

Dimerix Overview

(ASX: DXB)

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

March 2020



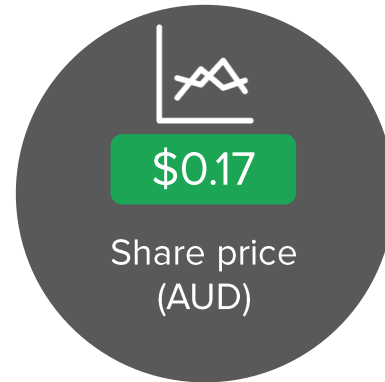
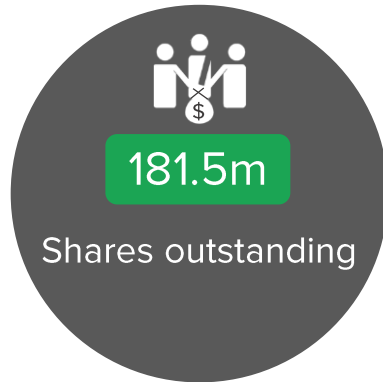
Dimerix

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.

Corporate Snapshot (ASX:DXB)



Research Coverage

Taylor Collison | 20Nov2019 | Rating: Buy | Price Target: A\$0.51

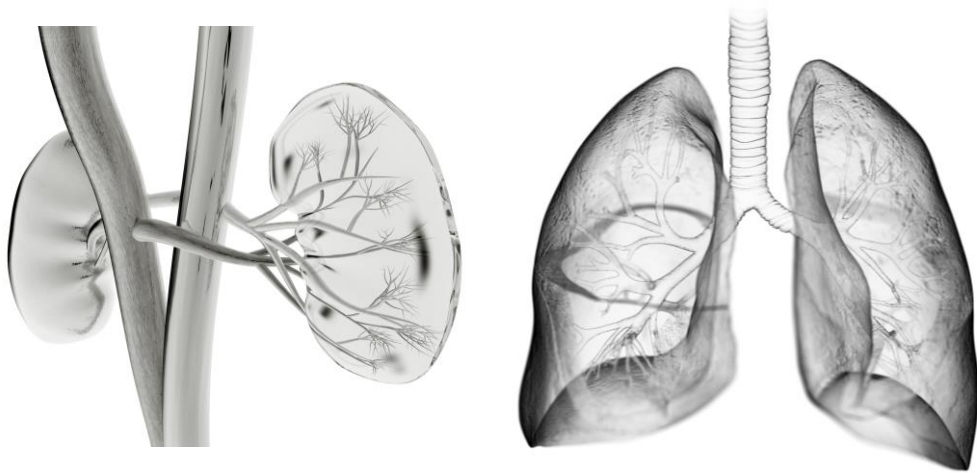
Share price performance



A pipeline of drugs identified using Receptor-HIT

Dimerix Technology Platform

- Patented tool that enables understanding of real-time receptor interactions, particularly GPCRs
- Can drive the discovery of new drugs and research programs
- Programs based on the critical scientific rationale that GPCRs act as a complex with other GPCRs and have novel pharmacology when in complex

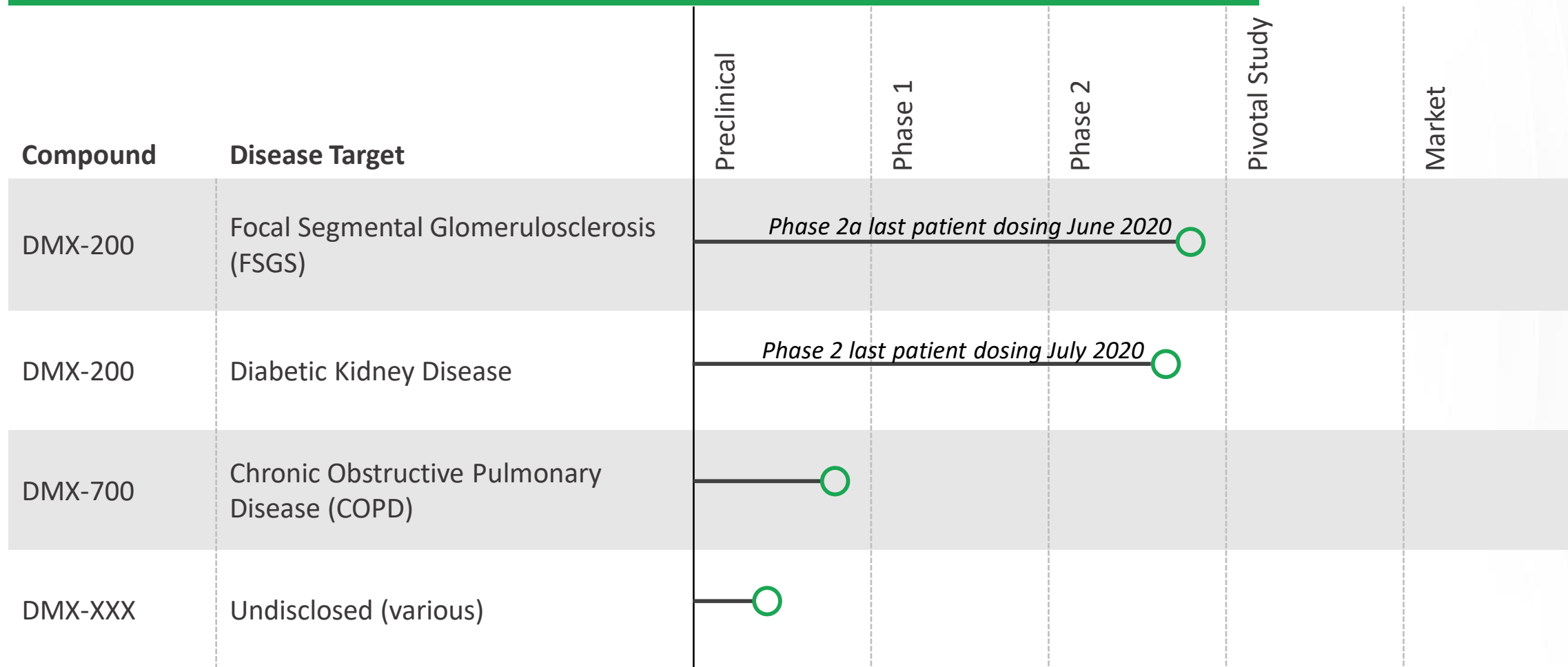


Strategic Fit

- Dimerix is developing a **commercial pipeline** of drugs for G Protein-Coupled Receptors (GPCR) largely targeting chemokine pathway diseases with a **clear unmet need**
- Dimerix can utilise its current core **competencies** and **capabilities** to execute on the disclosed opportunities
- Dimerix has identified **new uses** for existing drugs to drive the **discovery** of new drugs and research programs
- Dimerix has **multiple products** in its pipeline, at different development stages, **diversifying** risk and increasing potential future sources of revenue

