



For Immediate Release

Bio-Europe 2019 Conference Presentation

MELBOURNE, Australia, 11 November 2019: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, is pleased to provide a copy of the presentation from the Bio-Europe 2019 Conference.

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About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company developing innovative new therapies in areas with unmet medical needs for global markets. Dimerix is currently developing its proprietary product DMX-200 for both Diabetic Kidney Disease and Focal Segmental Glomerulosclerosis (FSGS). DMX-200 was identified using Dimerix' proprietary assay, Receptor Heteromer Investigation Technology (Receptor-HIT), which is a scalable and globally applicable technology platform enabling the understanding of receptor interactions to rapidly screen and identify new drug opportunities. Receptor-HIT is licensed non-exclusively to Excellerate Bioscience, a UK-based pharmacological assay service provider with a worldwide reputation for excellence in the field of molecular and cellular pharmacology.

About DMX-200

DMX-200 is the adjunct therapy of a chemokine receptor (CCR2) antagonist administered to patients already receiving irbesartan, an angiotensin II type I (AT1) receptor blocker and the standard of care treatment for kidney disease. DMX-200 has granted patents in various territories until 2032.

In 2017, Dimerix completed its first Phase 2a study in patients with a range of chronic kidney diseases. No significant adverse safety events were reported, and all study endpoints were achieved. In a subsequent sub-group analysis, significant clinical efficacy signals were seen in the diabetic group.

DMX-200 administered to patients already taking irbesartan reduced proteinuria levels by a further 36%. This reduction in proteinuria is highly correlated with improved renal function and delay in kidney failure and dialysis. The compelling results from this study prompted the decision to initiate two different clinical studies in 2018: one for patients with Diabetic Kidney Disease; and the second for patients with another form of kidney disease, Focal Segmental Glomerulosclerosis (FSGS).

Dimerix is a biopharmaceutical company
developing innovative new therapies in
areas with unmet medical needs

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FSGS is a serious and rare disease that attacks the kidney's filtering units (glomeruli) causing serious scarring which leads to permanent kidney damage and kidney failure and for which there is a recognised medical need for a new or improved treatment. FSGS affects both children and adults.

DMX-200 for FSGS has been granted Orphan Drug Designation by the FDA and EMA. Orphan Drug Designation is granted to support the development of products for rare diseases and qualifies Dimerix for various development incentives including: seven years (FDA) and ten years (EMA) of market exclusivity if regulatory approval is received, exemption from certain application fees, and an abbreviated regulatory pathway to approval.

About DMX-700

COPD is a progressive and life-threatening lung disease. The primary cause of COPD is exposure to tobacco smoke (either active smoking or secondary smoke), however is also caused by exposure to indoor and outdoor air pollution, occupational dusts and fumes and long-term asthma. COPD is the fourth-leading cause of death in the world and although treatments exist to improve the symptoms of COPD, there is currently no way to slow progression of the condition or cure it. Moreover, among the top five causes of death globally, this disease is the only one with increasing mortality rates. The global COPD treatment market was valued at US\$14 billion in 2017 and is projected to increase at a compound annual growth rate of 4.9% to 2026.

Initial studies have been completed, and Dimerix has completed a key step in securing ownership over what it believes is an important new drug discovery by lodging a provisional patent application for DMX-700. Over the next 12 months Dimerix will conduct further proof of concept studies to perform the value added verification in support of a robust product development pathway and patent position.

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Dimerix Overview

November 2019



Forward looking statements

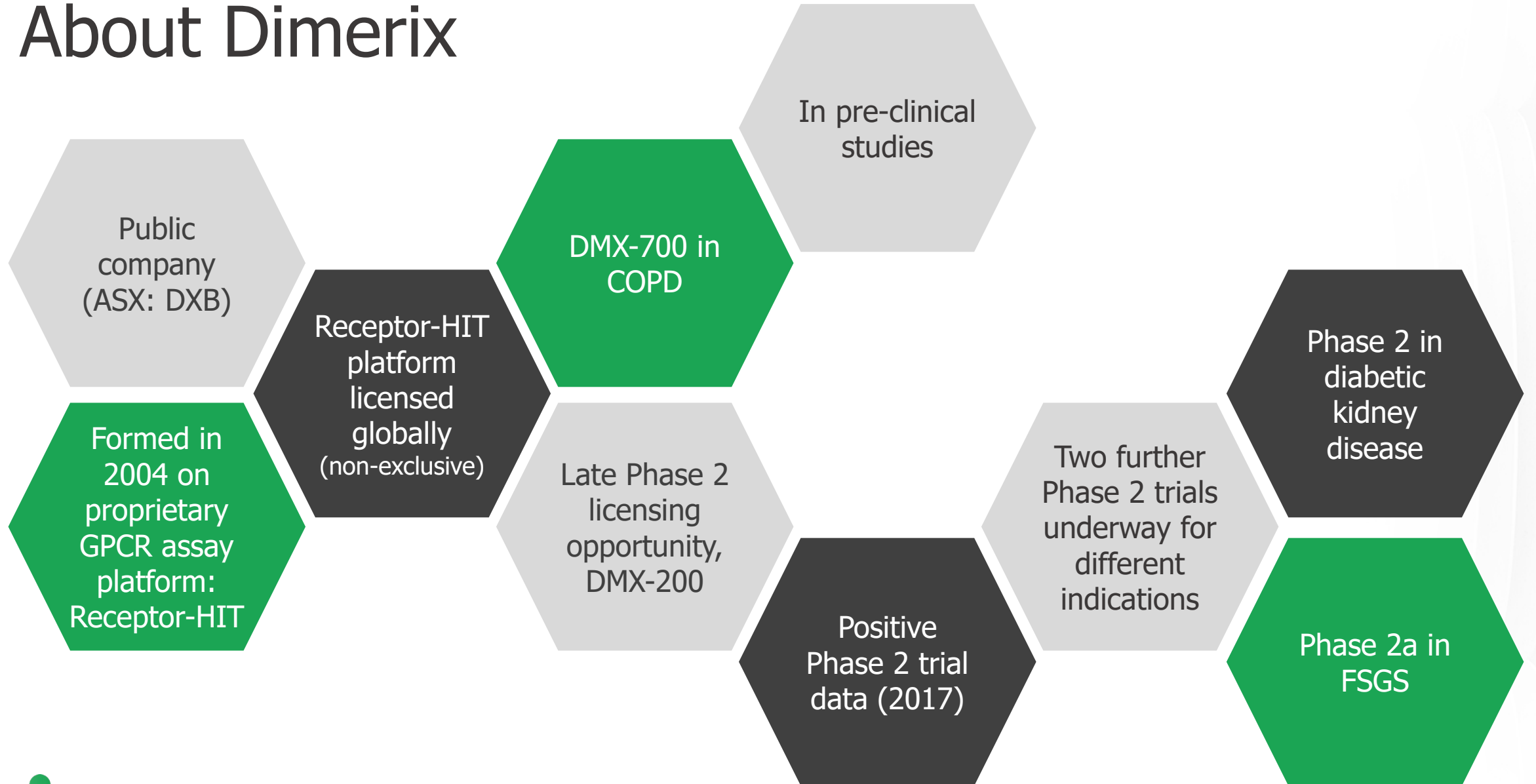
This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Dimerix to be materially different from the statements in this presentation.

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.

Agenda

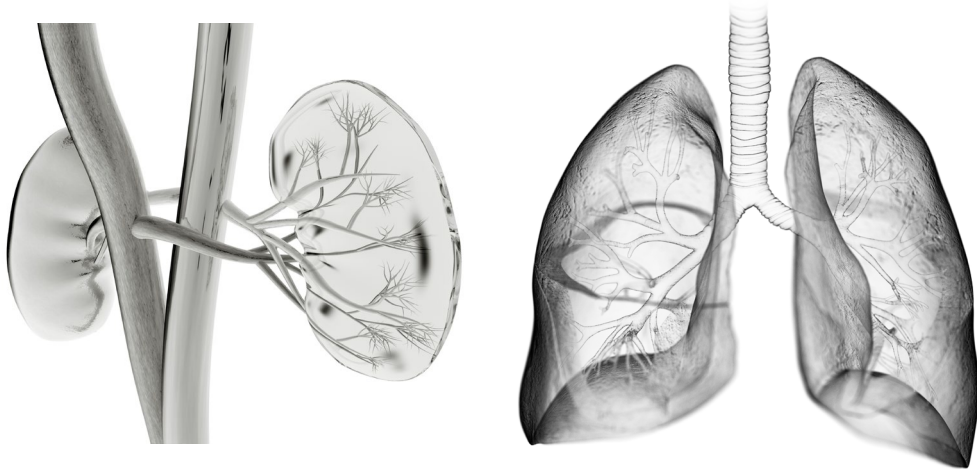
1. Introduction to Dimerix
2. Receptor-HIT
3. DMX-200 in Diabetic Kidney Disease
4. DMX-200 in Focal Segmental Glomerulosclerosis (FSGS)
4. DMX-700 in Chronic Obstructive Pulmonary Disease (COPD)
5. Summary

