

DMX-200 CLINICAL TRIAL UPDATE

- The independent Safety Review Committee overseeing the Company's ongoing two Phase 2 studies has affirmed a positive recommendation that both trials continue without modification;
- 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.

MELBOURNE, Australia, 07 January 2020: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, today announced an update for their two Phase 2 clinical trials, including the outcome of the first independent safety review for both trials.

An independent Safety Review Committee, comprised of global experts in renal clinical research, has held two pre-planned meetings to review safety data from the patients enrolled in both the Phase 2a ACTION study in FSGS and the Phase 2 ACTION study in Diabetic Kidney Disease. The Committee did not identify any safety concerns in patients administered DMX-200 and unanimously recommended that the study continue as planned with the next meeting of the Committee to be held at the end of the study.

The FSGS study completed recruitment in July 2019, with the last patient dosed in September 2019 following final protocol screening. The study remains on track to complete final patient dosing in June 2020, with top line data anticipated shortly thereafter.

The Diabetic Kidney Disease study completed recruitment in September 2019, with the last patient dosed in January 2020 following final protocol screening. The study has successfully dosed an additional 5 patients, totalling 45 patients dosed with DMX-200, to ensure a study completion population of N=40 required for adequate statistical powering. Final patient dosing is scheduled for July 2020, with top line data anticipated shortly thereafter (previously anticipated Quarter 2).

"We are very pleased with the independent assessment of the safety and tolerability of DMX-200 and the overall progress made on the DMX-200 clinical development programs", commented Dr Nina Webster, CEO and Managing Director of Dimerix. "The data adds to the accumulating



favourable safety profile of DMX-200. We look forward to reporting the Phase 2 trial outcomes in FSGS and in Diabetic Kidney Disease later in 2020, both of which represents a major clinical milestone for Dimerix”.

With the phase 2 results for both studies due report shortly, the Company has attracted significant interest from major pharmaceutical companies globally. Dimerix CEO & Managing Director, Dr Nina Webster, will be attending the Biotech Partnering Showcase conference coinciding with JP Morgan Healthcare in San Francisco next week to follow up with companies expressing interest.

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

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*Authorised for lodgement by:
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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

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developing innovative new therapies in
areas with unmet medical needs

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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.

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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