

## **DIMERIX ANNOUNCES NEW DRUG PIPELINE CANDIDATE – DMX-700**

MELBOURNE, Australia, 10 October 2019: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, today announced its next development pipeline candidate; DMX-700 for the treatment of Chronic Obstructive Pulmonary Disease (COPD). The new discovery was identified using Dimerix' proprietary Receptor-HIT assay and is one of a number of potential candidates under preliminary assessment.

The potential new pipeline opportunity, DMX-700 for COPD, is built on the Dimerix core competency of understanding the complex pharmacology of chemokine G Protein-Coupled Receptor (GPCR) targets, and thus has a good strategic fit with current business model and corporate strategy. As such, Dimerix can utilise its current core competencies and capabilities to execute the development program.

### **About Chronic Obstructive Pulmonary Disease (COPD)**

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. In 2016, the Global Burden of Disease Study reported a prevalence of 251 million cases of COPD globally, and it was estimated that 3.17 million deaths were caused by the disease in 2015 (5% of all deaths globally in that year)\*. 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.

There is a significant unmet need in COPD, which is recognised by key organisations such as the National Institute of Health (NIH) and globally by the World Health Organisation (WHO) and the Centers for Disease Control and Prevention (CDC). In 2017, the NIH released the COPD National Action Plan in an effort to support research, diagnosis and treatment of the disease. Following this recognition, in 2018 the FDA issued revised guidance to help sponsors developing drugs to treat COPD. The new guidance will enable shorter clinical trials using surrogate and patient-reported endpoints.

*\*WHO Factsheet – Chronic Obstructive Pulmonary Disease:*

[www.who.int/en/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-\(copd\)](http://www.who.int/en/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-(copd))

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

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### About DMX-700

Receptor-HIT has identified a heteromer association between two receptors expressed on the lung. Both of these receptors have been independently implicated in the pathophysiology of COPD, however investigations into each single receptor have provided disappointing results to date. Dimerix anticipates that this is due to the heteromer nature of the receptor and has discovered that simultaneous inhibition of both receptors may significantly improve efficacy. The receptor targets and DMX-700 will remain undisclosed pending additional data and patent positioning.

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. The new provisional patent application, number 2019903606, has a priority date of 26 September 2019 and once granted would expire post 2040. It is anticipated that DMX-700 will be protected by Composition of Matter patents, Formulation patents and Method of Use patents, providing a strong competitive position.

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. DMX-700 is a New Chemical Entity, however the safety profile is well understood. As such, it is anticipated that Dimerix would initiate human clinical studies in less than 2 years.

“We have very high hopes for this drug candidate making a real difference in the lives of those suffering from COPD, where there is a significant unmet need”, Dimerix CEO and Managing Director commented. “Dimerix continues to assess potential opportunities that fit with the company strategy. We intend to focus on selecting appropriate pipeline candidates within our resource and funding capabilities. All potential opportunities screened are commercially attractive and could result in patient preferred products”.

An updated Corporate Presentation accompanies this release.

For further information, please visit our website at [www.dimerix.com](http://www.dimerix.com) or contact:

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### **About Receptor-HIT**

Cell-based assays are important tools used by the global pharmaceutical industry in drug discovery and development. Dimerix's patented cell-based assay, known as Receptor-HIT (Heteromer Investigation Technology), can be applied to a number of stages of the drug development process and has previously been used under licence by leading global pharmaceutical companies to profile a wide range of receptor targets. Compared with the traditional analysis of single target receptors in isolation, Receptor-HIT is able to identify differences in signalling behaviour when receptors interact as complexes, known as heteromers. Receptor-HIT can be applied to receptors such as G protein-coupled receptors (GPCRs); a large and important family of drug targets that play a central role in many biological processes and are linked to a wide variety of diseases.

Dimerix's core technology platform allows characterisation of different receptors that functionally interact and result in different pharmacology when natural ligands or small molecule drugs, peptides or antibodies bind to them. This platform technology was used to identify and characterise the GPCRs targeted in Dimerix's lead clinical program, DMX-200 – allowing rapid progress from proof of concept in vitro into Phase 2 clinical trials.

### **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).

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.