About Dimerix



A pipeline of drugs identified using Receptor-HIT

Programs based on the critical scientific rationale that GPCRs act as a complex with other GPCRs and have novel pharmacology when in complex

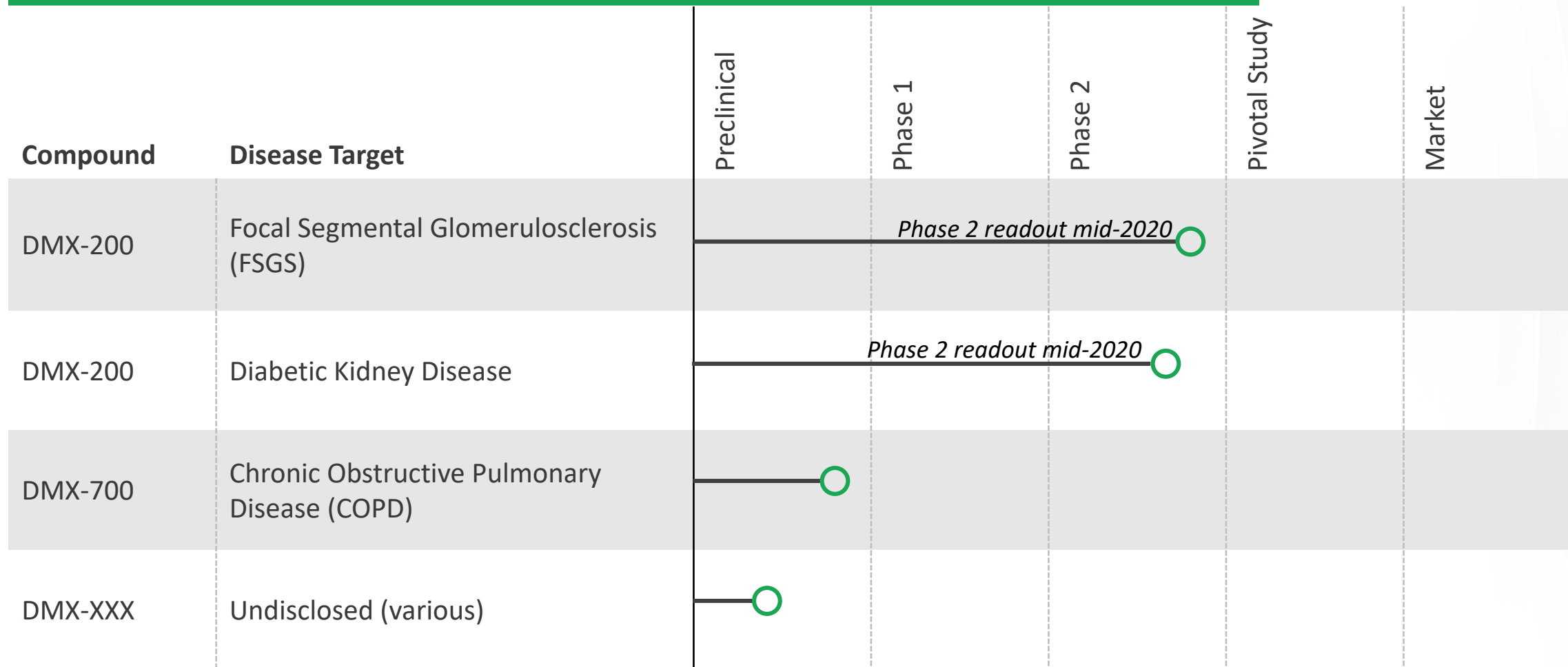


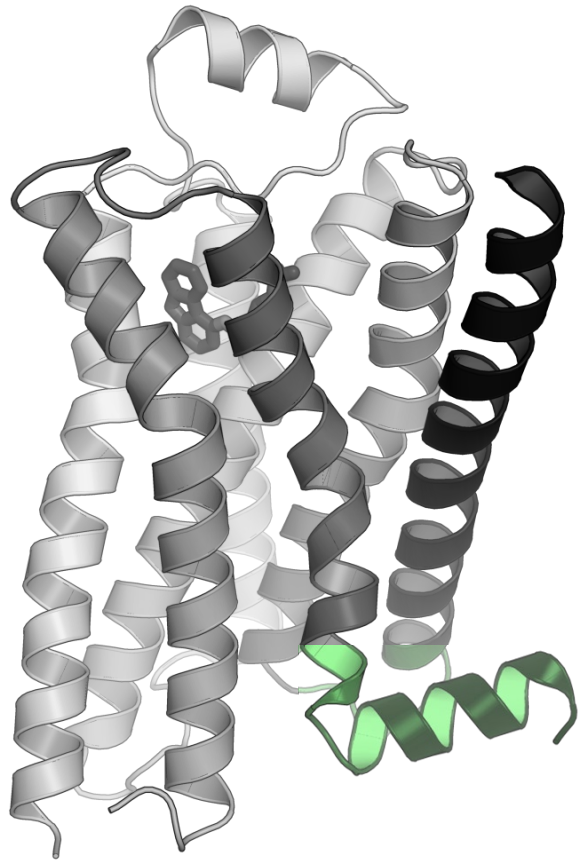
Strategic Fit

- 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 in 2020



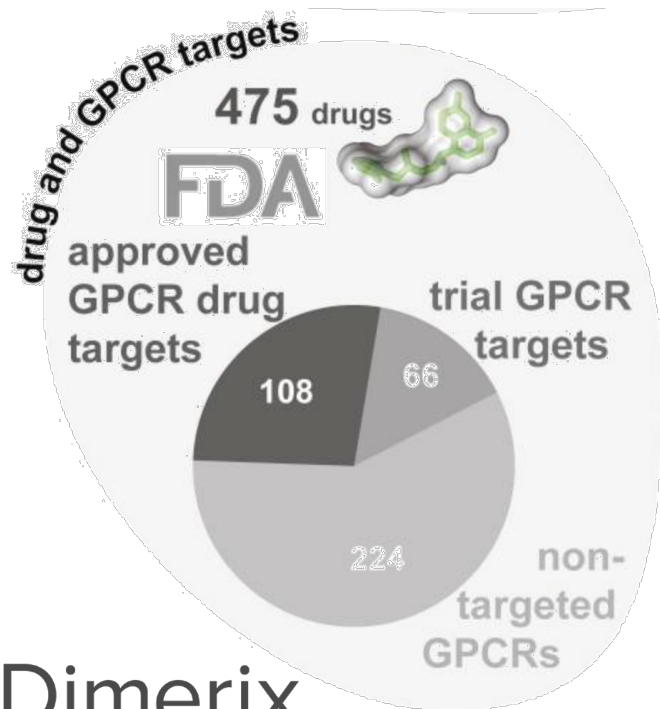


Introduction to Receptor-HIT

Evolution of GPCR drug discovery

G Protein-Coupled Receptors

- A large family of cell surface receptors
- Involved in most processes in the body – normal and disease state
- GPCRs are the target of 30-40% of all known drugs
- Discovery led to 2012 Nobel Prize for Chemistry for Robert Lefkowitz and Brian Kobilka

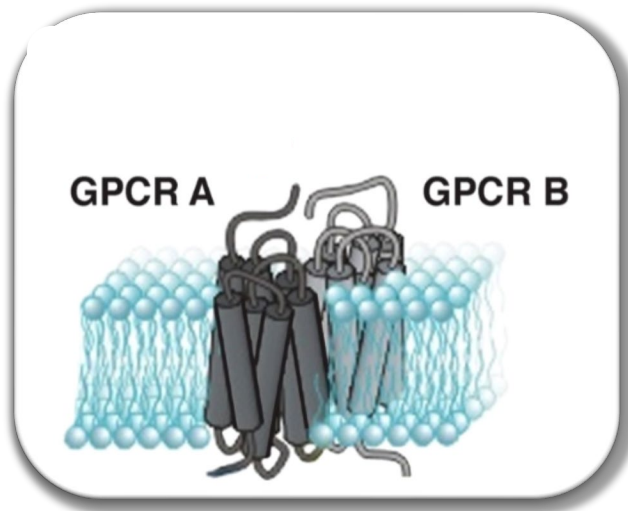


US\$180 billion in sales

Why are there so few GPCRs successfully targeted?

