For Immediate Release

POWERFUL TRIAL DESIGN TO LEAD NEXT STAGE DMX-200 CHRONIC KIDNEY DISEASE SUBGROUP STUDIES

Highlights

- Dimerix to launch next stage of lead program, DMX-200, with **two simultaneous Phase 2 clinical trials** in the area of Chronic Kidney Disease
- Leading global contract research organisation IQVIA has been engaged; 11 Australian trial sites identified
- Recruitment expected to begin in Q3 calendar 2018

MELBOURNE, Australia, 15 May 2018: Dimerix Limited (ASX: DXB), a clinical stage biotechnology company, is pleased to announce designs for its coming clinical trials for lead therapeutic program DMX-200.

Dimerix will undertake two separate trials for patients with two forms of Chronic Kidney Disease (CKD): Focal Segmental Glomerulosclerosis (FSGS) and Diabetic Kidney Disease (DKD*). These have been designed as **randomised, double blind placebo-controlled, crossover studies**, to maximise potential for data while being highly efficient and cost-effective.

Last year, Dimerix completed a Phase 2a "all comers" clinical trial, where DMX-200 was studied in patients with a group of diseases in the broad category of CKD. In addition to meeting the primary safety end point across the study, a Diabetic Kidney Disease (DKD) subgroup showed a clinically and statistically significant efficacy response that far exceeded other investigational agents in development. Following their completion of dosing, a further outcome saw a number of patients apply to remain on DMX-200 under the Therapeutic Goods Administration's Special Access Scheme.

The data in patients with DKD patients was sufficiently compelling to support a follow up trial of DMX-200 in this large and commercially attractive patient group.

In parallel, Dimerix will be undertaking the previously planned Phase 2a trial for patients with the disease FSGS, for which the Company has Orphan Drug Designation (ODD) in the USA.

Two separate trials – in FSGS and DKD

With input from leading clinicians in the area of Chronic Kidney Disease and potential pharmaceutical partners, Dimerix will take forward the DMX-200 program with two clinical trials.

These studies will investigate the **A**T1R and **C**CR2 **T**argets for **I**nflammat**o**ry **N**ephrosis, and have been titled **ACTION**.

ACTION FOR FSGS: Phase 2a trial will study the effects of DMX-200 in around 10 patients with FSGS – endpoints including safety and efficacy (proteinuria reduction).

ACTION FOR DKD: Phase 2b trial will study the effects of DMX-200 in around 40 patients with DKD – primary end point change in 24hr albumin creatinine ratio (ACR) based on identified patient responses in the Phase 2a study.

Each trial will test for safety and efficacy across the patient groups at more than 10 identified clinical trial sites in Australia. The ACTION trials will be conducted under the direction of recently appointed Principal Investigator, Professor Simon Roger (refer to 7 May 2018 announcement), with public hospital leadership provided by Professor David Power. Ethics committee submissions for the private practice and public hospital lead sites are expected to be filed shortly.

Dimerix is also pleased to announce that IQVIA (previously QuintilesIMS - a leading global contract research organisation - CRO) has been engaged as a key vendor to facilitate the ACTION studies, and will provide essential trial services including clinical project management, data management, biostatistics and medical writing. The Company will also gain access to the strategic support of IQVIAs renal centre of excellence.

With careful planning, the DMX-200 program has been positioned such that both the DKD and FSGS trials will commence at the same time and will be run across all the same trial sites, using the same Principal Investigators, and same vendors. This set up provides significant cost and time savings for Dimerix.

Dimerix's CEO, Kathy Harrison commented, "The major benefit of raising additional funds in the last capital raise has been that we now have the opportunity to progress to efficacy trials in both FSGS and DKD, with the trials designed to maximise Dimerix's ability to partner the DMX-200 program. In addition, running these trials in parallel brings significant cost-saving benefits"

FSGS regulatory framework

The FSGS trial is part of Dimerix's targeted development program to take DMX-200 to a position of Phase 3-ready for this Orphan indication. The nature of the regulatory framework under the Orphan scheme is such that registration as a drug can often be achieved with fewer trials in a smaller number of patients and therefore have a faster path to these important and valuable markets.

Combined with progressing the manufacturing and non-clinical data required to obtain an Investigational New Drug application for FSGS, the Phase 2a trial will position the program for partnering or further funding rounds to take DMX-200 through Phase 3 for FSGS.