Development pipeline

3 product candidates in the pipeline, with 2 clinical read outs expected mid-2020



Board of Directors & Management



James Williams, PhD, MBA
Non-Executive Chairman



Nina Webster, PhD, M IP Law, MBA
Chief Executive Officer /
Managing Director



Sonia Poli, PhD
Non-Executive Director



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



Hamish George, BCom, CA, GIA(Cert)
Chief Financial Officer / Company
Secretary

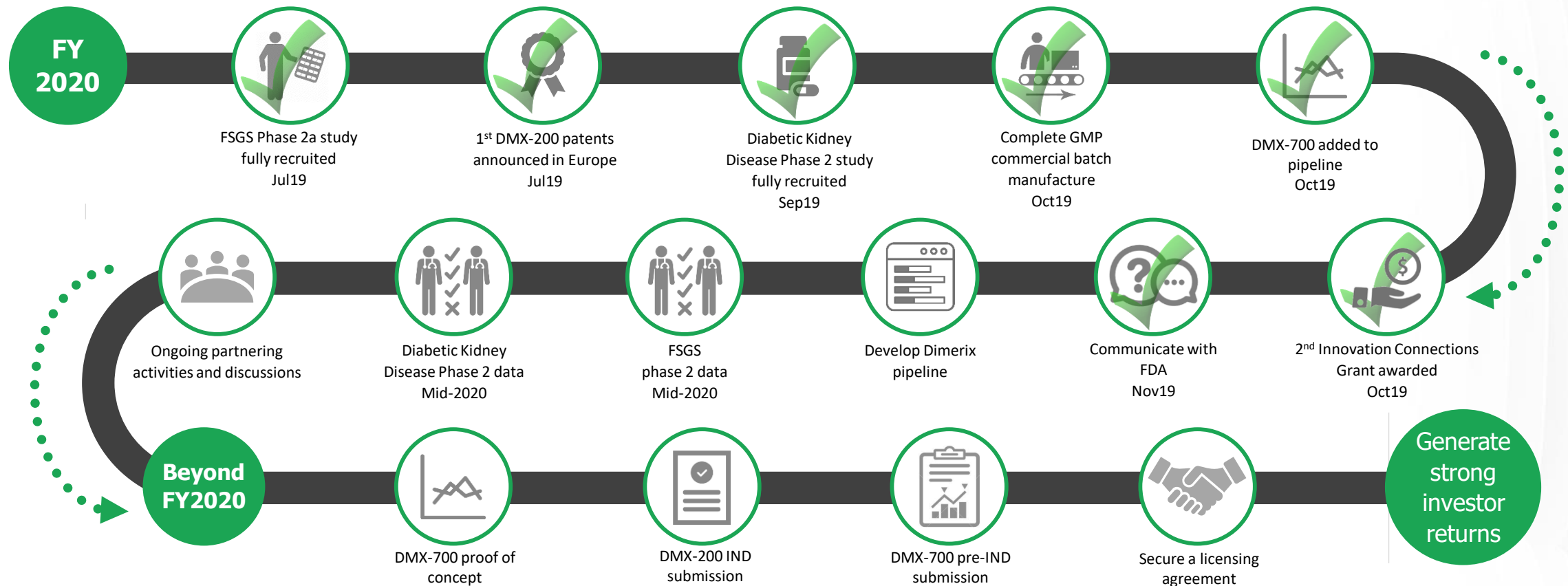


Robert Shepherd, PhD
Research & Development
Director



Extensive experience in global product development and commercialisation

Financial Year 2019/2020 value driving events





Introduction to DMX-200

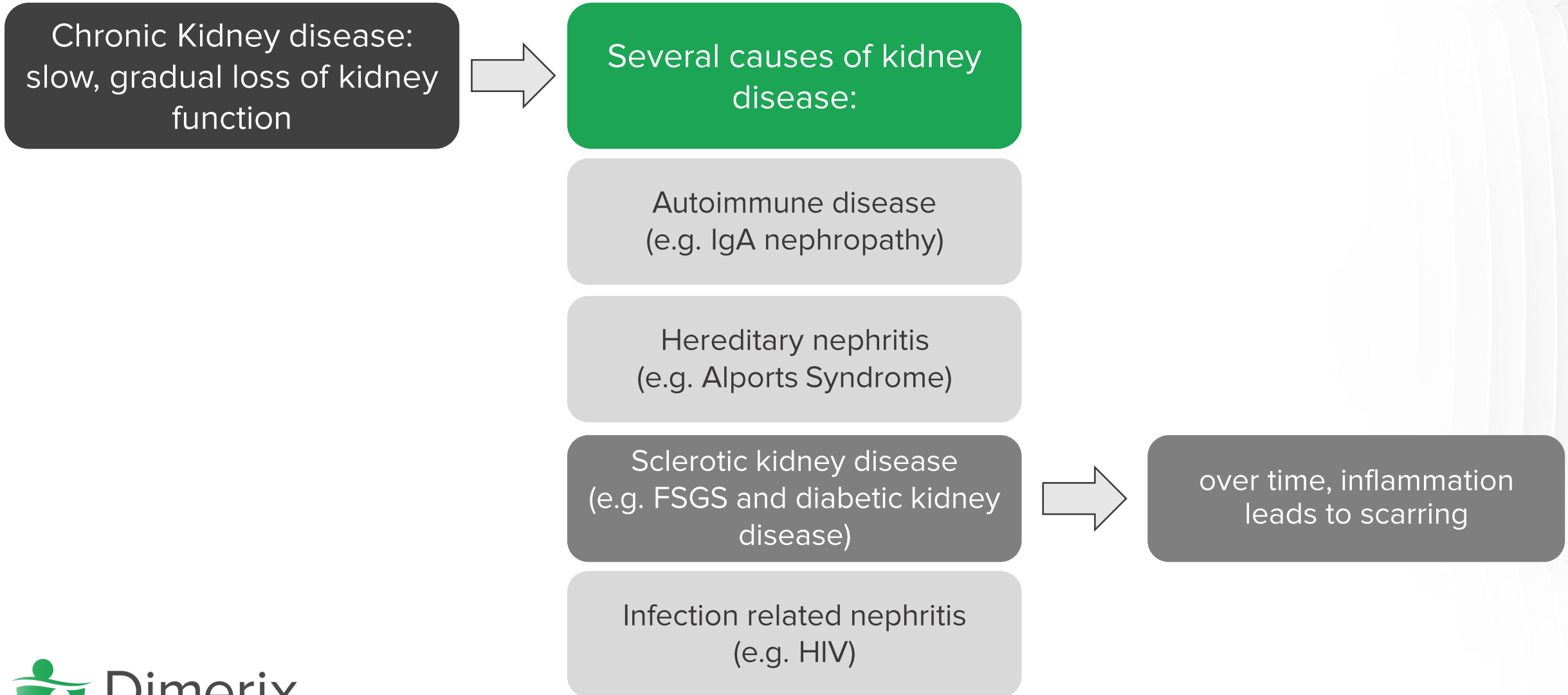
What is DMX-200

DMX-200: a small molecule known as propagermanium for patients already receiving angiotensin receptor blockade