Dimerix technology – Receptor-HIT

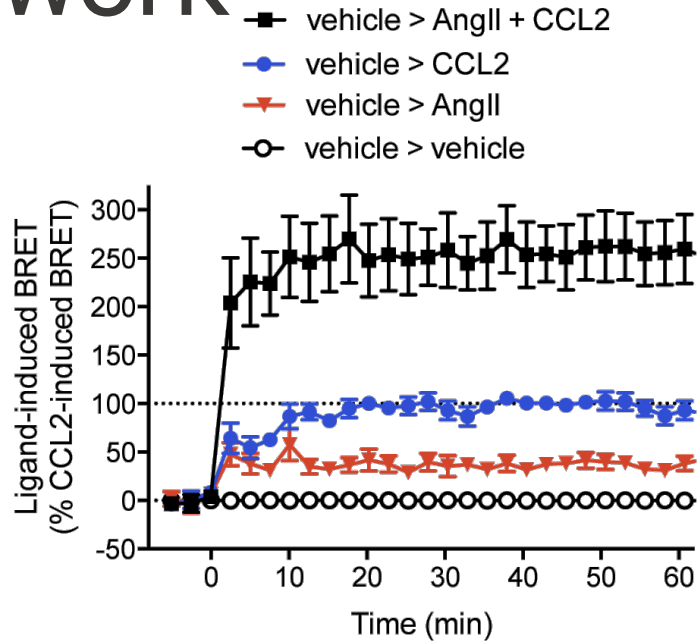
- Patented tool that enables understanding of real-time receptor interactions
- Particularly suited to GPCRs
- Can identify **new uses** for existing drugs, deorphanize receptors, and drive the **discovery** of new drugs and research programs



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.*

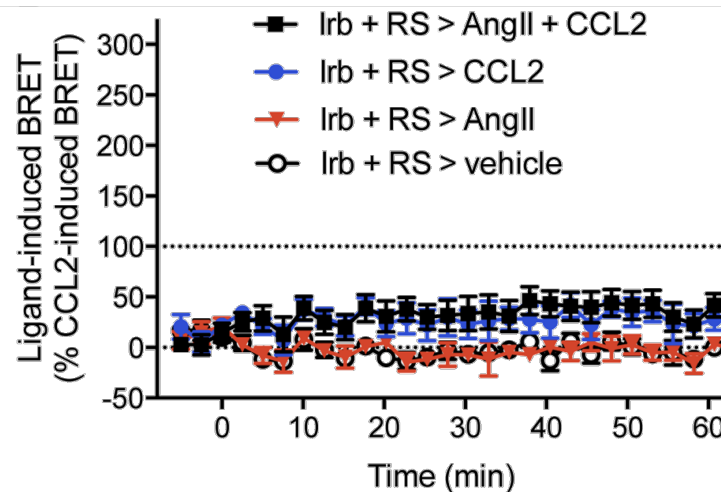
Assay is granted patents in key territories, protection until 2029

Discovery of DMX-200 – Receptor-HIT at work



Using **proprietary discovery platform Receptor-HIT**, Dimerix identified:

- Formation of AT1R and CCR2 heteromers;
- Novel pharmacology (potentiation of signaling)
- Dual blockade of AT1 receptor and CCR2 is required for total inhibition of signalling





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
- Administered to patients already on standard of care treatment (irbesartan)
- Product attributes: deliver best-in-class benefits to patients
- Inhibits activity of a cellular receptor of inflammation: CCR2 (C-C Chemokine Receptor Type 2)
- Never been approved by a regulatory authority in the US, Europe or Australia
 - DMX-200 is not available as a generic drug and is considered a New Chemical Entity* (NCE) in the US

**NCE status
in US and
Europe**

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

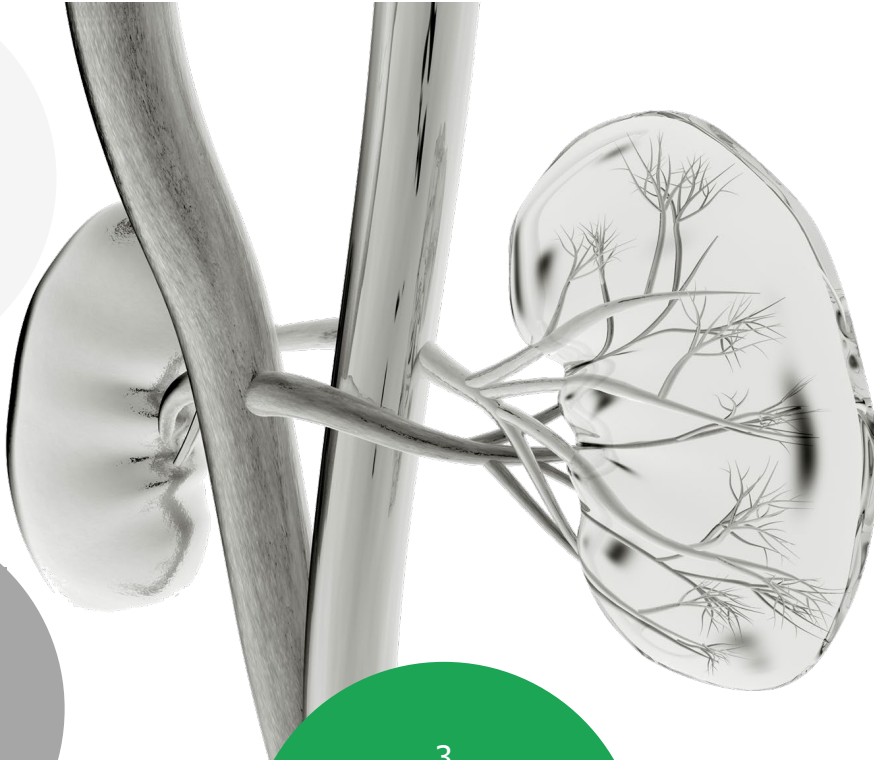
DMX-200 proposed mechanism of action

DMX-200 addresses three key mechanisms that causes renal damage and chronic 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
- Known safety profile with no adverse events seen
 - Lower risk development

Clinical experience



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

- pharmacokinetic and safety clinical study



1 x Phase 2a study (DMX-200-201)

- Safety, tolerability study, and efficacy study

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

Safety and tolerability of DMX-200 as an adjunct therapy to irbesartan treatment in patients with proteinuric kidney disease

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")

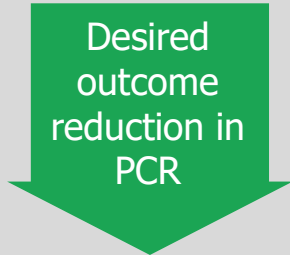
- The proportion of responders, defined as those participants achieving normalisation of proteinuria or a 50% reduction in proteinuria

All endpoints met:

- safe and well tolerated

Responders

- 6/24 patients had a 50% decrease in PCR during treatment with DMX-200



Desired
outcome
reduction in
PCR

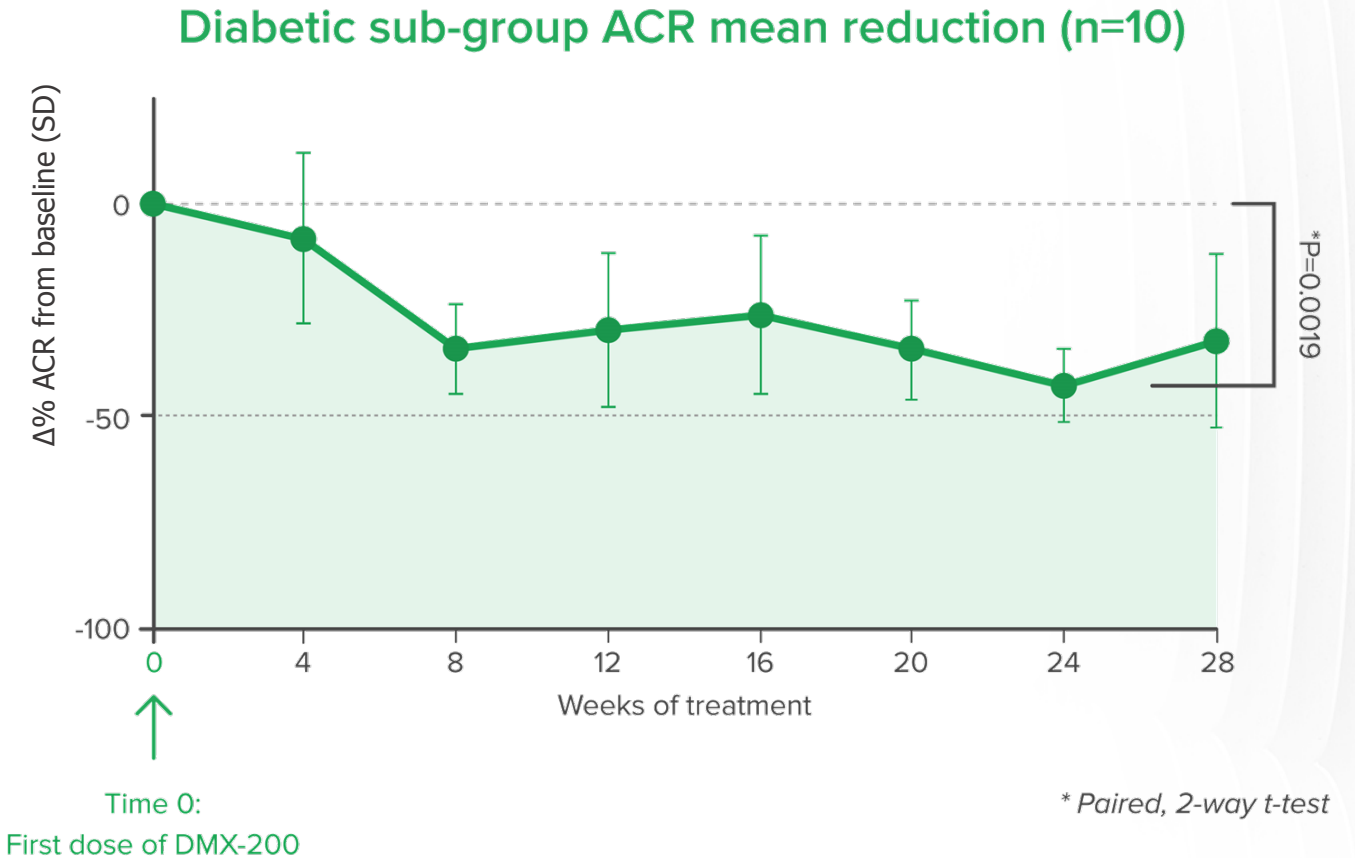
DMX-200 Phase 2a study

Diabetic sub-group ACR mean reduction (n=10)

- 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 35.6% in diabetic sub-group

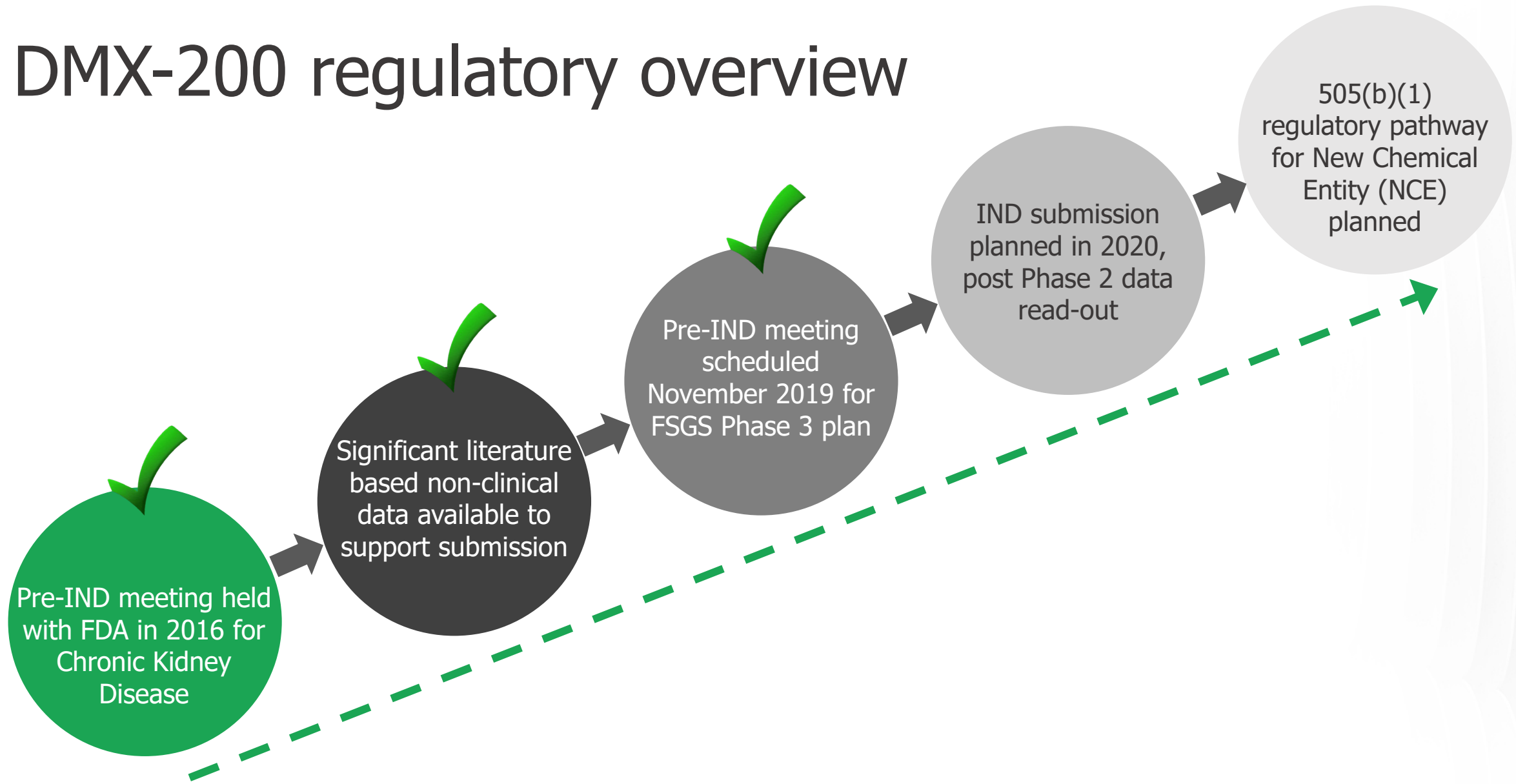
Reduction of proteinuria by >30% may increase time to dialysis by 3-5 years and reduce health costs by \$100,000 per patient per year



CMC overview

- ✓ USA based contract manufacturer appointed for commercial supply of API
- ✓ FDA approved manufacturing facility
- ✓ Exclusive development and methodology to manufacture API owned by Dimerix
- ✓ In-house capability for commercial supply of finished product
- ✓ Analytical methods validated
- ✓ Commercial scale GMP batch manufacture completed

DMX-200 regulatory overview



Intellectual Property

Patents



- Multiple granted patents in numerous territories
- New patent applications underway in line with commercialisation strategy
- Granted method of use patents in key territories strengthens the company's competitive position
- Granted patents may block some competitor product development plans
- Granted method of use patents expire ~2033

Exclusivity

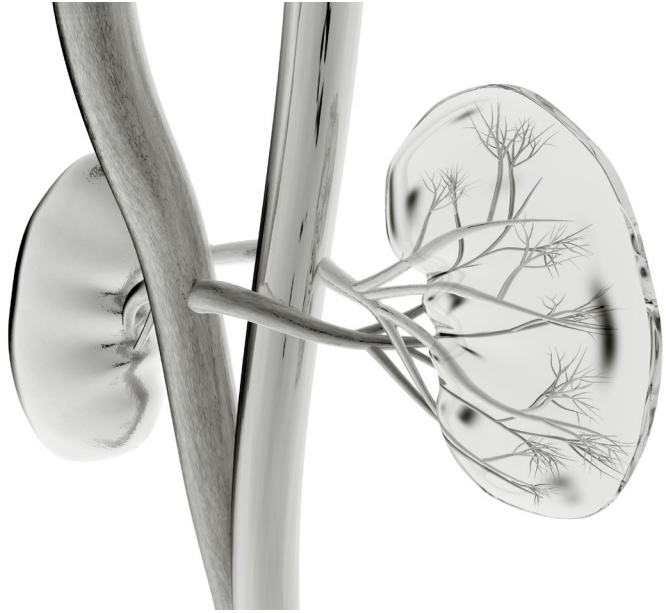


- New Chemical Entity can attract minimum 5 years exclusivity (more for orphan)
- DMX-200 advantage of submitting an NCE new drug application in the US & EU whilst simultaneously relying on existing safety data

Manufacturing



- Exclusively owned IP & know-how associated with DMX-200 manufacturing processes & validated methodology
- Completed manufacture of demonstration batch



DMX-200 in Diabetic Kidney Disease

DMX-200 proposed indication



for the treatment of diabetic nephropathy
in patients with type 2 diabetes

Market dynamics

Diabetic Kidney Disease

- Also known as Diabetic Nephropathy
- 23 million diagnosed diabetics in the US*
 - *36.5% of these had kidney disease**
 - *~8.3 million with Diabetic Kidney Disease in the US alone*
 - *Diabetes incidence estimated to grow 54% by 2040[†]*
- 10% of diabetics develop kidney disease within 10 years of diagnosis[#];
- Progressive disease, leading to kidney failure and blood dialysis