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# Introducing DMX-700 and Company Update

October 2019



Dimerix

# Forward looking statements

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*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)

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## Financial information

Share price (09Oct19)	\$0.115
52 week low / high	A\$0.72 / 0.15
Shares on issue	158.8m

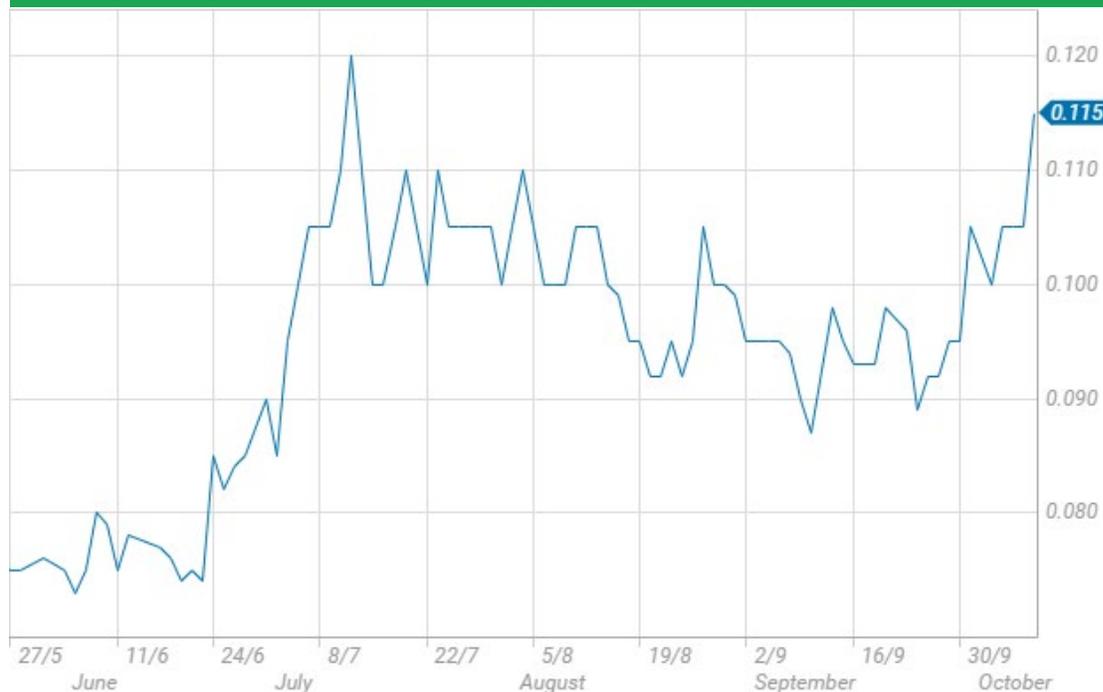
<b>Market Capitalisation</b>	<b>A\$18.3 million</b>
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Cash (as at 30Jun19)	A\$3.6 million
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Debt (as at 30Jun19)	\$0
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<b>Enterprise value</b>	<b>A\$14.7 million</b>
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## Share price performance



# Executive summary

Dimerix is a biopharmaceutical company developing innovative new therapies in areas with unmet medical needs using its scalable, proprietary platform technology

## Three product candidates in active development:

- DMX-200 in two Phase 2 studies:

- Focal Segmental Glomerulosclerosis (FSGS)**
- Diabetic Kidney Disease**

Clinical read-out for both studies in Q2 2020

- DMX-700 preparing for clinical studies:

- Chronic Obstructive Pulmonary Disease (COPD)**

In clinic within 2 years

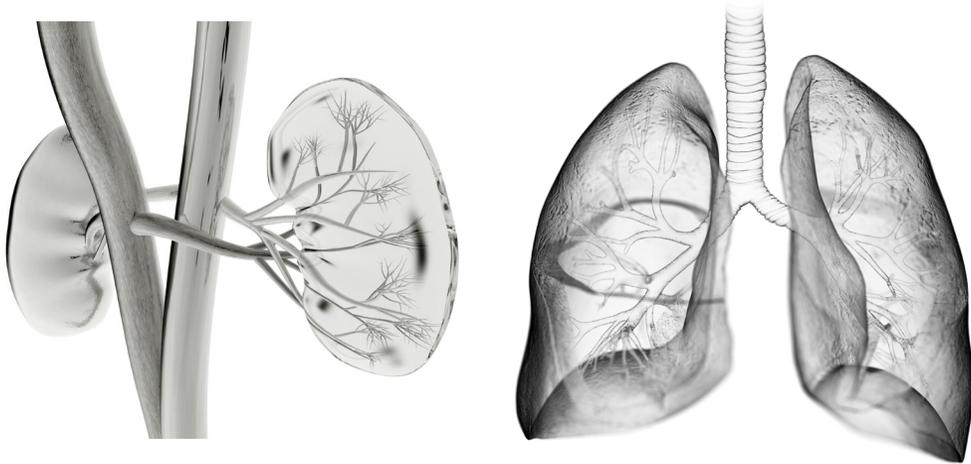
## Receptor-HIT platform technology:

