

For Immediate Release

ASX/Media Release

Dimerix reaches 10 patient milestone and on Track to Report Interim Phase II Trial Data of DMX-200 in Patients with Chronic Kidney Disease in Q3 2016

MELBOURNE, Australia, 6 June 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 is on track to report interim data from its Phase II trial of DMX-200 in patients with chronic kidney disease (CKD) after passing the milestone of 10 patients dosed.

Dimerix Executive Chairman Dr James Williams said, "The milestone of dosing 10 patients is an important one, as it should enable interim information to be elucidated under the trial. It confirms we are meeting the recruitment targets and timelines previously communicated to the market."

In total 11 patients have been dosed and the first two patients recruited have completed the dose escalation stage.

Identified using Dimerix's proprietary screening assay, termed Receptor-Heteromer Investigation Technology (Receptor-HIT), DMX-200 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) which is registered in the USA for hypertension and treatment of diabetic nephropathy in certain patients.

Part A of the current Phase II open label trial aims to recruit up to 30 patients at four sites across Melbourne with the aim of demonstrating safety and reduction of proteinuria in patients with CKD. Proteinuria is common in CKD patients and is a strong independent risk factor for disease progression. Reducing proteinuria reduces the risk of CKD progression and its consequences of progressive loss of renal function leading to renal failure, and the development and progression of cardiovascular disease.

Patients in the study are already being prescribed irbesartan and, as part of the trial protocol, commence on a dose of 30mg of propagermanium per day. The Investigators review the patients at four week intervals, and escalate the patients' dose to 60, 90, 150 and 240mg per day over each four week period. The supply of propagermanium to patients following their participation in the trial can be approved under the Australian TGA's Special Access Scheme. The first patient to complete the DMX-200 Phase II trial is continuing to access propagermanium under this Special Access Scheme.

Dimerix aims to provide an interim data analysis based on 10-15 patients in the trial before the end of the third quarter of 2016.

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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 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 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.

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 will be the best dose identified from Part A. The company expects to review the design of Part B in consultation with the United State Food and Drug Administration (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 initially pursuing registration for an orphan indication. The company has achieved orphan designation for Focal Segmental Glomerulosclerosis (FSGS) from the FDA.

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.