

Dimerix

FSGS Phase 2a results presentation

29 July 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

- Primary and secondary endpoints met in the Phase 2a study of DMX-200 in FSGS patients
- DMX-200 was found to be generally safe and well-tolerated in FSGS patients
- 86% patients demonstrated a reduction of proteinuria with DMX-200 versus placebo
- A 29% reduction in proteinuria was observed across all patients receiving DMX-200 compared to placebo
- 29% of patients achieved a >40% reduction in proteinuria on DMX-200 compared to placebo
- Statistically powered, Phase 2 clinical study in diabetic kidney disease due to read-out in 4 – 6 weeks
- Multiple patients from both FSGS & diabetic kidney disease study continue on DMX-200 via TGA Special Access Scheme



Corporate Snapshot (ASX:DXB)



\$75m

Market capitalisation
(AUD)



\$0.38

Share price
(AUD)



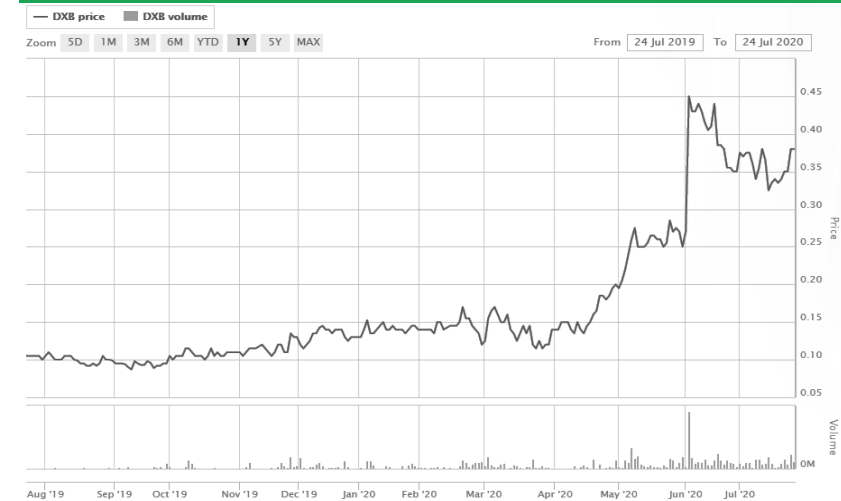
\$7.8m

in cash & cash
equivalents*;
(AUD)

Top 10 shareholders

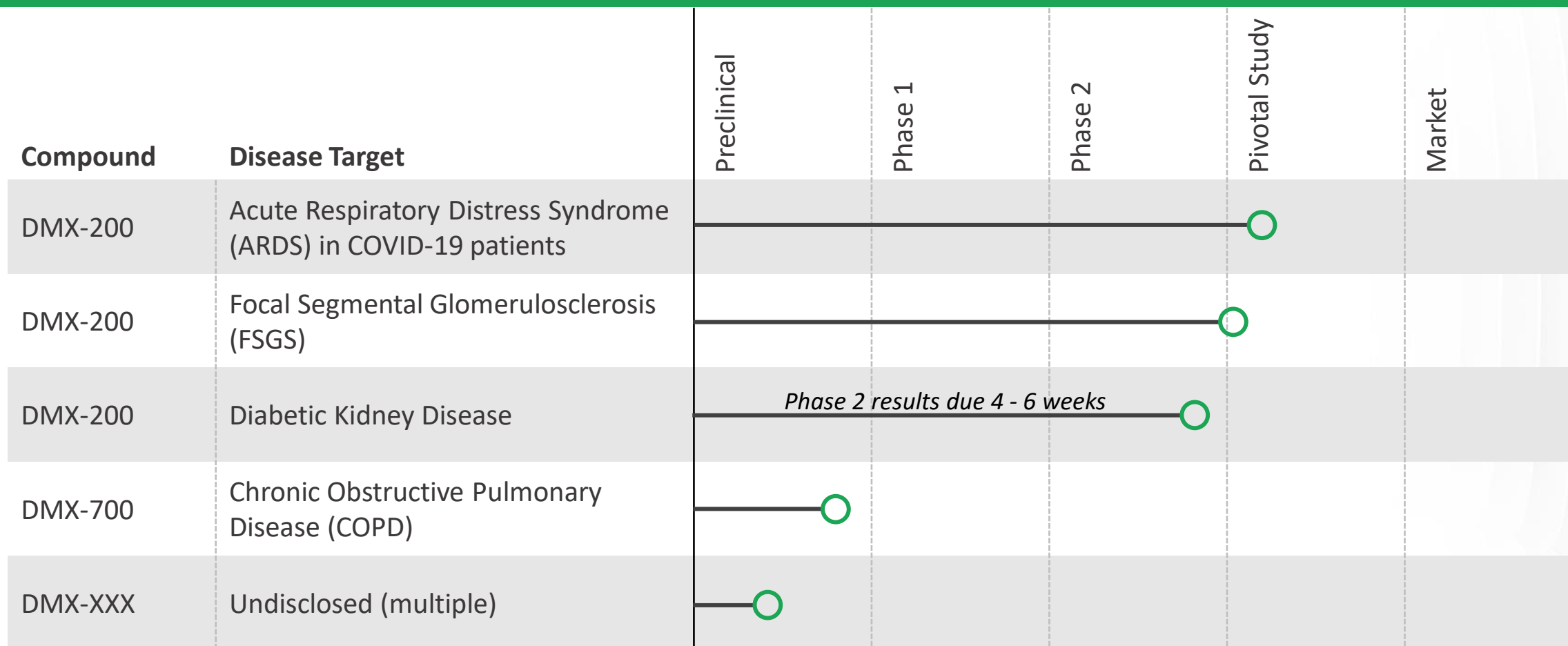
Position	Holder Name	Holding	% Holding
1	MR PETER MEURS	25,529,309	13%
2	BAVARIA BAY PTY LTD	7,316,992	4%
3	YODAMBAO PTY LTD	6,312,603	3%
4	PFLEGER FAMILY A/C	2,105,988	1%
5	TOROHA PTY LTD	2,044,932	1%
6	TT NICHOLLS PTY LTD	1,816,667	1%
7	JAMPASO PTY LTD (WILLIAMS)	1,778,742	1%
8	CS FOURTH NOMINEES PTY LIMITED	1,741,623	1%
9	MR JAMES CAMILLERI	1,720,804	1%
10	DR DAVID PACKHAM	1,689,391	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, 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