- Other potential pipeline candidates under assessment
- Receptor-HIT assay licensed globally

Additional potential pipeline candidates identified

# A pipeline of drugs identified using Receptor-HIT

Targeting different GPCR receptor pairs

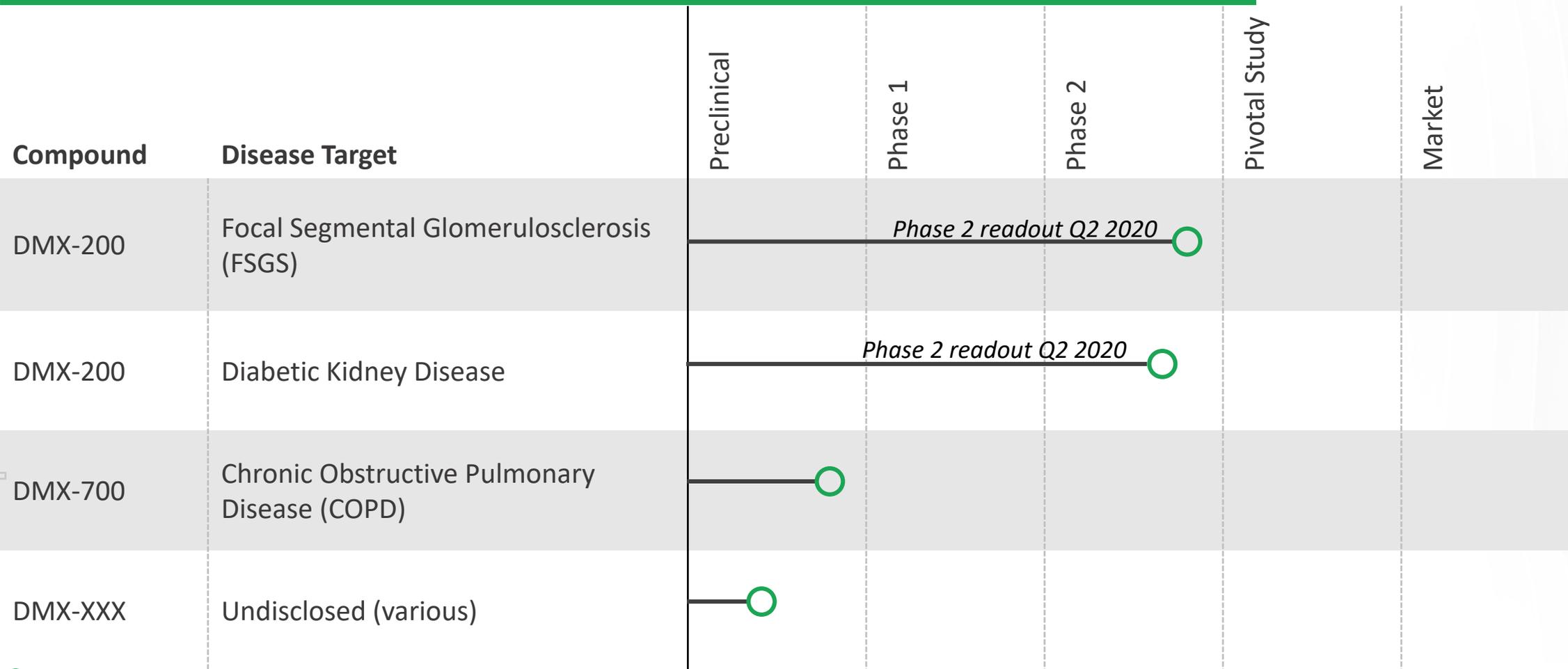


Strategic Fit

- 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 Q2 2020



# Board & Management



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

*ICeutica, Yuuwa, AdAlta, Polyactiva*  
Experienced Director of ASX-listed companies

- Co-founded Dimerix
- Co-founded Yuuwa Capital (\$40M venture fund)
- ✓ BSc (Hons) - Biochemistry
- ✓ PhD - Pharmacology
- ✓ 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, Kinosis*

