

FDA CONFIRMS PHASE 3 STUDY DESIGN IN FSGS KIDNEY DISEASE

- US Food and Drug Administration (FDA) advice consistent with European Medicines Agency (EMA) advice received by Dimerix in June 2021
- FDA confirms Dimerix single Phase 3 design, with interim analysis, appropriate to support potential accelerated marketing approval in US
- FDA confirms use of any angiotensin receptor blockers (ARBs) as appropriate standard of care background therapy for FSGS patients
- DMX-200 has Orphan Drug Designation in the US and Europe, and the equivalent Innovative Licensing and Access Pathway (ILAP) designation in the UK, for the treatment of FSGS
- Phase 3 clinical study sites selected and site initiation planned for August 2021, following appropriate ethics submissions

MELBOURNE, Australia, 19 July 2021: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, today confirmed that the US FDA met with Dimerix for a Type C (guidance) meeting and formal minutes have now been issued by the FDA. At the meeting, the FDA reviewed a dossier that included the Dimerix Phase 3 DMX-200 clinical study design for Focal Segmental Glomerulosclerosis (FSGS) and the previously reported positive Phase 2 clinical data.

Accelerated approval on interim data

The FDA was broadly supportive of the proposed Phase 3 study design. The meeting minutes from the FDA provided clarity on the single Phase 3 study in FSGS patients to support accelerated approval endpoints, such as protein in the urine (proteinuria) and its relationship to kidney function (eGFR slope). The FDA confirmed that improvement in proteinuria was an acceptable surrogate endpoint for accelerated approval, with sufficient demonstration of the relationship to kidney function. The FDA also provided guidance on the statistical analysis of the data used to support the accelerated approval.

Dimerix has designed several interim analyses into the proposed Phase 3 design to capture evidence of proteinuria and kidney function during the study, aimed at generating sufficient evidence for generating regulatory agencies to assess DMX-200 for accelerated marketing approval. The FDA has confirmed that this general approach is also acceptable, providing further advice on the first interim analysis review.

Phase 3 clinical site initiation planned for August 2021, following ethics submissions

The detailed feedback Dimerix has received from the FDA on the Phase 3 protocol proposal is generally consistent with advice from the EMA received in June 2021, which is also under review by the MHRA (UK regulatory agency). The closely aligned advice from both the FDA and the EMA provides confidence in the study design and appropriate endpoints for marketing approval. As such, Dimerix can now complete all remaining study start up tasks and begin initiation of clinical sites in the global study following ethics submissions.

In preparation for global study initiation, IQVIA has been appointed as the lead Contract Research Organisation (CRO). IQVIA is the largest global CRO and has extensive and recent experience in running late-stage global FSGS clinical studies. Importantly for FSGS patients, the operational impact of COVID-19 has already been considered and incorporated into the Phase 3 study protocol to ensure efficient and effective site and patient participation. Sites will be initiated country by country, based on a number of factors including speed of regulatory submissions and reviews as well as COVID-19 status.

“The valuable feedback we have received from the FDA, which aligns with that received from EMA in June, provides us further clarity and confidence that the planned FSGS Phase 3 study meets US and European regulatory expectations for marketing approval, including the potential for accelerated marketing approval.

Particularly encouraging is the FDA’s support for accepting a reduction in proteinuria as a surrogate for accelerated approval of DMX-200 for FSGS, based on its relationship with kidney function.

The positive Phase 2 clinical data reported in 2020 suggests that treatment with DMX-200 may indeed result in clinically meaningful improvements in kidney function when added to the standard of care in patients with FSGS.”

Dr Nina Webster, CEO & Managing Director, Dimerix

Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe, and the equivalent Innovative Licensing and Access Pathway (ILAP) designation in the UK, for the treatment of FSGS. These designations provide regulatory and financial benefits to help bring new drugs to market faster, including reduced fees during the product development phase, protocol assistance from the regulatory authorities, and 7-year (US) and 10-year (Europe) market exclusivity following product approval.

Concurrent with the Phase 3 study in FSGS, Dimerix is supporting two global Phase 3 studies in patients with COVID-19, assessing the next study design in diabetic kidney disease patients and advancing the DMX-700 program for patients with Chronic Obstructive Pulmonary Disease towards the clinical stage of development.

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 Diabetic Kidney Disease, Focal Segmental Glomerulosclerosis (FSGS) and Acute Respiratory Distress Syndrome (ARDS), and is developing DMX-700 for Chronic Obstructive Pulmonary Disease (COPD). DMX-200 and DMX-700 were both 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 hypertension and kidney disease. DMX-200 is protected by 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. 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). DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

FSGS

FSGS is a rare disease that attacks the kidney's filtering units, where blood is cleaned (called the 'glomeruli'), causing irreversible scarring. This leads to permanent kidney damage and eventual end-stage failure of the organ, requiring dialysis or transplantation. For those diagnosed with FSGS the prognosis is not good. The average time from a diagnosis of FSGS to the onset of complete kidney failure is only five years and it affects both adults and children as young as two years old. For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney. At this time, there are no drugs approved for FSGS anywhere in the world, so the treatment options and prognosis are poor.

FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000, and worldwide about 210,000. The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year. Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for FSGS. This is a special status granted to a drug to treat a rare disease or condition; the designation means that DMX-200 can potentially be fast-tracked, and receive tax and other concessions to help it get to market.

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.

Dimerix reported positive Phase 2a data in FSGS patients in July 2020.