- All primary and secondary endpoints met in all studies
- Safe and well tolerated in healthy volunteers and renal patients
- DMX-200 compares favourably to compounds currently in development
- Compelling data leading to DMX-200 Phase 3 clinical study for FSGS patients

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

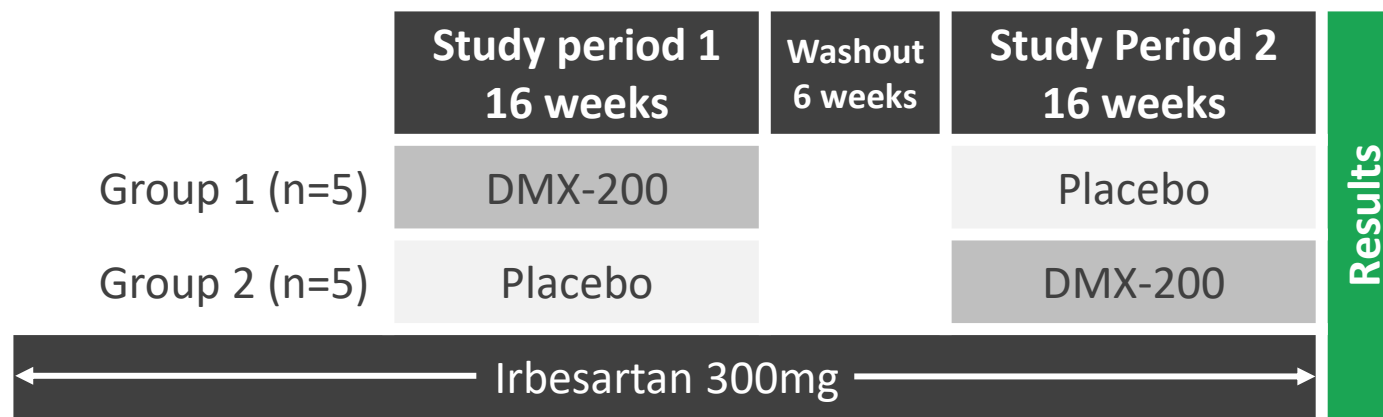
Certain kidney cells express both receptors, thus using only 1 compound does not block activation and results in only a partial response

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

Current Phase 2a trial in FSGS

Phase 2a DMX-200-202 (ACTION for FSGS) is a *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.
- Indication: for the treatment of elevated serum creatinine and proteinuria in patients with FSGS



FSGS Phase 2a study data: Primary endpoint

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 FSGS who are receiving irbesartan



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



FSGS Phase 2a study data – Efficacy endpoint

Top Line Data

Mean reduction in proteinuria (%PCR grouped analysis):

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

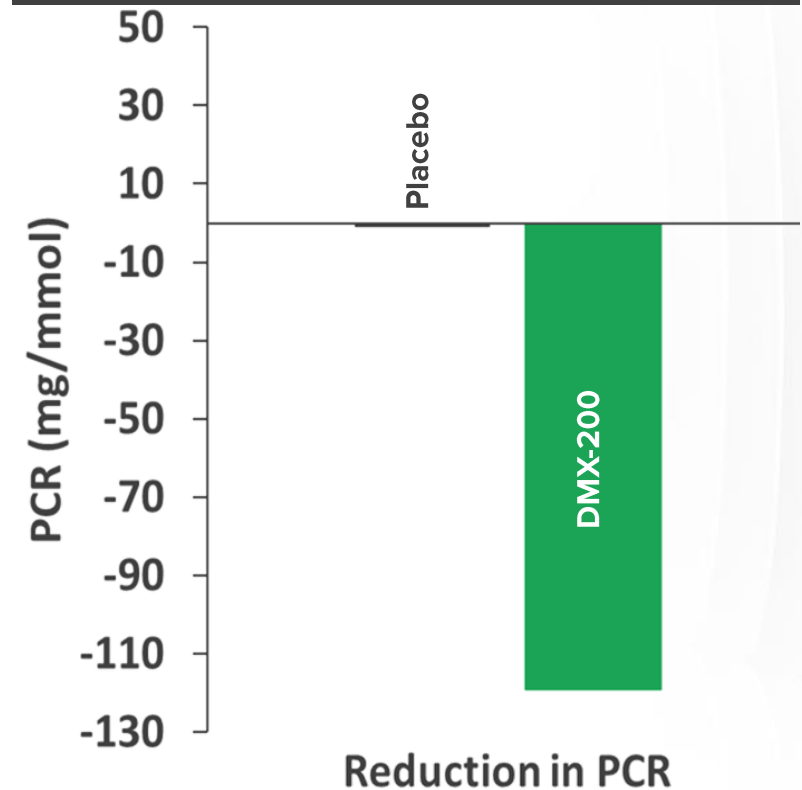
Average reduction in proteinuria:

- 119 mg/mmol (1052mg/g) on DMX-200; versus
- 1 mg/mmol (8.84mg/g) on placebo

Proportion of patients demonstrating a reduction versus placebo:

- 6/7 (86%) of patients demonstrated reduced proteinuria on DMX-200 versus placebo
- 2/7 (29%) of patients demonstrated >40% reduction in proteinuria

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



Synergistic effect

DMX-200 unique proposition: total benefit is greater than the sum of the two parts

- Administration of DMX-200 to patients already taking a stable dose of an angiotensin receptor blocker
 - = both receptors on the same cell are targeted simultaneously
 - = both receptors are inhibited
 - = suppresses the inflammatory signal
- Unlike other investigational drugs currently in development for FSGS:
 - patients stay on the standard of care angiotensin receptor blocker (ARB)
 - any proteinuria effect from irbesartan would have occurred prior to starting the study
 - reduction in proteinuria seen in the trial can be attributed to DMX-200 only

Effect seen in the study is in addition to the effect of the ARB

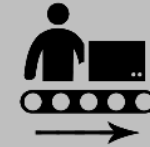
Chemistry, Manufacturing and Control (CMC)



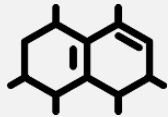
US based contract manufacturer appointed for commercial supply of API



FDA approved manufacturing facility



US based manufacturer engaged for finished product manufacture



Analytical methods validated



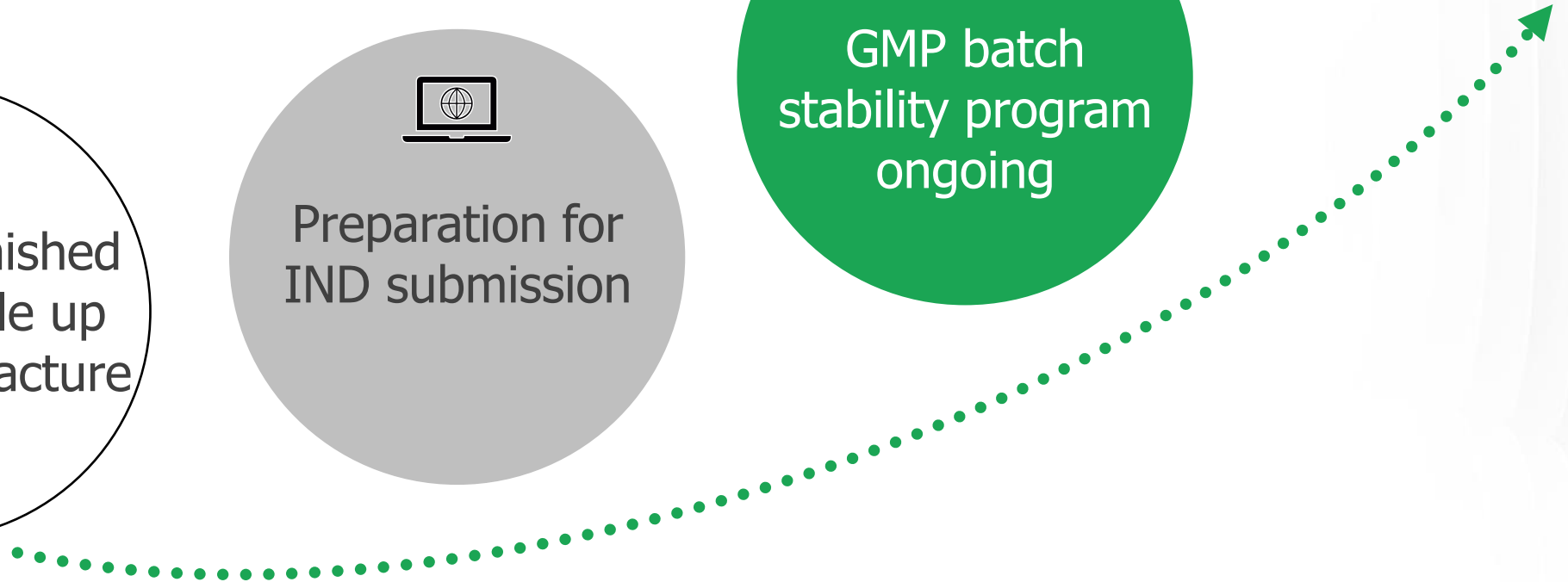
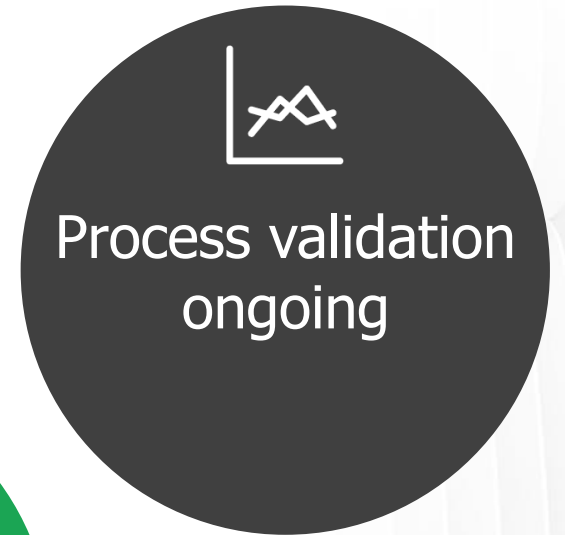
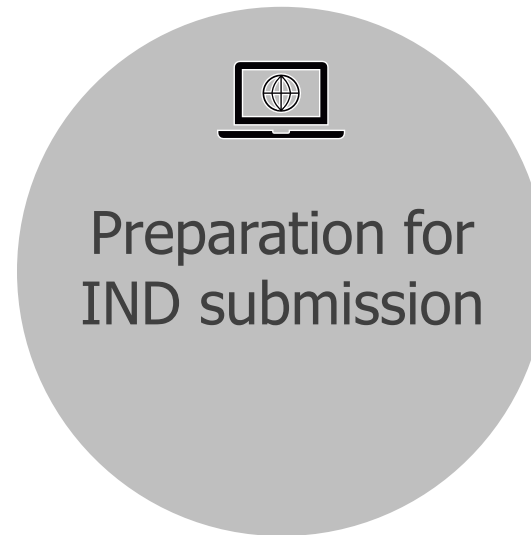
Commercial scale GMP batch manufacture completed