- 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*

- Experienced executive in pharmaceutical operations
- Background in small molecules development and analytical development
- ✓ BSc (Hons) - Chemistry
- ✓ PhD - Industrial Chemistry



**David Franklyn**  
BEcon  
Non-Executive Director

*Village National, Onterran*

- Capital markets background
- Extensive experience in financial analysis, corporate advice, business management and investor relations
- experienced company director, of various ASX listed companies
- ✓ BEcon - Economics



**Robert Shepherd**  
PhD  
R & D Director

*Medicines Development, Phosphogenics*

- Experienced pharmaceutical executive in project management
- Led multidisciplinary R&D teams for over 10 years
- ✓ BSc (Hons) - Genetics
- ✓ PhD - Vaccines

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# Introduction to COPD

# What is COPD?

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Chronic obstructive pulmonary disease (COPD) is a progressive & life-threatening lung disease affecting individuals of all ages caused by:

- tobacco smoke
- indoor and outdoor air pollution
- occupational dusts and fumes
- long-term asthma



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

- COPD limits pulmonary airflow that is not fully reversible
- Usually progressive with an abnormal inflammatory response

4<sup>th</sup> leading cause of death worldwide

No cure available & existing treatments aimed at relieving symptoms only

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 market

Global COPD treatment market US\$14 billion (2017) & projected to increase at CAGR >4% to 2026

COPD is responsible for \$72 billion/year in direct healthcare expenditures in US

## 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

The market will be **ACCELERATING** growing at a **CAGR** of nearly

**4%**

**INCREMENTAL GROWTH** ▶  
**\$3.52 bn**

2018

2023

The year-over-year growth rate for **2019** is estimated at

**3.79%**

No cure available & existing treatments aimed at relieving symptoms only

Asia Pacific expected to be fastest growing COPD market at CAGR ~8.7%

# Current treatment of COPD

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Products on the market:

1<sup>st</sup> line treatment:  
inhalable steroids  
used to treat  
symptoms &  
exacerbations of  
COPD

No medication exists  
that prevents the  
long-term decline in  
lung function of  
COPD patients

Products in clinical development:

- 5 products in early stage development
- There are no late-stage (Phase 3) trials of targeted therapies for COPD

Clear unmet need

# 2018 - Changed regulatory environment

- Historically, COPD hard clinical endpoints (e.g. mortality and hospitalisations)
  - large number of subjects
  - prolonged observational periods
  - amplified difficulty given many of the historical drug candidates cause only small effects on lung function; thus required even larger/longer trials to see any efficacy signal
- In 2018, FDA finalised guidance to help sponsors developing drugs to treat COPD
  - surrogate endpoint measures approved
  - significantly shorter trial size and duration, with endpoints measured in weeks and not years

2018 – FDA Guidance:

significantly shorter  
clinical trial size and  
duration required

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# Introduction to DMX-700

# Introducing DMX-700 for COPD

- DMX-700 has been selected as the ideal candidate for the treatment of COPD based on the ability to block heteromer signalling in receptors active in COPD
- Initial studies on the receptor pair have been conducted by Professor Kevin Pflieger and his team at the University of Western Australia, under an Innovation Connections grant awarded to Dimerix in November 2018
- The two molecules working together, each with an established safety profile:
  - Reduced development timeframe – clinical trials in approximately 2 years
  - New Chemical Entity globally

