-19 patients conclusion

DMX-200 – working on inflammatory signalling pathway

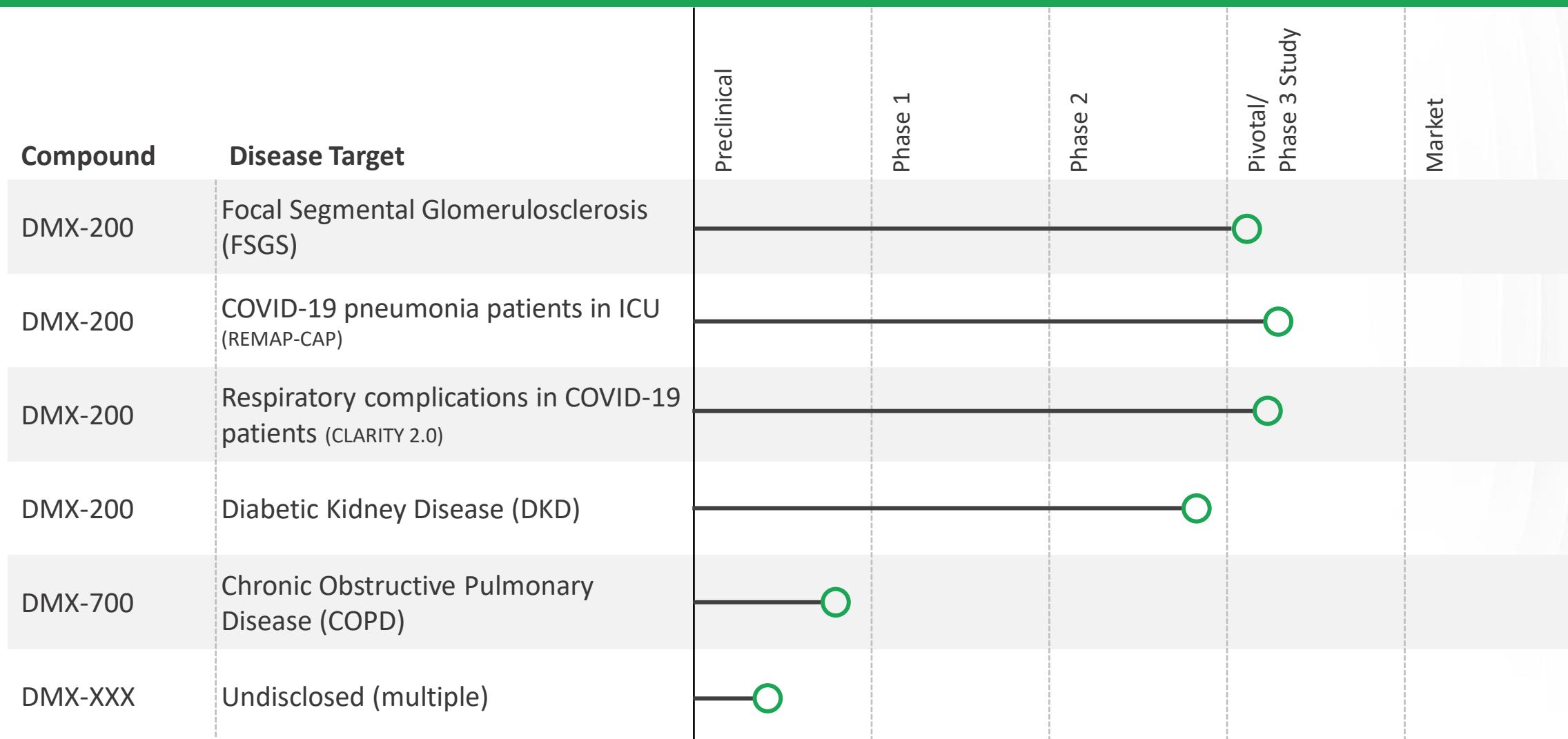
DMX-200

- Small molecule – new chemical entity
- Inhibits activity of a cellular receptor of inflammation: CCR2
- 240mg oral delivery daily - 120mg capsule administered twice daily
- Administered to patients already on angiotensin receptor blocker (ARB)
- Extensive regulatory engagement – orphan designation secured in US and EU

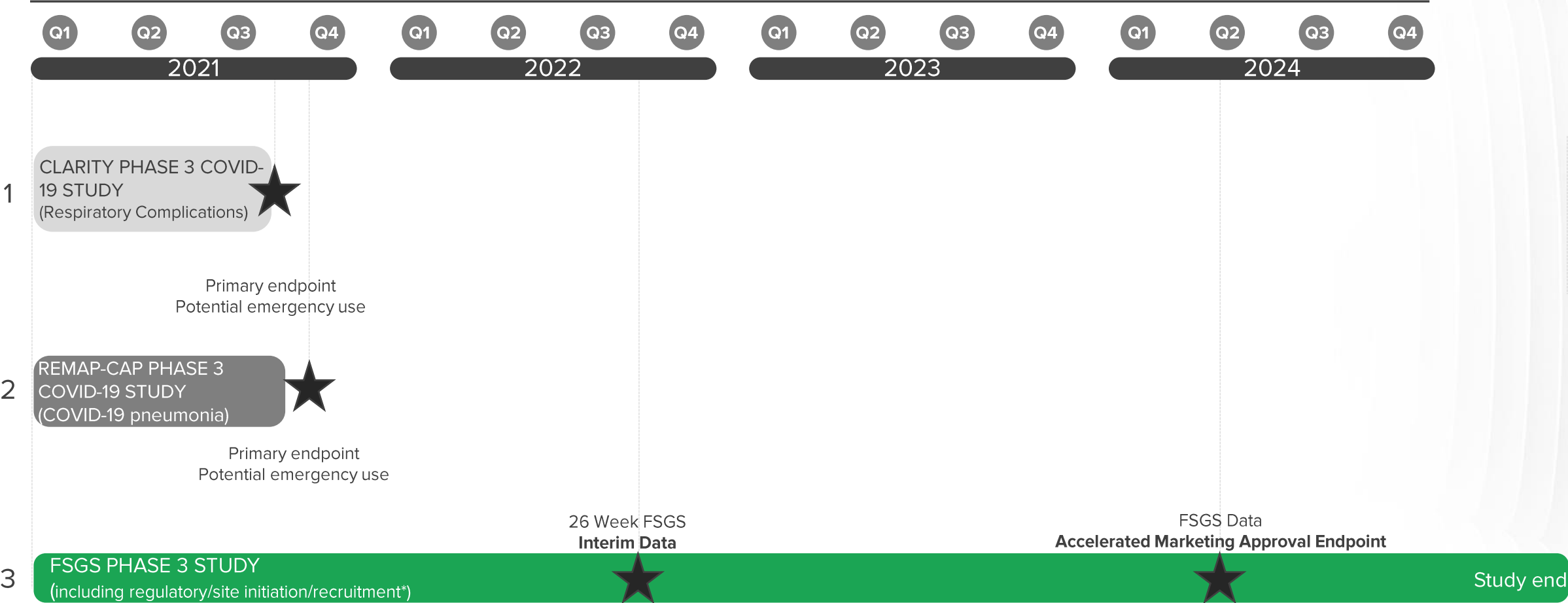


Development pipeline

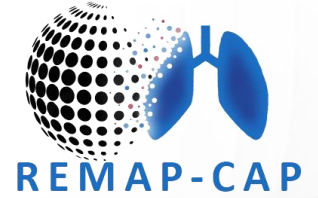
5 product candidates in the pipeline, with 4 clinical opportunities



