

PATIENTS CONTINUE DMX-200 TREATMENT UNDER TGA SPECIAL ACCESS SCHEME

Highlights

- Patients completing Dimerix current DMX-200 Phase 2 clinical studies to continue treatment with DMX-200 on physicians' request under the Special Access Scheme;
- Both studies are, and will remain, blinded until completion;
- FSGS Phase 2a study last patient dosing scheduled in June 2020, and top line data anticipated shortly thereafter;
- Diabetic Kidney Disease Phase 2 study last patient dosing scheduled in July 2020, and top line data anticipated shortly thereafter.

MELBOURNE, Australia, 03 March 2020: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, today announced that patients from the current phase 2 trials will continue treatment with DMX-200 via the Therapeutic Goods Association's (TGA) compassionate use Special Access Scheme (SAS) following completion of the study protocol and recommendation by their physicians. These patients are in addition to previously reported SAS patients from the phase 2 trial completed in 2017 who also continue to be treated with DMX 200 via the TGA's SAS.

The TGA approved the SAS Category B applications based on the safety profile of DMX-200, as well as clinical evidence that DMX-200 may benefit patients. Dimerix will facilitate continued access to DMX-200 via the physician through the Special Access Scheme at the physician's request.

"We are very happy to support the medical professionals and patients seeking treatment for their disease and who have very few medical options," commented Dr Nina Webster, CEO and Managing Director of Dimerix. "The current blinded clinical studies are exploring the effect of DMX-200 over several months of treatment, however it is pleasing that physicians have requested extended treatment of their patients with DMX-200. We look forward to reporting the Phase 2 trial outcomes in FSGS and in Diabetic Kidney Disease later in 2020, both of which represents a major clinical milestone for Dimerix".

What is the Special Access Scheme?

Most therapeutic goods are required to undergo an evaluation for quality, safety, and efficacy, and be included on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia.

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

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In recognition that there are circumstances where patients need access to therapeutic goods that are not listed on the ARTG, the TGA facilitates a Special Access Scheme for physicians seeking to use medicines that have not yet been approved in Australia. The SAS refers to arrangements which provide for the supply of an unapproved therapeutic good for individual patients, on a case by case basis. Applications under the SAS are made to the TGA by their treating doctor, and approval to treat the patient takes into account the safety of the drug as well as supporting evidence that the drug may benefit the patients, along with the failure of any current therapies.

Dimerix Phase 2 clinical studies of DMX-200

The Phase 2 Diabetic Kidney Disease study completed recruitment in September 2019, with the last patient dosed in January 2020. The study dosed an additional 5 patients, totalling 45 patients, to ensure a study completion population of N=40 as required for adequate statistical powering. Final patient dosing is scheduled for July 2020, with top line data anticipated shortly thereafter.

The Phase 2a FSGS study completed recruitment in July 2019, with the last patient dosed in September 2019 following final protocol screening. The study remains on track to complete final patient dosing in June 2020, with top line data anticipated shortly thereafter.

As previously advised, both studies are designed as double-blinded, placebo-controlled, cross-over studies whereby each patient will receive both the drug and the placebo control for a defined period of time, the order of which remains unknown until the completion of the entire study.

The Phase 2 trial outcomes in FSGS and in Diabetic Kidney Disease both represent major clinical milestones for Dimerix and are both anticipated mid-2020.

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

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Authorised for lodgement by the Board of the Company

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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).

Diabetic Kidney Disease (DKD) is a common and serious complication for patients with Type 1 and Type 2 diabetes, where the kidney is progressively damaged by the inflammatory processes of diabetes. 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.

About DMX-700

DMX-700 is a pre-clinical program being developed for the treatment of the progressive and life-threatening lung disease Chronic Obstructive Pulmonary Disease (COPD). The primary cause of COPD is exposure to tobacco smoke (either active smoking or secondary smoke), however it is also caused by exposure to indoor and outdoor air pollution, occupational dusts and fumes and long-term asthma. COPD is the fourth-leading cause of death in the world and although treatments exist to improve the symptoms of COPD, there is currently no way to slow progression of the condition or cure it. Moreover, of the top five causes of death globally, this disease is the only one with increasing mortality rates. The global COPD treatment market was valued at US\$14 billion in 2017 and is projected to increase at a compound annual growth rate of 4.9% to 2026.

Dimerix has conducted initial in vitro studies that identified an improved strategy for treating COPD, and has completed a key step in securing ownership over what it believes is an important new drug discovery by lodging a provisional patent application for DMX-700. During 2020, Dimerix will conduct further proof of concept studies to perform the value-added verification in support of a robust product development pathway and patent position.

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