**New Chemical Entity**  
Attracting 5 year exclusivity

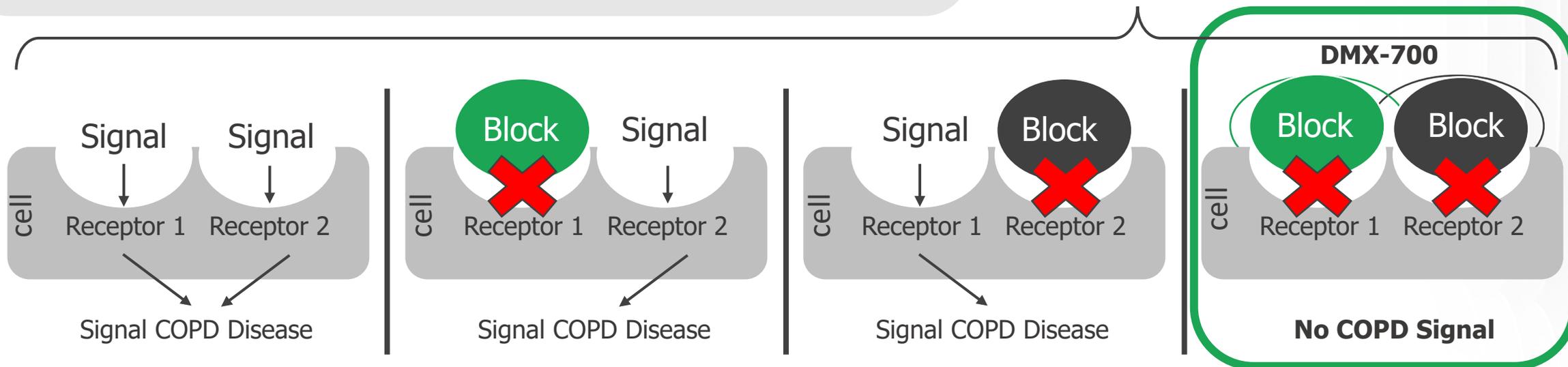
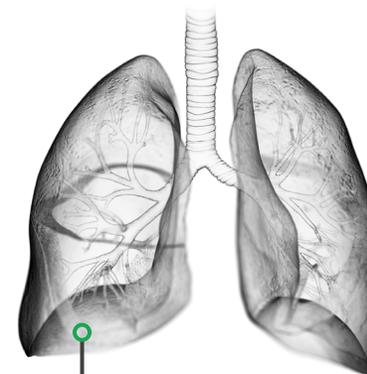
Timeline to clinic  
~2 years