Three near term value propositions



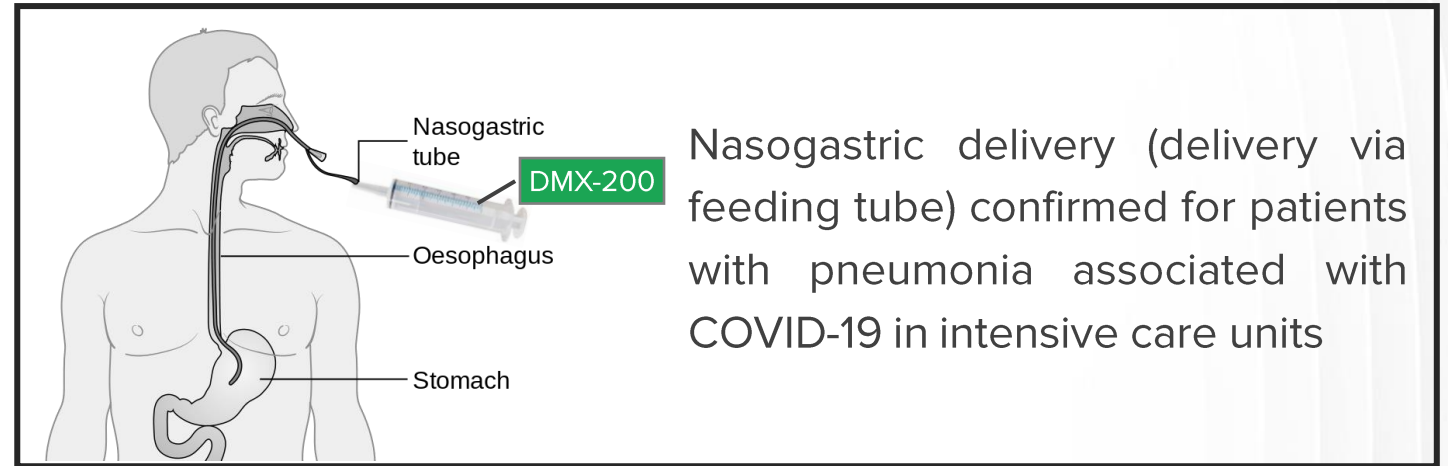
REMAP-CAP primary endpoint at day 21



Global, multicentre, randomised, standard of care vs. DMX-200 platform study in >200 patients with COVID-19 pneumonia



Composite end-point that includes: mortality & number of days patient is alive and does not require organ support up to study day 21



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



Study domain recruitment initiated March 2021
Despite vaccines:

- 3rd wave advancing across Europe
- Multiple new strains identified

CLARITY 2.0 primary endpoint at day 14



Prospective, multi-centre, randomised, double blind, placebo-controlled study in 600 patients in India



To assess safety & efficacy of dual treatment with DMX-200 & an ARB in patients hospitalised with COVID-19 disease, assessed by the Clinical Health Score* measured at day 14

7-Point Ordinal Scale of Clinical Health Status*



- 1 • Not hospitalised, no limitations on activities
- 2 • Not hospitalised, limitation on activities
- 3 • Hospitalised, not requiring supplemental oxygen
- 4 • Hospitalised, requiring supplemental oxygen
- 5 • Hospitalised, on non-invasive ventilation or high-flow oxygen devices
- 6 • Hospitalised, on invasive mechanical ventilation or ECMO
- 7 • Death

COVID-19 and pneumonia market potential

What is Community Acquired Pneumonia (CAP)?

- Pneumonia is an acute inflammation of the lungs, caused by an infection by bacteria, viruses, or fungi
- COVID-19 pneumonia is caused by SARS-CoV-2

Facts and Figures



\$17 billion

Pre-COVID:
Pneumonia
responsible for US\$17
billion in healthcare
costs each year in the
US



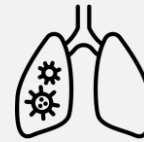
2.8 million

COVID-19: caused
124 million cases
globally to date,
resulting in 2.8 million
deaths in 12 months
and counting



3 million

Non-COVID-19: lower
respiratory tract
infections are
estimated to cause 3
million deaths annually
pre-COVID



50 %

Pneumonia is
responsible for half of
all cases of sepsis
and septic shock



20-30%

20-30% of all patients
with pneumonia
require admission to
Intensive Care Units

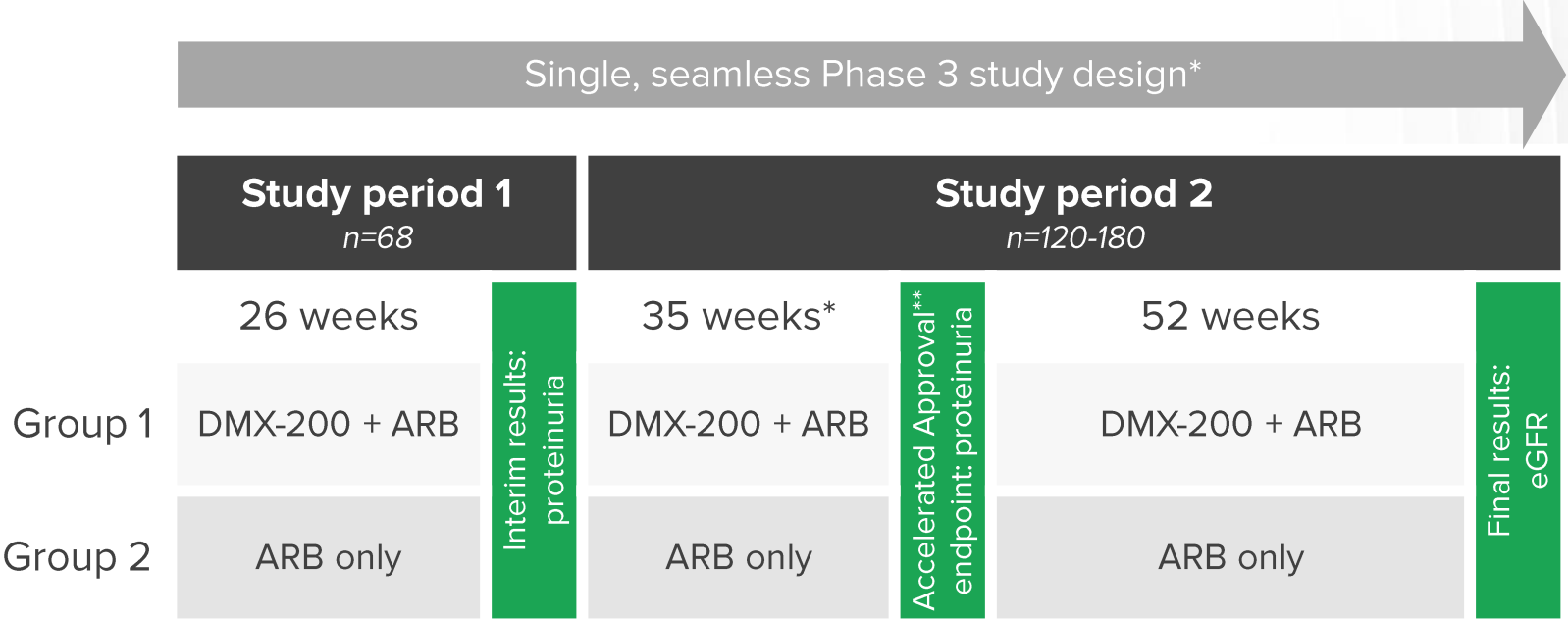


US\$3,120

The cost of treatment
with Remdesivir (for
COVID-19) for 5 days

FSGS phase 3 study primary endpoint

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



Why FSGS: unmet need and market potential

FSGS: rare kidney disease characterized by inflammation and scarring of the kidney's filtration units, affecting children and adults