- Twice daily, capsule administration
- Inhibits activity of a cellular receptor of inflammation: CCR2 (C-C Chemokine Receptor Type 2)
- Administered to patients already on standard of care treatment (angiotensin receptor blocker)
- Product attributes: deliver best-in-class benefits to patients
- Never been approved by a regulatory authority in the US, Europe or Australia
 - DMX-200 is a New Chemical Entity* (NCE)

*NCE can attract 5 years exclusivity in US and EU
(7 years in US and 10 years in EU for Orphan Drugs)

Causes of kidney disease



DMX-200 proposed mechanism of action

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

1
hyperfiltration of
and hypertension
within blood
vessels of the
glomeruli

2
inflammatory cell
infiltration of the
kidneys:
subsequent
fibrosis

3
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

Competitive advantage

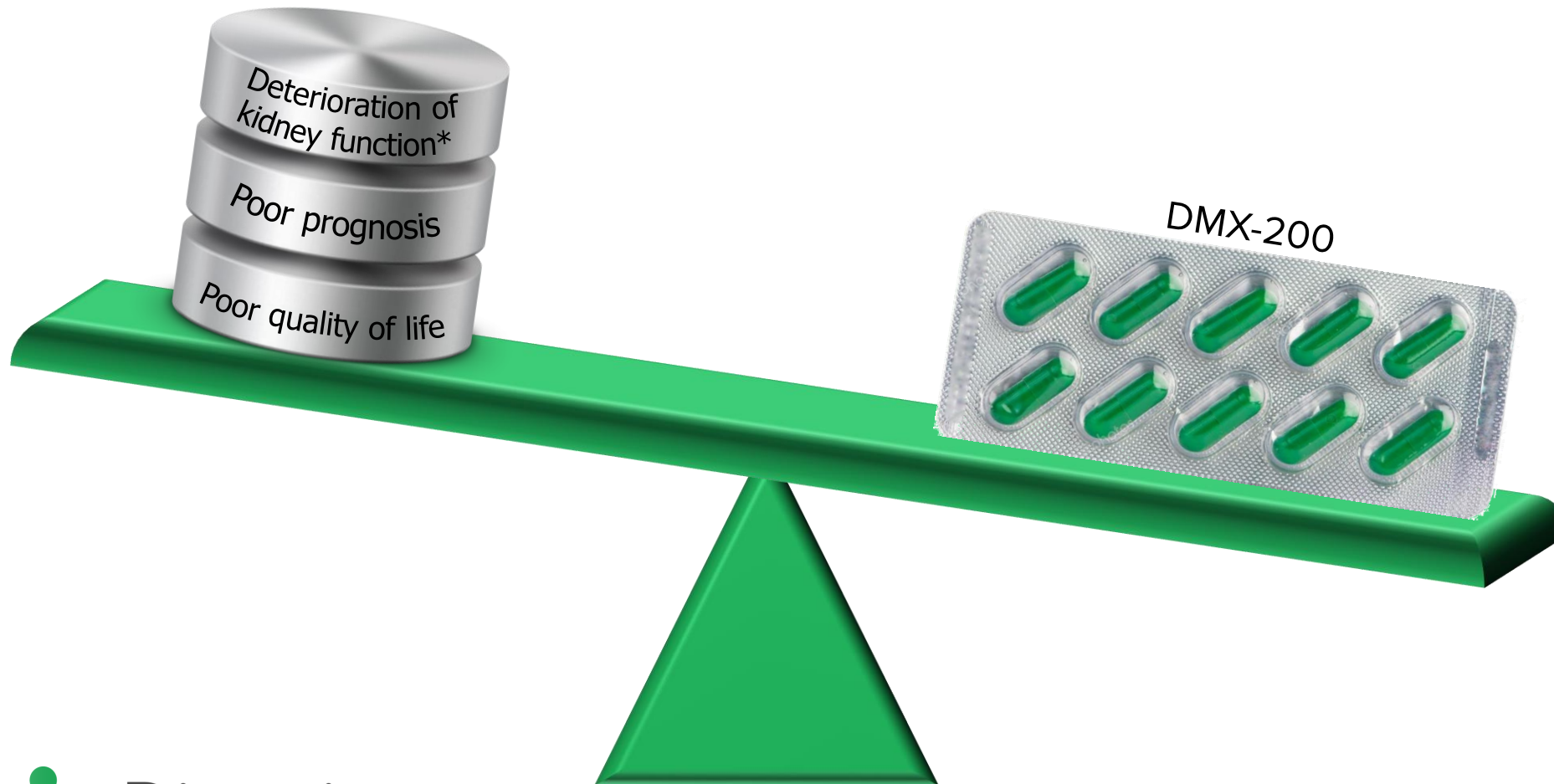
Current standard of care (AT1R blocker)

- Large unmet need in growing market

DMX-200 compares favourably to compounds currently in development:

- Strong, superior efficacy data
 - 36% reduction in proteinuria in Phase 2a
- Known safety profile with no adverse events seen
 - Lower risk development

DMX-200 value: patients, payers & healthcare system



- Known compound: established safety profile
- May increase life of the kidneys (time to dialysis) by 3-5 years
- Estimated annual cost savings of \$100,000/patient/year[#]

Diabetic kidney disease market dynamics



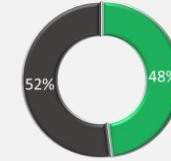
US market size 2018[^]

US\$5.8 billion



Market growth will **accelerate**
at a CAGR (2019-2022)[^]

5.1%



Growth originating from the
Americas[‡]

48%



Diabetic patients that
have kidney disease^{*}

40%



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



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[^]