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

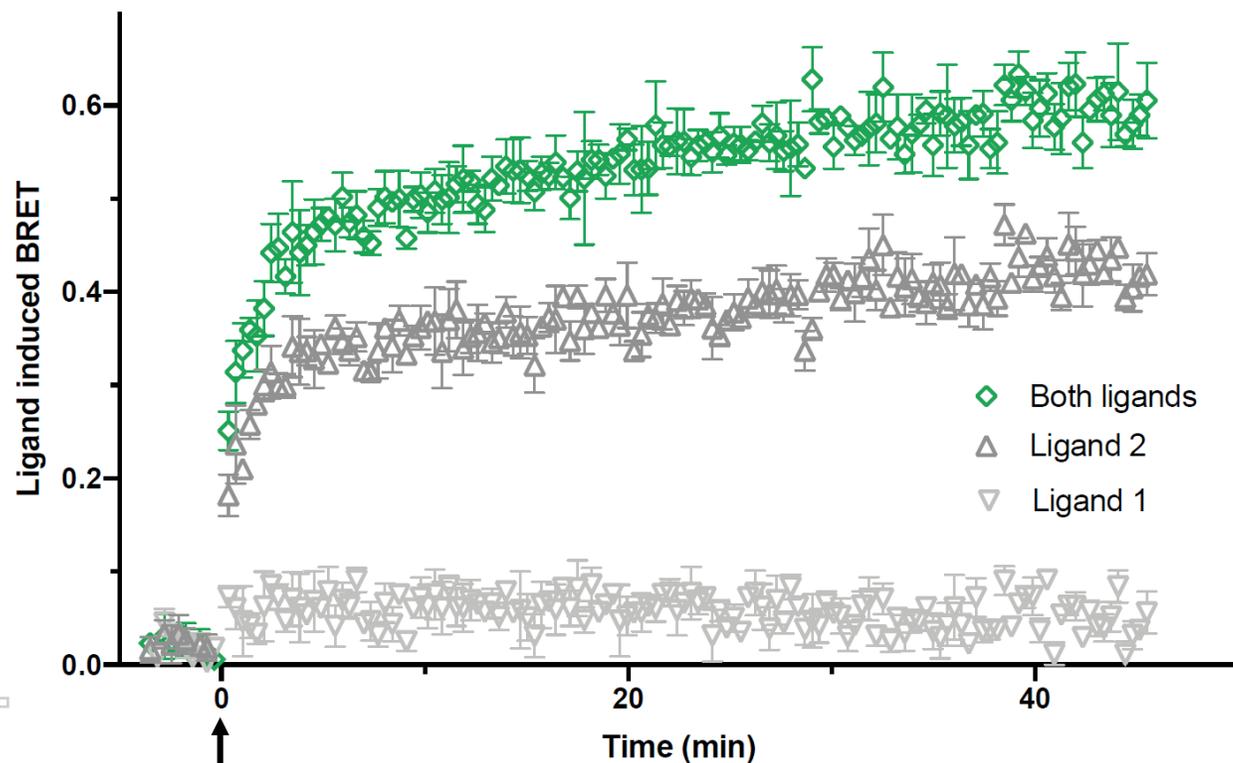
# DMX-700 proposed mechanism of action

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



When only Receptor 1 ligand administered:  
**signal observed**

When only Receptor 2 ligand administered:  
**larger signal observed**

When both Receptor ligands administered  
**More than additive signal observed**

DMX-700 targets blocking both receptors simultaneously in cells co-expressing receptor 1 and 2, to achieve a synergistic effect

# Key potential market advantages

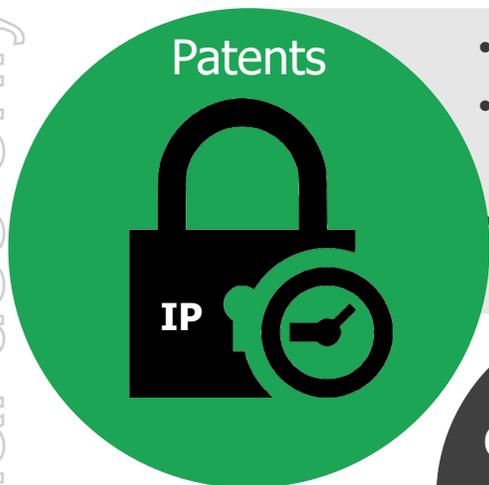
- DMX-700 is anticipated to give superior efficacy based on Receptor 1 and Receptor 2 heteromer activity being targeted simultaneously
- The safety profile of each active ingredient in DMX-700 is well understood:
  - lower risk than a new chemical entity that has not gone through an IND process

Clear unmet need

- Patients with COPD remain without any treatment that limits progression of the disease or controls exacerbations:
  - poor quality of life caused by the disease
  - poor side effect profile of key existing therapies
  - little treatment innovation in the COPD space for many years

# DMX-700 intellectual property position

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Patents

- Multiple prospects identified
- Final compound selection will be determined by the proposed further pharmacological and pre-clinical studies
- Proposed compounds each have well characterised safety and pharmacology profiles, although none are currently FDA approved

Composition of matter patent  
Granted



Specific compound will be announced during next phase of development  
Multiple potential compounds  
High confidence in securing desired compound

Formulation patent  
Planned



Method of Use patent  
Provisional patent filed

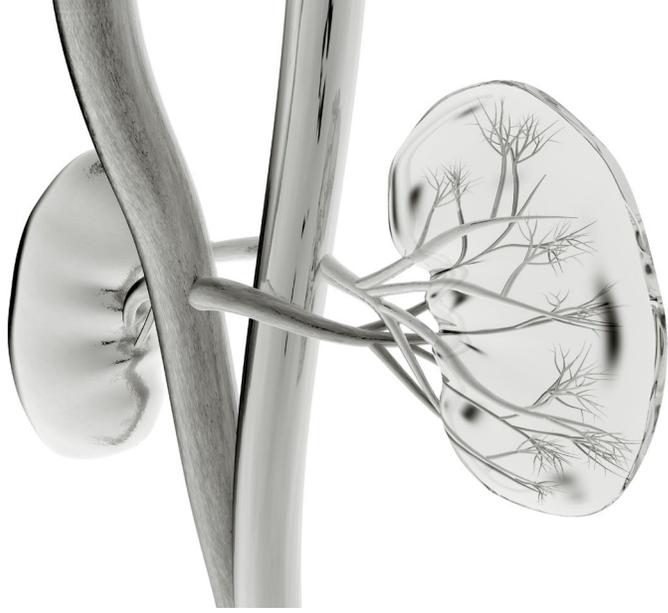


- New Chemical Entity can attract minimum 5 years exclusivity

# DMX-700 development plan

- Receptor targets and DMX-700 will remain undisclosed pending additional data and patent positioning
- Clearly delineated stage-gate development approach
- Known safety profile means reduced time to clinic
- Clinical studies planned within 2 years

