

DIMERIX FULLY RECRUITED FOR DMX-200 PHASE 2 CLINICAL TRIAL IN FSGS

MELBOURNE, Australia, 10 July 2019: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, is pleased to announce that its Phase 2a study of DMX-200 in patients with Focal Segmental Glomerulosclerosis (FSGS) is now fully recruited, with all 10 patients enrolled.

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 irbesartan. As previously announced, each participant in the study will receive 16 weeks DMX-200 and 16 weeks placebo, separated by a 6-week washout period. The first patient is expected to complete treatment in August 2019 and Dimerix will facilitate continued access to DMX-200 via their physician through the TGA Special Access Scheme. Clinicians at the study sites have reported no safety concerns to date, and Dimerix expects to report study results in the second quarter of calendar year 2020.

Focal Segmental Glomerulosclerosis is a serious and rare disease that attacks the kidney's filtering units (glomeruli) causing scarring of the tissues, leading to permanent kidney damage and kidney failure. FSGS affects both children and adults. There are no treatments currently approved for the treatment of FSGS and thus there is 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 is a biopharmaceutical company developing innovative new therapies in areas with unmet medical needs

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“The completion of recruitment is an important milestone for this study and for the many medical professionals and patients seeking treatment for such a rare disease who often have very few medical options,” said Dr Nina Webster, CEO and Managing Director of Dimerix. “Good progress is being made on our FSGS program, and we look forward to reporting at the completion of the clinical phase of the study.”

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.

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