Studies on Australian Chronic Kidney Disease therapy DMX-200 expanded following compelling Phase 2 trial outcomes

Two trials with efficient crossover design now planned in specific kidney disease indications Focal Segmental Glomerulosclerosis and Diabetic Kidney Disease.

MELBOURNE, VICTORIA, AUSTRALIA, May 15, 2018 /EINPresswire.com/ -- • Patients with Diabetic Kidney Disease on initial “all comers” Phase II trial showed clinically and statistically significant efficacy response
• Two trials with efficient crossover design now planned in specific kidney disease indications; one for patients with Focal Segmental Glomerulosclerosis and another for those with Diabetic Kidney Disease
• Recruitment for next stage trials expected to begin in Q3 calendar 2018

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> *Dimerix Chief Medical Officer, Associate Professor David Packham*

Australian biotech Dimerix has announced that it will more deeply investigate the therapeutic effects of its Chronic Kidney Disease therapy DMX-200 on Diabetic Kidney Disease, after patients within this specific kidney disease indication showed a compelling response to the drug during an initial “all comers” Phase II trial last year.

As well as meeting the primary safety end point across the initial Phase II study, patients with Diabetic Kidney Disease showed a clinically and statistically significant efficacy response. Following their completion of dosing, a number of patients in Australia applied to remain on DMX-200 under the Therapeutic Goods Administration’s Special Access Scheme.

Dimerix will now progress DMX-200 into two separate but concurrent Phase II clinical studies; a study focused specifically on the drug’s therapeutic effects on Diabetic Kidney Disease, as well as a planned study on a further specific kidney disease indication, Focal Segmental Glomerulosclerosis, characterised by kidney scarring [1] for which the company has received Orphan Drug Designation in the US.

Diabetic Kidney Disease and Focal Segmental Glomerulosclerosis are subcategories of Chronic Kidney Disease (CKD). Kidney Health Australia states that around 1 in 10 Australians aged 18 years and over have indicators of CKD, such as reduced kidney function and the presence of the protein albumin in the urine. According to the organisation, people with CKD have a 2 to 3-fold greater risk of cardiac death than those without it. Effective treatment is important because, when managed appropriately, the otherwise inevitable deterioration in kidney function can be reduced by as much as 50%.[2] CKD is also recognised as a huge cost to healthcare systems; as a patient’s condition deteriorates they eventually require blood dialysis, which costs close to AUD$100,000 per annum per patient.[2]

DMX-200 tackles CKD by adding a safe anti-inflammatory drug, propagermanium, to the standard of care treatment, irbesartan. The two drugs work synergistically to block the signals that cause inflammation, which is a major contributor to the disease's progression.[3]

Dimerix developed DMX-200 using its proprietary Receptor HIT platform, which identifies pairs of different receptors that function in a joint manner when modulated by ligands, small molecule drugs, peptides or antibodies. DMX-200 has been shown to improve the outcome of Chronic Kidney Disease in patients by reducing proteinuria (abnormal quantities of protein in the urine) by more than 50 per cent in 25% of patients in a clinical trial completed in 2017.

Both Phase II trials of DMX-200 will be randomised, double blind placebo-controlled, crossover trials, which is an efficient and cost-effective trial design; every patient on each of the trials will receive irbesartan for at least three months prior to and throughout the trial, and will receive DMX-200 or placebo at different periods of the study.

Dimerix's Chief Medical Officer, Associate Professor David Packham said the design also means that, in receiving both the study drug and placebo, each patient acts as his or her own control and mitigates the impact of variability in disease behaviour from patient to patient.

"We have selected the most robust method of ensuring accurate detection of an efficacy signal for both trials," Dr Packham said. "The fact that all participants who complete the trial are certain of having received the trial drug for one of two treatment periods will make this much more attractive to patient participation and recruitment."

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.

More: www.dimerix.com

[1] National Kidney Foundation. 2017. Focal Segmental Glomerulosclerosis (FSGS). [ONLINE] Available at: https://www.kidney.org/atoz/content/focal. [Accessed 15 May 2018].
[2] Kidney Health Australia. 2018. Kidney Fast Facts. [ONLINE] Available at: http://kidney.org.au/cms_uploads/docs/kidney-health-australia-kidney-fast-facts-fact-sheet.pdf. [Accessed 15 May 2018].
[3] US National Library of Medicine National Institutes of Health / Akchurin OM1, Kaskel F.. 2015. Update on inflammation in Chronic Kidney Disease. [ONLINE] Available at: https://www.ncbi.nlm.nih.gov/pubmed/25662331. [Accessed 15 May 2018]

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