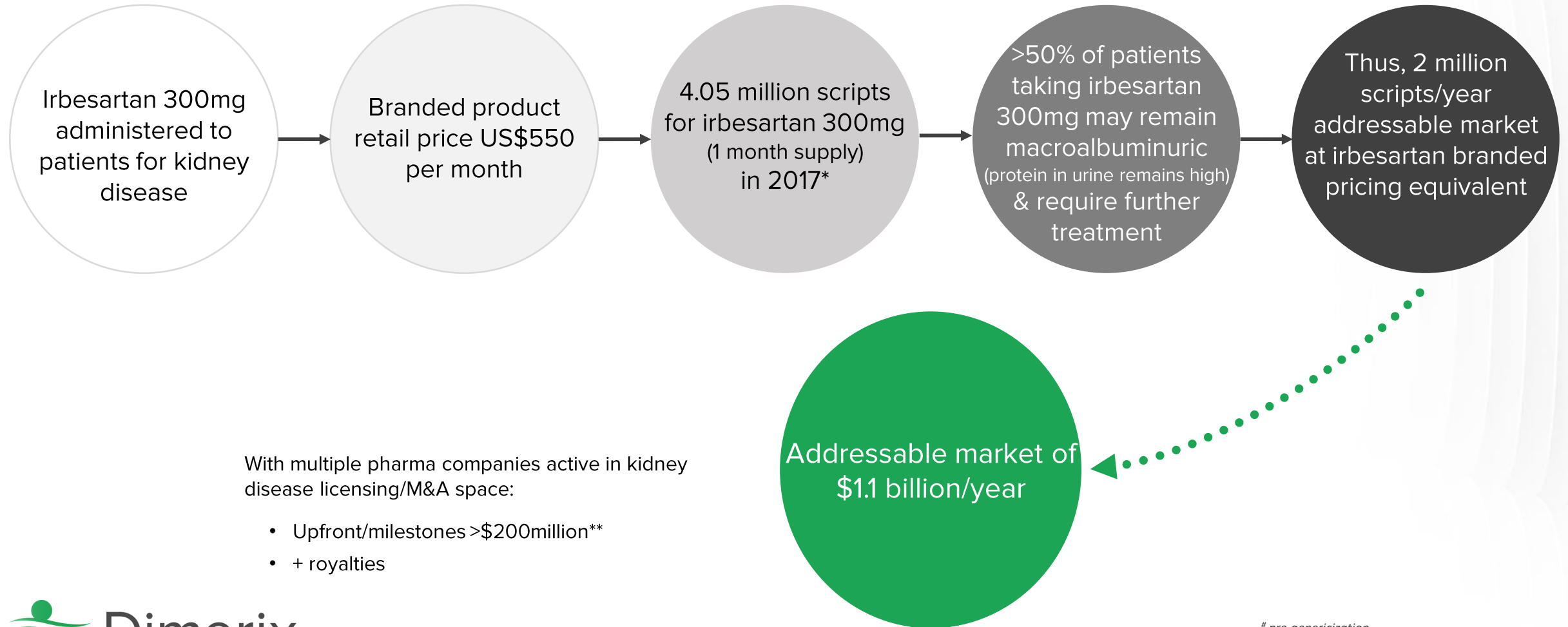
^{*} Alicic R, Rooney M, Tuttle K (2017) Diabetic Kidney Disease Challenges, Progress, and Possibilities, Clinical Journal of American Society of Nephrology [ONLINE Available at <https://cjasn.asnjournals.org/content/12/12/2032> [Accessed 02Mar20]

[‡] Technavio (2019); Global Diabetic Nephropathy Market 2018-2022 [ONLINE Available at <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 [ONLINE Available at <https://www.marketresearchfuture.com/reports/diabetic-neuropathy-treatment-market-8359> [Accessed 02Mar20]

DMX-200 for diabetic kidney disease value in US

Large market with low competition



FSGS market: serious and rare kidney disease



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

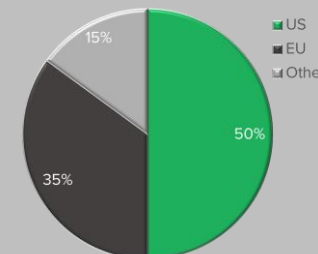


US incidence[†]

80,583



Market growth will **accelerate**
at a CAGR (2017-2025)[#]
>8.0%



Sales by territory[†]



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 [ONLINE Available at <https://www.ncbi.nlm.nih.gov/books/NBK532272/>] [Accessed 02Mar20]

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

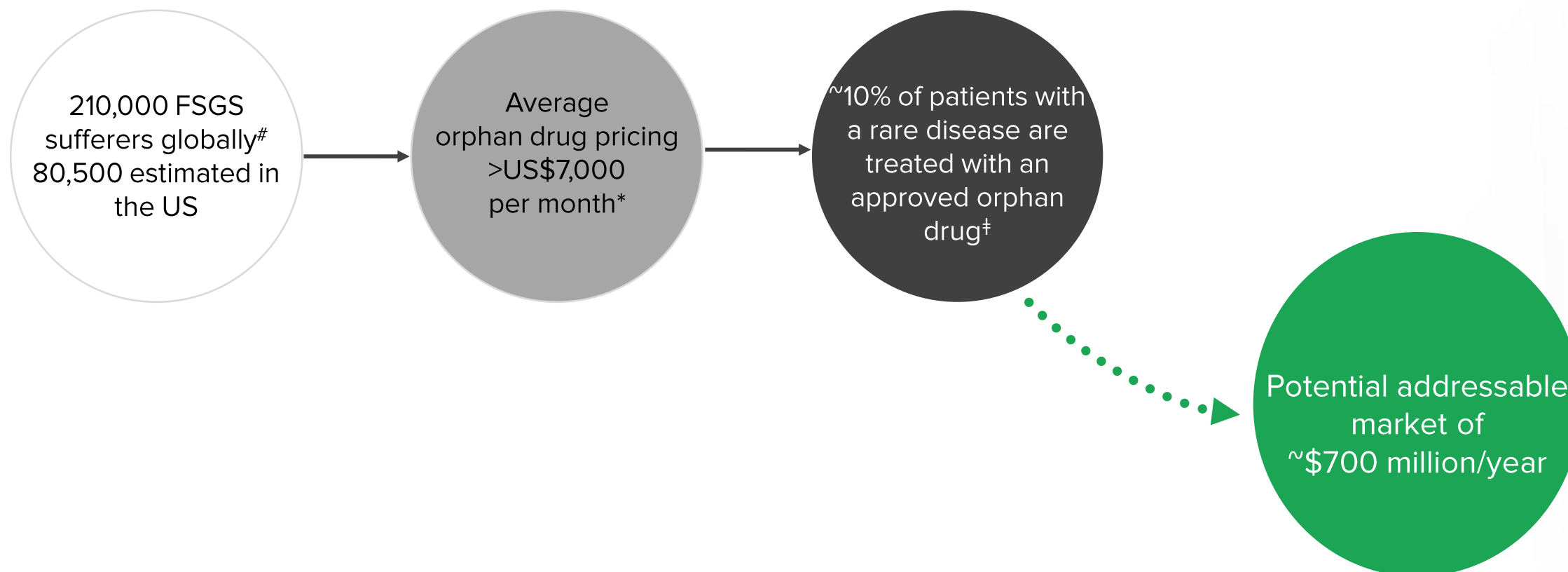
[‡] Rosenberg A, Kopp J (2017); Focal Segmental Glomerulosclerosis, Clinical Journal of American Society of Nephrology [ONLINE Available at <https://cjasn.asnjournals.org/content/12/3/502>] [Accessed 02Mar20]

[†] 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 [ONLINE Available at <https://www.transparencymarketresearch.com/focal-segmental-glomerulosclerosis-market.html>] [Accessed 02Mar20]

