For Immediate Release

DIMERIX RECEIVES ORPHAN DRUG DESIGNATION IN THE EUROPEAN UNION FOR DMX-200 IN FSGS

MELBOURNE, Australia, 21 November 2018: Dimerix Limited (ASX: DXB), a clinical-stage drug development company, announced today that the European Commission has designated DMX-200 as an orphan medicinal product for the treatment of Focal Segmental Glomerulosclerosis (FSGS), a type of Chronic Kidney Disease. The European Commission's approval follows a positive opinion in October from the European Medicine Agency's (EMA) Committee for Orphan Medicinal Products (COMP).

FSGS is a 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. Receiving Orphan Drug Designation (ODD) in Europe for FSGS means that Dimerix has established 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*."[1] Furthermore, the EMA has determined that Dimerix has "*provided sufficient justification for the assumption that [DMX-200] will be of significant benefit to those affected by the condition,"* and that, as an alternative to currently marketed products, *"this constitutes a clinically relevant advantage*".[1]

ODD provides regulatory and financial benefits to help bring DMX-200 to market in Europe quicker, including reduced fees during the product development phase, direct access to centralised marketing authorisation in Europe, and 10-year market exclusivity following product approval. Dimerix now has ODD for the European and United States markets; DMX-200 was granted ODD from the United States Food and Drug Administration (FDA) in December 2015.

Dimerix is currently enrolling patients for two separate, concurrent Phase 2 clinical programs; DMX-200 for FSGS; and DMX-200 for Diabetic Kidney Disease (patients with this type of kidney disease showed a clinically and statistically significant efficacy response in an initial Phase 2a clinical study concluded in 2017).

"The European Commission's decision to grant orphan drug designation to DMX-200 for the treatment of FSGS is a key regulatory milestone that will further drive our clinical development program," said Dr Nina Webster, CEO of Dimerix. "We believe that DMX-200, which has already received orphan drug designation for the treatment of FSGS from the FDA in the United States, has the potential to provide a much-needed innovative therapeutic option for patients who have been diagnosed with FSGS."

European orphan framework

Orphan designation is granted in Europe to drugs intended for the treatment of life-threatening or

---

[1] *The EMA Decision will be published in the near future in the Community Register of Orphan Medicinal Products (http://ec.europa.eu/health/documents/community-register/html/orphreg.htm)*

chronically debilitating diseases that affect no more than five in 10,000 people in the European Union and for which no satisfactory treatments are available, or where the new therapy has the potential to be a significant benefit to those affected by the disease.

DMX-200 study for FSGS

The Phase 2a study for FSGS will enroll 10 eligible patients, who will receive 2 treatment blocks of 16 weeks (separated by a 6 week washout period) during which they will receive either placebo or DMX-200 in the first treatment block, and switched to the alternative in the second treatment block. Every patient must also be receiving 300 mg daily of Irbesartan for at least 3 months prior to screening, so that any reduction in proteinuria seen in the trial can be solely attributed to DMX-200.

Subject to patient recruitment rates, preliminary results are anticipated for both studies in Q4 calendar year 2019.

For further information, please visit our website at www.dimerix.com or contact the individuals outlined below.

—END—

At the Company
Dr Nina Webster, Dimerix Limited
Chief Executive Officer
Tel: 1300 813 321
E: investor@dimerix.com

Investor Relations
Glen Zurcher, IR Department
Account Director
Tel: +61 420 249 299
E: glen.zurcher@irdepartment.com.au

About Dimerix Bioscience Pty Ltd

Dimerix Limited's (ASX: DXB) wholly owned subsidiary Dimerix Bioscience Pty Ltd is a dynamic, clinical-stage drug development company, developing and commercialising patient-preferred and patent protected pharmaceutical products for global markets. Dimerix is currently developing its product DMX-200 for both Diabetic Kidney Disease and Focal Segmental Glomerulosclerosis (FSGS). DMX-200 was identified using Dimerix' proprietary assay, termed 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.