For Immediate Release

ASX/Media Release

Dimerix Receives TGA Special Access Scheme Approval to Continue to Supply Propagermanium to Kidney Patients on its DMX-200 Phase II trial

Melbourne, Australia, 19 April 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 the Therapeutic Goods Administration in Australia (TGA) has confirmed that Dimerix can continue to supply propagermanium to participants in the DMX-200 clinical trial upon clinician approval and participant agreement.

The TGA is the principal authority responsible for regulating medicines and their use within Australia. The Special Access Scheme is in recognition that there are circumstances where patients need access to therapeutic goods that are not on the Australian Register of Therapeutic Goods (ARTG).

DMX-200 combines two existing drugs, a chemokine receptor CCR2 blocker (propagermanium) used for its anti-inflammatory properties and not on the ARTG, and an angiotensin II type I receptor blocker (irbesartan) registered for treatment of hypertension. Preclinical testing of DMX-200 in models relevant for kidney disease showed a significant reduction in proteinuria, strongly supporting the potential of DMX-200 to improve the same condition in patients.

The TGA approval is on a case-by-case basis and relates to the first two participants in the Phase II study of DMX-200 in patients with chronic kidney disease (CKD). These two patients will shortly complete the full 24 weeks treatment period for Part A of the trial. The request under the Special Access Scheme was filed at the request of the Principal Investigator.

The trial is currently recruiting up to 30 patients at a total of four sites across Melbourne with the aim of demonstrating safety and reduction of proteinuria at 24 weeks of treatment in chronic kidney disease 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, and the development and progression of cardiovascular disease.

Dimerix Executive Chairman Dr James Williams said, “Approval under the Special Access Scheme is significant. All trial participants are already on irbesartan thus continuing access to propagermanium indicates that the Investigators involved do not have any safety concerns and consider there is potential benefit for patients to continue on the treatment. We believe this will support further recruitment into the trial.”

The therapeutic rationale for DMX200 was developed from Dimerix’s core patented technology, known as Receptor – Heteromer Identification Technology (Receptor – HIT) which can be used to elucidate novel receptor (or drug target) interactions in disease. Applying this technology to receptors such as G-protein coupled receptors (GPCR’s), Dimerix is able to identify potential pathological effects when receptors interact as heterodimers, indicating novel and more effective routes for therapeutic intervention compared with the traditional therapeutic target development against a single receptor.

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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.