For Immediate Release

PHASE 3 STUDY IN FSGS KIDNEY PATIENTS COMMENCES

- ACTION3 Phase 3 study in FSGS patients commences with first ethics submission
- Up to 167 clinical sites across 18 countries expected to participate
- All patients on background therapy of any angiotensin receptor blocker
- Preliminary FSGS interim analysis anticipated Q4 2022

MELBOURNE, Australia, 25 August 2021: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company with multiple Phase 3 opportunities, is pleased to announce that it has now commenced ACTION3, the Phase 3 clinical study in patients with focal segmental glomerulosclerosis (FSGS), with the first ethics submission having been filed in Australia, enabling commencement of patient recruitment once approved.

Up to 167 sites in up to 18 countries across North America, South America, Europe, United Kingdom, and Asia Pacific regions are expected to participate in this study, with Australia and New Zealand identified as the first countries planned to initiate patient recruitment across 5 sites collectively and other countries following shortly after.

ACTION Phase 3 Study Design

The Phase 3 study, which is titled **"A**ngiotensin II Type 1 Receptor (AT1R) & **C**hemokine Receptor 2 (CCR2) **T**argets for **I**nflammat**o**ry **N**ephrosis" – or ACTION3 for short, is a pivotal (final), multi-centre, randomised, double-blind, placebo-controlled study of the efficacy and safety of DMX-200 in patients with FSGS who are receiving a stable dose of an angiotensin II receptor blocker (ARB). Once the ARB dose is stable, patients, aged 18 to 75 years, will be randomized to receive either DMX-200 (120 mg capsule twice daily) or placebo.

The primary endpoint for potential accelerated marketing approval is the percent change in protein in the urine (proteinuria) from Baseline to Week 35 following treatment with DMX-200 compared with placebo; and the primary endpoint for full approval is the slope of eGFR from Baseline to Week 104 following treatment with DMX-200 compared with placebo.

A blinded interim analysis will be performed in approximately 70 patients following Part 1 of the study to confirm both efficacy and study powering (for statistical measures), which based on the estimated patient recruitment rate, is anticipated as early as the December quarter of 2022. The decision to continue the study will be made by an independent data monitoring committee based on the results of this interim analysis. If the study is recommended to proceed, the remaining 180 patients will be enrolled into Part 2 of the study.

Dimerix HQ
425 Smith St, Fitzroy 3065
Victoria, Australia
T. 1300 813 321
E. investor@dimerix.com

"The team at Dimerix is delighted to have commenced the operational activities for the ACTION3 study in FSGS patients. We are well on track to begin patient recruitment for the study once ethics approval has been achieved, with first patient screening expected to be in Q4 2021.

We have designed interim analyses into the Phase 3 study design to capture evidence of proteinuria and kidney function improvement during the study, aimed at generating sufficient data to support an accelerated marketing approval. With the key regulators' expectations aligned, including the US FDA and the European EMA, and the encouraging data reported in the prior Phase 2a study, we are excited to deliver on the FSGS program, potentially providing patients with a much-needed treatment option."

Dr Nina Webster, CEO & Managing Director, Dimerix

Global Study Coordination

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.

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 often only five years and it affects both adults and children as young as two years old. It is also more prevalent in the black population. 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.

Orphan Drug Designation

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.

Two Phase 3 Clinical Studies in Respiratory Complications Associated with COVID-19

Dimerix lead drug candidate, DMX-200, is also part of two different investigator-led Phase 3 studies in COVID-19 patients with respiratory complications. For one of these studies, Dimerix was awarded $1 million from MTPConnect's Biomedical Translation Bridge (BTB) program provided by the Australian Government's Medical Research Future Fund, with support from UniQuest.

Dimerix proactively supports both studies driven by the REMAP-CAP and CLARITY 2.0 teams in providing them information for the regulatory submissions and in supplying DMX-200 to the study sites. Dimerix looks forward to reporting on progress and as key milestones are met. Importantly, if DMX-200 does show benefit in patients with COVID-19, the treatment would likely be equally applicable to any strain of COVID and it may also show benefit in respiratory complications associated with other infections, such as pneumonia and influenza. Thus, this provides an opportunity that could extend well beyond the impact of COVID-19.

Dimerix continues to progress the Phase 3 pivotal program in FSGS, a rare kidney disorder without an approved pharmacologic treatment that often leads to end-stage kidney failure, as well as support the two Phase 3 COVID studies, assess the next study design in diabetic kidney disease patients and finally advance the COPD program towards the clinical stage of development.

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

Dr Nina Webster
Dimerix Limited
Chief Executive Officer & Managing Director
Tel: +61 1300 813 321
E: investor@dimerix.com

Rudi Michelson
Monsoon Communications
Tel: +61 3 9620 3333
Mob: +61 (0)411 402 737
E: rudim@monsoon.com.au

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 respiratory complications associated with COVID-19, 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.