# Dimerix

*Investor Presentation*

December 2020

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# 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.*

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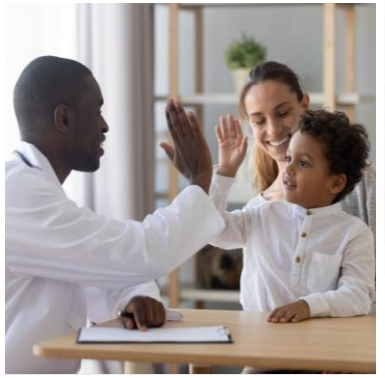
# About Dimerix

Public company (ASX: DXB)

Multiple late-stage clinical programs with early monetisation opportunities

Commercial manufacturing established for DMX-200 launch



DMX-200: renal

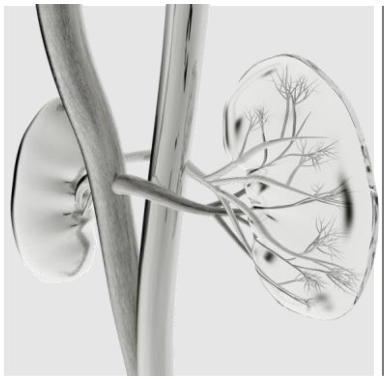
Lead Phase 3 program in orphan renal condition with Accelerated Approval end point

>US$1 billion market opportunity

DMX-200: COVID-19

Two late stage (Phase 3) studies with near term readouts

Potential for Emergency Use Approval



Additional earlier stage programs from discovery engine

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# Corporate overview

| Share performance | | |
|---|---|---|
| ASX | Ticker Symbol | ASX:DXB |
| | Share price | ~A$0.235 |
| | Total ordinary shares on issue | 197,749,297 |
| | Market Capitalisation (20Oct20) | ~A$46 million |
| | Trading range (last 12 months) | A$0.105 - 0.78 |

| Key metrics | | |
|---|---|---|
| | Average volume | 1,877,843 |
| | 52 week change | 89% |
| | Cash Balance (30Sep20*) | A$6.5 million |
| | Top 20 Shareholders own | 33.35% |
| | Institutional shareholders | <10% |

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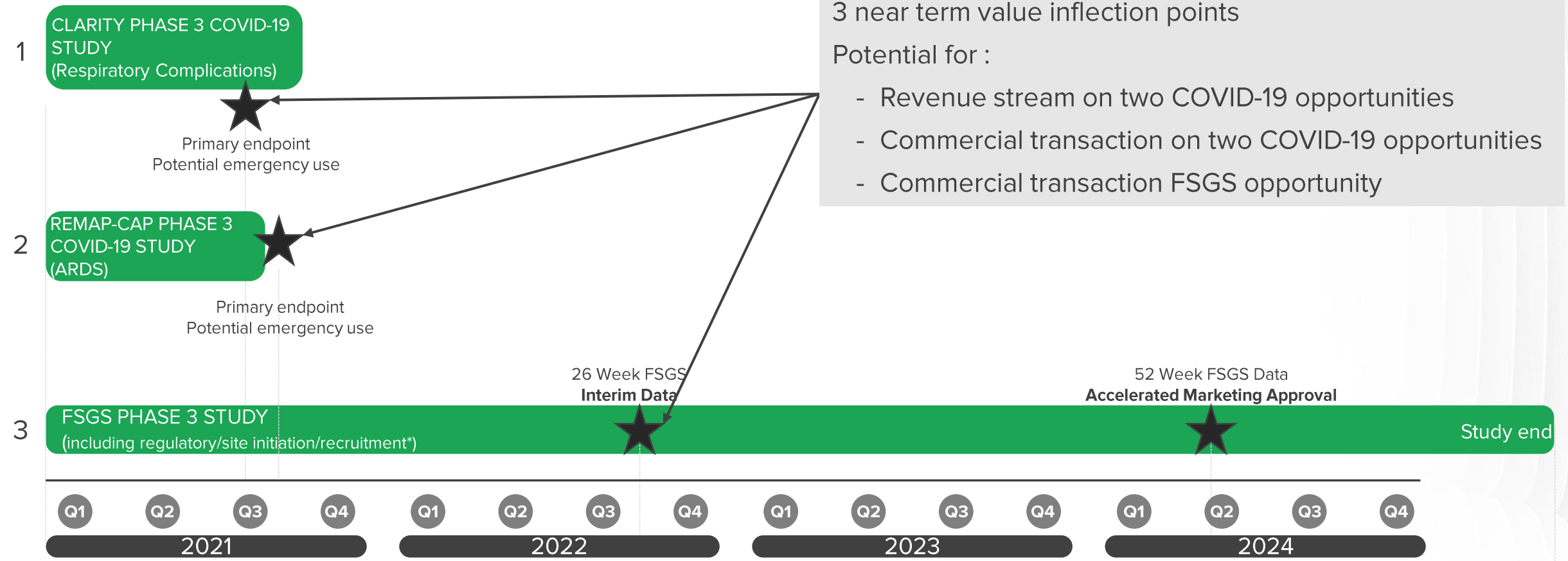
*includes R&D Tax incentive refund received Oct20