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# DMX-200 Overview

# DMX-200 overview

DMX-200: a small molecule known as propagermanium

- Twice daily, capsule administration
- Administered to patients already on standard of care treatment (Irbesartan)
- Never been approved by a regulatory authority for clinical use in the US, Europe or Australia
  - DMX-200 is considered a New Chemical Entity\* (NCE)

**New Chemical Entity**  
Never been FDA  
approved

DMX has completed a Phase 1 and a Phase 2a clinical studies in kidney disease, providing clinically and statistically significant results:

- **36% reduction in proteinuria (in addition to the 24% reduction seen with irbesartan)**

Compelling data encouraged Dimerix to progress into 2 Phase 2 clinical studies:

- Phase 2 in Focal Segmental Glomerulosclerosis (FSGS) – an orphan indication
- Phase 2 in Diabetic Kidney Disease

# Phase 2 trial in Diabetic Kidney Disease

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## DMX-200 in Diabetic Kidney Disease (DKD)

Progressive disease, leading to kidney failure and blood dialysis

23 million diagnosed diabetics in the US\*

Diabetes incidence estimated to grow 54% by 2040†

>20% of diabetics had 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



	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				

Study completion anticipated Q2 2020 (calendar year)

# Phase 2a trial in FSGS

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Faster path to market with set market exclusivity period

## DMX-200 in Focal Segmental Glomerulosclerosis (FSGS)

Serious and rare kidney disease: orphan indication

~210,000 individuals affected globally

>93,000 patients on kidney transplant waiting list in US

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



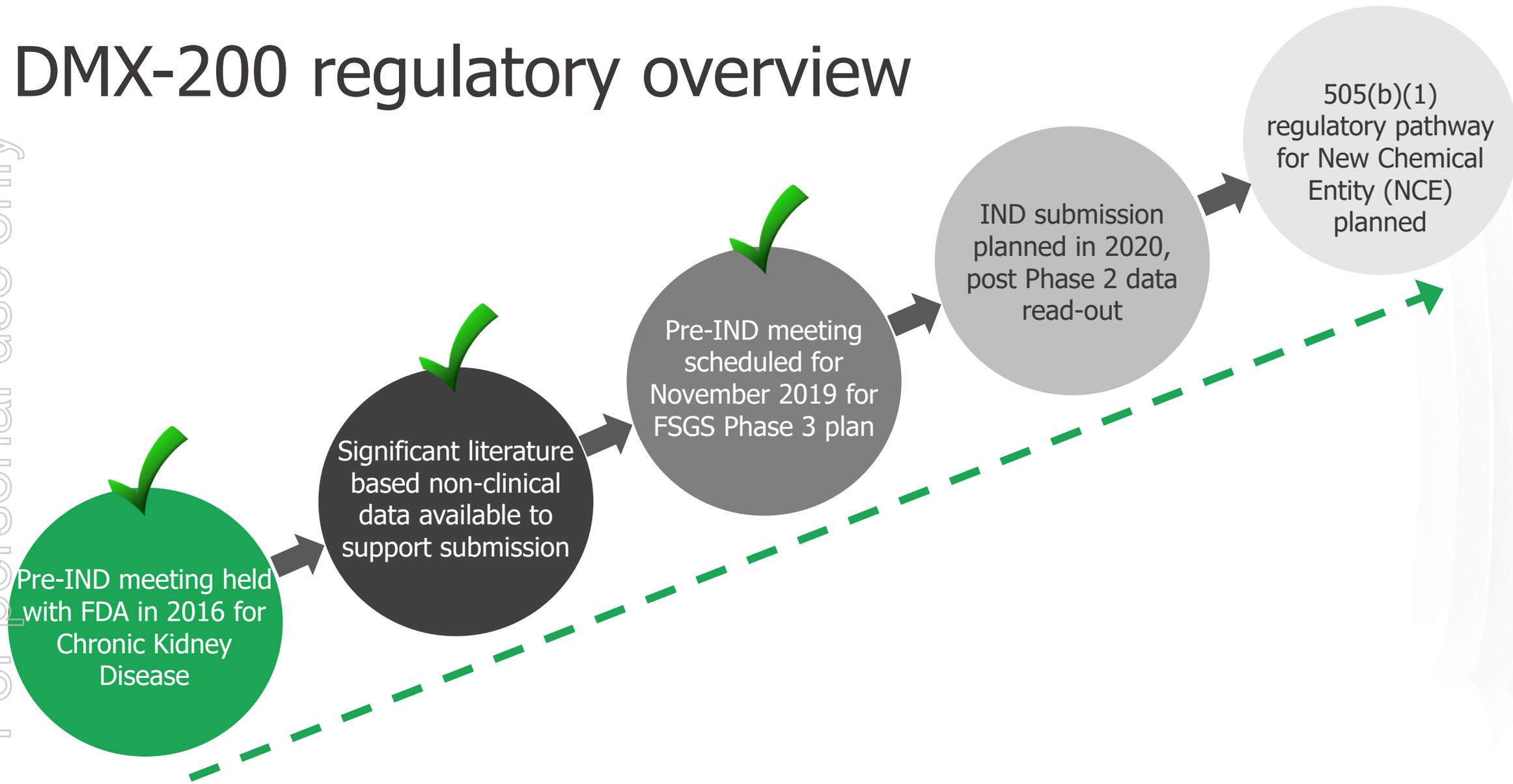
- Double-blind, randomised, placebo-controlled, crossover study evaluating the safety and efficacy of DMX-200 in patients with FSGS who are receiving a stable dose of Irbesartan

