For Immediate Release

ASX Announcement

Dimerix Completes Recruitment of Part A of its Phase 2 Trial of DMX-200 in Chronic Kidney Disease

MELBOURNE, Australia, 6 December 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 that it has completed recruitment of patients into Part A of its Phase 2 trial for DMX-200, an innovative new treatment chronic kidney disease that combines two different existing drugs.

The Phase II trial is being conducted in two parts - Part A is a dose escalation phase to explore the safety and potential reduction of proteinuria in patients with chronic kidney disease (CKD) at increasing doses of DMX-200. Participants are expected to complete this phase of study by mid next year and the data will inform the optimal dose for Part B which is an expansion study, in which up to another 30 patients will be recruited.

Part A of the trial commenced in September 2015 with the aim of recruiting up to 30 patients at four sites across Melbourne to explore the safety and potential reduction of proteinuria in patients with CKD. This dose escalation phase of the study has now formally completed recruitment, with a total of 27 participants having been dosed. Five patients have already completed dosing and one has withdrawn, leaving 21 participants currently on study.

DMX-200 is being developed as an adjunct therapy, adding a chemokine receptor CCR2 blocker (propagermanium), to participants on stable angiotensin II type I receptor blocker (irbesartan), a drug which is registered in the USA for hypertension and treatment of diabetic nephropathy in certain patients.

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.

Dimerix CEO Kathy Harrison said, “Dimerix recently reported interim data from Part A of the trial which showed a good safety profile and encouraging signs of reduction of proteinuria. This trend has continued, hence the Company is confident that the current patient cohort will provide the data needed to support planning for part Part B of the study which will focus on the efficacy outcomes for the treatment.”

“We are on track to complete Part A and report data from this part of the trial in mid-2017 and start recruiting for Part B in the latter half of 2017. We look forward to updating the market on progress towards Part B in the new year.” Ms Harrison said.

Dimerix has secured orphan designation for DMX-200 for the treatment of Focal Segmental Glomerular Sclerosis (FSGS) in the USA.

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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 is being developed as an adjunct therapy, adding propagermanuim 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 that has recruited 27 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 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, Pfleger KD. PLoS One. 2015 Mar 25;10(3):e0119803. doi: 10.1371/journal.pone.0119803.