# Value roadmap

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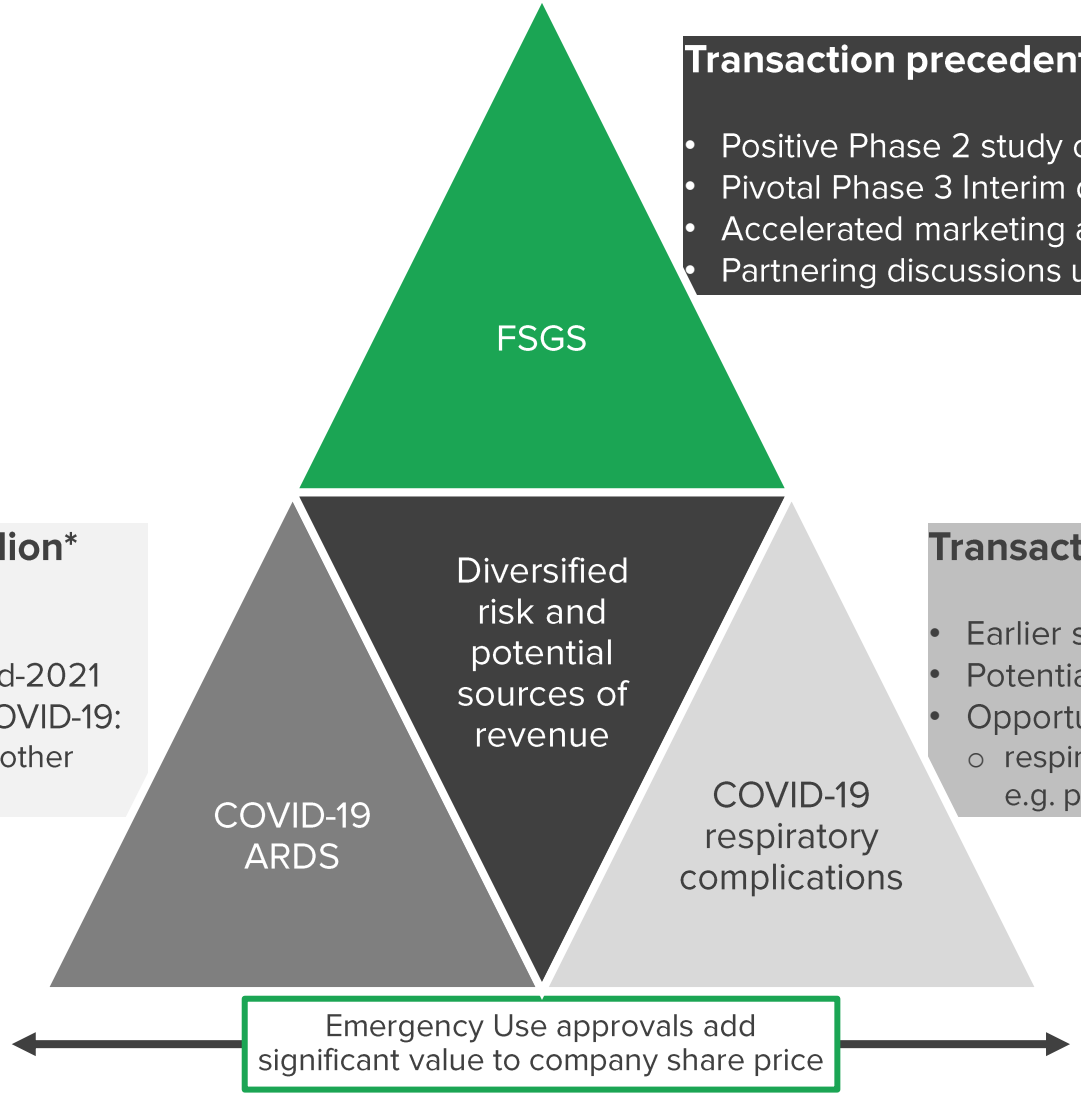
*Recruitment strategies in place to expedite recruitment

# Three near term value propositions

**Transaction precedent: >US$500 million (slide 11)**

- Positive Phase 2 study complete
- Pivotal Phase 3 Interim data anticipated 2022
- Accelerated marketing approval pathway
- Partnering discussions underway




**Transaction precedent: >US$500 million***

- No known prevention or cure of ARDS
- Potential for Emergency Use Approval mid-2021
- Opportunity extends beyond impact of COVID-19:
  - respiratory complications associated with other infections, e.g. pneumonia/influenza

**Transaction precedent: >US$300 million****

- Earlier stage of respiratory complications
- Potential for Emergency Use Approval mid-2021
- Opportunity extends beyond impact of COVID-19:
  - respiratory complications associated with other infections, e.g. pneumonia/influenza

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**Mesoblast:Novartis (2020) ; Citrus Pharmaceuticals:Novellus (2020); Faron:Pharmbio 2016*
***Adamis Pharmaceuticals:Matrix Biomed (2020); Giliead:Galapagos (2019) Insamed:AstraZeneca (2016)*

# FSGS commercial rationale

| Commercially attractive and growing markets |
| --- |
| • Major unmet medical need, affecting both children and adults |
| • Existing efficacy and safety data from prior clinical studies (including in FSGS) support progression to Phase 3 |
| • Clear recruitment window allowing consolidation of competitive advantage |
| • Exceptional IP and exclusivity provisions in major markets |
| • Strong transactional opportunities |

**Additional COVID-19 programs already funded to interim data points supporting potential Emergency Use designation and additional near term opportunity**

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# Why FSGS: >US$1 billion addressable market

FSGS: A 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

No FDA approved therapies

210,000 FSGS sufferers globally[#]
80,500 estimated in the US

>5,400 new US cases/year^

→

Average orphan drug pricing >US$7,000 per month (US$84,000/year)*

→

FSGS diagnosis by biopsy with patients having access to payer/insurer

High potential treatment uptake

Potential addressable market of >US$1 billion/year

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

**2018, IQVIA , Orphan Drugs in the United States: Growth Trends in Rare Disease Treatments, [ONLINE] Available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/orphan-drugs-in-the-united-states-growth-trends-in-rare-disease-treatments.pdf [accessed 19Jun19]*

[‡]*2018, IQVIA , Orphan Drugs in the United States: Exclusivity, Pricing and Treated Populations, [ONLINE] Available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/orphan-drugs-in-the-united-states-exclusivity-pricing-and-treated-populations.pdf [accessed 19Jun19]*

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

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# 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 | *acquisition* | *acquisition* | 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**