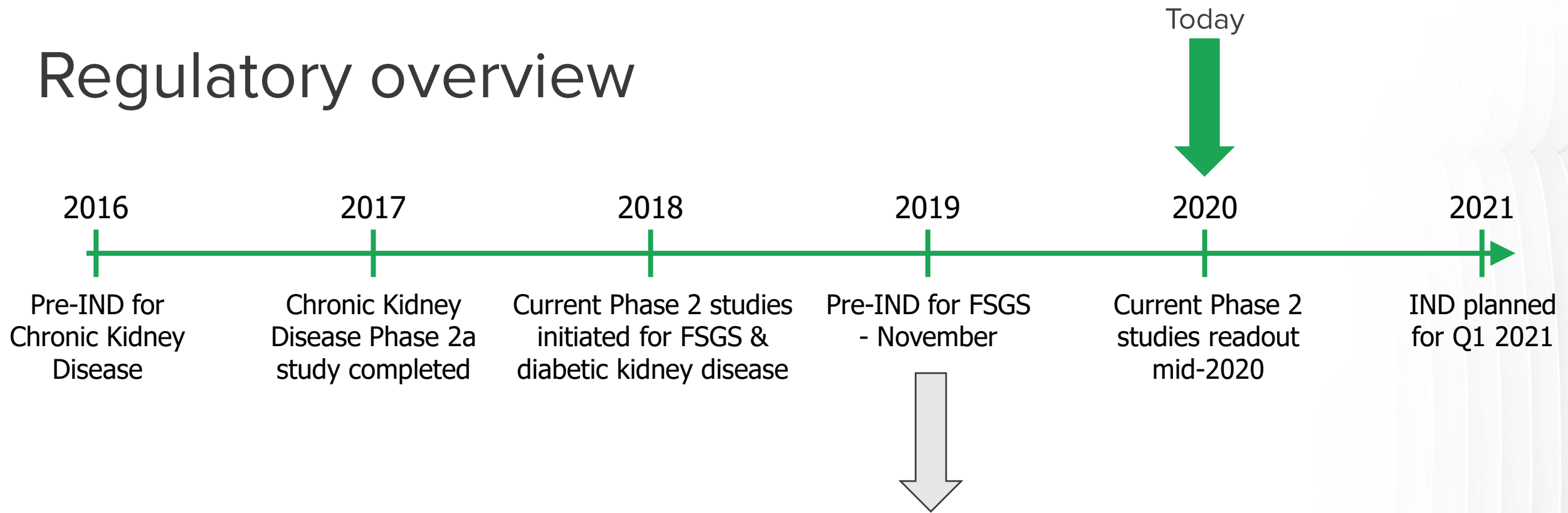
Exclusive development and methodology to manufacture API owned by Dimerix

