

## **DIMERIX DATA DEMONSTRATING DMX-700 EFFECT ON KEY COPD RECEPTORS**

- Treatment with DMX-700 shown to inhibit signalling of key receptors associated with COPD
- Studies independently carried out by The University of Western Australia and by Excellerate Bioscience laboratories in the UK
- DMX-700 development continues to progress towards clinical development phase
- Research supported by Australian Government Innovation Connections grant awarded to Dimerix and The University of Western Australia November 2019
- PCT patent application protecting Dimerix's DMX-700 intellectual property has been filed
- DMX-700 data to be presented at leading global industry conference Drug Discovery Digital on 8 October 2020

MELBOURNE, Australia, 7 October 2020: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, today announced additional positive in vitro data to support further development of its drug candidate DMX-700 to treat chronic obstructive pulmonary disease (COPD), the fourth-leading cause of death in the world.

The DMX-700 drug candidate has been shown to block Interleukin 8 receptor beta (IL-8R $\beta$ , also known as CXCR2) and angiotensin II receptor type 1 (AT1R) that have been independently implicated in the pathophysiology of COPD. Novel findings on molecular pharmacology profiling, using a number of techniques including using Receptor-HIT, has demonstrated that the DMX-700 drug candidate abolished receptor signalling involved in neutrophil recruitment.

IL-8 is produced by epithelial cells, airway smooth muscle cells and endothelial cells, and in many chronic inflammatory diseases including COPD, is expressed at elevated levels leading to abnormal recruitment of neutrophils that cause damage to the lung tissue. Prior studies have shown that inhibiting signalling of IL-8R $\beta$  reduces neutrophil movement and subsequently reduces mucus production and inflammation in COPD.

### **IL-8 & AngII receptors implicated in COPD**

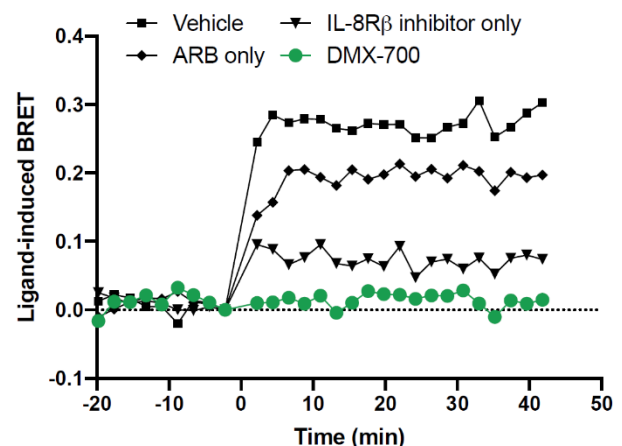


Figure 1: DMX-700 inhibits both the IL-8R $\beta$  and AT1R signal, as measured by ligand-induced BRET

Clinical studies run by other parties investigating the efficacy of IL-8R $\beta$  inhibitors alone in the treatment of COPD have been disappointing to date. However, using its proprietary heteromer identification and characterisation platform, Receptor-HIT, Dimerix identified the heteromer nature of the IL-8R $\beta$  with AT1R and has discovered that simultaneous inhibition of both receptors may significantly improve treatment efficacy for patients with COPD.

Funded in part by an Australian Government Innovation Connections grant with The University of Western Australia, studies were conducted on behalf of Dimerix by the laboratory of Professor Kevin Pflieger, Director Biomedical Innovation at The University of Western Australia, Head of Molecular Endocrinology and Pharmacology at the Harry Perkins Institute of Medical Research, Deputy Director of the Australian Research Council Centre for Personalised Therapeutics Technologies, and Chief Scientific Advisor to Dimerix, as well as independently by Excellerate Bioscience Pty Ltd, a UK-based pharmacological assay service provider with a worldwide reputation for excellence in molecular and cellular pharmacology.

Professor Pflieger will present some of the technical DMX-700 data on the IL-8R $\beta$  and AT1R heteromer interaction on 8 October 2020 as part of the *GPCRs in drug discovery* session hosted by the British Pharmacological Society at *Drug Discovery Digital*, a virtual conference being held online 6-16 October 2020. Professor Pflieger's slides will be made available on the Dimerix website prior to his presentation (<https://investors.dimerix.com/investor-centre/?page=presentations-webcasts>).

The DMX-700 development plan will continue to progress towards the clinical phase, with in vivo assessment in an appropriate COPD model to confirm in vitro observations in relevant pre-clinical models of the disease. The components of DMX-700 have a known safety profile in human studies, meaning an accelerated clinical development path can be pursued once in vivo efficacy is demonstrated. As a G Protein-Coupled Receptor (GPCR) targeting candidate, Dimerix can use its current core competencies and expertise in GPCRs to execute on this opportunity.

Dimerix has now lodged a PCT patent application for the treatment, amelioration or prevention of COPD with DMX-700. The PCT global patent application, number [PCT/AU2020/050987], has a filing date of 18 September 2020 and a priority date of 26 September 2019 and once granted would expire post 2040. The DMX-700 drug candidate details will remain undisclosed pending additional data and patent positioning.

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

COPD is a progressive and life-threatening lung disease. The most common 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, which equates to 5% of all deaths globally in that year (*WHO Factsheet – Chronic Obstructive Pulmonary Disease*). 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 Institutes of Health (NIH) and globally by the World Health Organization (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.

In addition to the DMX-700 in Chronic Obstructive Pulmonary Disease program, Dimerix continues to work on its late stage FSGS and diabetic kidney disease renal clinical programs and a study in patients with Acute Respiratory Distress Syndrome associated with COVID-19.

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

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*Authorised for lodgement by the Board of the Company*

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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 Diabetic Kidney Disease, Focal Segmental Glomerulosclerosis (FSGS) and Acute Respiratory Distress Syndrome (ARDS), as well as DMX-700 for Chronic Obstructive Pulmonary Disease (COPD). DMX-200 and DMX-700 were both 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 hypertension and kidney disease. DMX-200 is protected by 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 stable 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). DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

It is estimated that 40% of people with diabetes have kidney disease and many may not know it yet. With the incidence of diabetes growing so rapidly globally, so too will the incidence of kidney disease. This is a rapidly growing market, with few treatment options at this time. Dimerix reported statistically and clinically significant outcomes in a Phase 2 study in diabetic kidney disease patients in September 2020.

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. Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

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 most common cause of COPD is exposure to tobacco smoke (either active smoking or secondary smoke), however it 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 PCT patent application for DMX-700. Dimerix DMX-700 development plan continues to progress towards the clinical phase, with some further in vivo assessment in an appropriate COPD model to confirm target engagement, pharmacokinetics and pharmacodynamics in support of a robust product development pathway and patent position.