ASX/Media Release **14 December 2015**

Dimerix Limited receives Orphan Designation for its lead drug candidate targeting patients with chronic kidney disease

Melbourne AUSTRALIA, 14 December 2015: Dimerix Limited (ASX: DXB) today announced it had received Orphan Designation from the United States Food and Drug Administration (FDA) for propagermanium and irbesartan, the constituent parts of its drug candidate DMX-200 for the treatment of a condition known as focal segmental glomerulosclerosis (FSGS), a leading cause of chronic kidney disease, which is a serious medical condition.

There are no therapies currently approved by the FDA for FSGS. Patients with FSGS who progress to kidney failure and receive a kidney transplant, have a 30 to 40 per cent chance of the condition reoccurring. The individual components of the name FSGS refer to the appearance of the kidney tissue on biopsy.

The Orphan Drug Designation program provides orphan status to drugs which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases and disorders that affect fewer than 200,000 people in the US, or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug.

Orphan Drug Designation qualifies the sponsor for seven-year FDA-administered market Orphan Drug Exclusivity (ODE) on successful approval of the drugs. It also qualifies the sponsor for various regulatory and financial support measures as the treatment progresses through pre-clinical and clinical development in the US.

Dimerix Limited Executive Chairman Dr James Williams said, “Securing Orphan Designation for our lead program represents an important step in our strategy for the rapid commercial development of DMX-200 for the treatment of chronic kidney disease. We expect this orphan designation, when combined with pending data from our current Phase II trial in Australia, will help accelerate our current clinical and commercial development path in the important US medical market.”

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The DMX-200 Phase II Trial

The trial is a single arm, open label trial in adult patients with chronic kidney disease (with proteinuria). The primary end points are the incidence and severity of adverse events and the clinically significant changes in the safety profile of participants. The secondary end points are obtained from statistical analysis of biomarker data at each time point including change from baseline, and the proportion of responders defined as those participants achieving normalisation of proteinuria (proteinuria within normal limits) or those participants achieving a 50% reduction in proteinuria. The trial has two parts, Part A is a dose escalation trial recruiting up to 30 patients. All patients recruited to the trial will be on stable irbesartan therapy, and will be treated with propagermanium dosed orally three times per day. Each patient will commence on 30mg PPG/day and the dose increased each 28 days to a maximum of 240mg/day, or until proteinuria is absent or reduced to a level the clinician considers acceptable.

The Company expects to carry out an interim analysis of the Part A data to confirm the safety of the therapy and observe any biomarker changes on up to 15 patients. It is expected interim data will be available by mid 2016.

Part B is an expansion study, in which up to 30 patients are recruited on the best dose identified from Part A. The company expects to review the design of Part B in consultation with the FDA and in light of all data available to the company, prior to commencement of Part B. These discussions will be in line with the company's strategy of pursuing registration for an orphan indication in which the sufferers exhibit chronic kidney disease. The company has achieved orphan designation for Focal Segmental Glomerulosclerosis (FSGS) from the FDA. The trial has commenced at four sites in Melbourne, Australia, and may be expanded into other jurisdictions to meet recruitment targets and regulatory goals.

Chronic Kidney Disease

Chronic kidney disease can result from diabetes, high blood pressure and diseases that cause inflammation specifically in the kidneys. Proteinuria is the most common manifestation of the disease. As the disease progresses it can lead to end-stage renal disease (ESRD) where the kidneys fail. The only treatment for ESRD is a kidney transplant or regular blood-cleansing treatments called dialysis. More than 26 million people suffer from the disease in the United States.

Focal Segmental Glomerulosclerosis

Focal segmental glomerulosclerosis (FSGS) is a rare disease which causes scarring in the part of the kidney which filters blood (glomeruli) and is one of the most common causes of primary (or idiopathic) glomerular diseases in adults. The condition causes asymptomatic proteinuria or nephrotic syndrome. Generally, FSGS is a progressive form of kidney disease, accounting for 2.3% of patients with end-stage renal disease (ESRD). FSGS can re occur in 30-40% of patients who receive a kidney transplant.

DMX 200

DMX-200 combines two existing drugs, irbesartan and propagermanium. Irbesartan is an off-patent angiotensin II type I receptor blocker indicated for the treatment of hypertension and nephropathy in Type II diabetic patients. Propagermanium (PPG) is a chemokine receptor (CCR2) blocker, which has been used for the treatment for Hepatitis B. DMX-200 has been shown to improve the outcome of chronic kidney disease by reducing proteinurea by more than 50 per cent in animal models.

Dimerix Bioscience Limited

Dimerix Limited's wholly owned subsidiary Dimerix Bioscience Limited is a clinical-stage pharmaceutical company committed to discovering and developing new therapeutic paradigms identified using its proprietary screening assay, termed Receptor-Heteromer Investigation Technology (Receptor-HIT). This assay enables the identification of pairs of receptors that function in a joint manner (interact) when ligands, small molecule drugs, peptides or antibodies, bind to them. The Receptor-HIT technology was used to identify DMX-200 and an internal drug development program, initially for the treatment of a subset of patients with chronic kidney disease. In addition to its own therapeutic programs, the company also earns revenue by providing this technology to global pharmaceutical firms.

(1) Functional interaction between angiotensin II receptor type 1 and chemokine (C-C motif) receptor 2 with implications for chronic kidney disease.

Ayoub MA, Zhang Y, Kelly RS, See HB, Johnstone EK, McCall EA, Williams JH, Kelly DJ, Pfleger KD.
PLoS One. 2015 Mar 25;10(3):e0119803. doi: 10.1371/journal.pone.0119803. eCollection 2015.