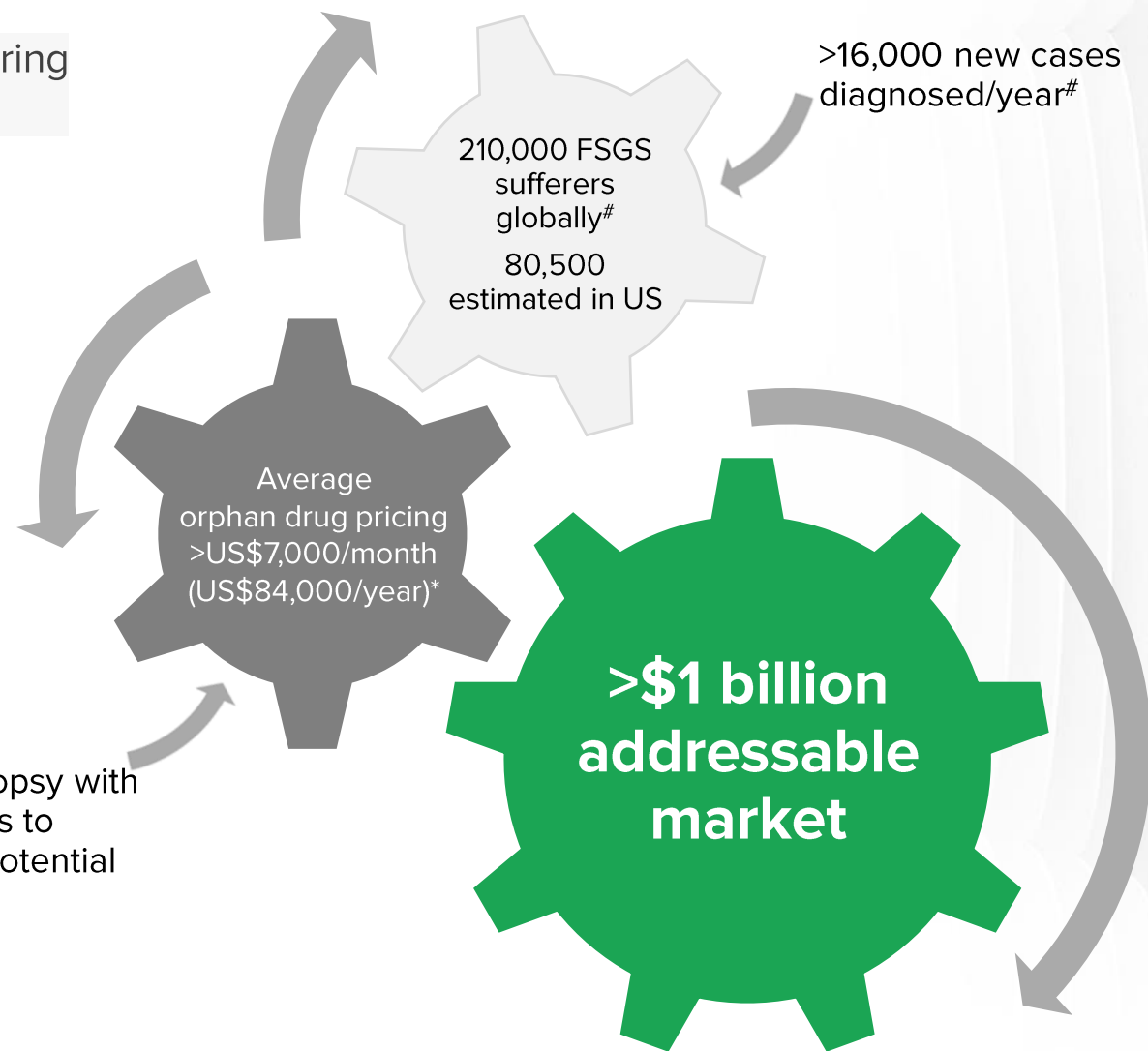
Renal failure in <5 years from diagnosis – dialysis or transplant

~20,000 FSGS patients in US with end-stage kidney disease - only ~1,000 receive kidney transplants each year

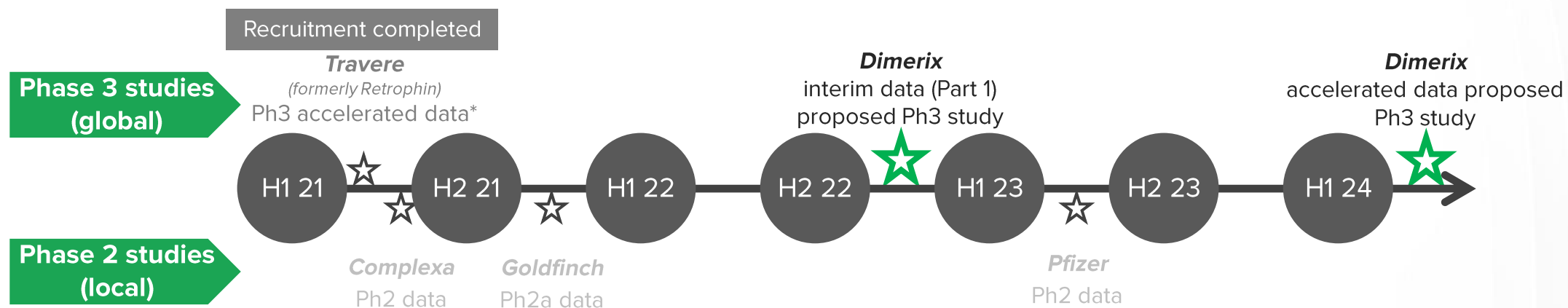
Unfortunately, FSGS comes back to attack the new kidney 30-50% of the time[^]

No FDA approved therapies

FSGS diagnosis by biopsy with patients having access to payer/insurer = high potential treatment uptake



FSGS competitive positioning



- No other global FSGS studies underway
- Critical recruitment window for DXB FSGS program
- Dimerix well positioned to help patients seeking treatment who often have very few medical options

- Sparsentan: a dual acting ARB/endothelin receptor blocker (alternative to irbesartan)
 - Data demonstrates DMX-200 may be complementary to Sparsentan

Kidney asset transactions by clinical phase

Kidney assets are in active M&A space, including:

	Preclinical		Phase 1	Phase 2		Phase 3		
Company	Epigen to Novo Nordisk	Goldfinch to Gilead (Goldfinch to complete development)	Ionis to AstraZeneca	Orphan Technologies to Retrophin Inc	Vera Therapeutics to Merck	Angion Biomedica to Vifor	Cara to Vifor	Cara to Vifor
Year	May-18	May-19	Feb-18	Oct-20	Nov-20	Nov-20	May-18	Oct-20
Structure	licensing	licensing (multiple kidney targets)	licensing	<i>acquisition</i>	<i>acquisition</i>	licensing (ex-China)	licensing (ex-US)	licensing (US)
Upfront (US\$)	undisclosed	\$55m	\$30m	\$90m	undisclosed	\$60m	\$70m	\$100m
Milestones (US\$)	\$200m	>\$1b	\$300m	\$427m	\$717m	\$260m	\$350m	-
Royalties	undisclosed	undisclosed	undisclosed	-	-	10-40% (tiered)	undisclosed	Profit share (60:40)

n.b. milestones and royalties typically increase in later stage development deals

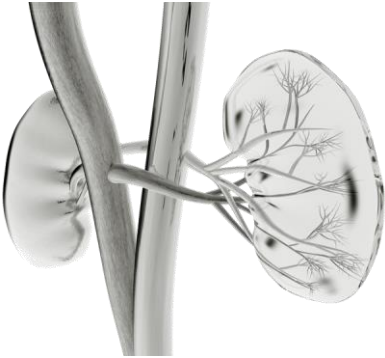
Average deal value exceeds US\$500m (~A\$650 million) excluding royalties

Positive interim data in FSGS Phase 3 (alone) supports substantial transaction value

Additional asset value propositions

Longer term opportunities

Diabetic Kidney Disease



Addressable market
US\$1.1 billion

Key driver is the rise in diabetes global incidence

DKD

Diversifying
risk and
potential
sources of
revenue

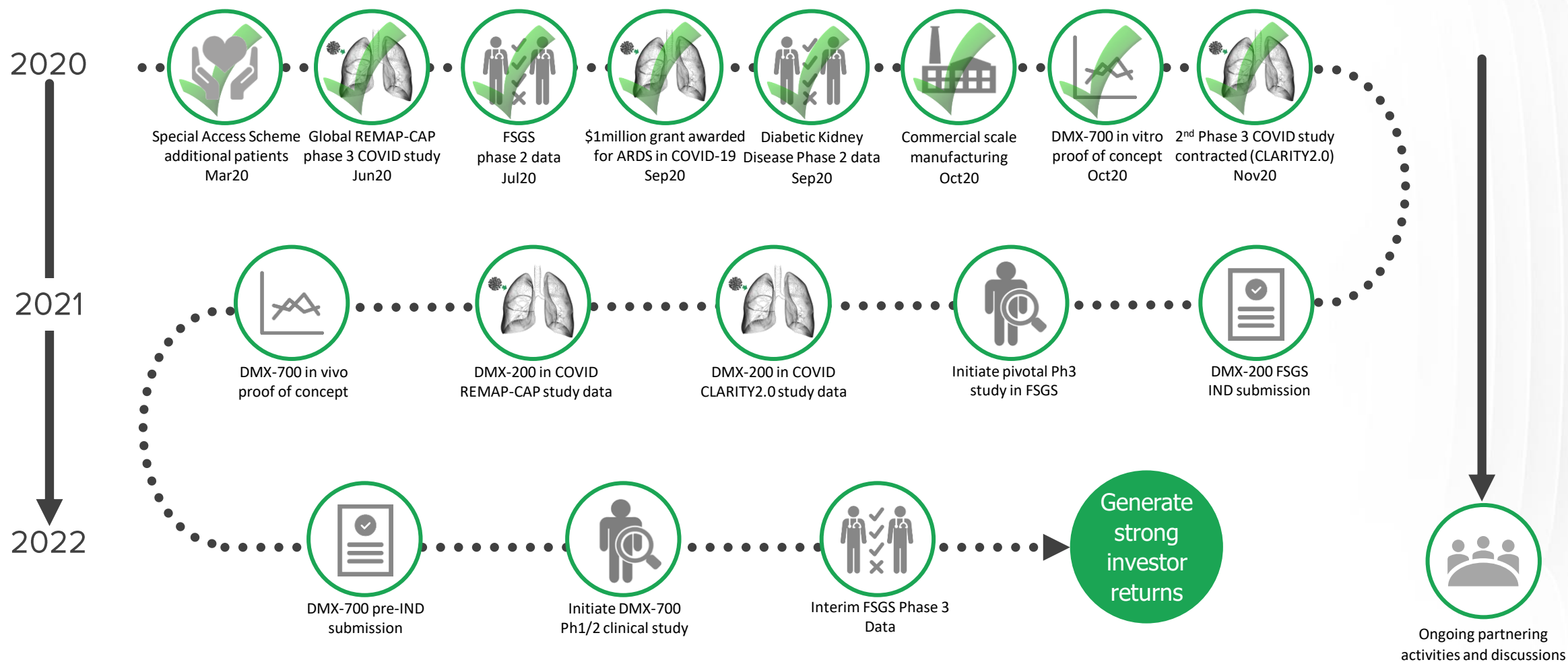
COPD

Chronic Obstructive Pulmonary Disease



Global COPD treatment market (2017)
US\$14 billion

Value driving events

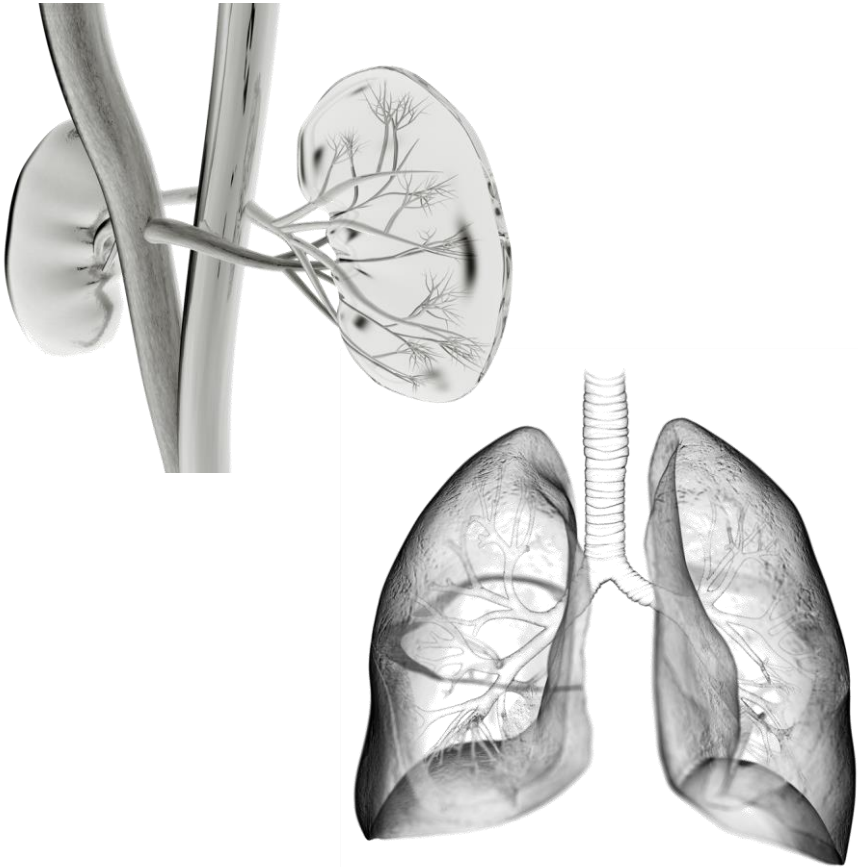


DIMERIX

End of Presentation



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E. bd@dimerix.com



Additional Supporting Materials

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, iCeutica
- 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, Minoryx