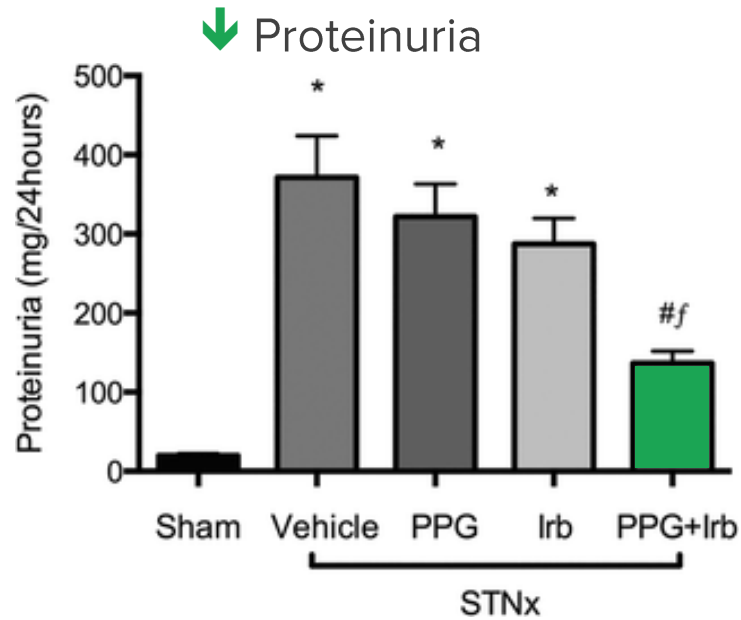
DMX-200 for FSGS value in US

Orphan drug status with low competition



Pre-clinical: reduction in proteinuria in STNx rats

- The STNx model is broadly recognised as the gold standard model for FSGS



PPG: Propagermanium (CCR2 antagonist)
 Irb: Irbesartan
 * $P < 0.05$ vs sham
 # $P < 0.05$ vs un-treated STNx
 f $P < 0.05$ vs STNx+Irb

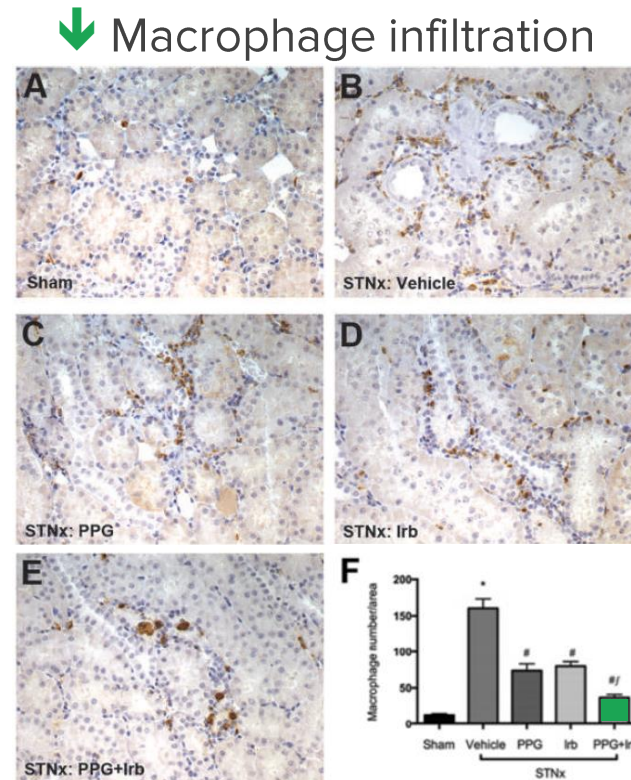


Fig 7. WT-1 (podocyte) staining from STNx rats. As illustrated by representative photomicrographs, in comparison with sham rats (A), STNx rats (B) were associated with a significant increase in podocyte loss. Treatment of STNx rats with either PPG (C) or Irb (D) alone did not affect podocyte loss significantly, whereas treatment with PPG+Irb (E) was associated with reduced podocyte loss. Magnification x400. Quantitative data (F) are expressed as mean \pm SEM. *, $P < 0.05$ vs sham; #, $P < 0.05$ vs vehicle-treated STNx rats. Animal numbers: Sham = 20, STNx = 19, STNx+PPG = 17, STNx+Irb = 19 and STNx+PPG+Irb = 16.

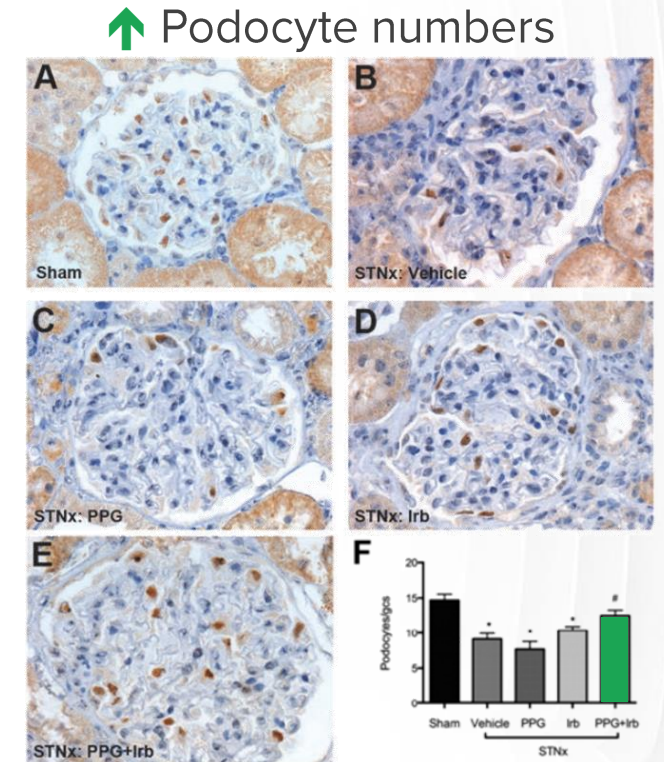


Fig 8. Glomerulosclerosis in STNx rats. As illustrated by representative photomicrographs, in sham rats (A) there was minimal glomerulosclerosis as determined by PAS stain, while STNx rats (B) demonstrated severe glomerulosclerosis. Intervention with PPG alone in STNx rats had no effect on reducing glomerulosclerosis (C). Treatment of STNx rats with Irb (D) or a combination of PPG+Irb (E) was associated with a significant reduction in glomerulosclerosis when compared to vehicle-treated STNx rats (B). Magnification x400. Quantitative data (F) are expressed as mean \pm SEM. *, $P < 0.05$ vs sham; #, $P < 0.05$ vs vehicle-treated STNx rats. Animal numbers: Sham = 20, STNx = 19, STNx+PPG = 17, STNx+Irb = 19 and STNx+PPG+Irb = 16.

