For Immediate Release

DMX-200 PHASE 2 CLINICAL STUDY IN DIABETIC KIDNEY DISEASE COMPLETES RECRUITMENT

MELBOURNE, Australia, 26 September 2019: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, is pleased to announce that enrolment has been completed for its Phase 2 study of DMX-200 in patients with Diabetic Kidney Disease. The primary end point for the study is the percent reduction in albuminuria (protein in the urine) compared to baseline. Furthermore, an independent statistician has reviewed the variance in baseline data acquired to date and has confirmed that the trial is sufficiently powered to determine a statistically significant result.

The Phase 2 study is a double-blind, randomised, placebo-controlled, crossover study designed to evaluate the efficacy and safety of DMX-200 in patients with Diabetic Kidney Disease who are receiving a stable dose of irbesartan. Each participant will receive 12 weeks of the study drug, DMX-200, and 12 weeks placebo, separated by a 6-week washout period. Clinicians at the study sites have reported no safety concerns to date, and Dimerix expects to complete the study in the second quarter of calendar year 2020.

The Phase 2 study follows on from a successful Phase 2a study completed in 2017 in patients with a range of chronic kidney diseases. The 2017 study met all primary and secondary endpoints, as well as showing particularly compelling efficacy in the sub-group of patients with diabetic kidney disease.

There were 23 million diagnosed diabetics in the US in 2017, and the incidence of diabetes is estimated to grow by 54% by the year 2040. Approximately 20% of all diabetics suffer from kidney disease, which is a progressive disease leading to kidney failure which requires dialysis. There is no cure for diabetic kidney disease, and current treatment options are ineffective as the kidneys deteriorate towards failure. The current treatment options include medications to reduce high blood pressure, dialysis or kidney transplant. The progressive nature of kidney disease inevitably results in poor outlook for patients, as it most often results in a poor quality of life and total kidney failure. Dialysis costs are in the region of US$100,000 per patient per year and consume in excess of 12 hours per week in regular clinic visits. Alternatively, a kidney transplant costs in the region of US$260,000 per patient, with ongoing and expensive anti-rejection drugs also costing thousands of dollars per year. These options are a huge burden on both the patient and the healthcare system. DMX-200 has the potential to significantly increase the life of the kidney, reducing the burden for both the patient and the healthcare system.

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In parallel to the clinical trials, Dimerix continues with activities to support future regulatory submissions, including manufacturing validation and commercial scale up activities that are now underway, along with plans for the commercialisation phase.

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