



**Immediate Release**

## **HALF-YEAR REPORT TO 31 DECEMBER 2019**

MELBOURNE, Australia, 19 February 2020: Dimerix Limited (ASX: DXB), a clinical-stage drug development company, today released its Financial Report for the half-year ended 31 December 2019, along with an update on Dimerix' two Phase 2 clinical studies in the areas of kidney Disease: DMX-200 for Diabetic Kidney Disease; and DMX-200 for Focal Segmental Glomerulosclerosis (FSGS).

### **Financial Results:**

- Research and development expenditure of \$2,512,510 (31 December 2018: \$1,208,849)
- Corporate and administration expenses of \$611,504 (31 December 2018: \$695,167)
- Cash reserves at 31 December 2019: \$3.85 million

### **2019 Half-year Highlights**

- FSGS Phase 2a study last patient dosing scheduled in June 2020, and top line data anticipated shortly thereafter
- Diabetic Kidney Disease Phase 2 study last patient dosing scheduled in July 2020, and top line data anticipated shortly thereafter
- DMX-700 for Chronic Obstructive Pulmonary Disease (COPD) pre-clinical studies initiated
- R&D Tax Incentive of \$1.18 million received in October 2019
- Dimerix Awarded Second Innovation Connections Grant
- Dimerix held pre-IND meeting on DMX-200 with FDA in November 2019
- \$2.5 million placement to new and existing sophisticated investors completed in December 2019
- Confirmation that the Diabetic Kidney Disease Phase 2 study is sufficiently powered to determine a statistically significant result
- Additional patents granted for DMX-200 in United States and Europe

Dimerix has two Phase 2 studies currently underway: DMX-200 for FSGS; and DMX-200 for Diabetic Kidney Disease, and an asset in pre-clinical development: DMX-700 for COPD. The two Phase 2 clinical studies are both double-blind, randomised, placebo-controlled, crossover studies, evaluating the safety and efficacy of DMX-200 in patients who are receiving Irbesartan, the current standard of care for both FSGS and Diabetic Kidney Disease. The Phase 2 trial outcomes in FSGS and in Diabetic Kidney Disease are both anticipated mid-2020, both of which represent a major clinical milestone for Dimerix.

Multiple patients from the phase 2 trial conducted in 2017 continue to be treated with DMX-200 via the Therapeutic Goods Association's Special Access Scheme, which is a strong indication of the benefits DMX-200 provides for kidney disease patients.

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

**Dimerix HQ**  
425 Smith St, Fitzroy 3065  
Victoria, Australia  
T. 1300 813 321  
E. [info@dimerix.com](mailto:info@dimerix.com)



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

Dr Nina Webster, Dimerix Limited  
Chief Executive Officer  
Tel: 1300 813 321  
E: [investor@dimerix.com](mailto:investor@dimerix.com)

*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 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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425 Smith St, Fitzroy 3065  
Victoria, Australia  
T. 1300 813 321  
E. [info@dimerix.com](mailto:info@dimerix.com)



#### **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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