CMC NDA package suitability confirmed with FDA

CMC next steps

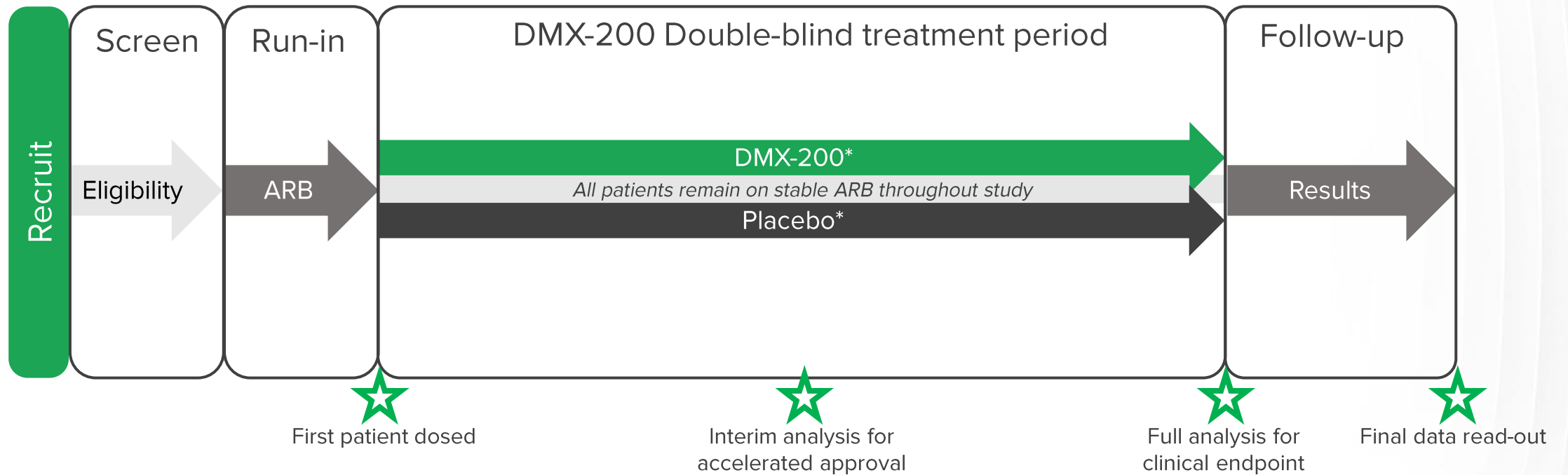


Regulatory overview



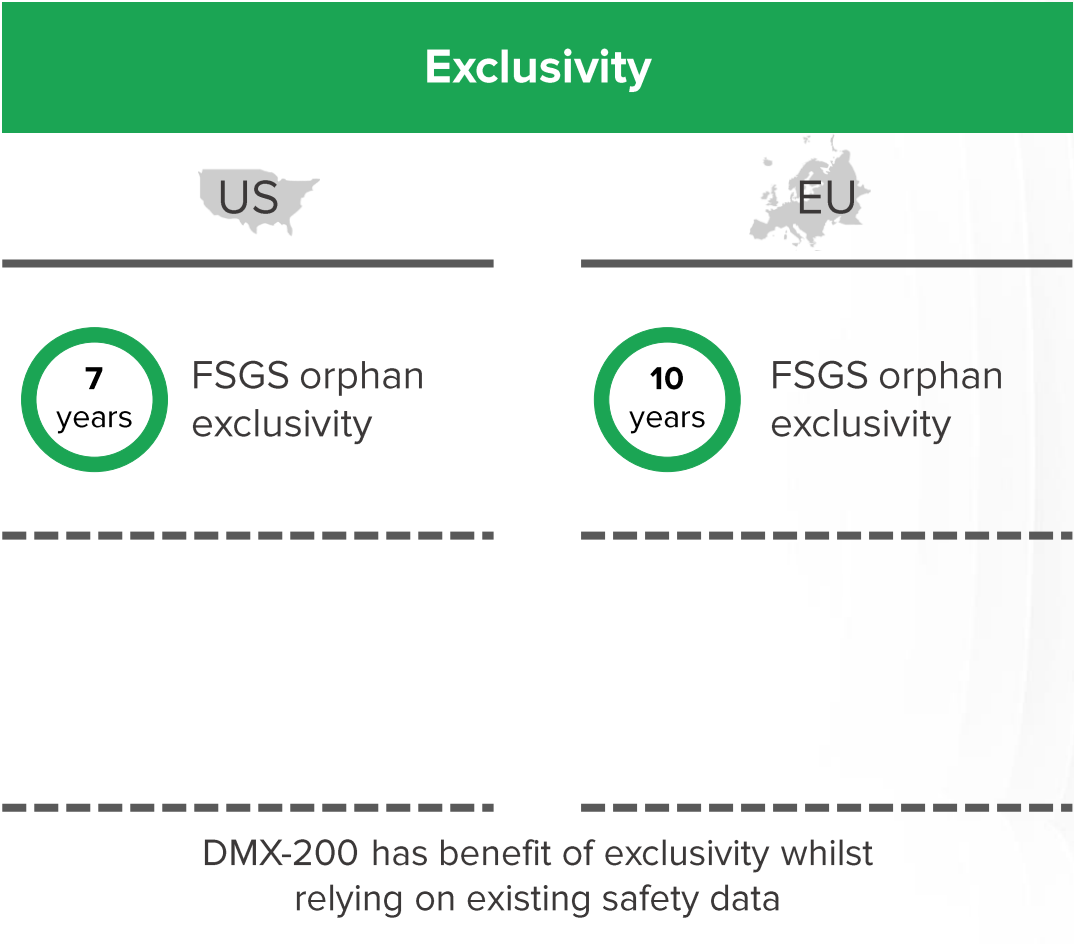
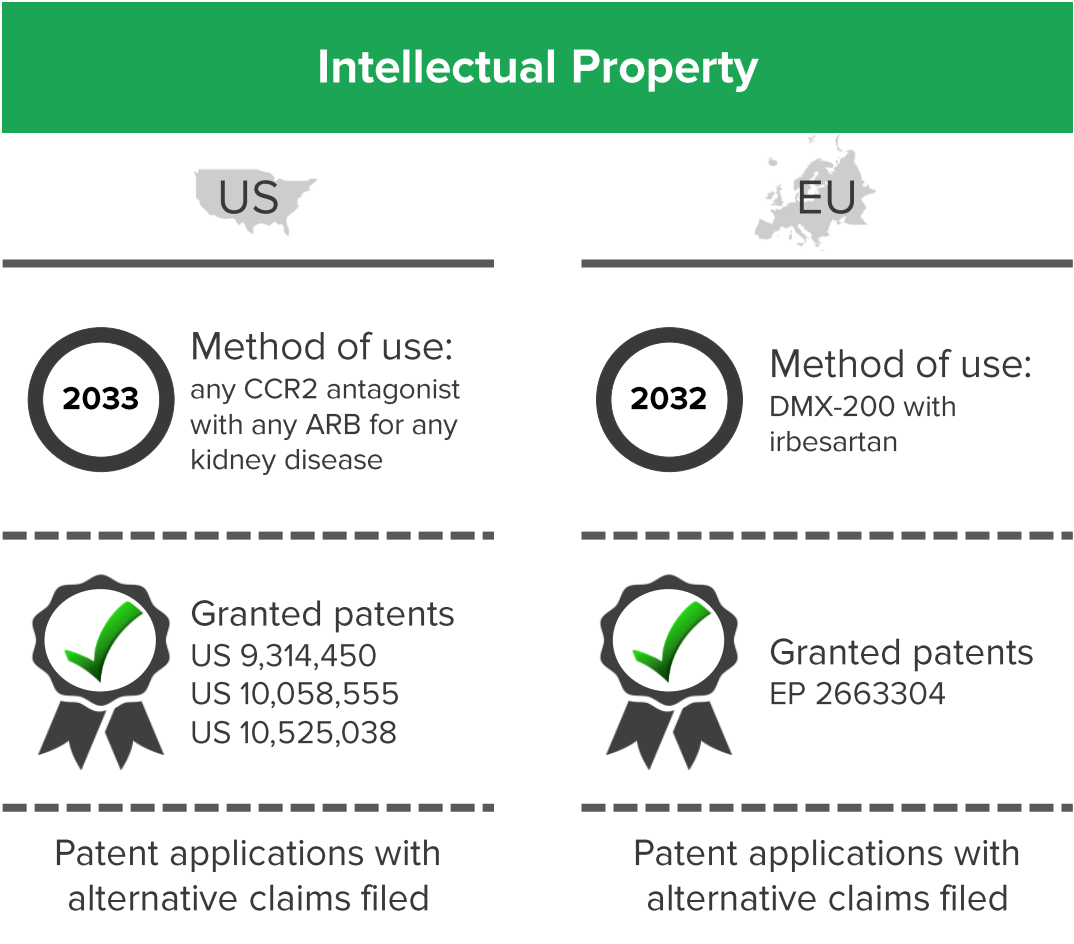
- Confirmation of endpoints for accelerated marketing approval;
- Single Phase 3 study appropriate for marketing approval;
- Proteinuria as an appropriate endpoint;
- Non-clinical package appropriate for NDA and registration; and
- Proposed specifications for API manufactured by Dimerix are appropriate for registration

Phase 3 FSGS study design overview[^]



Assessing ways to improve recruitment efficiency and increase study power

DMX-200 Intellectual property and exclusivity



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**



30%-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]

