

For Immediate Release
ASX/Media Release
Dimerix receives ethics committee approval for pharmacokinetic trial of new extended release formulation

MELBOURNE, Australia, 24th October 2017: Dimerix Limited (ASX: DXB), is pleased to announce that it has received ethics committee approval for a study in healthy volunteers to determine the pharmacokinetic properties of the novel extended release propagermanium tablet to be used in the Company's DMX-200 Phase 2b trial in Chronic Kidney Disease.

The trial is an industry-standard, randomised cross-over design in which healthy volunteers will be given the extended or immediate release propagermanium formulations. The concentration of propagermanium in the blood and the urine will be determined at set time points after each dose to enable Dimerix to study the rate that propagermanium is released into and excreted out of the body. The study will also examine the effect that food has on the pharmacokinetics of propagermanium in the tablet form to mimic the real-world conditions for patients ahead of the coming Phase 2b efficacy trial.

Ethics Committee approval has been granted by Bellberry Limited, a national, private not-for-profit organisation which provides streamlined scientific and ethical review of human research projects across Australia. The study will be run at Linear Clinical Research in Perth.

Kathy Harrison, CEO of Dimerix said, "Ethics committee approval provides us with the permission needed to proceed with the important next step of confirming the pharmacokinetic activity of our extended release tablet. It is expected to be a short trial which will be completed before the end of 2017, setting us up to start the Phase 2b efficacy study in 2018."

Design of the Phase 2b study using the extended release tablets is well underway and incorporates the feedback from leading nephrologists including those on the Dimerix Medical Advisory Board.

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About Dimerix Bioscience Pty Ltd

Dimerix Limited's (ASX: DXB) 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 in 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 companies.

For more information see www.dimerix.com

About the DMX-200 program

DMX-200 which successfully completed a Phase 2a clinical trial in humans, is being developed as an adjunct therapy, adding propagermanium 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⁾.

Dimerix released the results of its Phase 2a clinical trial in humans for DMX-200 in July 2017. The trial met its primary endpoint of safety and tolerability in the participating patient group, which included patients with diabetic nephropathy (10), IgA nephropathy (6), and other proteinuric diseases (11). As a secondary endpoint, DMX-200 was shown to reduce levels of proteinuria in a number of patients. This was deemed a "clinically meaningful" result by leading clinicians. Preparations for a Phase 2b trial are underway which will test for efficacy and is expected to start by the end of calendar 2017.

About Chronic Kidney Disease

Chronic Kidney Disease (CKD) is a disorder in which patients show progressive loss of renal function usually accompanied by excess protein in the urine (proteinuria). Levels of proteinuria predict rate of decline of renal function (higher levels = more rapid decline). In part this is believed to reflect direct toxicity, or damage, to the kidneys by proteinuria itself. This establishes a cycle of worsening renal function leading in turn to increasing proteinuria and further kidney damage. Many CKD patients progress to a need for renal replacement therapy or dialysis and / or experience excessive morbidity and mortality from cardiovascular-related diseases.

The prevalence of CKD is rising and as such there is urgent need for treatments that can benefit CKD patients, including reducing proteinuria. In most cases of CKD residual proteinuria continues even with optimal use of existing therapies. Accordingly, therapies designed to further reduce, or abolish, proteinuria, are eagerly sought.

The rationale behind the DMX-200 program is to provide patients with a therapy that can reduce proteinuria in addition to that achieved with standard best therapy. The unmet need of CKD patients is reinforced by Dimerix's Orphan Drug Designation.

⁽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.