- Dialysis costs of ~\$100,000/patient/year[¥]
- Dialysis severely affects quality of life:
 - >12 hours treatment per week required

[†] Diabetic Kidney Disease: Challenges, Progress, and Possibilities. American Journal of Nephrology, 2017. [ONLINE Available at <https://cjasn.asnjournals.org/content/early/2017/07/12/CJN.11491116> [Accessed 01Oct18]]

* US National Diabetes Statistics Report, 2017. [ONLINE] Available at <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>. [Accessed 01Oct18]

[#] Kidney Health Australia. 2018. Diabetic Kidney Disease. [ONLINE] Available at https://kidney.org.au/cms_uploads/docs/diabetic-kidney-disease--kidney-health-australia-fact-sheet.pdf [Accessed 11Sep18]

[¥] Kidney Health Australia. 2018. Kidney Fast Facts. [ONLINE] Available at http://kidney.org.au/cms_uploads/docs/kidney-health-australia-kidney-fast-facts-fact-sheet.pdf. [Accessed 15 Sep 2018]

DMX-200 for Diabetic Kidney Disease value in US: large market with low competition

Irbesartan 300mg
administered to
patients for kidney
disease

Branded product
retail price US\$590*
per month

4.05 million scripts
for irbesartan 300mg
(1 month supply)
in 2017*

>50% of patients
taking irbesartan
300mg may remain
macroalbuminuric
(protein in urine remains high)
& require further
treatment

Thus, 2 million
scripts/year
addressable market
at irbesartan
branded pricing
equivalent

Addressable
market of
\$1.1 billion/year

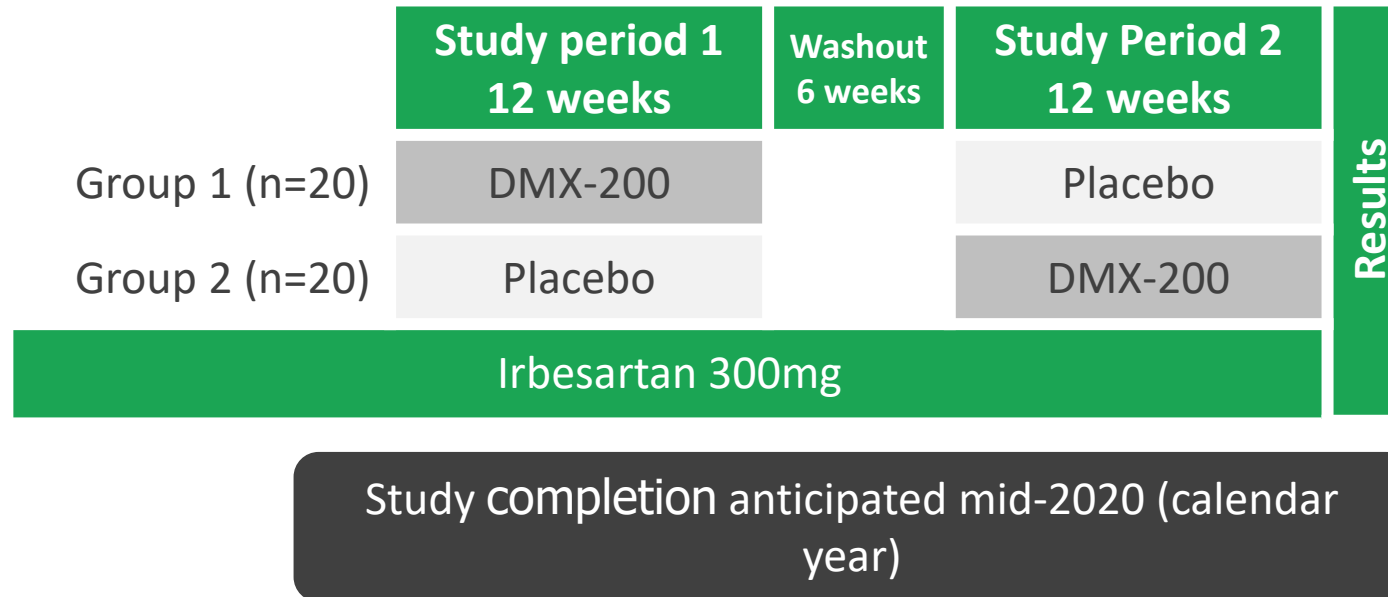
Phase 2 trial in Diabetic Kidney Disease

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

- *N=40. Primary endpoint proteinuria. Secondary endpoint safety and biomarker analysis.*
- *Indication: for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with type 2 diabetes*
- *Powered to resolve 30% reduction in ACR.*
- *Study completion expected Q2 2020*

