Australian biotech Dimerix now recruiting patients: Diabetic Kidney Disease & orphan kidney scarring phase 2 trial

Dimerix seeks to replicate compelling data seen in initial phase 2 clinical trial of potential kidney disease therapy DMX-200.

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> With DMX-200, Dimerix has the potential to deliver a first-in-class treatment... extending the time before a patient requires dialysis or even avoiding dialysis completely if caught early enough."
> *Dr Nina Webster, Dimerix CEO*

- Trial sites in Victoria and NSW now recruiting for both studies, a further eight sites to open in coming weeks across Queensland, Victoria and NSW
- Study 1: Phase 2b Diabetic Kidney Disease patient trial to further investigate compelling outcomes of DMX-200 in an initial phase 2a trial last year
- Study 2: Phase 2a Focal Segmental Glomerulosclerosis patient trial to investigate the potential of DMX-200 in treating the orphan kidney disease

Australian biotech Dimerix has announced that it has started recruiting patients for a further two phase 2 clinical trials of its kidney disease treatment, DMX-200, with these studies focused specifically on the drug's therapeutic effects on Diabetic Kidney Disease and the orphan condition Focal Segmental Glomerulosclerosis.

The Phase 2b trial focused on Diabetic Kidney Disease will recruit around 40 patients and seek to replicate compelling data seen in an initial phase 2a 'all comers' trial completed last year involving patients diagnosed broadly with Chronic Kidney Disease.

The Focal Segmental Glomerulosclerosis (FSGS) Phase 2a study will recruit around 10 patients and seek to demonstrate a proof of principle to enable DMX-200 to proceed into further development for the orphan disease. DMX-200 has already been granted orphan drug designation for FSGS in the US.

Renal Research in Gosford, NSW and the Austin Hospital in Melbourne began recruiting patients this week for both studies, with a further eight sites to open over the next two months across Melbourne, Sydney, Gold Coast and Brisbane.

The studies will investigate DMX-200's effects on the AT1R and CCR2 Targets for Inflammatory Nephrosis and have been titled ACTION. Both trials will be randomised, double blind placebo-controlled, crossover trials in which all participants are certain to receive DMX-200 for one of two treatment periods.

Dimerix CEO, Dr Nina Webster, said, "Patients with kidney disease face a progressive decline that often results in end-stage renal diseases, requiring dialysis and/or kidney transplant. With DMX-200, Dimerix has the potential to deliver a first-in-class treatment to many of these patients in need, extending the time before a patient requires dialysis or even avoiding dialysis completely if caught early enough.

“Dimerix, and our medical advisory team, are impressed by the clinical data we have seen for DMX-200 to date and are pleased to see DMX-200 move back in the clinic to expand on these encouraging patient responses. We have placed great emphasis on robust trial designs, which give us the best chance of giving patients a new therapy to try and of ensuring accurate detection of an efficacy signal in both trials to meet the clinical endpoints. These studies should be attractive to patients and I hope to report outcomes in late 2019.”

Diabetic Kidney Disease, one of many types of chronic kidney disease, is caused by diabetes with indicators such as reduced kidney function and the presence of the protein albumin in the urine (proteinuria). Kidney Health Australia states that around 10% of people with diabetes develop early signs of kidney disease in the first 10 years after being diagnosed, and between 20-30% of people with diabetes will develop kidney disease by 20 years after being diagnosed [1]. According to the organisation, people with kidney disease have a 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%[1,2]. Kidney disease 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 kidney disease by co-administering a safe anti-inflammatory drug, propagermanium, to the standard of care treatment, irbesartan. The patent protected and unique combination of these two drugs works 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. In the clinical trial completed in 2017, DMX-200 was 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 Furthermore, in the sub-group of patients with type 2 diabetes, there was a clinical and significant average (mean) fall of 36% in proteinuria which, if confirmed in the recently initiated 2b Diabetic Kidney Disease study, would be expected to translate into many years extension to the life of the patient’s kidneys.

Details of the trials are available on both ANZCTR and clinicaltrials.gov websites.

Patients interested in joining the trial should speak to their nephrologist.

[1] Kidney Health Australia. 2018. Diabetic Kidney Disease. [ONLINE] Available at https://kidney.org.au/cms_uploads/docs/diabetic-kidney-disease--kidney-health-australia-fact-sheet.pdf [Accessed 11Sep18]
[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]

Ilona Marchetta
IR Department
+61 416 156 136
email us here