

### **Immediate Release**

## **HALF-YEAR REPORT TO 31 DECEMBER 2020**

MELBOURNE, Australia, 22 February 2021: Dimerix Limited (ASX: DXB), a clinical-stage drug development company, today released its Half-Year Financial Report for the half-year ended 31 December 2020.

#### **Financial Results:**

- Research and development expenditure of \$3,657,253 (31 December 2019: \$2,512,510)
- Corporate and administration expenses of \$717,861 (31 December 2019: \$611,504)
- Cash reserves at 31 December 2020: \$4.9 million

## 2020 Half-year Highlights

- Last patient completed dosing in DKD Phase 2 clinical study in July 2020
- Positive top-line results in FSGS Phase 2a clinical study announced in July 2020
- Dimerix awarded \$1 Million MRFF funding towards study in COVID-19 Patients in September 2020
- Positive top-line results in DKD Phase 2 clinical study announced in September 2020
- \$2.3 million R&D Tax Incentive received in October 2020
- DMX-700 data demonstrated effect on key COPD receptors in October 2020
- Positive additional data to support DMX-200 development announced in October 2020
- Acute Respiratory Disease Syndrome in COVID-19 Patients protocol published in November 2020
- Second Study to include DMX-200 in COVID-19 Patients announced in November 2020
- Dimerix plans for next study in diabetic kidney disease announced in January 2021

Dimerix continues to undertake planning for the proposed Phase 3 pivotal program in FSGS, a rare kidney disorder without an approved pharmacologic treatment that often leads to end-stage kidney failure, as well as further progress two Phase 3 studies of DMX-200 in COVID-19 patients, assess the next study design in diabetic kidney disease patients and finally advance the COPD program towards the clinical stage of development.

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Authorised for lodgement by the Board of the Company



### **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 which reduces inflammation when 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.