- 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

Medical Advisory Board



Professor Hidido Heerspink
PhD
Chairman

Professor of Clinical Trials and Personalized Medicine: University Medical Center Groningen, the Netherlands. He specialises in the research of novel treatment approaches to slow the onset of diabetic cardiovascular and renal disease. Hidido has been instrumental in interactions between industry, researchers and regulatory agencies in the validation of surrogate endpoints for renal trials.



Professor Alessia Fornoni
MD, PhD, FASN
Member

Professor of Medicine & Molecular & Cellular Pharmacology: University of Miami. Chief of the Katz Family Division of Nephrology and Hypertension. She has an extensive history of translational excellence for patients with renal disease and has uncovered novel pathogenetic mechanisms and therapeutic approaches for glomerular disorders.



Professor Jonathan Barratt
MD, PhD, FRCP
Member

Mayer Professor of Renal Medicine: Department of Cardiovascular Sciences; University of Leicester and Nephrologist. Jonathan is the IgA nephropathy Rare Disease Group lead for the UK National Registry of Rare Kidney Diseases (RaDaR) and a member of the steering committee for the International IgA Nephropathy Network.



Associate Professor Lesley Inker
MD, MS, FRCP
Member

An attending physician and Director of the Kidney and Blood Pressure Center in the Division of Nephrology at Tufts Medical Center. Lesley's major research interest is in the estimation and measurement of glomerular filtration rate (GFR) and in defining alternative endpoints for CKD progression trials based on GFR decline and changes in albuminuria.



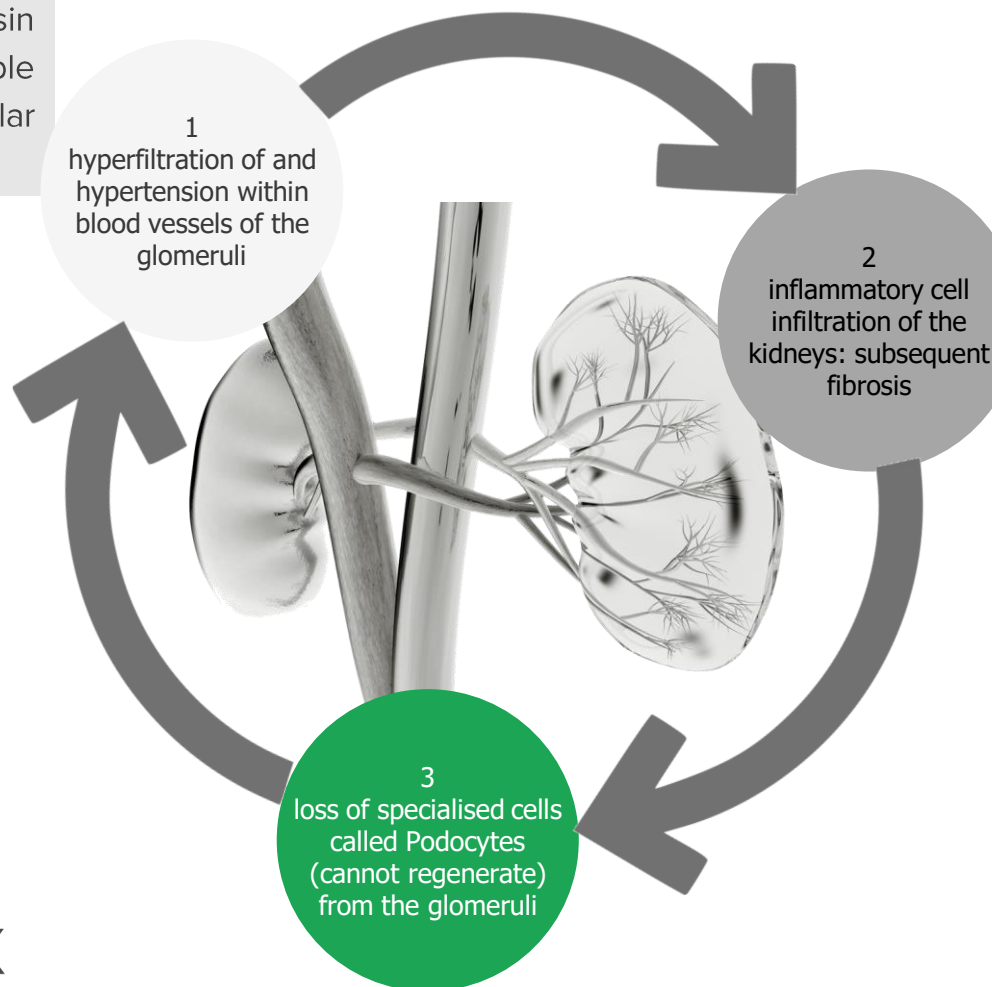
Dr Muh Geot Wong
MBBS, PhD, FRCP
Member

Renal Physician and Head of the Renal Clinical trials at the Royal North Shore hospital, Sydney, Australia. Muh Geot's main areas of research are in understanding the mechanisms of kidney fibrosis, biomarkers research, and identifying strategies in delaying progressive kidney disease including glomerular diseases.

DMX-200 proposed mechanism of action

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

Irbesartan blocks angiotensin receptors (AT1R) responsible for hyperfiltration & glomerular hypertension



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

- Monocyte chemoattractant protein-1 (MCP-1):
 - key chemokine that regulates migration & infiltration of immune cells responsible for inflammation
 - lower levels of MCP-1 translates to less inflammation
- CCR2 is the receptor for MCP-1

Dimerix' proprietary discovery tool determined a functional interaction between AT1R and CCR2

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**

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 signals across studies
- Consistently safe and well tolerated in both healthy volunteers and renal patients (total of 95 patients dosed)
- DMX-200 safety profile and efficacy outcomes compares favourably to compounds currently in development
- Consistent data collectively leading to DMX-200 future development

