For Immediate Release

ASX/Media Release

Interim analysis supports continued development of DMX-200 for the treatment of Chronic Kidney Disease

KEY POINTS:

- **Data from 21 participants shows the therapy is well tolerated with an encouraging safety profile**
- **Twenty seven percent (27%, 3/11) patients who have reached or passed the mid-point of the study have shown an ~ 50% reduction or greater in proteinuria over and above standard of care**
- **Final data from Part A of the Phase 2 study is expected in 2H 2017**

MELBOURNE, Australia, 4th October 2016: Dimerix Limited (ASX: DXB), a clinical-stage biotechnology company, today announced a positive analysis of the interim clinical data from part A of it's phase 2 study in patients with chronic kidney disease.

As of 26 September, 21 of 30 study participants had been dosed, with 2 having completed the study, and one having ceased. A total of 11 participants had completed the 90 mg dose, being the mid-point of the study. The total "participant months' exposure" to the drug to date was 67 months. Interim data demonstrates good safety and tolerability, and suggests that significant reductions of proteinuria (~ 50% or greater) are possible, having been observed in 27% (3/11) participants who had reached at least the mid-point of the study.

These findings are especially encouraging as reductions in proteinuria are difficult to achieve in this disease setting, where participants are already on standard of care of a Renin Angiotensin System (RAS) inhibitor, in this case irbesartan. Irbesartan has been shown in large-scale clinical trials to reduce proteinuria on average by approximately 25% from baseline in patients with chronic kidney disease. Participants therefore commenced this study with their proteinuria reduced as far as possible on standard of care.

Co-Principal Investigator, Clinical Associate Professor David Packham of the Melbourne Renal Research Group said "Recent recruitment to the trial has been excellent and exceeded expectations. The total months participant exposure to the drug to date appear to show an excellent safety and tolerability profile with Treatment Emergent Adverse Events very much in line with that expected of the study population. Sufficient data has now been generated to inform dosage selection and progression to part B of the planned Trial."

Dimerix Executive Chairman Dr James Williams said, "Interim data from Part A of this study increases our confidence in the safety of DMX-200 in this patient population, and indicates that clinically significant reductions in proteinuria are possible in some patients. We are now in the final stages of recruitment for Part A and ready to move to next stage of the Trial. Chronic kidney disease affects over 26 million people in the USA alone, and represents a large unmet medical need with progression of disease resulting in end stage renal disease."

As previously announced, the 2 participants who have completed the study continued to access treatment through the Therapeutic Good Administration (TGA) special access scheme, at the request of their doctor. One of these achieved >50% reduction in proteinuria (66%) at the 90mg dose (their maximum dose). In this Part A (dose escalation) of the study, the time on study from first dosing is up to 32 weeks. The average age of the participants is 62 (range 36 – 87). In addition to the study drugs, participants are taking between 2 and 20 concomitant medications (average 9) for management of other conditions and symptoms of kidney disease.

To date an 87 year old participant has ceased the study due to the emergence of anaemia secondary to a gastrointestinal bleed, thought to be associated with a pre-existing polyp whilst on the blood thinning drug, warfarin. The event occurred coincident with the patient's first dose of study drug, and Dimerix considers this event unlikely to be due to DMX-200.

Part A of study will cease recruitment at the earlier of 30 participants recruited, or the end of November 2016. Part A is therefore expected to be completed by the middle of 2017, with Part B planned to commence shortly thereafter.

DMX-200 was identified using Dimerix's proprietary screening assay, termed Receptor-Heteromer Investigation Technology (Receptor-HIT), and 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), which is registered in the USA for hypertension and treatment of diabetic nephropathy. Dimerix has already secured orphan designation for DMX-200 for FSGS.

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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 [(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. 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.