

DMX-200 CLINICAL UPDATE

- FSGS Phase 2 study recruitment expected to complete July 2019
- Diabetic Kidney Disease Phase 2 study recruitment 80% complete
- Trial opening to patients in Western Australia, through Linear Clinical Research

MELBOURNE, Australia, 26 June 2019: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, announced an update for their two Phase 2 clinical studies and the opening of recruitment at Linear Clinical Research in Western Australia, following strong interest from Western Australian patients.

Dimerix has two Phase 2 studies currently underway: DMX-200 for FSGS; and DMX-200 for Diabetic Kidney Disease, and is sufficiently funded to complete both studies.

For both studies, some eligible patients have had to be transitioned onto Irbesartan for the required minimum 3 months period prior to entering studies, resulting in a minor impact to anticipated completion dates. This period of baseline treatment with the current standard of care treatment for both diabetic and FSGS patients is critical as it will allow the full treatment effect of DMX-200 to be observed during the study. Linear Clinical Research has been opened in Western Australia at the request of physicians and patients, and this will help enable recruitment of the remaining patients for the studies. Results are now anticipated in Q2 2020 for both studies.

DMX-200 in FSGS Phase 2a Study

Participants will receive 16 weeks propagermanium and 16 weeks placebo, separated by a 6-week washout period, during the double-blind, randomised, placebo-controlled, crossover study evaluating the safety and efficacy of DMX-200 in patients with FSGS who are receiving a stable dose of irbesartan.

	Study period 1 16 weeks	Washout 6 weeks	Study Period 2 16 weeks	Results
Group 1 (n=5)	DMX-200		Placebo	
Group 2 (n=5)	Placebo		DMX-200	
Irbesartan 300mg				

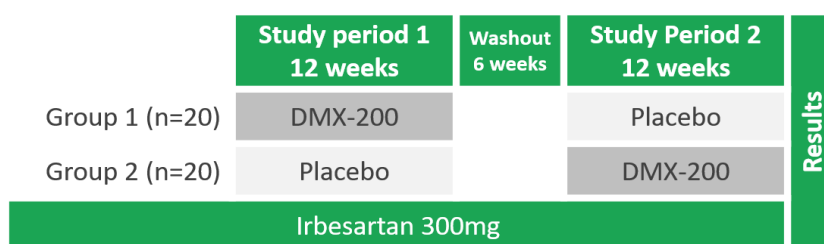
FSGS Study Design



The FSGS Phase 2 a study is expected to complete recruitment in July 2019, with eligible patients having been identified. The first patient is expected to complete treatment in August 2019 and Dimerix will enable continued access to DMX-200 through their physician via the TGA Special Access Scheme. Study results are expected in Q2 2020 (previously Q1 2020).

DMX-200 in Diabetic Kidney Disease Phase 2 Study

Participants will receive 12 weeks propagermanium and 12 weeks placebo, separated by a 6-week washout period, during the double-blind, randomised, placebo-controlled, crossover study evaluating the safety and efficacy of DMX-200 in patients with diabetic kidney disease who are receiving a stable dose of irbesartan.



Diabetic Kidney Disease Study Design

The first diabetic kidney disease patient is expected to complete treatment in June 2019 and Dimerix will also enable continued access to DMX-200 through their physician via the TGA Special Access Scheme. The study is currently 80% recruited, and recruitment is expected to complete Q3 2019, with study results anticipated in Q2 2020 (previously Q1 2020).

Trials Opening to Patients in Western Australia

“Dimerix is pleased to be able to offer the opportunity for Western Australian patients to participate in the trials at Linear Clinical Research”, said Dr Nina Webster, CEO and Managing Director of Dimerix. “We are now seeing strong recruitment across sites and are close to achieving full recruitment. These results are pivotal for the company as they will provide further clinical data to support the company’s regulatory and partnering strategy”.

For further information, please visit our website at www.dimerix.com or contact:

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Dimerix is a biopharmaceutical company developing innovative new therapies in areas with unmet medical needs

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About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company developing innovative new therapies in areas with unmet medical needs for global markets. Dimerix is currently developing its proprietary product DMX-200 for both Diabetic Kidney Disease and Focal Segmental Glomerulosclerosis (FSGS). DMX-200 was identified using Dimerix' proprietary assay, Receptor Heteromer Investigation Technology (Receptor-HIT), which is a scalable and globally applicable technology platform enabling the understanding of receptor interactions to rapidly screen and identify new drug opportunities. Receptor-HIT is licensed non-exclusively to Excellerate Bioscience, a UK-based pharmacological assay service provider with a worldwide reputation for excellence in the field of molecular and cellular pharmacology.

About DMX-200

DMX-200 is the adjunct therapy of a chemokine receptor (CCR2) antagonist administered to patients already receiving irbesartan, an angiotensin II type I (AT1) receptor blocker and the standard of care treatment for kidney disease. DMX-200 has granted patents in various territories until 2032.

In 2017, Dimerix completed its first Phase 2a study in patients with a range of chronic kidney diseases. No significant adverse safety events were reported, and all study endpoints were achieved. In a subsequent sub-group analysis, significant clinical efficacy signals were seen in the diabetic group.

DMX-200 administered to patients already taking irbesartan reduced proteinuria levels by a further 36%. This reduction in proteinuria is highly correlated with improved renal function and delay in kidney failure and dialysis. The compelling results from this study prompted the decision to initiate two different clinical studies in 2018: one for patients with Diabetic Kidney Disease; and the second for patients with another form of kidney disease, Focal Segmental Glomerulosclerosis (FSGS).

FSGS is a serious and rare disease that attacks the kidney's filtering units (glomeruli) causing serious scarring which leads to permanent kidney damage and kidney failure and for which there is a recognised medical need for a new or improved treatment. FSGS affects both children and adults.

DMX-200 for FSGS has been granted Orphan Drug Designation by the FDA and EMA. Orphan Drug Designation is granted to support the development of products for rare diseases and qualifies Dimerix for various development incentives including: seven years (FDA) and ten years (EMA) of market exclusivity if regulatory approval is received, exemption from certain application fees, and an abbreviated regulatory pathway to approval.

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