DKD trial history and market place

DKD is an area of significant unmet medical need with very large and increasing patient numbers world wide, but with a longer and more expensive path to market compared with Orphan indications such as FSGS.

However, the compelling subgroup data in a small DKD patient subgroup seen in the Phase 2a trial has created an opportunity for Dimerix to leverage the existing knowledge of DMX-200 and kidney disease and take DMX-200 into a further efficacy trial (double blind, placebo-controlled) in DKD to make DMX-200 an asset with great potential for partnering agreements.

Kathy Harrison further commented, "Having these two clinical assets, backed by a broad granted US patent, results in a multi layered commercially attractive asset."

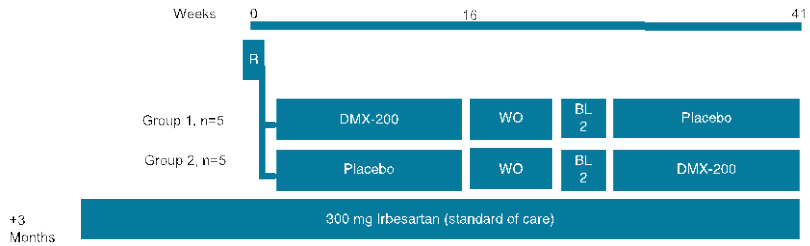
Trial format – randomised, placebo controlled cross over design, for each trial

Through consultation with key opinion leaders, a highly efficient and cost-effective placebo controlled, cross over design has been selected as the most appropriate format for both trials.

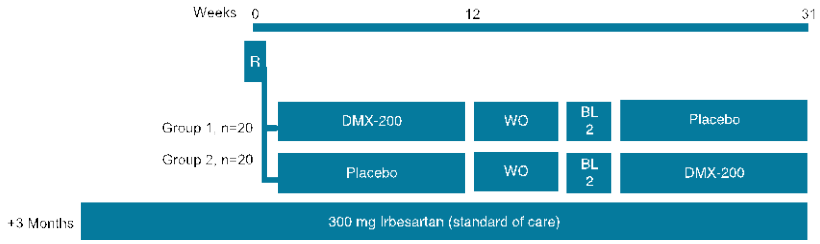
This trial format functions in such a way that every patient on each of the trials will receive the best standard of care medication (irbesartan) for at least 3 months prior to and throughout the trial, and will receive DMX-200 or placebo at different periods of the study.

The study designs are shown in the figures below. The benefit of using this design is that every patient receives the trial drug DMX-200 and placebo in an order that is both randomised and blinded to patient and investigators. This means that safety and efficacy data is collected for every patient on each trial. A further important benefit of the trial design is that because each patient has the study drug and placebo, the patient acts as their own control, mitigating the impact of variability in disease behaviour from patient to patient.

ACTION study for FSGS: n=10



ACTION study for DKD n=40



* WO – wash out period, BL – Baseline Testing

Speaking about the trial format, Dimerix's Chief Medical Officer, Associate Professor David Packham said, "We have selected the most robust method of ensuring accurate detection of an efficacy signal for both our FSGS and DKD trials. As every patient will receive both study drug and placebo with a 6-week washout period between treatments we will be able to assess individual patient responses and avoid confounding factors due to differences in the natural history of the diseases under study between patients. Further, the fact that all participants who complete the trial are certain of having received trial drug for one of two treatment periods will make this much more attractive to patient participation and recruitment."

Timelines

Consistent with recent guidance, Dimerix expects to file ethics applications for both trials this quarter (Q2 CY2018) and be recruiting for both studies in Q3 CY2018. Preliminary data is expected for the DKD study in Q3 CY2019, and for FSGS in Q4 CY2019.

*DKD was formerly termed diabetic nephropathy (DN)

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For further information, please visit our website at www.dimerix.com or contact the individuals outlined below.

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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.

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. Sub set analysis released in November 2017 showed both a statistically significant and clinically meaningful reduction in proteinuria in the diabetic nephropathy cohort of patients

Dimerix intends to take DMX-200 into clinical trials to test efficacy in calendar 2018 starting with its lead program in focal segmental glomerulosclerosis (FSGS), for which it has orphan drug designation in the US as well as for diabetic kidney disease (DKD).

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, Pfleger KD. PLoS One. 2015 Mar 25;10(3):e0119803. doi: 10.1371/journal.pone.0119803.