

LAST PATIENT COMPLETES DOSING IN DIMERIX FSGS PHASE 2 CLINICAL STUDY

- **Patient dosing completed in Phase 2a clinical study of DMX-200 in FSGS patients**
- **No serious adverse events related to the drug reported to date**
- **Top line results 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, 17 June 2020: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, is pleased to advise that the last patient has completed dosing in its clinical study in Focal Segmental Glomerulosclerosis (FSGS). No serious adverse events related to the drug have been reported to date and Dimerix expects to provide top line results for the study by end of July 2020.

The Phase 2a study is a double-blind, randomised, placebo-controlled, crossover study designed to evaluate the safety and preliminary signs of efficacy of DMX-200 in patients with FSGS who are receiving a steady dose of an angiotensin receptor blocker, irbesartan. As previously announced, each participant in the study received 16 weeks DMX-200 and 16 weeks placebo, separated by a 6-week washout period.

The primary endpoint for the study is safety, as measured by the number and severity of adverse events and clinically significant changes in the patient safety profile with the use of DMX-200 compared to placebo in participants with FSGS who are receiving irbesartan. The secondary endpoints include efficacy measures such as the percent change from baseline in 24-hour protein to creatinine ratio after 16-weeks of treatment with DMX-200 as compared to placebo and the proportion of patients who achieve a pre-defined reduction in proteinuria during treatment with DMX-200 as compared to placebo.

Importantly, Dimerix has facilitated continued compassionate access to DMX-200 for multiple patients who have completed the study via their physician through the TGA Special Access Scheme.

Focal Segmental Glomerulosclerosis is a serious and rare inflammatory disease that attacks the kidney's filtering units (glomeruli) causing scarring of the tissues, leading to permanent kidney damage and kidney failure. FSGS affects children and adults. There are no treatments currently approved for the treatment of FSGS and a strong unmet medical need.

Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for the treatment of FSGS. Dimerix established with the respective regulatory agencies that *"the intention to treat FSGS with DMX-200 was justified based on preliminary non-clinical data which showed a reduction in the number of podocytes lost and an improvement in proteinuria."* Furthermore, as stated by the respective regulatory agencies, the orphan designation indicates that *"Dimerix has provided sufficient justification that if approved, [DMX-200] is likely to be of significant benefit to those affected by the condition"* and that *"[DMX-200] would provide a clinically relevant advantage as an alternative to any currently marketed products."* Orphan designation also provides regulatory and financial benefits to help bring DMX-200 to market in the US and Europe faster, including reduced fees during the product development phase, protocol assistance from the regulatory authorities, and 7-year (US) and 10-year (Europe) market exclusivity following product approval.

Dimerix has two Phase 2 studies underway: DMX-200 for FSGS; and DMX-200 for Diabetic Kidney Disease (last patient scheduled to receive last dose in July 2020), an asset in pre-clinical development, DMX-700 for chronic obstructive pulmonary disease (COPD), and a recently added new 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:

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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. 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 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.