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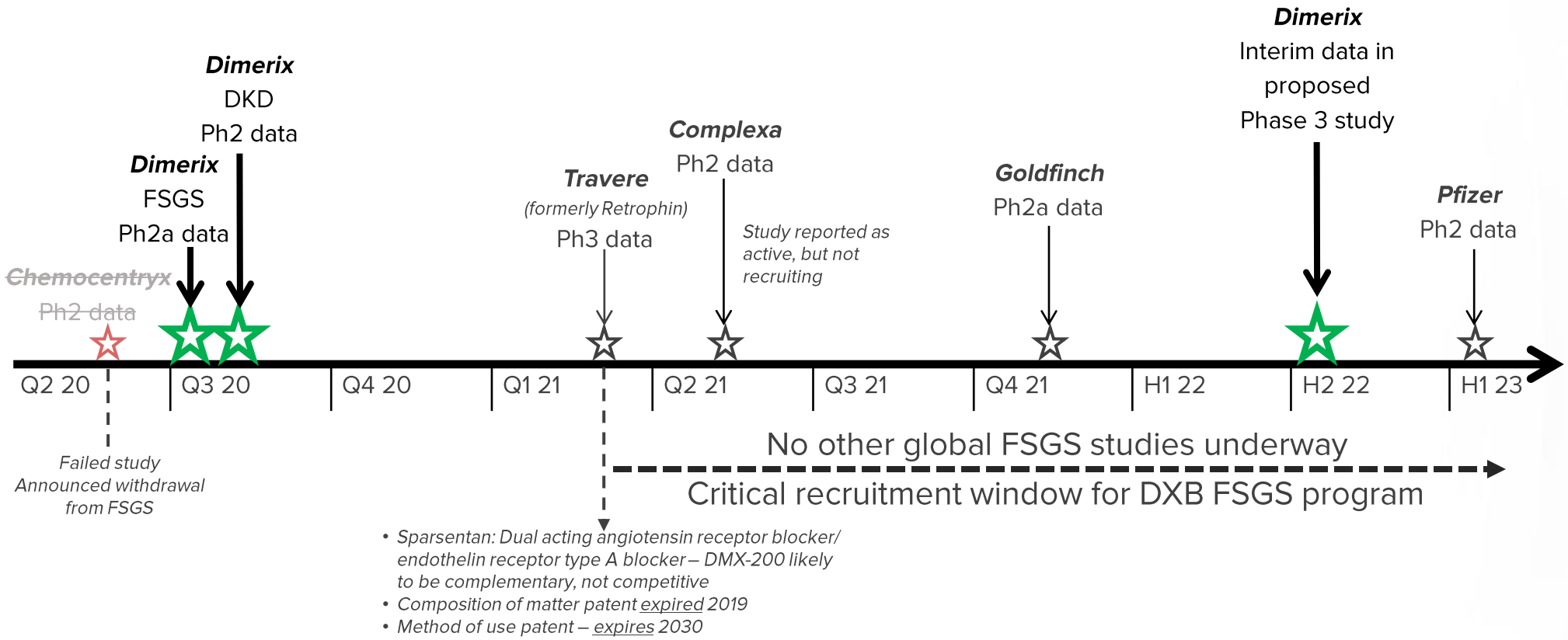
# FSGS competitive positioning




**Dimerix well positioned to help patients seeking treatment who often have very few medical options**

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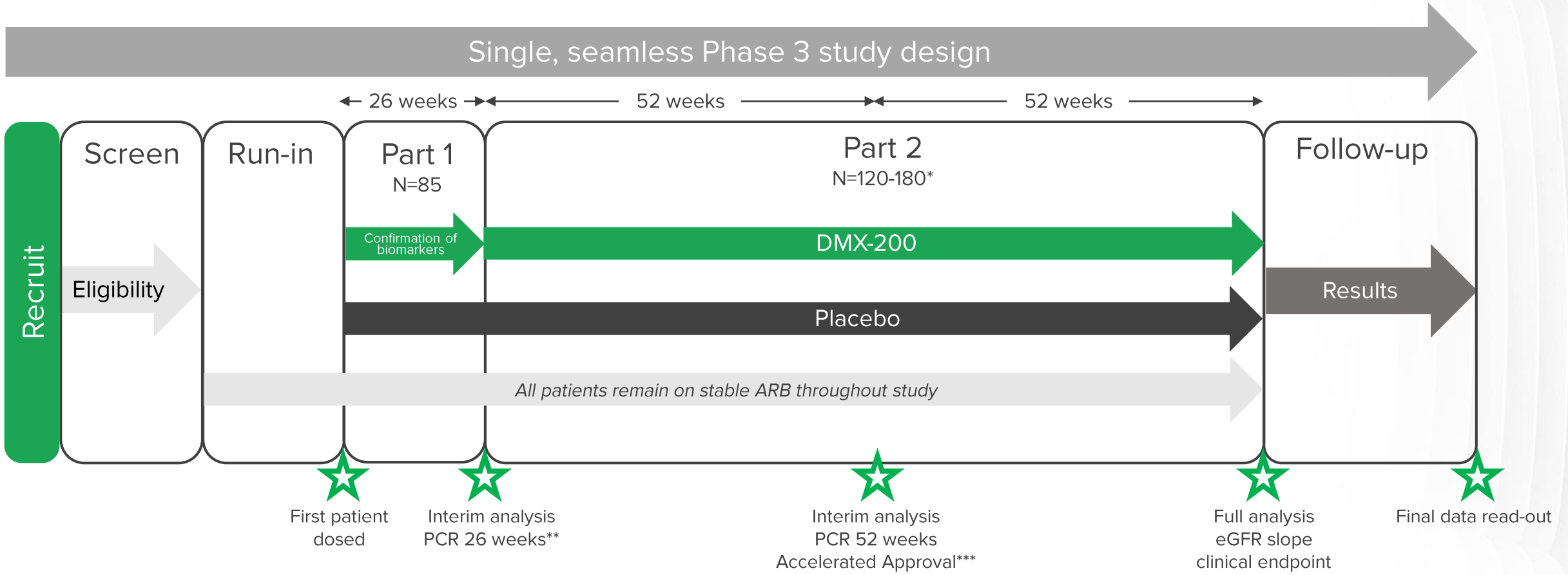
*Data based on company annual reports 2019 and/or clinicaltrials.gov*

# Proposed Phase 3 FSGS study design overview*




* *Subject to final approval of the study design/procedures by FDA (or equivalent) and review by biostatistician*
** *Confirmation of biomarker response and pre-specified analysis*
*** *Accelerated Approval: Marketing approval for "serious conditions that fill an unmet medical need based on a surrogate or an intermediate clinical endpoint*