	Study period 1 16 weeks	Washout 6 weeks	Study Period 2 16 weeks	Results
Group 1 (n=5)	DMX-200		Placebo	
Group 2 (n=5)	Placebo		DMX-200	
Irbesartan 300mg				

Study completion anticipated Q2 2020 (calendar year)

# DMX-200 regulatory overview

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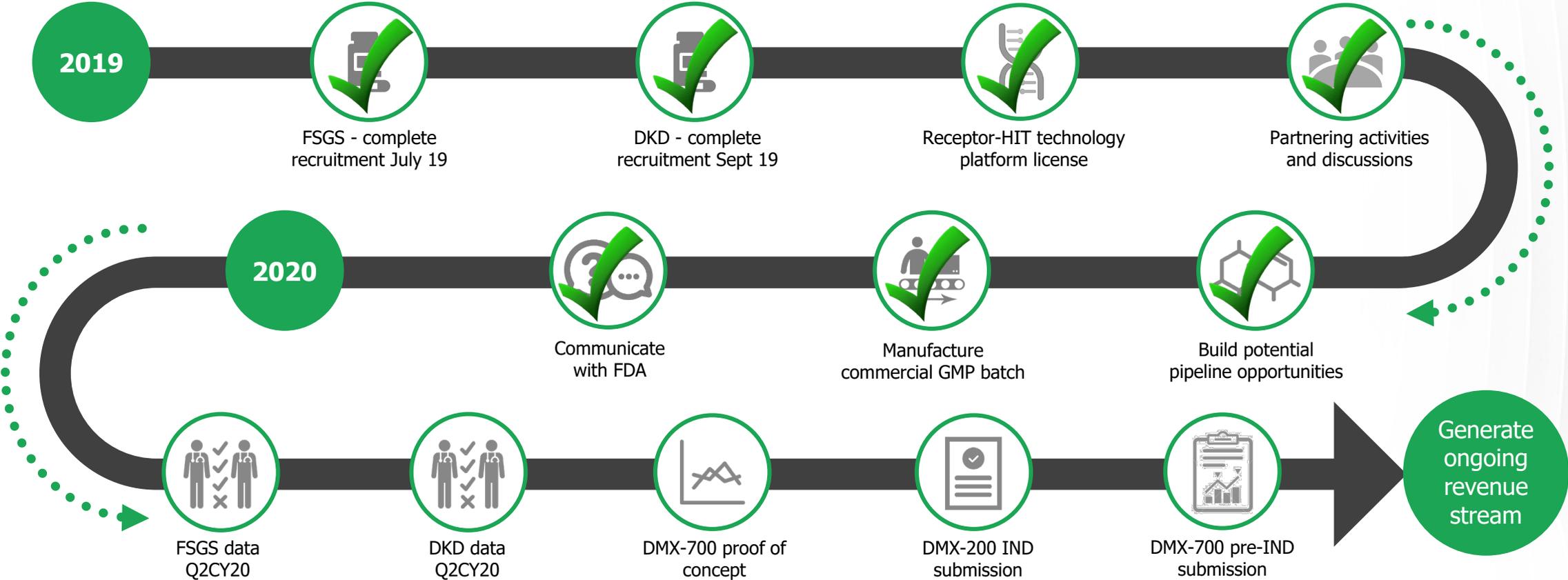


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Summary

# Dimerix value creation

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End of Presentation



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