Phase 2 trial in Diabetic Kidney Disease

- 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



Phase 2 trial in Diabetic Kidney Disease

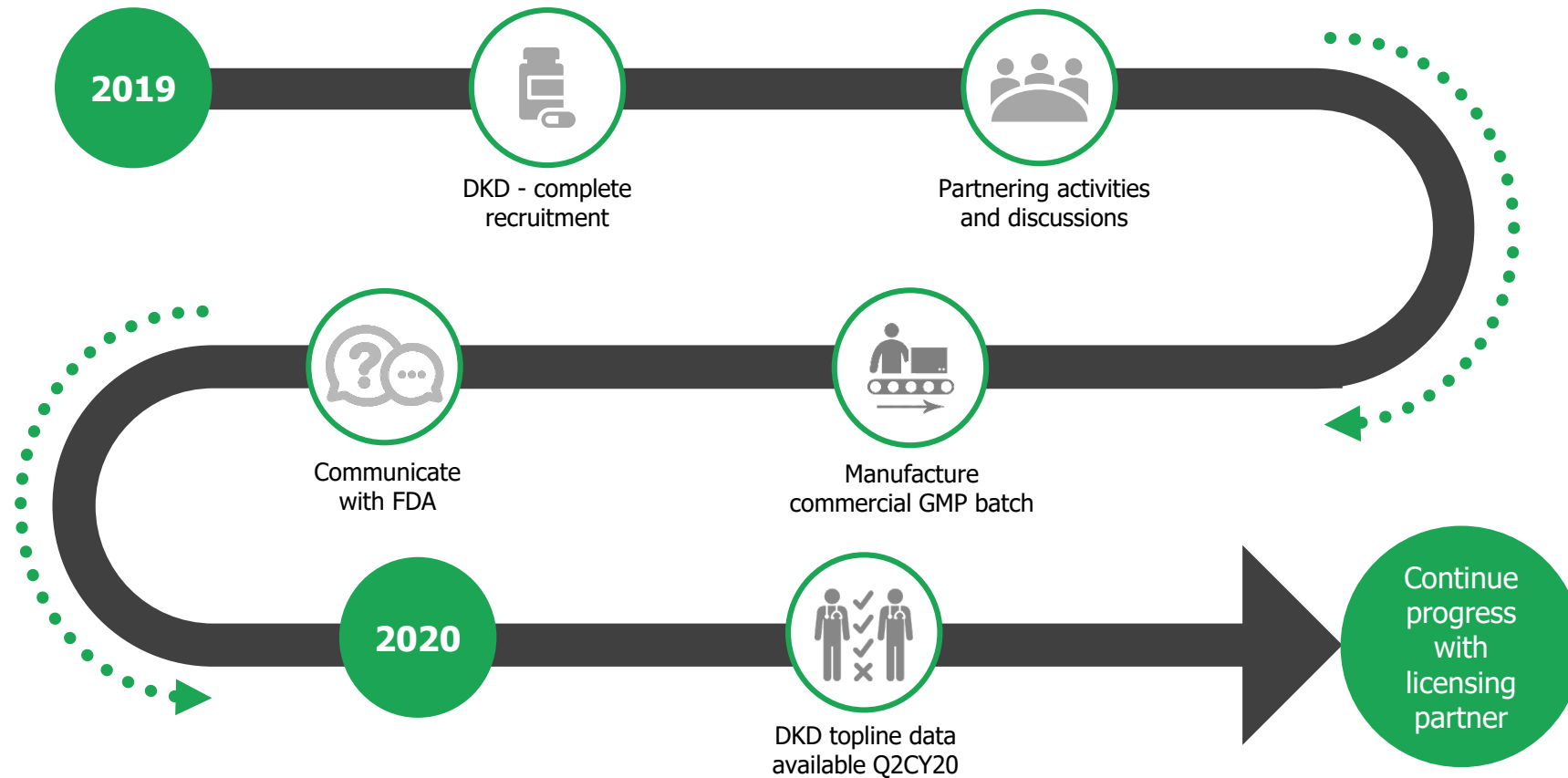
Primary endpoint

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

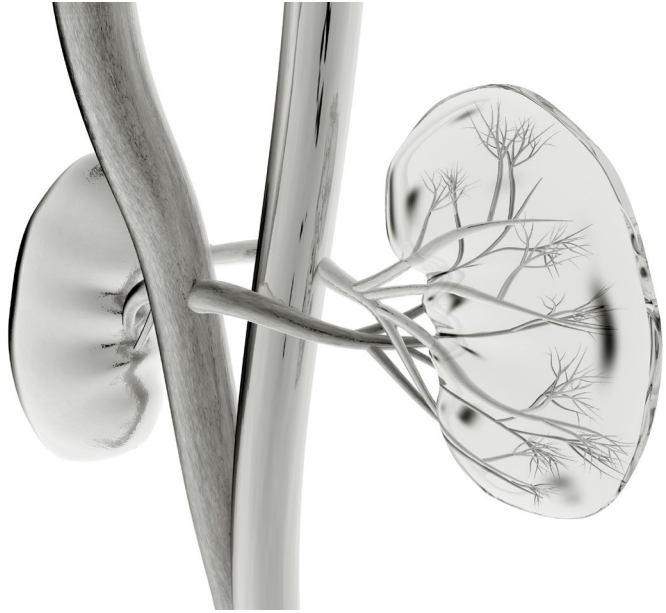
- Assessment of frequency of patients who achieve an albuminuria-based response during treatment (reduction of $\geq 30\%$ geometric mean ratio);
- Change from baseline after treatment with DMX-200 as compared to placebo in:
 - ACR;
 - PCR;
 - Total albumin excretion;
 - Total protein excretion;
 - Serum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

Development timelines



Summary

- ✓ DKD is a large & growing market
- ✓ Unmet need, with low competition
- ✓ Granted patents with additional patents pending
- ✓ Strong existing Phase 2a data demonstrating superior efficacy
- ✓ Existing long-term safety data available
 - Reduced risk and development program
- ✓ Product supply at commercial scale secured
- ✓ Phase 2 fully recruited
- ✓ Global licensing rights currently available



Introduction to DMX-200 in FSGS

DMX-200 proposed indication



for the treatment of focal segmental
glomerulosclerosis

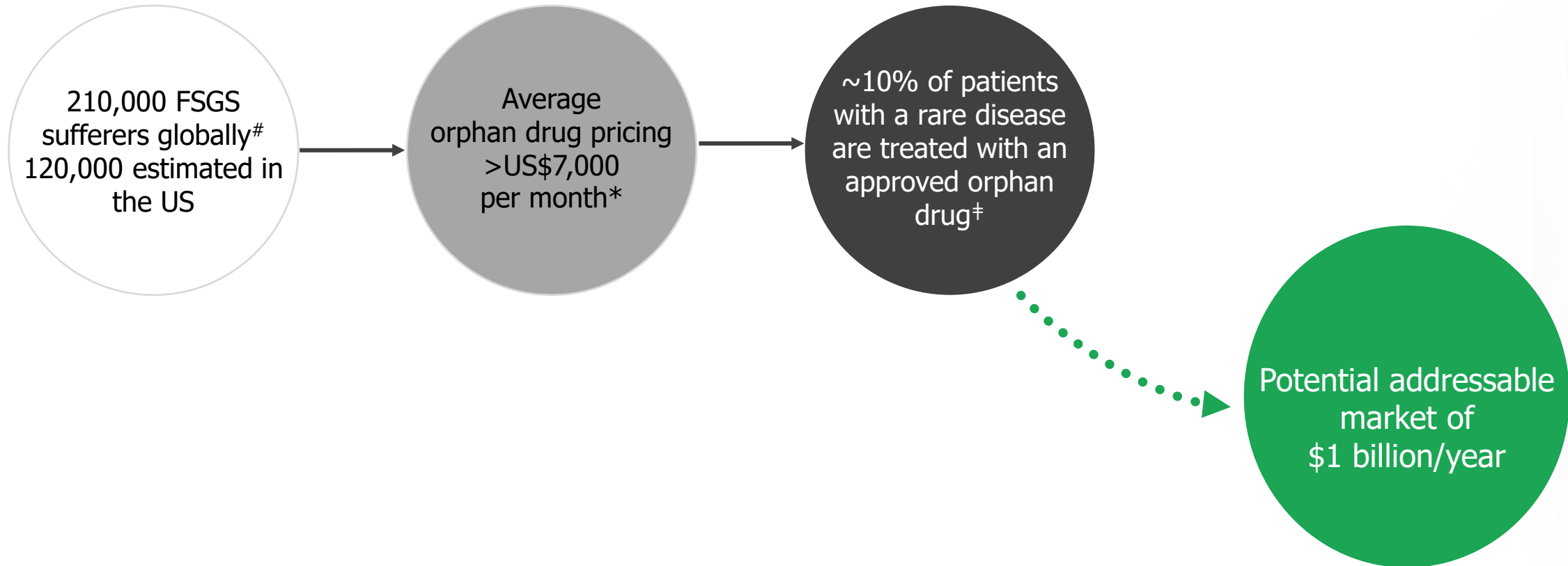
Market dynamics

Focal Segmental Glomerulosclerosis

- A serious and rare kidney disease: orphan indication
- Rapid progression to end-stage renal disease
- ~210,000 individuals globally
- Eventually require blood dialysis
- >93,000 patients on kidney transplant waiting list in US
- Kidney transplant costs >\$262,000 in the 1st year
- **DMX-200 has US and EU Orphan Drug Designation for FSGS**
- Faster path to market with set market exclusivity period

- Dialysis costs of ~\$100,000/patient/year
- Dialysis severely affects quality of life:
 - >12 hours treatment per week required

DMX-200 for FSGS value in US: orphan drug status with low competition



Phase 2a trial in FSGS

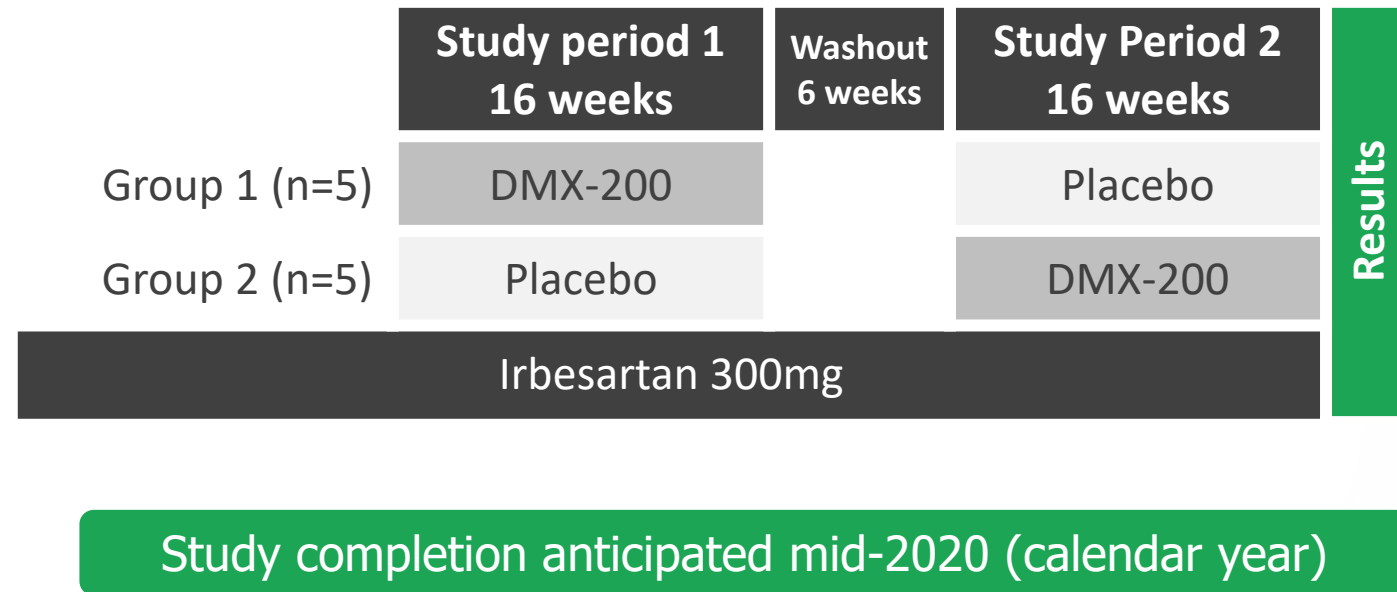
Phase 2a DMX-200-202 (ACTION for FSGS)- *A Phase 2a, Double-blind, Randomised, Placebo-Controlled, Crossover Study Evaluating the Safety and Efficacy of Propagermanium in Patients with Primary Focal Segmental Glomerulosclerosis who are Receiving Irbesartan*