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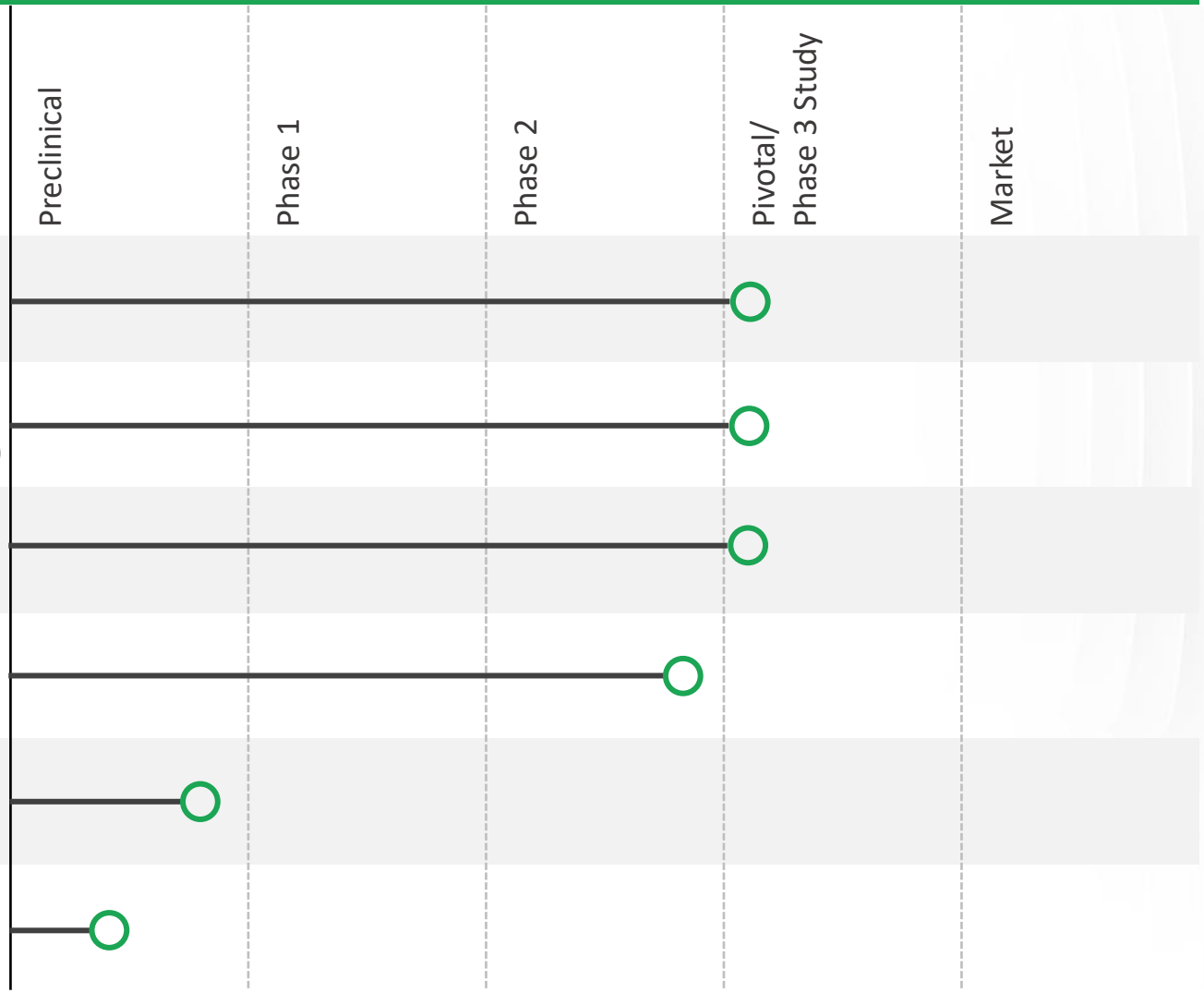
# Development pipeline

**5 product candidates in the pipeline, with 4 clinical opportunities**

| Compound | Disease Target |
|---|---|
| DMX-200 | Focal Segmental Glomerulosclerosis (FSGS) |
| DMX-200 | Acute Respiratory Distress Syndrome (ARDS) in COVID-19 patients (REMAP-CAP) |
| DMX-200 | Respiratory complications in COVID-19 patients (CLARITY 2.0) |
| DMX-200 | Diabetic Kidney Disease (DKD) |
| DMX-700 | Chronic Obstructive Pulmonary Disease (COPD) |
| DMX-XXX | Undisclosed (multiple) |

