



Immediate Release

## HALF-YEAR REPORT TO 31 DECEMBER 2018 & DMX-200 CLINICAL TRIALS UPDATE

MELBOURNE, Australia, 26 February 2019: Dimerix Limited (ASX: DXB), a clinical-stage drug development company, today released its Half-Year Financial Report for the half-year ended 31 December 2018, along with an update on the 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 – Operating Loss and Cash Position:

- Operating loss for the half-year ended 31 December 2018: \$1.76 million (2017: \$1.86 million)
- Cash reserves at 31 December 2018: \$5.3 million

ACTION for FSGS Phase 2 clinical trial update:

- 70% patients have been recruited into the trial
- Patient enrolment is on track for dosing completion in Q4'2019

ACTION for Diabetic Kidney Disease Phase 2b clinical trial update:

- 25% patients have been recruited into the trial
- Patient enrolment is on track for dosing completion in Q4'2019

Dimerix is pleased to advise that 7 patients have been recruited into the 10 patient Phase 2 clinical trial in FSGS, and 10 patients into the 40 patient Phase 2b clinical trial in Diabetic Kidney Disease. No serious adverse safety related events have been reported to date in either trial. The recruitment rate for each trial picked up significantly in February, following the December/January holiday period where many sites were closed, and we hope to maintain this momentum moving forward. Dimerix will provide additional recruitment updates in due course.

The two 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. Clinical trial sites were initiated, and patient recruitment commenced in September, and patient dosing has occurred in line with anticipated timelines.

Multiple patients from the phase 2 trial 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 patients in reducing proteinuria.

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

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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.

### 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 trial 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 trials 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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