

For Immediate Release**ASX/Media Release****Dimerix key patent allowed in Japan for use of lead drug candidate in the treatment of kidney disease**

MELBOURNE, Australia, 31 January 2017: Dimerix Limited (ASX: DXB), a clinical stage biotechnology company committed to discovering and developing new therapeutic treatments identified using its proprietary screening assay, today announced the Japanese Patent Office has allowed a key patent covering the use of its lead compound DMX-200 for the treatment of kidney disease.

The allowed claims under Japanese patent application no. 2013-547780, entitled “Combination Therapy” cover the use of the chemokine receptor blocker propagermanium and angiotensin receptor blocker (ARB), irbesartan, to be used in combination to treat a range of diseases. This Japanese Patent covers the adjunct therapy currently in clinical trials in Australia. Dimerix’s granted US and Australian patents contain claims which cover CCR2 antagonists and ARBs more broadly. Additional applications are pending in Japan.

Dimerix’s lead program, DMX-200, is currently in Phase II clinical trials for Chronic Kidney Disease (CKD) and has been granted US Orphan Drug Designation status for a condition called Focal Segmental Glomerulosclerosis (FSGS) which is a leading cause of kidney failure in adults.

DMX-200 has been shown to improve the outcome of chronic kidney disease by significantly reducing proteinuria in animal models of the disease. DMX-200 combines two existing drugs, a chemokine receptor blocker (propagermanium), used under prescription in Japan for treatment of hepatitis and available elsewhere as a dietary supplement, and an angiotensin receptor blocker (irbesartan), used for the treatment of hypertension.

Dimerix Chief Executive Officer Kathy Harrison said, “As we continue to meet our clinical and commercial milestones, this new patent will further strengthen Dimerix’s commercial and partnering potential in one of the world’s largest and most important markets for innovative new medical therapies.”

When granted the patent will provide exclusivity in Japan through to 2032.

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Dimerix Bioscience Pty Ltd

Dimerix Limited's wholly owned subsidiary Dimerix Bioscience Pty Ltd is a clinical-stage pharmaceutical company committed to discovering and developing new therapeutic models identified using its proprietary 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 in 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 companies. For more information see www.dimerix.com

DMX 200

DMX-200 is being developed as an adjunct therapy, adding propagermanium to a stable dose of irbesartan. 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 of Hepatitis B in Japan and is available in the USA for its anti-inflammatory properties. DMX-200 has been shown to improve the outcome of chronic kidney disease by reducing proteinuria by more than 50 per cent in animal models⁽¹⁾.

The DMX-200 Phase II Trial

The trial is a single arm, open label study 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 per cent reduction in proteinuria.

The trial has two parts. Part A is a dose escalation trial recruiting up to 30 patients and completed enrolment at the end of November 2016. 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 complete Part A in mid 2017.

Part B is an expansion study, in which up to 30 patients will be given the optimal dose identified from Part A.

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.

⁽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, Pflieger KD. PLoS One. 2015 Mar 25;10(3):e0119803. doi: 10.1371/journal.pone.0119803.