Phase 2a trial in FSGS completed

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

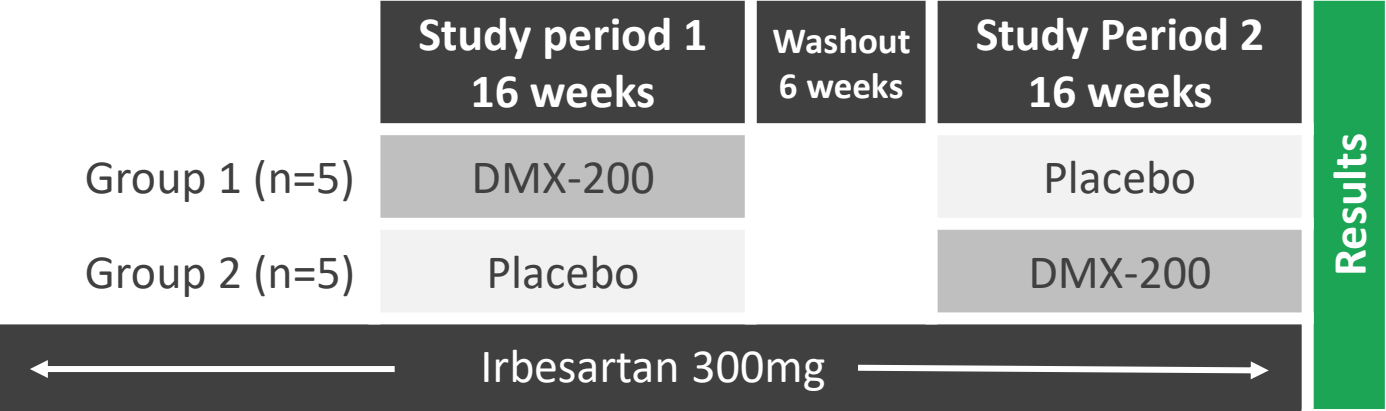
- 10 patients enrolled, 7 patients qualified for the evaluable population and final analysis
- Primary endpoint: safety. Secondary endpoint: proteinuria and biomarker analysis.
- Patient population: Patients with primary FSGS who are receiving irbesartan



Analysis population
criteria defined in
Statistical Analysis
Plan (SAP)



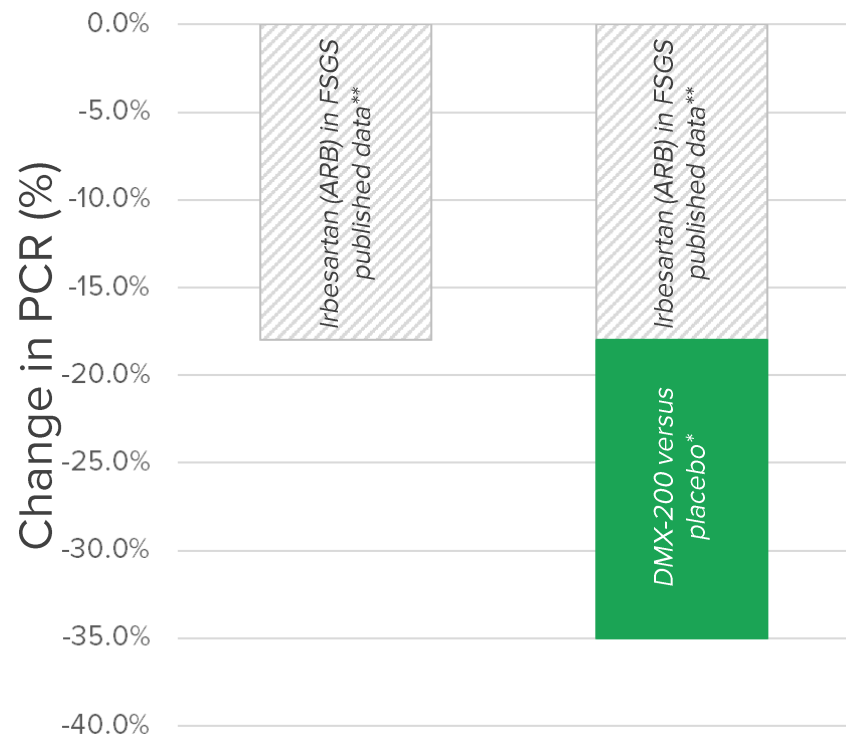
10 patients
enrolled in study:
7 qualified for the
final analysis



Dimerix

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

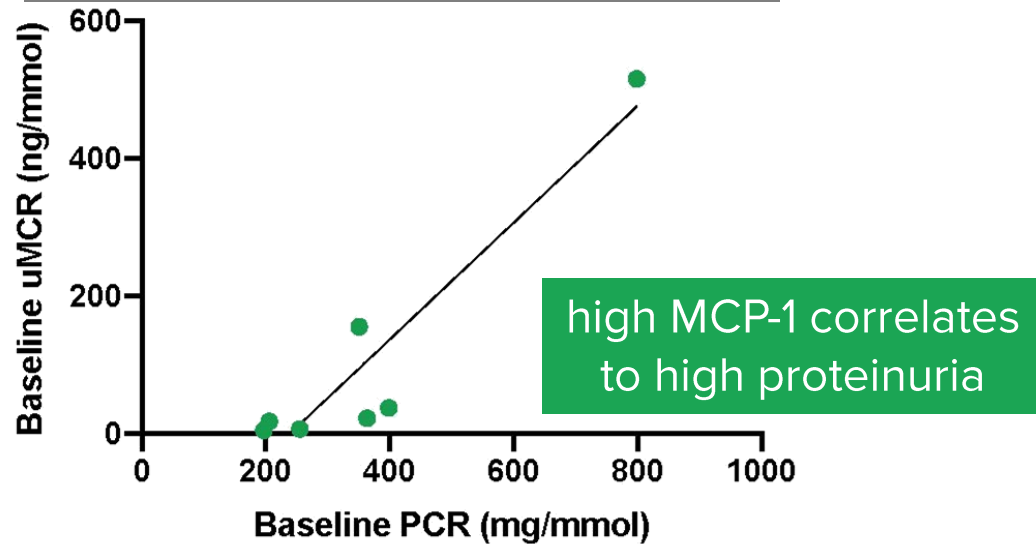


- DMX-200 demonstrated clear benefit to patients with FSGS
 - 86% of patients demonstrated reduced proteinuria on DMX-200 versus placebo
 - 29% of patients demonstrated >40% reduction in proteinuria
 - Results comparable to other compounds in development
- DMX-200 was safe and well-tolerated
- DMX-200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

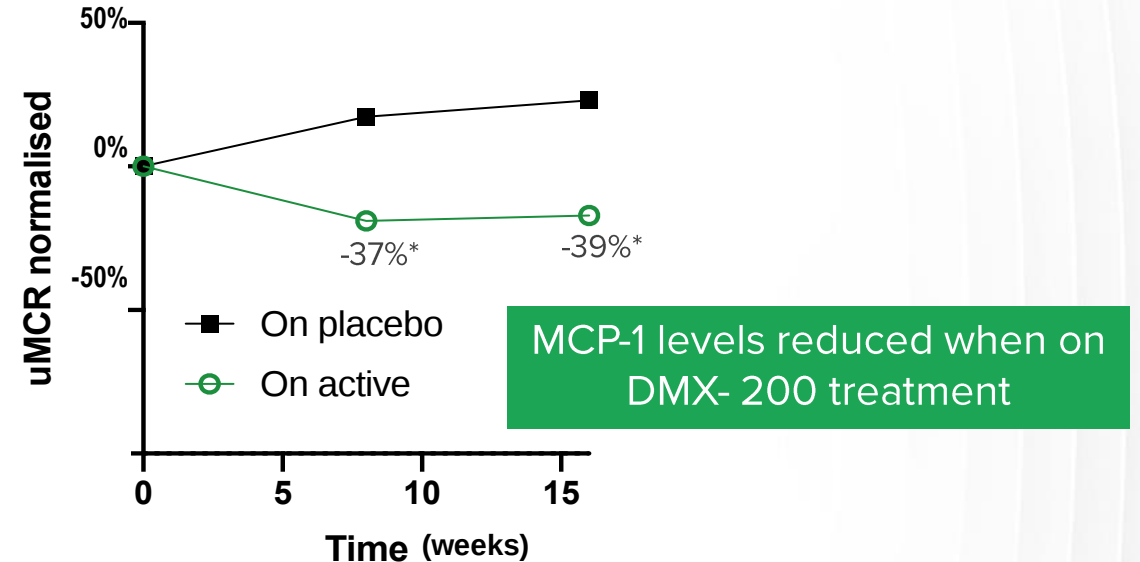
No safety concerns – reduced development risk
DMX-200 compares favourably to compounds currently in development