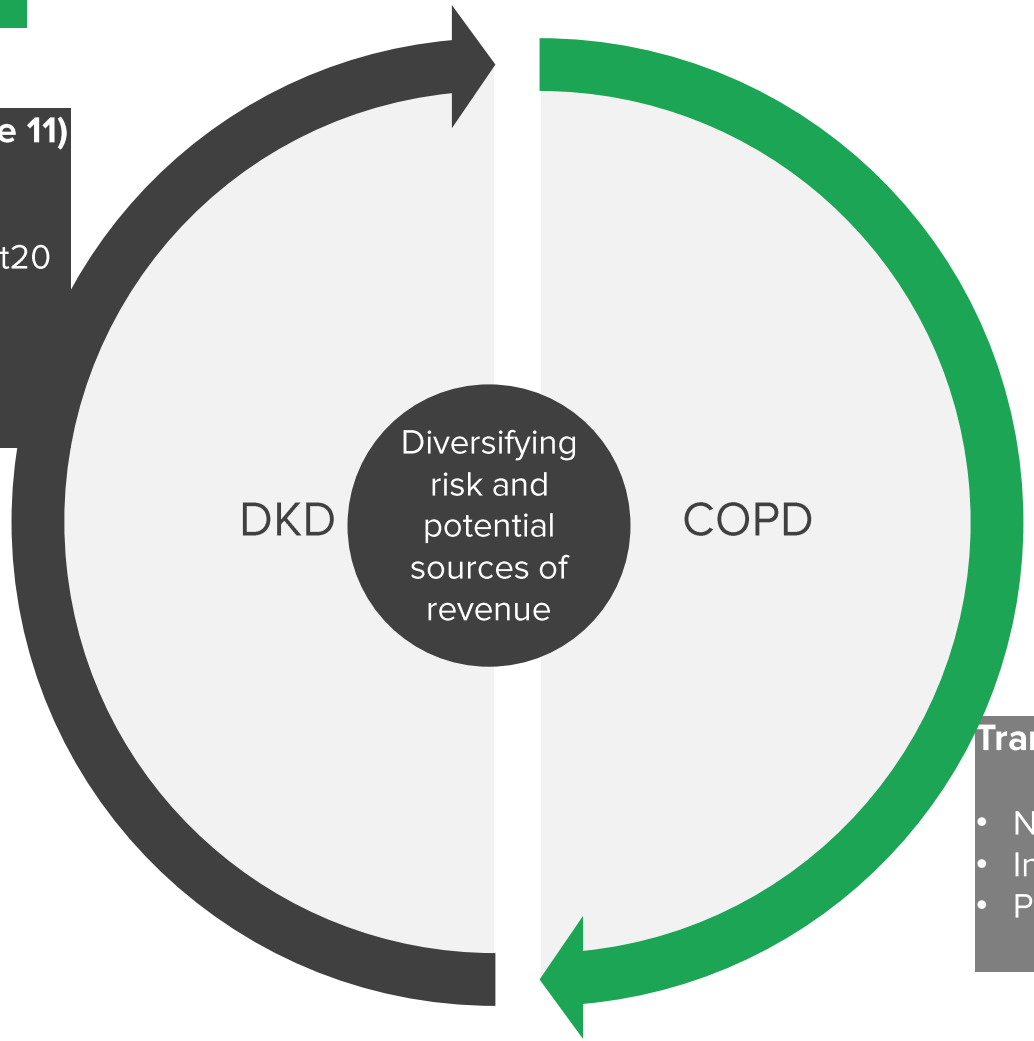


# Additional asset value propositions

Longer term opportunities

**Transaction precedent: >US$500 million (slide 11)**

- Positive Phase 2 study complete
- Data released Sep20, with additional data in Oct20
- Medical Advisory Board assessing next development steps
- Partnering discussions underway




**Transaction precedent: >US$750 million***

- No cure available
- In vivo confirmation anticipated 2021
- Prepare for Phase 1/2 clinical study

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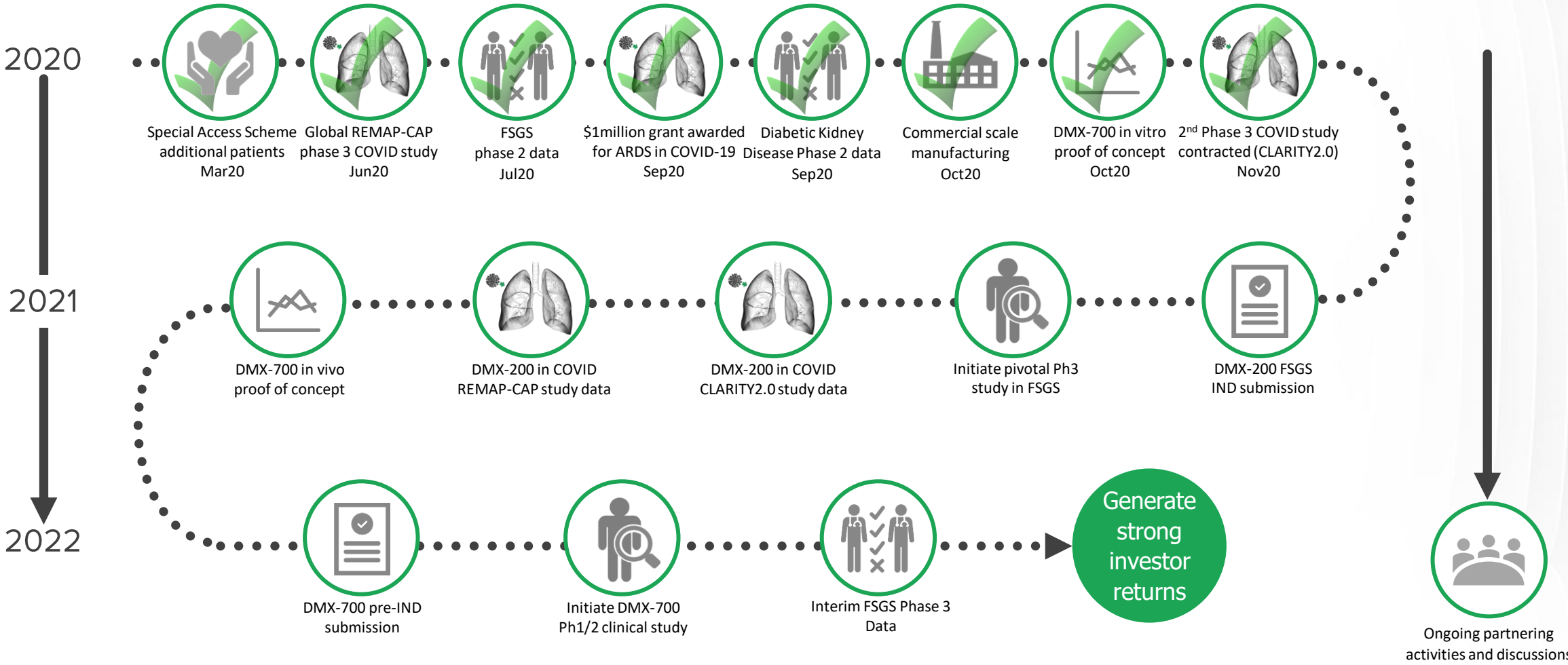
*Pulmatrix:RespiVert (2017); AstraZeneca:Almirall (2014)

# Value driving events

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# DIMERIX

End of Presentation

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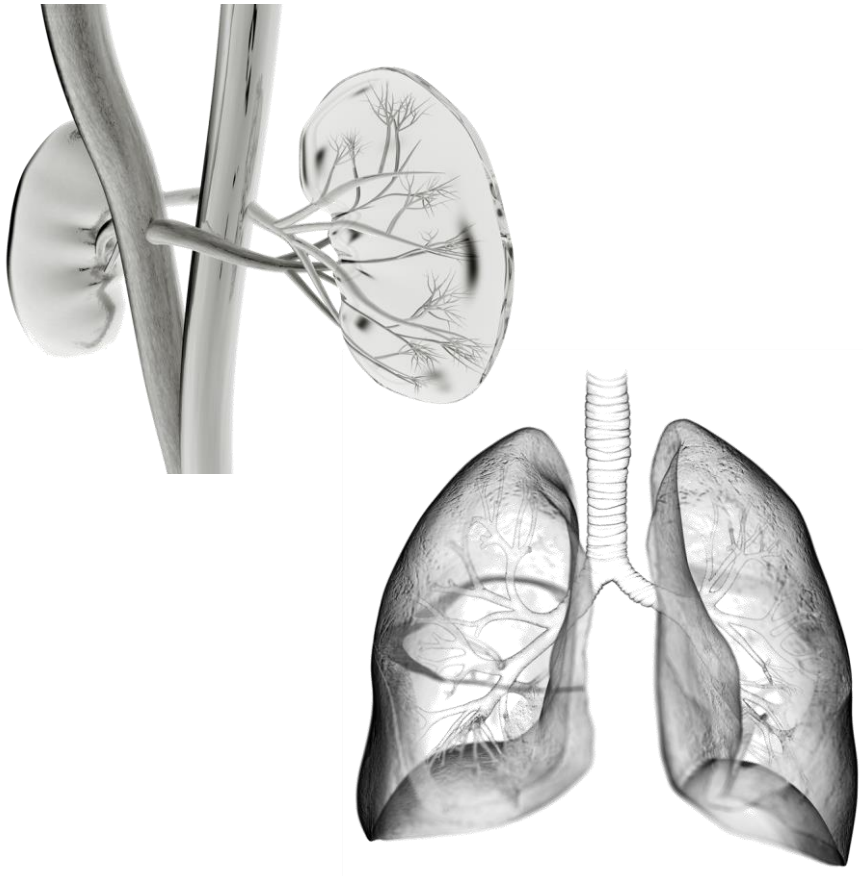