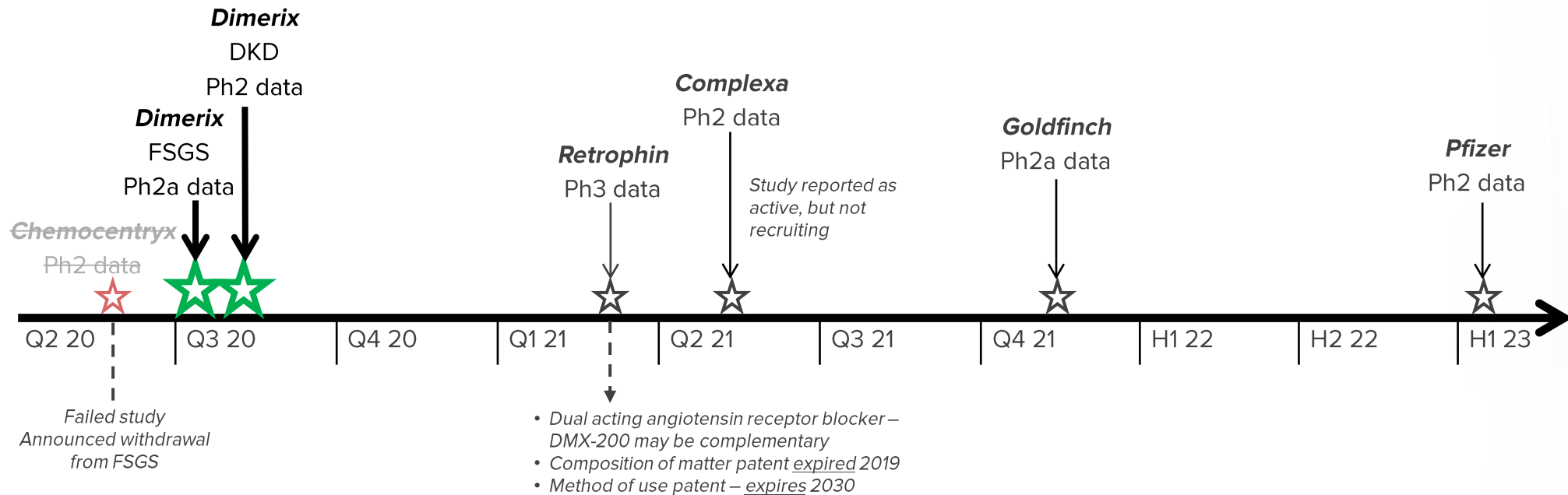
[‡] Rosenberg A, Kopp J (2017); Focal Segmental Glomerulosclerosis, Clinical Journal of American Society of Nephrology [https://cjasn.asnjournals.org/content/12/3/502] [Accessed 02Mar20]

[†] 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]

Competitive positioning

Current FSGS studies underway:



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

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 no marketed competition



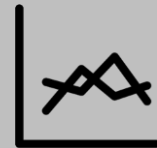
Scientific rationale compares favourably to compounds currently in development



Pharmaceutical grade (GMP) drug process developed and validated



Full capability in place to scale up for commercial supply

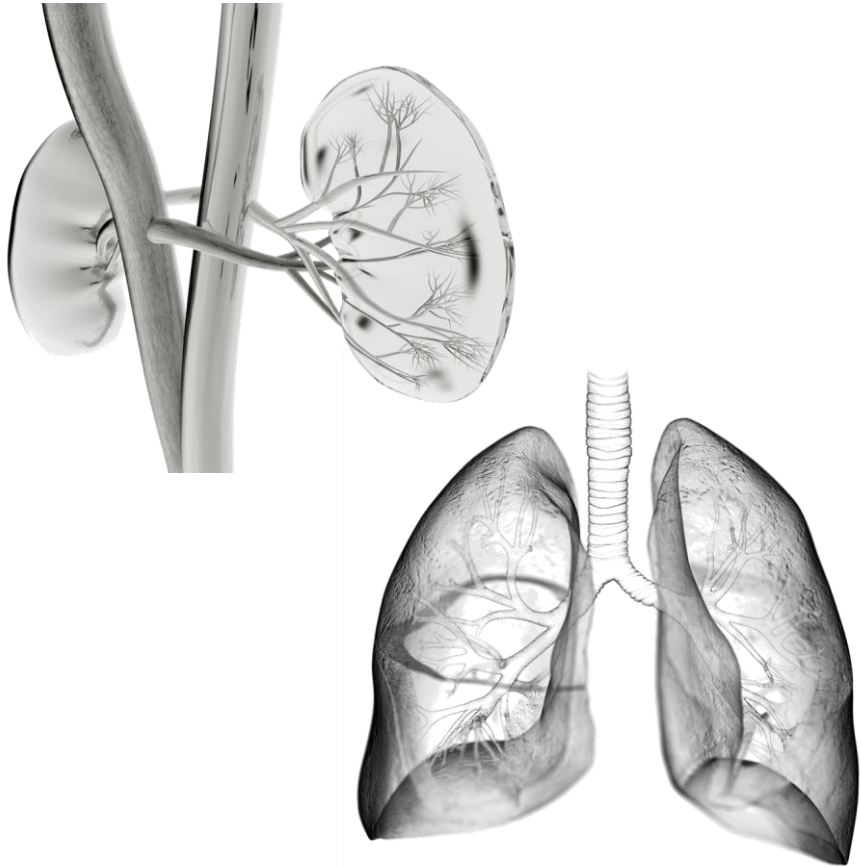


Planning continues for proposed global Phase 3 pivotal program in FSGS



Patents granted and pending, 100% owned by company

Assets 100% owned by Dimerix



Additional Assets

Current Phase 2 trial in diabetic kidney disease

- 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 a stable dose of Irbesartan

n=40
(45 patients dosed)

Powered to resolve
30% reduction in
ACR

Primary Endpoint:
Efficacy
% change in ACR

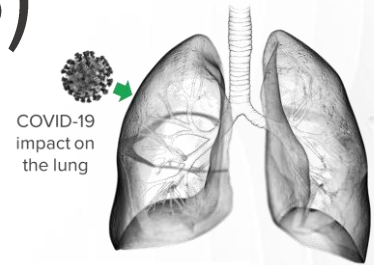
	Study period 1 12 weeks	Washout 6 weeks	Study Period 2 12 weeks	Results
Group 1 (n=20)	DMX-200		Placebo	
Group 2 (n=20)	Placebo		DMX-200	
Irbesartan 300mg				