DMX-200 effect on inflammatory biomarker

Average baseline MCP-1 versus average baseline proteinuria



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



- 16 weeks treatment with DMX-200 vs placebo reduced inflammatory biomarker by 39%:
 - DMX-200 blocks receptor responsible for inflammation
 - translates to reduced inflammation and subsequent fibrosis (scarring) in the kidney

Medical Advisory Board Recommendation

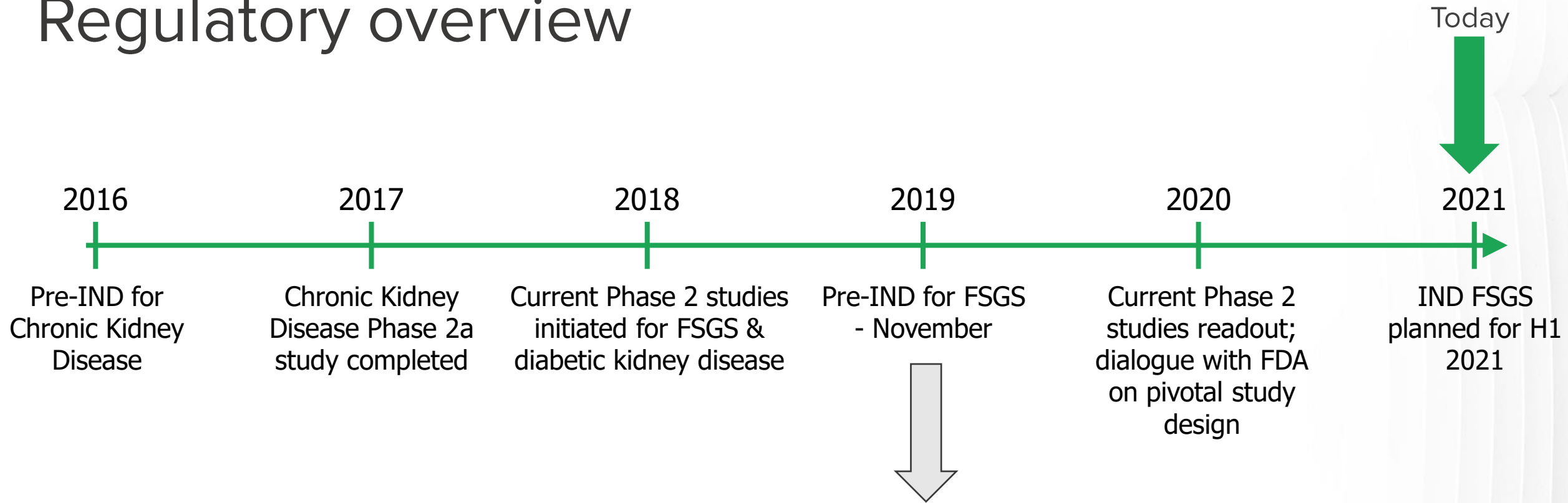
“The positive signals suggest that treatment with DMX-200 may indeed result in clinically meaningful improvements in kidney function when added to the standard of care in patients with FSGS”

“The study achieved encouraging data to support the ongoing development of DMX-200 for FSGS”

“This should be confirmed by a larger pivotal randomised controlled trial as was discussed by Dimerix with the FDA in November last year”

“Our assessment is that these data puts DMX-200 in a great position in the global development efforts for new treatments for FSGS”

Regulatory overview



- Confirmation of proteinuria as an acceptable endpoint for accelerated marketing approval;
- Single Phase 3 study appropriate for marketing approval;
- Proposed non-clinical package appropriate for NDA and registration; and
- Proposed specifications for API manufactured by Dimerix appropriate for registration

DMX-200 Intellectual property and exclusivity

Intellectual Property		Exclusivity	
US	EU	US	EU
2033 Method of use: any CCR2 antagonist with any ARB for any kidney disease	2032 Method of use: DMX-200 with irbesartan	7 years FSGS orphan exclusivity	10 years FSGS orphan exclusivity
 Granted patents* US 9,314,450 US 10,058,555 US 10,525,038	 Granted patents* EP 2663304		
Patent applications with alternative claims filed	Patent applications with alternative claims filed	DMX-200 has potential benefit of exclusivity** whilst relying on existing safety data	

**Additional granted patents in other key territories*
***NCE: active moiety not approved before*

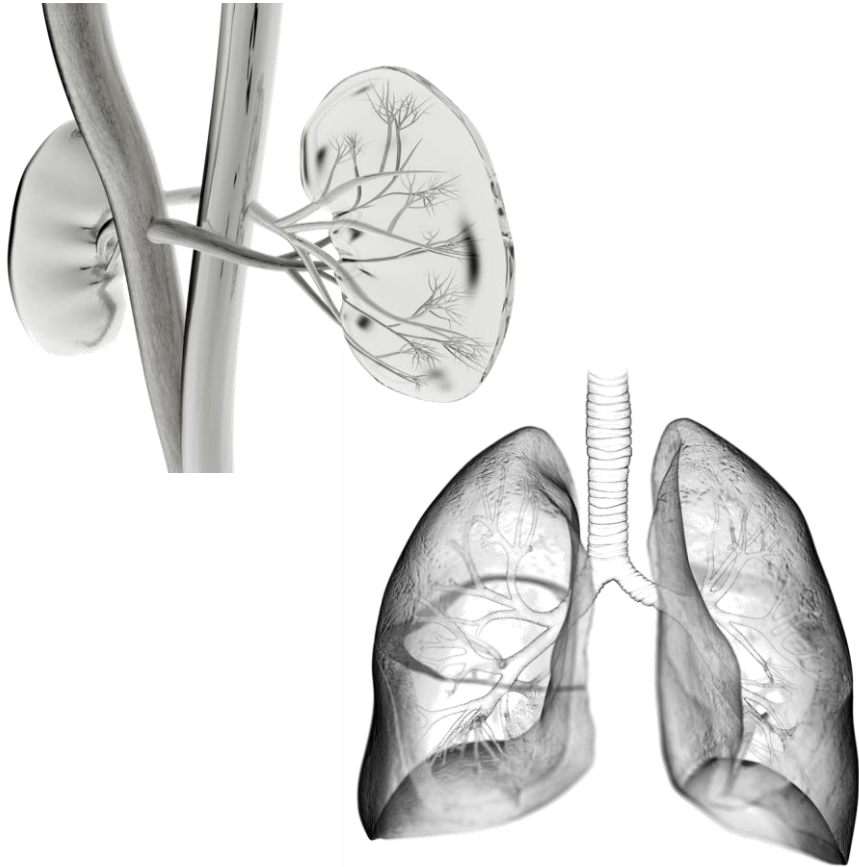
Phase 2 trial in diabetic kidney disease data

