

DMX-700 Program for Chronic Obstructive Pulmonary Disease Advances

- Mechanism of Action data further supports DMX-700 rationale in Chronic Obstructive Pulmonary Disease
- DMX-700 progresses to next stage of development
- Phase 2a study top line results in FSGS expected by end of July 2020
- Last patient in Phase 2 study in diabetic kidney disease scheduled to receive last dose in July 2020, with data shortly thereafter
- Dimerix continues to work closely with REMAP-CAP to support global study protocol that includes DMX-200 for Acute Respiratory Distress Syndrome (ARDS) caused by COVID-19

MELBOURNE, Australia, 06 July 2020: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, today announced an update to the DMX-700 program for Chronic Obstructive Pulmonary Disease (COPD), which has continued to progress in the background to the advancements in the two DMX-200 in renal programs and Acute Respiratory Disease Syndrome (ARDS) associated with COVID-19.

The DMX-700 program has made further advances in understanding the mechanism by which the, as yet undisclosed, receptors may be contributing to the lung damage associated with COPD. Specifically, the new data indicates that due to the functional interaction of the receptors identified using Dimerix' proprietary Receptor-HIT discovery tool, there is an increased presence and activation of the receptor complex at the cell surface which is expected to result in an increased pro-inflammatory effect. This understanding now allows the DMX-700 program to move to the next stage of development being the optimisation of the DMX-700 drug product candidate to limit signalling of these receptors, as well as progressing towards the in vivo dose ranging studies required prior to entering the clinical phase. Importantly, this new understanding of the fundamental biology of these receptors in COPD is also enabling Dimerix to further support and expand the DMX-700 intellectual property portfolio and patent positioning.

COPD is a progressive and life-threatening lung disease and is the fourth-leading cause of death in the world. Although treatments exist to assist with symptoms of COPD, there is currently no way to slow progression of the condition or cure it. As such, there is a significant unmet need in COPD which is recognised by key organisations such as the National Institutes of Health (NIH), 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

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. investor@dimerix.com

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.

“It is very pleasing to report that our program for Chronic Obstructive Pulmonary Disease has been making strong progress in the background to our three clinical phase programs, with all programs advancing despite COVID-19,” said Dr Nina Webster, CEO & Managing Director of Dimerix. “Dimerix has a strong product portfolio, all in commercially attractive and growing markets that have a high unmet need”.

In addition to the DMX-700 in COPD program, Dimerix has two Phase 2 clinical studies underway: DMX-200 for FSGS (top line data expected before the end of July 2020); and DMX-200 for Diabetic Kidney Disease (last patient scheduled to receive last dose in July 2020), and a recently added new global pivotal phase opportunity: DMX-200 in Acute Respiratory Distress Syndrome (ARDS) in patients with COVID-19.

For further information, please visit our website at www.dimerix.com or contact:

Dr Nina Webster, Dimerix Limited
Chief Executive Officer & Managing Director
Tel: +61 1300 813 321
E: investor@dimerix.com

Rudi Michelson
Monsoon Communications
Tel: +61 3 9620 3333
Mob: +61 (0)411 402 737
E: rudi@monsoon.com.au

Authorised for lodgement by the Board of the Company

—END—

About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company developing innovative new therapies in areas with unmet medical needs for global markets. In addition to this announcement, Dimerix is currently developing its proprietary product DMX-200 for Diabetic Kidney Disease, Focal Segmental Glomerulosclerosis (FSGS) and Acute Respiratory Distress Syndrome (ARDS). 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 hypertension and kidney disease. DMX-200 is protected by Dimerix' 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).

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.

DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

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 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 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.