- *N=10. Primary endpoint safety. Secondary endpoint proteinuria and biomarker analysis.*
- *Indication: for the treatment of elevated serum creatinine and proteinuria in patients with FSGS*
- *Study completion expected Q2 2020*



Phase 2a trial in FSGS

- 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



Phase 2a trial in FSGS

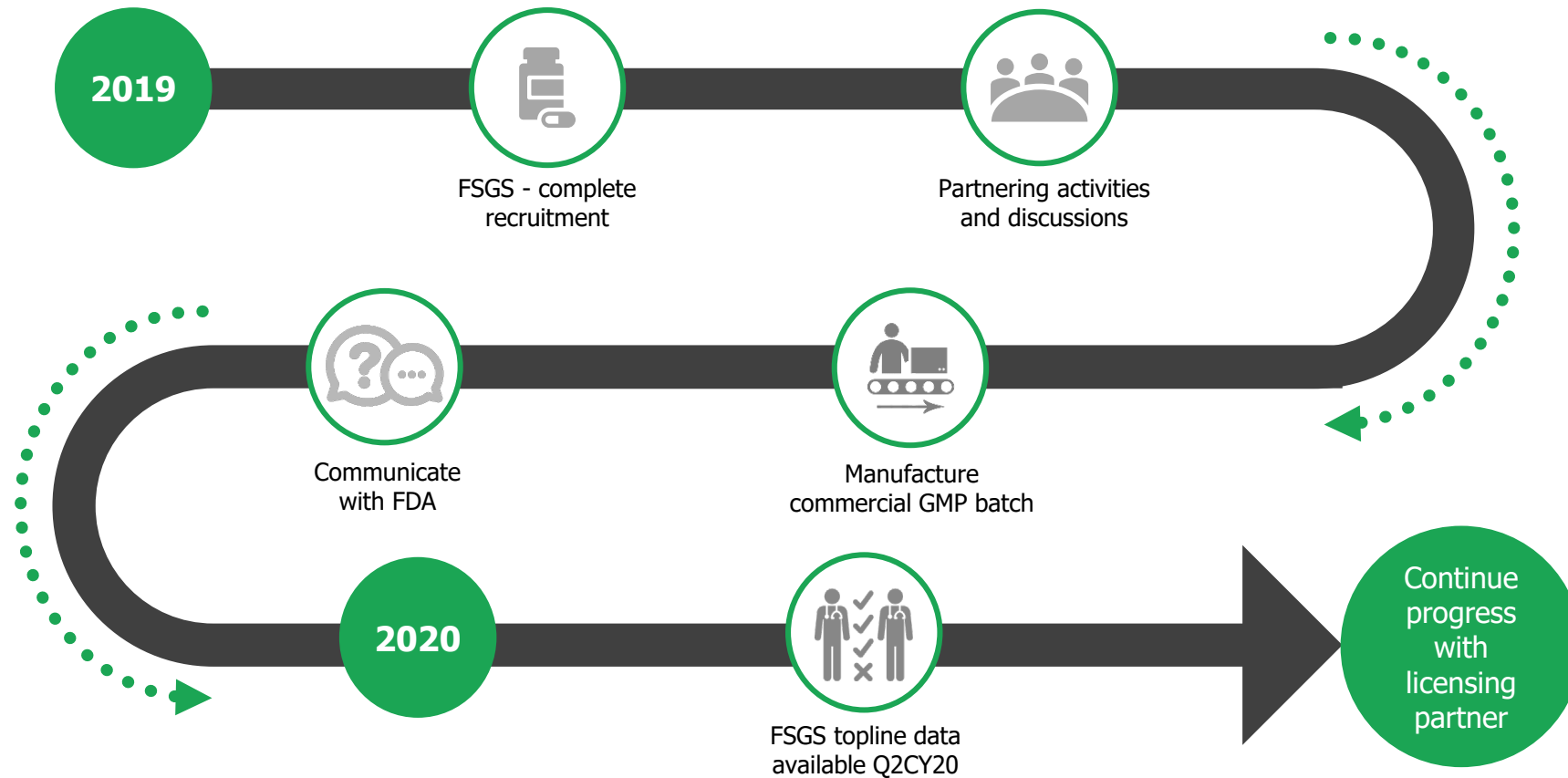
Primary endpoint

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

Secondary endpoints

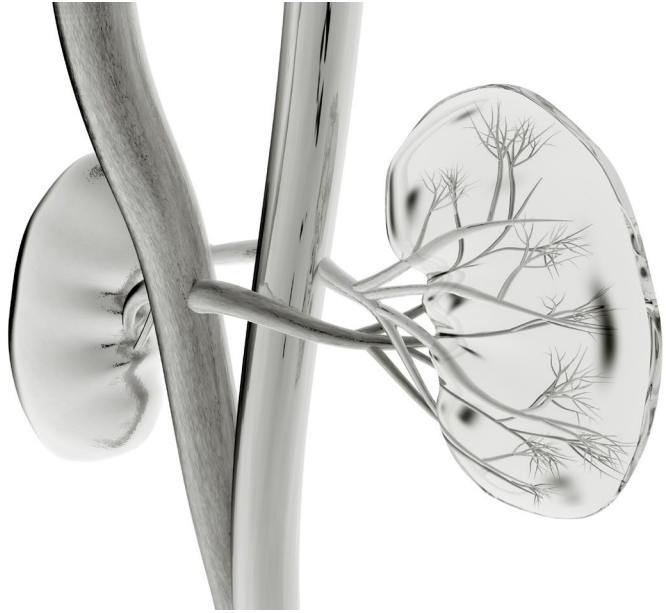
- Percent change from baseline in 24-hour PCR after 16-weeks of treatment with propagermanium as compared to placebo (mean of 2 values);
- Proportion of patients who achieve a response during treatment with propagermanium as compared to placebo

Development timelines



Summary

- ✓ FSGS is a small but 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 2a fully recruited
- ✓ Global licensing rights currently available



Introduction to DMX-700 in COPD

What is COPD?

DMX-700 in Chronic Obstructive Pulmonary Disease (COPD)

Progressive & life-threatening lung disease affecting individuals of all ages

caused by: tobacco smoke, air pollution, occupational dust/fumes, long-term asthma

COPD limits pulmonary airflow that is not fully reversible

Usually progressive with an abnormal inflammatory response

No cure available & existing treatments aimed at relieving symptoms only

4th leading cause of death worldwide

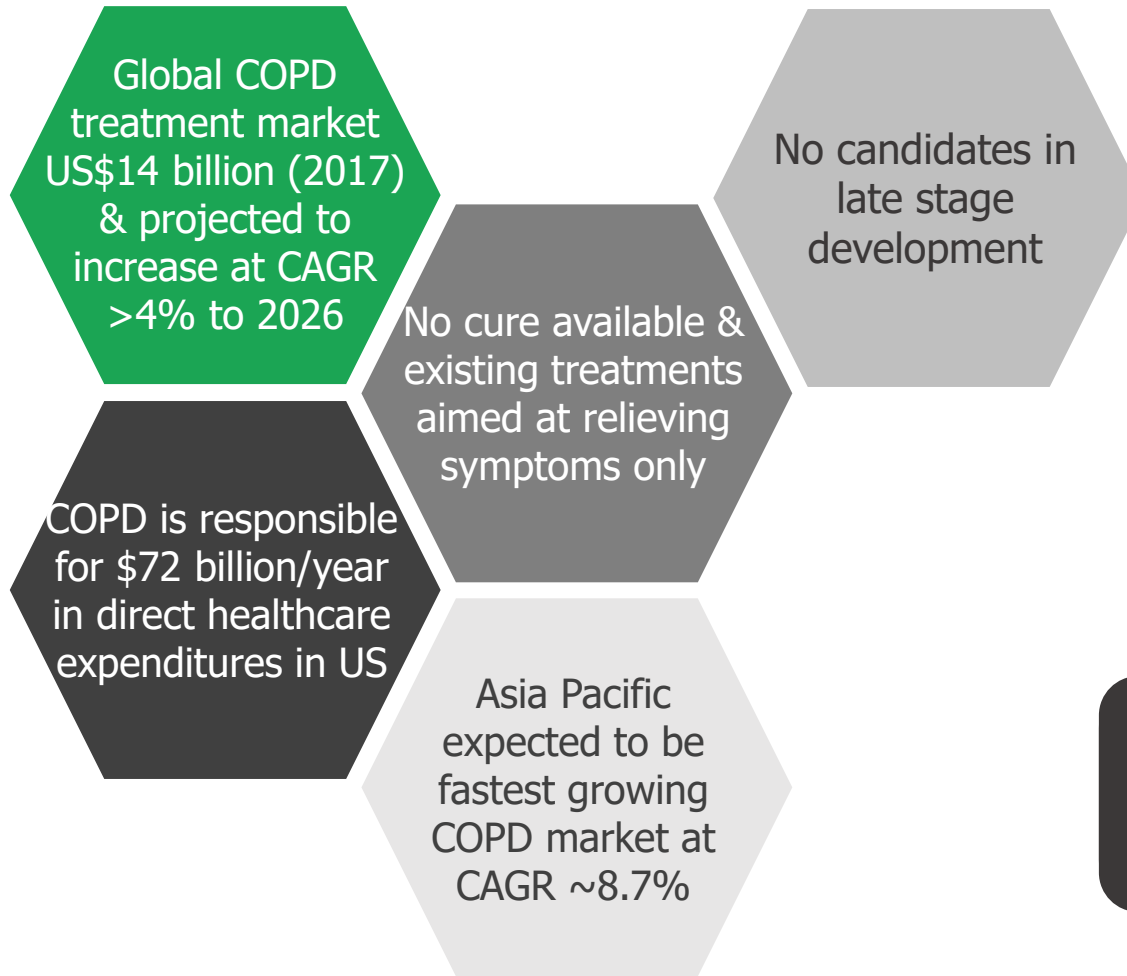
Among the top 5 causes of death, COPD is the only one with increasing mortality rates