DMX-200 demonstrated clear benefit to patients with diabetic kidney disease in the Phase 2 clinical study

Across the entire cohort (n=40)	
• 30% of all patients ended the study below albuminuria threshold for diabetic kidney disease diagnosis (<30mg/mmol) - a fantastic outcome for those patients • 22% reduction in albuminuria compared to placebo was observed at study end when normalised to first baseline	
Patients starting baseline ACR	
Lower starting baseline albuminuria (<57m/mmol; n=14):	Higher starting baseline albuminuria (>57mg/mmol; n=26):
50% saw albuminuria levels drop below threshold for diagnosis of DKD	37% reduction in albuminuria versus placebo at study end when normalised to first baseline

ACR = albumin to creatinine ratio

Dimerix, along with key global experts, are now assessing the design of a longer study that will allow the natural history of diabetic kidney disease patients to be contrasted against possible longer-term effects of DMX-200



Factsheets

FSGS market: serious and rare kidney disease



Orphan indication currently with
no FDA-approved therapies[‡]



US incidence[†]

80,583



Market growth will **accelerate**
at a CAGR (2017-2025)[#]

>8.0%



Average
orphan drug pricing
>US\$7,000
per month^{*}



Across all nephrotic syndromes,
FSGS accounts for ^{*‡}

- 40% cases in **adult**
- 20% cases in **children**



~40% of FSGS transplant
patients:
FSGS **disease recurs**[^]



Approximately 5 years from
diagnosis to
end-stage renal disease[‡]



More than 5,400 **new cases**
diagnosed each year in US[^]

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

^{*} Sangameswaran K, Baradhi K; (2019) Focal Segmental Glomerulosclerosis [<https://www.ncbi.nlm.nih.gov/books/NBK532272/>] [Accessed 02Mar20]

[^] Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis [<https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/>] [Accessed 02Mar20]

[‡] Rosenberg A, Kopp J (2017); Focal Segmental Glomerulosclerosis, Clinical Journal of American Society of Nephrology [<https://cjasn.asnjournals.org/content/12/3/502>] [Accessed 02Mar20]

[†] DelveInsight Market Research Report (2020); Focal Segmental Glomerulosclerosis (FSGS)- Market Insight, Epidemiology and Market Forecast -2030

[#] Transparency Market Research (2019); Focal Segmental Glomerulosclerosis (FSGS) Market [<https://www.transparencymarketresearch.com/focal-segmental-glomerulosclerosis-market.html>] [Accessed 02Mar20]

Phase 2 trial in diabetic kidney disease completed

Phase 2, Double-blind, Randomised, Placebo-Controlled, Crossover Study in Diabetic Kidney Disease (n=45)



DMX-200 resulted in statistically & clinically significant reduction in proteinuria versus placebo*



Supports proposed mechanism of action: effective where active inflammatory processes are driving disease progression



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



Diabetic patients that have kidney disease**
40%



The market is highly concentrated, with few players occupying market share‡



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



Addressable market
US\$1.1 billion
Key driver is the rise in diabetes global incidence^



Formulation can be differentiated from FSGS product formulation

* Reported 14 Sep2020

** Alicic R, Rooney M, Tuttle K (2017) Diabetic Kidney Disease Challenges, Progress, and Possibilities, Clinical Journal of American Society of Nephrology [https://cjasn.asnjournals.org/content/12/12/2032] [Accessed 02Mar20]

‡ Technavio (2019); Global Diabetic Nephropathy Market 2018-2022 [https://www.businesswire.com/news/home/20181227005118/en/Global-Diabetic-Nephropathy-Market-2018-2022-34-CAGR] [Accessed 02Mar20]

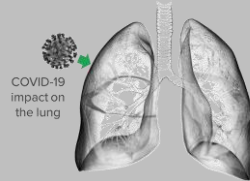
^ Market Research Future (2020); Diabetic Neuropathy Treatment Market Research Report – Global Forecast to 2025 [https://www.marketresearchfuture.com/reports/diabetic-neuropathy-treatment-market-8359] [Accessed 02Mar20]

Acute Respiratory Distress Syndrome (ARDS)

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



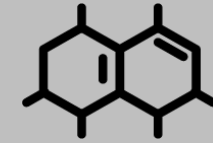
REMAP-CAP: global clinical study in COVID-19 pneumonia; >290 clinical sites in 19 countries*



REMAP-CAP/COVID-19 study protocol includes DMX-200*



>18,403,737 active COVID cases globally; >600,000 new cases/day**



Remdesivir Emergency Use Approval: retails for US\$3120 per 10 day treatment (A\$4555)



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^)

Respiratory complications

Second study in COVID-19 patients with earlier complications



CLARITY 2.0: A feasibility/Phase III partner study to CLARITY (Controlled evaluation of Angiotensin Receptor Blockers for COVID 19 respiraTorY disease)



Study will recruit COVID-19 patients at early stages of respiratory complications, prior to onset of ARDS*



Study led by Prof Meg Jardine (NHMRC Clinical Trials Centre, The University of Sydney, Australia) in collaboration with Prof Vivekanand Jha (The George Institute for Global Health (India))



Randomised, double blind, placebo-controlled study to recruit ~600 participants with COVID-19 in India



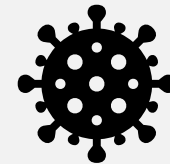
Primary Endpoint: 7-point clinical health score at 14 days; developed by the WHO for Coronavirus Disease 2019 (COVID-19) trials



DMX-200 aims to reduce damage from inflammatory immune cells blocking signalling & limiting movement into the lungs/other tissues damaged by the virus



CLARITY 2.0 is the second trial to include DMX-200 in COVID-19 patients**



Benefit in COVID-19 disease may translate to other respiratory infections such as influenza

DMX-700 - Chronic Obstructive Pulmonary Disease

Pre-clinical asset for the treatment of COPD by blocking heteromer signalling in receptors active in COPD



4th leading cause of death worldwide: of top 5 causes of death, only one with increasing mortality rates



No cure available & existing treatments aimed at relieving symptoms only



3.17 million deaths caused by COPD in 2015 (5% of all deaths globally that year)



COPD direct healthcare expenditures in US:

\$72 billion/year



Global COPD treatment market (2017)

US\$14 billion



Global COPD market projected to increase at CAGR >4% to 2026: Asia Pacific expected to be fastest growing COPD market at CAGR ~8.7%



Development plan progressing towards clinical phase: in vivo assessment in COPD model to confirm in vitro observations



DMX-700 targets blocking two receptors simultaneously (IL-8R β (also known as CXCR2) and AT1R) to achieve a synergistic effect