# Additional Supporting Materials

# Board & Management

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

*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

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

*Wyeth (Pfizer), Acrux, Immuron*
- Experienced in product development, commercial strategy development & execution
- Successfully commercialised multiple pharmaceutical products globally

✓BSc (Hons) - Pharmacology
✓PhD - Pharmaceutics
✓MBA - Business
✓M.IP.Law - Intellectual Property Law

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

*Mayne Pharma, Acrux, Hatchtech, Kinoxis*
- Extensive biotech drug development & commercial manufacturing experience
- Responsible for successful global commercialisation programs & NDA registrations

✓BSc (Hons) - Chemistry
✓MBA - Business

**Sonia Poli**
**PhD**
Non-Executive Director

*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

**Robert Shepherd**
**PhD**
R & D Director

*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

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

*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

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# Medical Advisory Board

**Professor Hiddo 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. Hiddo 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, FRCPC**
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.

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# DMX-200

## Proposed Phase 3 study of DMX-200 in Focal Segmental Glomerulosclerosis (FSGS)

**DMX-200**

- Small molecule known as repagermanium – new chemical entity
- Inhibits activity of a cellular receptor of inflammation: CCR2 (C-C Chemokine Receptor Type 2)
- 240mg oral delivery daily - 120mg capsule administered twice daily
- Administered to patients already on angiotensin receptor blocker (ARB) – FSGS standard of care treatment
- Extensive regulatory engagement – orphan designation secured in US and EU

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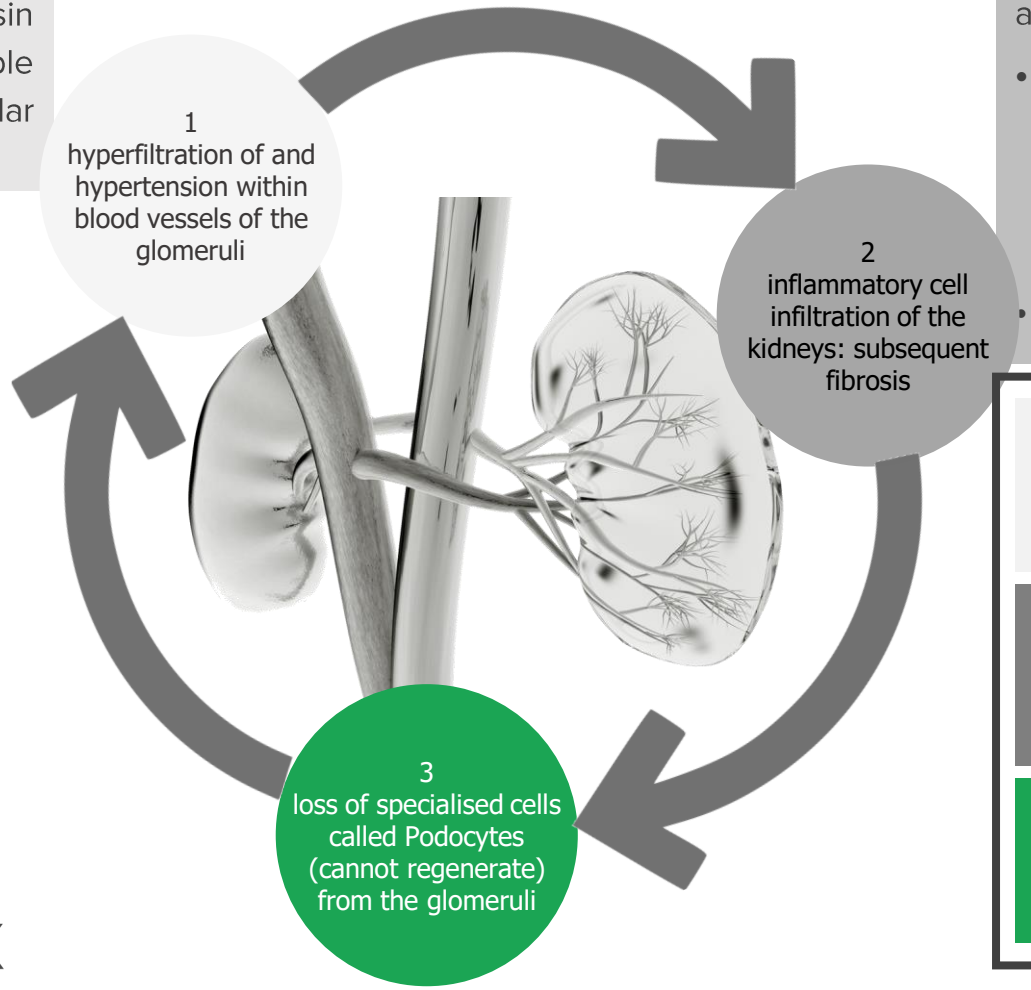
# DMX-200 proposed mechanism of action

## 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**

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# 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

