Dimerix

For Immediate Release

DIMERIX CONFIRMS PHASE 3 FSGS KIDNEY DISEASE STUDY DESIGN WITH EMA

- European Medicines Agency (EMA) advice generally consistent with prior FDA advice received by Dimerix
- EMA confirms single Phase 3 design, with potential for interim analysis to support conditional (accelerated) marketing approval in Europe
- EMA confirms angiotensin receptor blockers (ARBs) as appropriate standard of care background therapy for FSGS patients
- EMA confirms proposed non-clinical package and pharmaceutical-grade drug manufacture process are appropriate to support marketing authorisation application of DMX-200 in Europe
- DMX-200 has Orphan Drug Designation in the US and Europe for the treatment of FSGS
- Phase 3 clinical study initiation planned for early Q3-2021

MELBOURNE, Australia, 3 June 2021: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, today confirmed that the European Medicines Agency (EMA) has provided a written response on the proposed Focal Segmental Glomerulosclerosis (FSGS) Phase 3 study design. The EMA reviewed a dossier that summarised Dimerix' proposed Phase 3 clinical program for FSGS and its supporting data in the form of non-clinical studies, the manufacturing and process controls and all existing Phase 1 and Phase 2 renal clinical data accumulated to date.

Conditional (accelerated) approval on interim data

The written response from the EMA provided clarity on the remaining development stages of DMX-200 for FSGS through to market approval in Europe including the appropriate endpoints for conditional marketing approval in a single Phase 3 study, such as protein in the urine (proteinuria) and its relationship to kidney function. Conditional approval is the equivalent of accelerated approval for orphan indications awarded by the US Food and Drug Administration (FDA). The European Agency confirmed that "*the use of surrogate endpoints [such as protein in the urine (proteinuria)] can be supported, provided the improvement in surrogacy translates into clinically important outcome*." 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 ensuring regulatory agencies will have sufficient evidence to assess DMX-200 for conditional/accelerated marketing approval.

The EMA also confirmed that angiotensin receptor blockers (ARBs) are recognised as the standard of care in Europe and are acceptable as the background therapy to DMX-200 for FSGS patients. This was critically important to the program, given FSGS is not an approved indication for ARB usage in Europe.

The EMA also agreed that the proposed non-clinical package and specifications for the pharmaceutical-grade drug manufactured by Dimerix are appropriate for DMX-200 market registration.

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Phase 3 clinical study initiation plans for mid-2021

The Phase 3 protocol proposal is also under review by the FDA and MHRA (UK regulatory agency), and a virtual meeting between the FDA and Dimerix has been scheduled to confirm that specific study design endpoints also meet the criteria required to support accelerated approval for FSGS in the US. Once confirmed, Dimerix can begin initiating clinical sites globally and subsequent recruitment of patients, which is expected early Q3-2021.

In preparation for global study initiation, IQVIA has been appointed as the lead Contract Research Organisation (CRO). IQVIA is the largest global CRO with 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 clinical study protocol to ensure efficient and effective site and patient participation.

> "This formal response from the EMA has given us a valuable opportunity to ensure that the proposed FSGS development program meets with European regulatory expectations for marketing approval, including conditional/accelerated marketing approval.
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> FSGS patients today face poor outcomes with limited medical options, and we continue to progress our proposed development pathway forward that could deliver a much-needed pharmacologic treatment to the FSGS community. The clinical data to date suggest 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."
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> *Dr Nina Webster, CEO & Managing Director, Dimerix*

Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for the treatment of FSGS. Orphan designation provides 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.

About FSGS

FSGS is a rare disease and attacks the kidney's filtering units, where blood is cleaned (called the 'glomeruli'), causing irreversible scarring, which leads to permanent kidney damage and kidney failure, 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: sadly, it affects both adults and children as young as two years old. It is also more prevalent in the black population than in caucasians. For those who are lucky enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney. There are no treatments currently approved for the treatment of FSGS and thus there is a strong unmet medical need.

FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is 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.

Dimerix reported positive Phase 2a clinical data in FSGS patients in July 2020, also meeting primary and secondary endpoints for the study.

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.