For Immediate Release

ASX/Media Release

Dimerix receives US Patent allowance for chronic kidney disease drug candidate

Melbourne, Australia, 19 February 2016: 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 it had received a Notice of Allowance from the United States Patent and Trade Mark Office (USPTO) for its patent covering the use of DMX-200 in the treatment of kidney disease.

A Phase II study in patients with chronic kidney disease is currently recruiting in Melbourne with the aim of confirming safety and reduction of proteinuria at 24 weeks of treatment.

DMX-200 has been shown to improve the outcome of chronic kidney disease by significantly reducing proteinuria in animal models of the disease. It combines two existing drugs, a chemokine receptor CCR2 blocker (propagermanium) used for its anti-inflammatory properties and an angiotensin II type I receptor blocker (irbesartan) used for treatment of hypertension.

The allowed claims encompass the use of a multitude of CCR2 and angiotensin receptor blockers in combination to treat a broad range of diseases. On issuance, the patent will provide protection until January 2032. An extension of the patent term may also be available in the USA (and other regions), to compensate for the time taken to develop a pharmaceutical, once a pharmaceutical product protected by the patent is registered in the USA.

The allowance of the use claims in the US follows the grant of use and pharmaceutical composition claims in Australia last year. The same patent family is under active examination in Europe, Japan and other major markets.

Dimerix Executive Chairman Dr James Williams said, “Securing such broad patent use claims in an important pharmaceutical market provides enormous opportunities, both for the DMX-200 program in chronic kidney disease, which affects more than 26 million people in the US, as well as for broader licensing opportunities. This is a further validation of the strength and potential of our Receptor-Heteromer Investigation Technology.”

The allowance of the US patent triggers Milestone A of the Class A performance shares which were issued to the Dimerix Bioscience vendors on 3 July 2015. As such, 75,000,040 Class A Performance Shares convert to 75,000,040 ordinary shares. See the following Appendix 3B.

Dr James Williams will be presenting at the Wholesale Investor Life Science & Healthcare showcase in Sydney on 25th February 2016, which will provide an opportunity to explain the implication of this patent allowance.

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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 models 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. For more information see www.dimerix.com

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 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.

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. 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 during 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.

[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.