Data anticipated in 4 – 6 weeks



Acute Respiratory Distress Syndrome (ARDS)

in COVID-19 patients



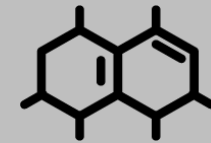
REMAP-CAP: global WHO endorsed clinical study; >200 clinical sites in 16 countries*



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



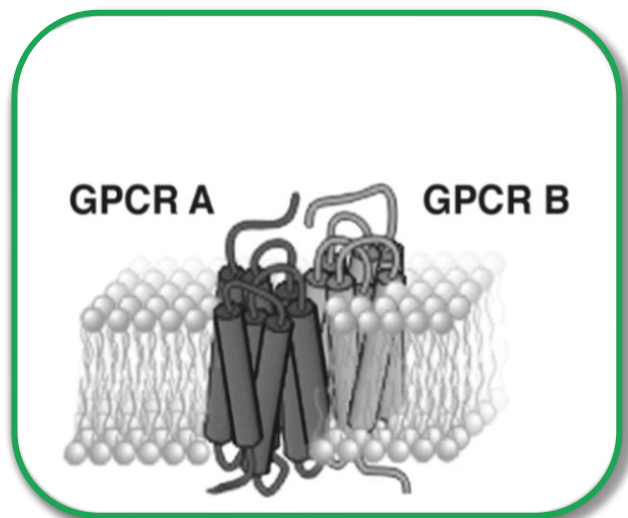
Actual molecules &
receptor targets
remain confidential
pending stage 1 data
& additional patent
submissions

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.*

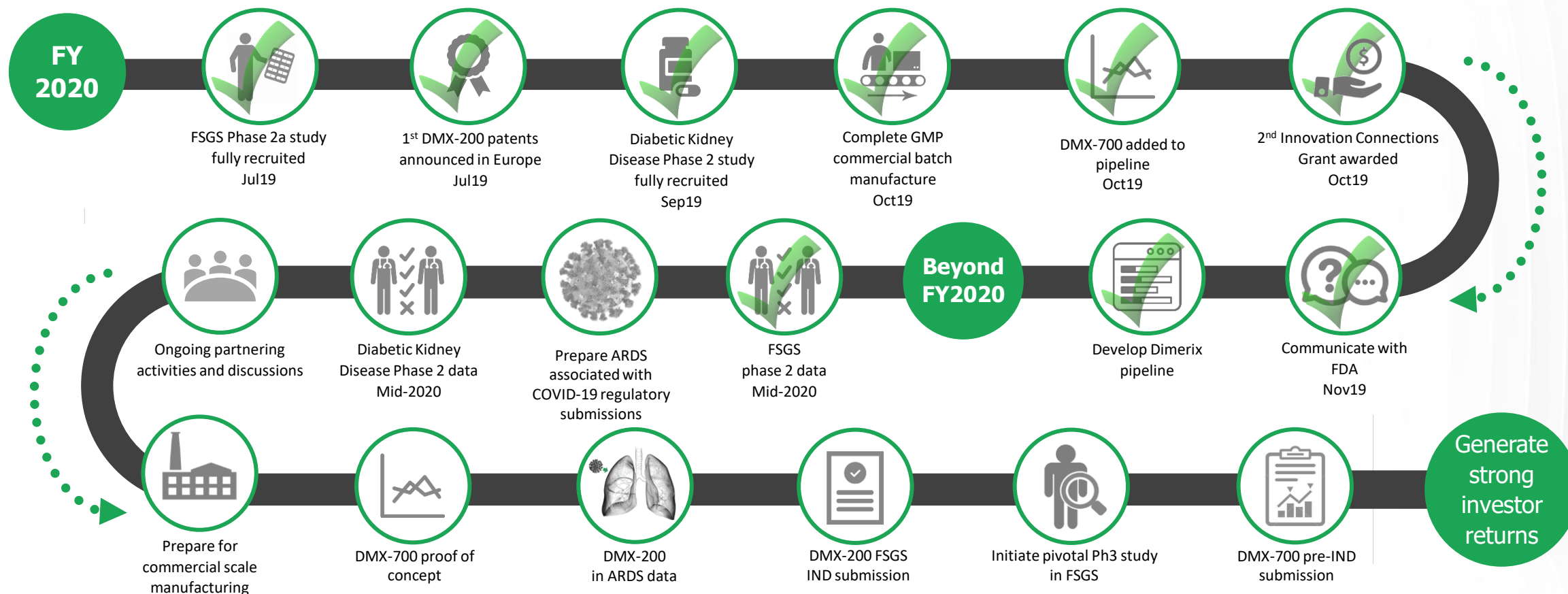
Assay has granted patents in key territories, protection until 2029



Dimerix

Summary

Financial Year 2019/2020/2021 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



Strong efficacy data in 2 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



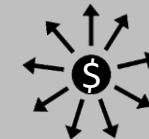
Approved by TGA for compassionate use in Australia



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



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



Additional assets to diversify risk and potential sources of revenue

Assets 100% owned by Dimerix



DIMERIX

End of Presentation



Dimerix

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