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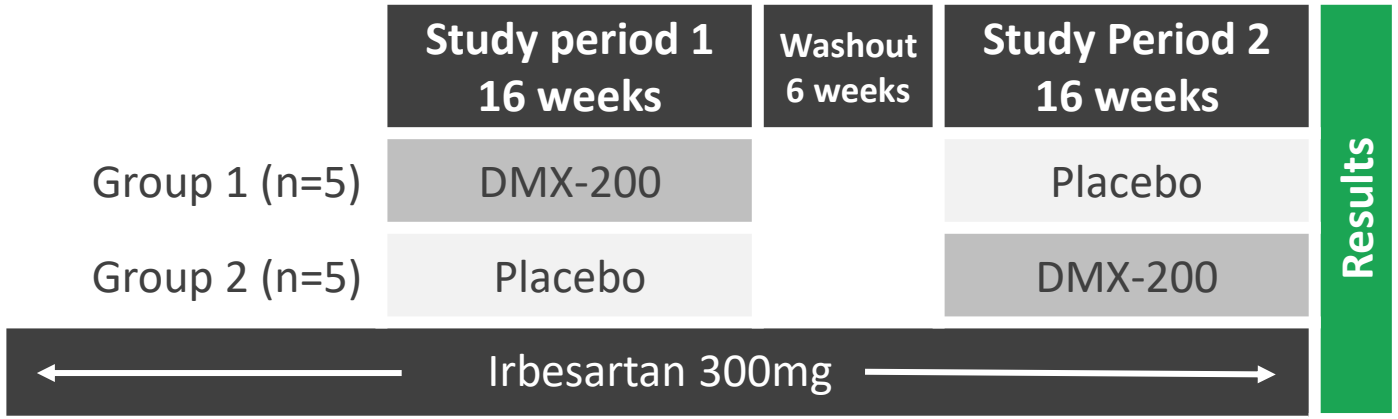
# Phase 2a trial in FSGS completed

**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

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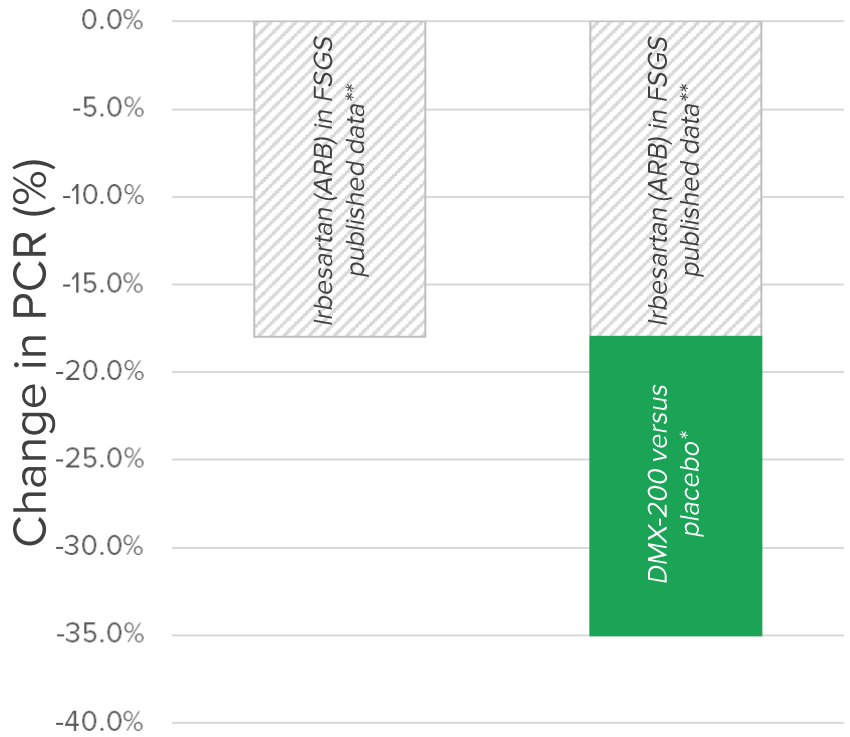
# DMX-200 treatment group met primary and secondary endpoints

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

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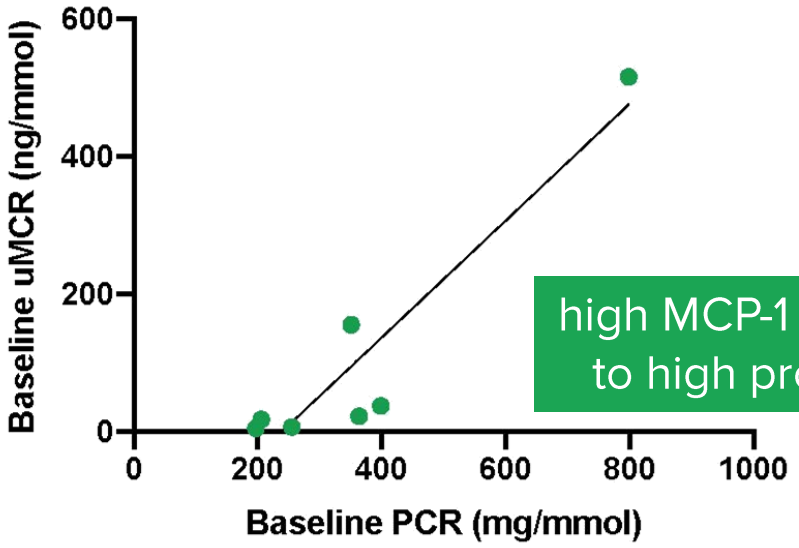
*PCR = protein creatinine ratio*
**Repeated measures mixed model analysis; top line data was reported as grouped analysis*
***Trachtman, et al., 2018. J Amer Soc Nephrology 29(11):2745-2754 (note: study design differs)*

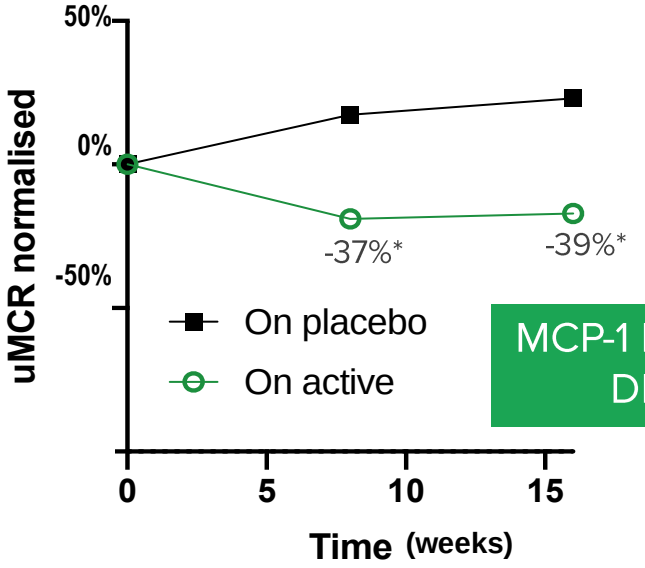
# DMX-200 effect on inflammatory biomarker