Clinical experience



1 x Phase 1 study (DMX-200-101)
Healthy volunteers

- pharmacokinetic and safety clinical study



1 x Phase 2a study (DMX-200-201)
Chronic Kidney Disease patients

- Safety, tolerability study, and efficacy study

All study endpoints met

2017: DMX-200 Phase 2a results summary (N=27)

Chronic Kidney Disease patients

Primary Endpoints (“safety”)

- Incidence and severity of Adverse Events
- Clinically significant changes in the safety profile of participants (biochemistry, hematology, urinalysis, physical examinations)

Secondary Endpoints (“efficacy signals”)

- The proportion of responders, defined as those participants achieving normalisation of proteinuria or a 50% reduction in proteinuria

All endpoints met:

- safe and well tolerated

Responders

- 6/24 patients had a 50% decrease in ACR – majority were diabetic kidney disease patients
- Sub-group – statistically significant and compelling result

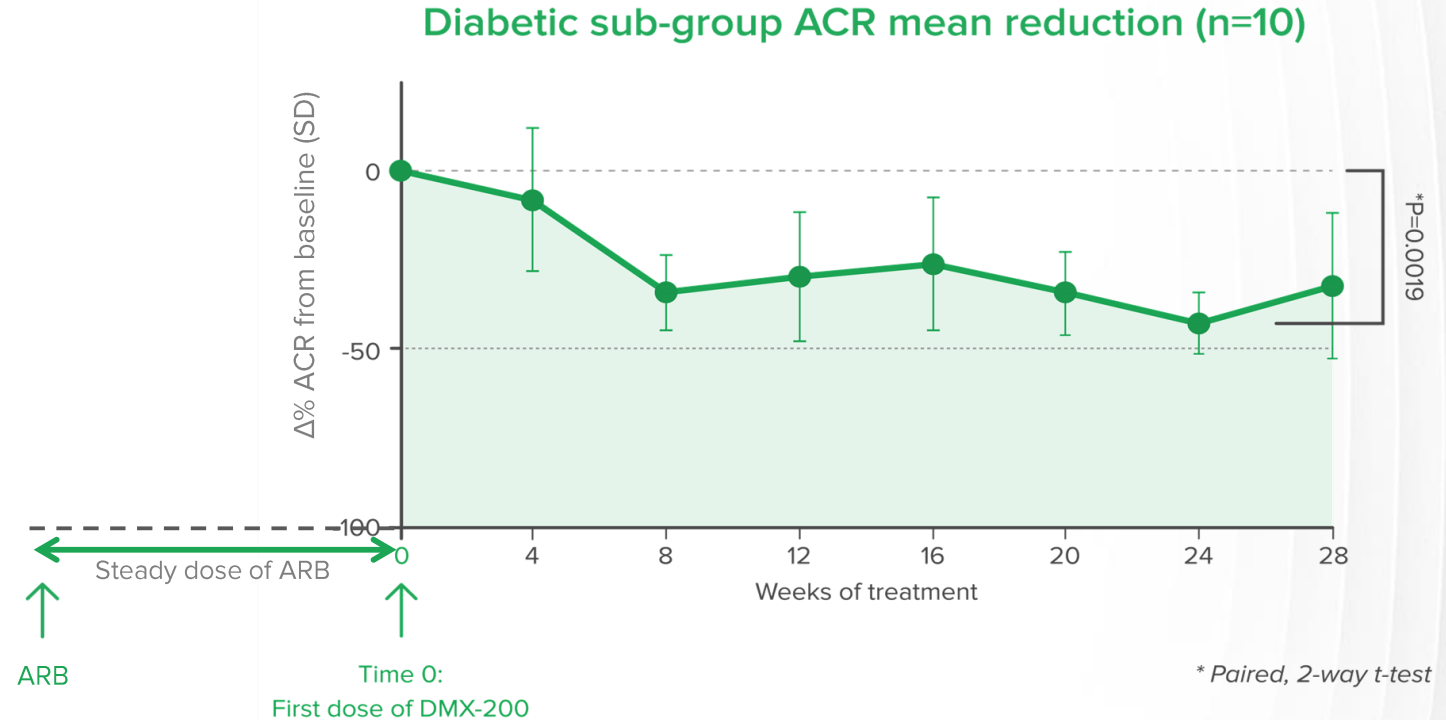
Desired
outcome
reduction in
ACR

2017: DMX-200 Phase 2a study - diabetic sub-group

- In 2001 - Irbesartan studied in a large group of type 2 diabetics
 - Proteinuria levels reduced by 24%
- In 2017 - DXB Phase 2a study:
DMX-200 + Irbesartan

In addition to irbesartan reduction, proteinuria levels reduced by a **further 36%** in diabetic sub-group

Reduction of proteinuria by >30% may increase time to dialysis by 3-5 years and reduce health costs by \$100,000 per patient per year



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 dose)