COPD incidence increasing due to aging populations and continued smoking prevalence

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



COPD landscape



Global Initiatives

- World Health Organization (WHO)
- COPD Foundation
- American Thoracic Society
- Centers for Disease Control & Prevention (CDC)
- National Institute of Health (NIH)

All working towards raising COPD awareness in the population

2018 – FDA Guidance:
significantly shorter clinical trial size and duration required
Hard endpoints versus surrogate endpoints
Endpoints in weeks not years

Introducing DMX-700 for COPD

- DMX-700 for the treatment of COPD by blocking heteromer signalling in receptors active in COPD
- Initial studies on the receptor pair have been conducted under an Innovation Connections grant awarded to Dimerix in November 2018
- The two molecules working together, each with an established safety profile
- Provisional patent application filed; additional applications anticipated

New Chemical Entity
Attracting 5 year exclusivity

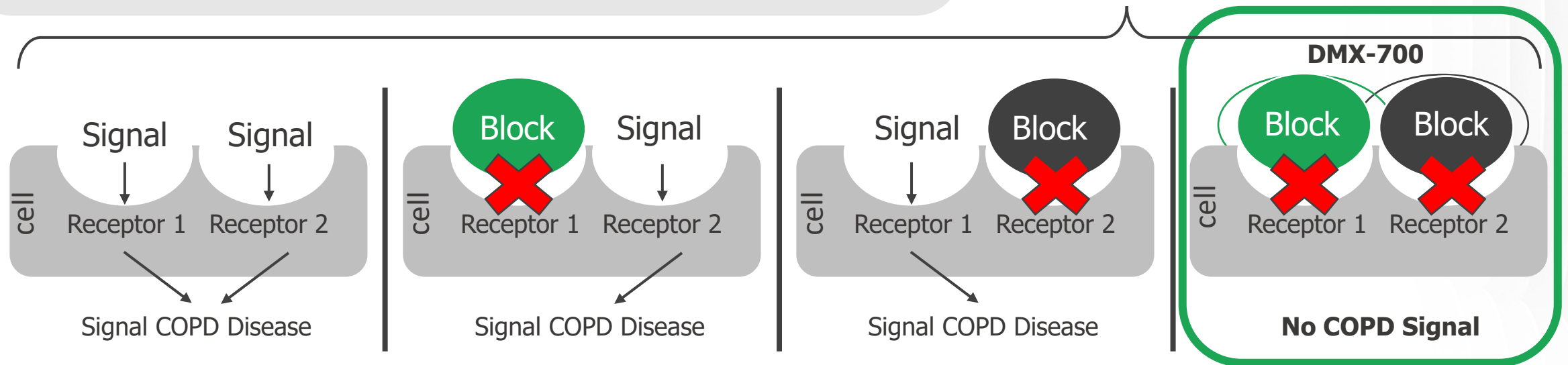
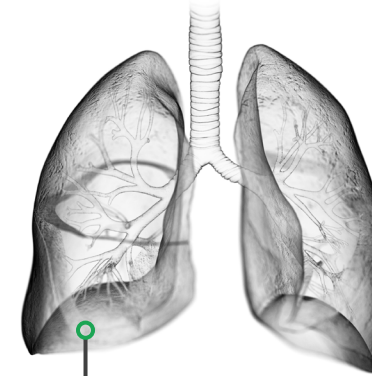
Timeline to clinic
~2 years

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

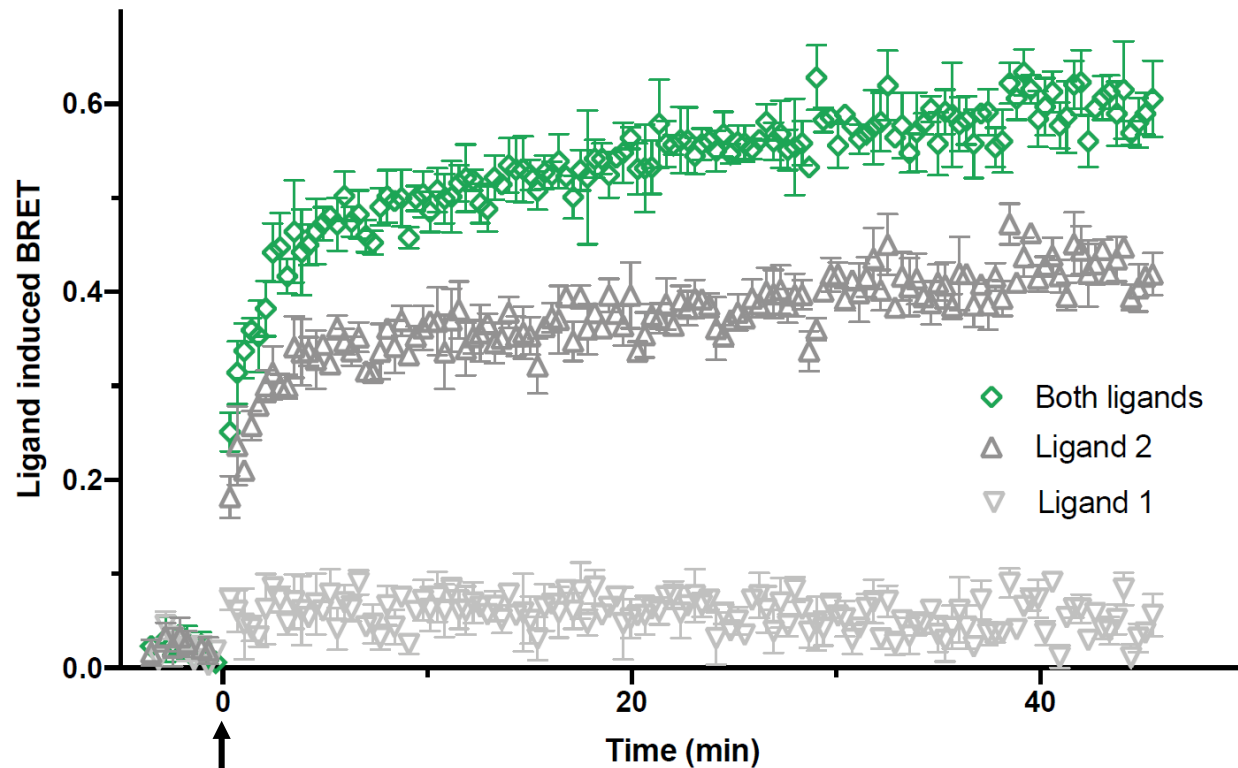
DMX-700 proposed mechanism of action

Certain lung cells express both receptors, thus blocking only one receptor does not block signalling and results in only a partial response to treatment

DMX-700 blocking both receptors simultaneously to provide a more complete response to treatment



DMX-700 pre-clinical data



Ligands administered

DMX-700 targets blocking both receptors simultaneously in cells co-expressing receptors 1 and 2

When both Receptor ligands administered
More than additive signal observed

When only Receptor 2 ligand administered:
larger signal observed

When only Receptor 1 ligand administered:
signal observed

DIMERIX

End of Presentation



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