Average baseline MCP-1 versus average baseline proteinuria




high MCP-1 correlates to high proteinuria

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




MCP-1 levels reduced when on DMX- 200 treatment

- 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

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*uMCR = Urinary MCP-1 creatine ratio*
*PCR = protein creatinine ratio*
**placebo adjusted difference*

# 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"*

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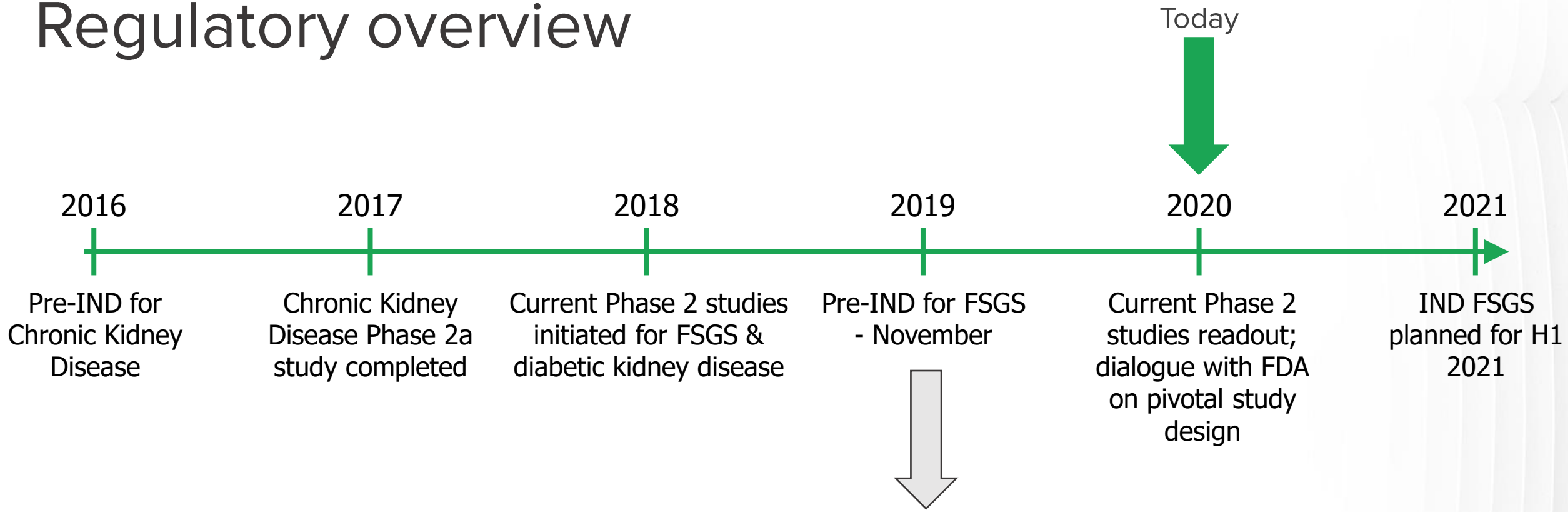
# Regulatory overview




- 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

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# DMX-200 Intellectual property and exclusivity

## Intellectual Property

### US

**2033** 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

### EU

**2032** Method of use:
DMX-200 with irbesartan

Granted patents*
EP 2663304

Patent applications with alternative claims filed

## Exclusivity

### US

**7** years FSGS orphan exclusivity

### EU

**10** years FSGS orphan exclusivity

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

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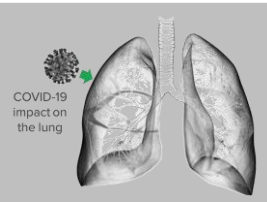
*Additional granted patents in other key territories
**NCE: active moiety not approved before

# Acute Respiratory Distress Syndrome (ARDS)

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

REMAP-CAP

REMAP-CAP: global clinical study in ARDS;
>260 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^)

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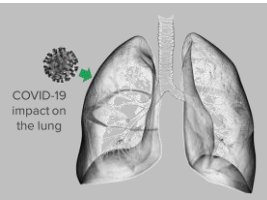
*https://www.remapcap.org
Detailed information of the REMAP-CAP trial can be found at ClinicalTrials.gov Identifier: NCT02735707
** https://www.worldometers.info/coronavirus/ 03Dec20
^Xiong et al.; Williams et al.; Shen et al.; Merad and Martin; Nature Editorial

# Respiratory complications

## Second study in COVID-19 patients with earlier complications

CLARITY

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

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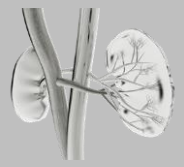
** ARDS: Acute Respiratory Distress syndrome*
*# ARB: Angiotensin Receptor Blocker*
*** DMX-200 also included in the REMAP-CAP/COVID-19 study protocol*

# 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*

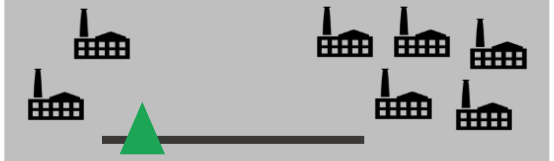


Supports proposed mechanism of action: effective where active inflammatory processes are driving disease progression

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

Dimerix

** 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]*

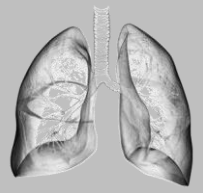
*‡ Technavio (2019); Global Diabetic Nephropathy Market 2018-2022 [https://www.businesswire.com/news/home/20181227005118/en/Global-Diabetic-Nephropathy-Market-2018-2022-34-CAGR] [Accessed 02Mar20]*

*^ 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]*

# 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-8Rβ (also known as CXCR2) and AT1R) to achieve a synergistic effect

Dimerix

*Aernout van Haarst A., McGarvey L., Paglialunga S., 2019 "Review of Drug Development Guidance to Treat Chronic Obstructive Pulmonary Disease: US and EU Perspectives"; in Clinical Pharmacology & Therapeutics, Vol.0 July 2019 (https://ascpt.onlinelibrary.wiley.com/doi/full/10.1002/cpt.1540)*

*COPD Market; Technavio market research report viewed on 12Sep19 at https://www.businesswire.com/news/home/20190206005309/en/*