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				

Last patient dosing scheduled July 2020



Current Phase 2 trial in diabetic kidney disease

Primary endpoint

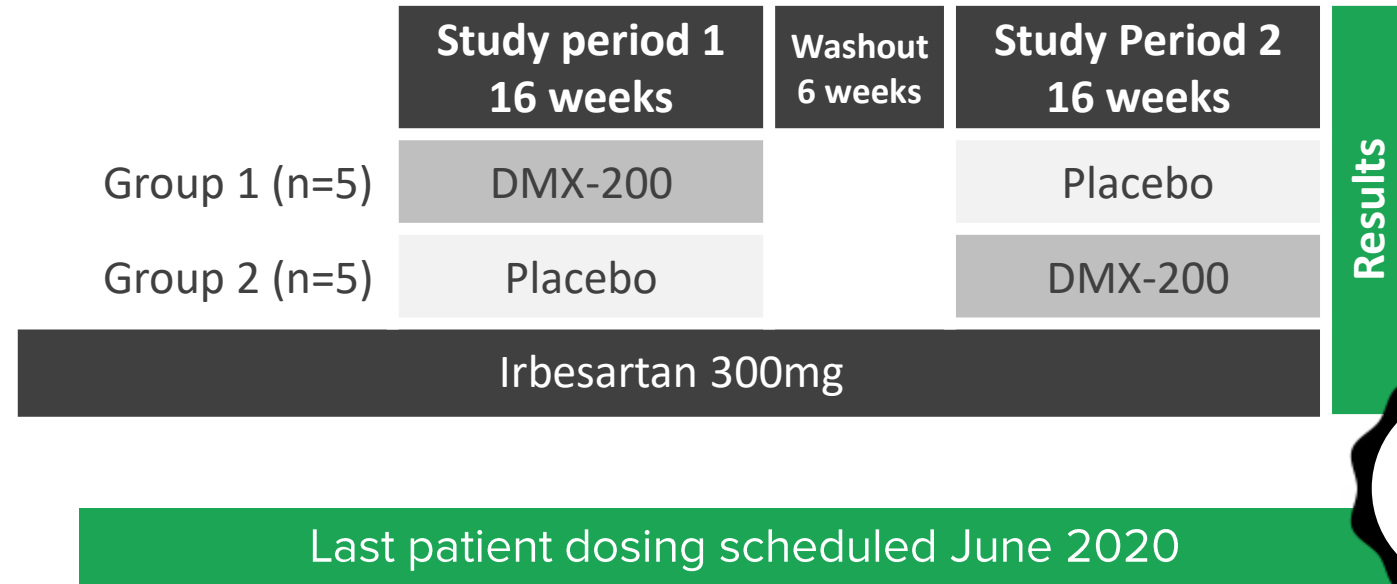
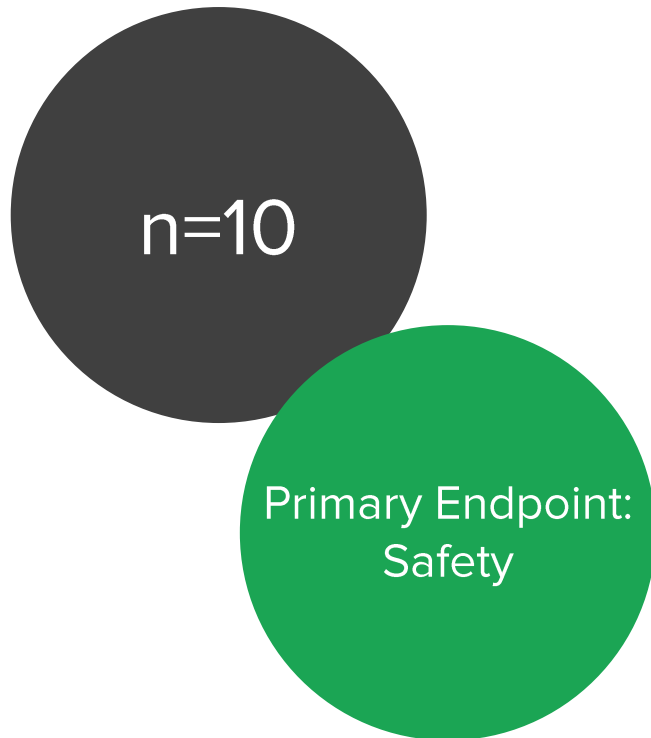
Percent change from baseline in 24-hour ACR after 11/12 weeks of treatment with DMX-200 as compared to placebo (mean of 2 values)

Secondary endpoints

- Assessment of frequency of patients who achieve an albuminuria-based response during treatment (reduction of $\geq 30\%$ geometric mean ratio);
- Change from baseline after treatment with DMX-200 as compared to placebo in:
 - ACR;
 - PCR;
 - Total albumin excretion;
 - Total protein excretion;
 - Serum creatinine;
 - Creatinine clearance;
 - eGFR
- Confirm the safety of DMX-200

Current Phase 2a trial in FSGS

- Phase 2a, double-blind, randomised, placebo-controlled, crossover study evaluating the safety and efficacy of DMX-200 in patients with primary FSGS who are receiving a stable dose of Irbesartan



Current Phase 2a trial in FSGS

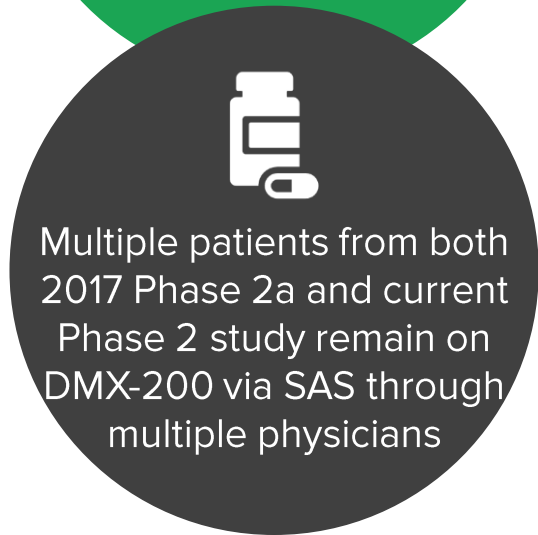
Primary endpoint

The Number of Adverse Events with the Adjunct use of Propagermanium Compared to Placebo in Participants with FSGS who are Receiving Irbesartan

Secondary endpoints

- Percent change from baseline in 24-hour PCR after 16-weeks of treatment with propagermanium as compared to placebo (mean of 2 values);
- Proportion of patients who achieve a response during treatment with propagermanium as compared to placebo

Special Access Scheme for compassionate use



- **Special Access Scheme (SAS):** access to therapeutic goods that have not yet been approved in Australia - on a case by case basis
- Application made to the Therapeutic Goods Administration (TGA – Australian regulatory agency) by the treating physician
- TGA approval takes into account the safety profile of DMX-200, as well as clinical evidence that DMX-200 may benefit patients and failure of any current therapies
- TGA approved SAS Category B applications for DMX-200
- Dimerix supplies the drug product once approved

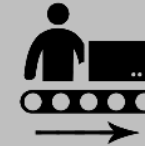
Chemistry, Manufacturing and Control



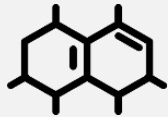
US based contract manufacturer appointed for commercial supply of API



FDA approved manufacturing facility



US based manufacturer engaged for finished product manufacture



Analytical methods validated



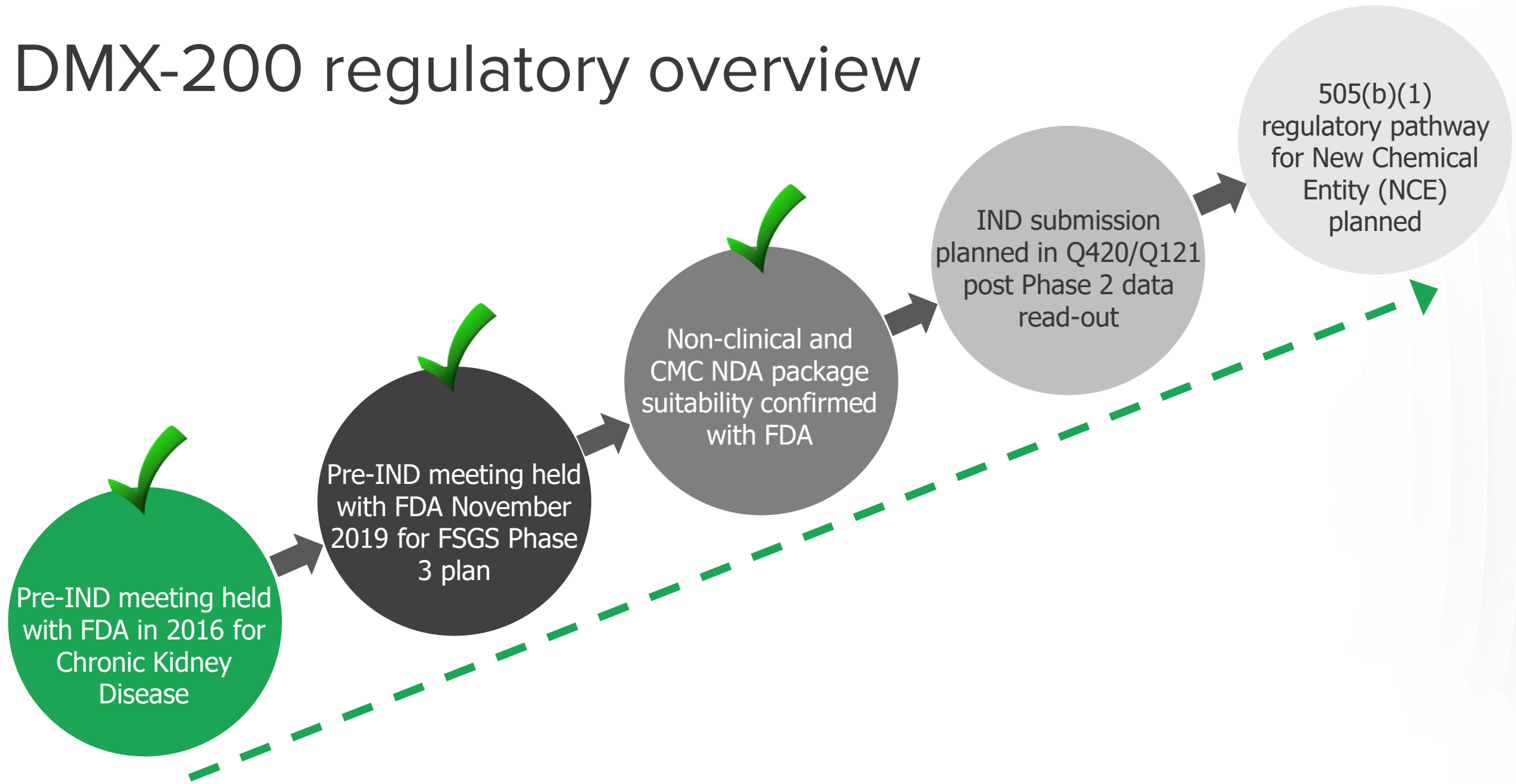
Commercial scale GMP batch manufacture completed





Exclusive development and methodology to manufacture API owned by Dimerix

CMC NDA package suitability confirmed with FDA

DMX-200 regulatory overview



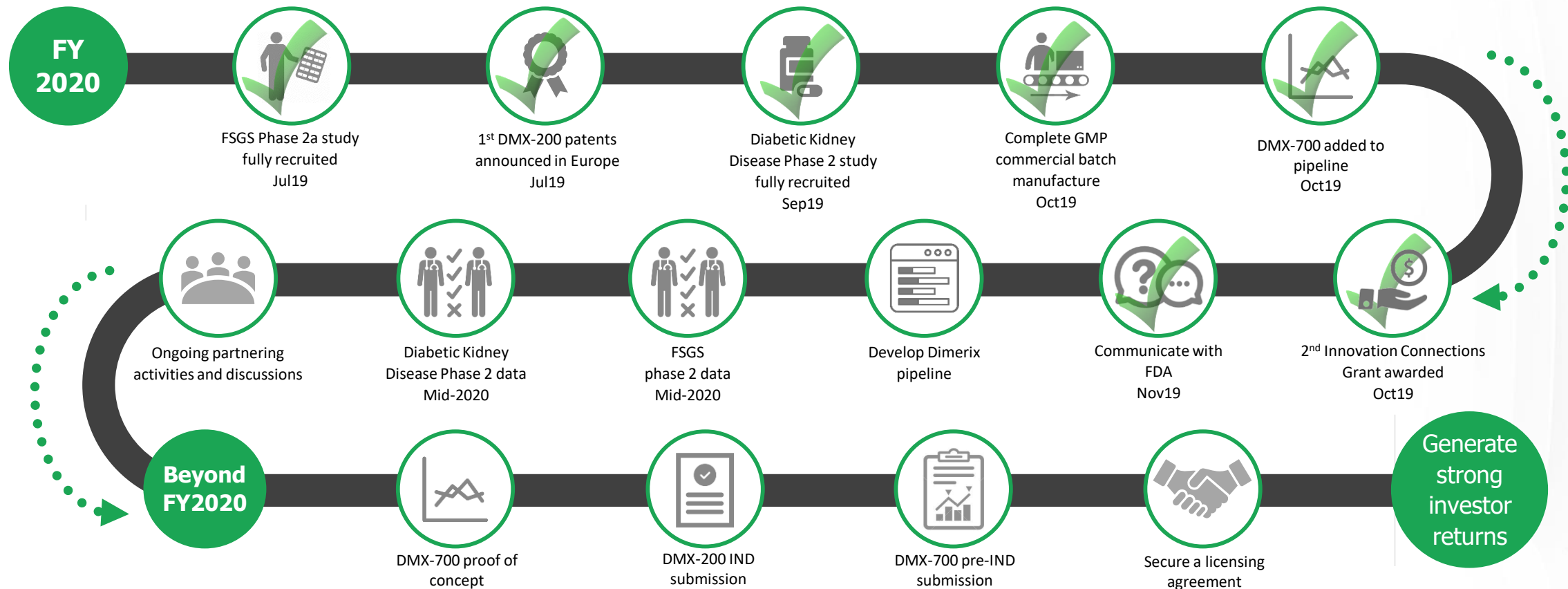
DMX-200 Intellectual property and exclusivity

Intellectual Property		Exclusivity	
US	EU	US	EU
<div>2033</div> <div>Method of use: any CCR2 antagonist with any ARB for any kidney disease</div>	<div>2032</div> <div>Method of use: DMX-200 with irbesartan</div>	<div>7 years</div> <div>FSGS orphan exclusivity</div>	<div>10 years</div> <div>FSGS orphan exclusivity</div>
<div></div> <div>Granted patents US 9,314,450 US 10,058,555 US 10,525,038</div>	<div></div> <div>Granted patents EP 2663304</div>	<div>5 years</div> <div>DKD exclusivity</div>	<div>8 years</div> <div>DKD exclusivity</div>
Patent applications with alternative claims filed	Patent applications with alternative claims filed	DMX-200 has benefit of exclusivity whilst relying on existing safety data	

DMX-200 summary

- ✓ Commercially attractive and growing market
- ✓ Orphan status with FDA and EMA
- ✓ Unmet need, with no current competition
- ✓ Granted patents with additional patents pending
- ✓ Existing long-term safety data available
 - Reduced risk and development program
- ✓ Product supply at commercial scale secured
- ✓ Phase 2 data expected mid-2020
- ✓ FDA confirmed non-clinical and CMC NDA package suitability and phase 3 study design principles
- ✓ DMX-200 approved for compassionate use in Australia following physician recommendation

Financial Year 2019/2020 value driving events



DIMERIX

End of Presentation



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