For Immediate Release

DMX-200 REMAINS ELIGIBLE FOR ACCELERATED APPROVAL

MELBOURNE, Australia, 27 May 2021: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, today confirmed that the Company is in active discussions with the FDA on the Phase 3 study design in focal segmental glomerulosclerosis (FSGS), including appropriate endpoints for Accelerated Approval.

According to the US Food and Drug Administration (FDA), Accelerated Approval is appropriate for drugs for serious conditions that fill an unmet medical need and can be based on a surrogate clinical endpoint, such as proteinuria levels in kidney disease. The data to support accelerated approval must demonstrate sufficient clinical benefit to justify any risks associated with the drug.

On 25th May 2021, US time, Travere Therapeutics, a US based company developing Sparsentan for FSGS, announced that "*available data from the interim assessment of the DUPLEX Study [in FSGS patients] would not be adequate to support an Accelerated Approval at this time*". The FDA review of Travere's interim Sparsentan data for the treatment of patients with FSGS indicates that the agency was seeking additional data on the safety or efficacy of this new chemical entity before granting Accelerated Approval. The details of the data reviewed by the FDA have not been released.

In February 2021, Travere reported positive interim data for their Phase 3 study in FSGS patients, whereby 16% more patients achieved a proteinuria reduction of ≥40% on sparsentan compared to irbesartan. Dimerix reported that 29% of patients demonstrated ≥40% reduction in proteinuria on DMX-200 in addition to irbesartan compared to placebo, also in addition to irbesartan as standard of care, in the Dimerix Phase 2 study reported in July 2020.

DMX-200 efficacy on the background of any approved angiotensin receptor blocker

Dimerix is in active discussions with the FDA and the European Medicines Agency (EMA) on the appropriate endpoints for its planned Phase 3 study in FSGS patients, including for Accelerated Approval. Further updates will be provided as information is released by the relevant agencies. All clinical data to date on DMX-200 demonstrates an exceptionally strong safety profile, with no serious adverse events related to the drug reported, and that the DMX-200 clinical benefit has outweighed any risks to date. The positive signals suggest that treatment with DMX-200 may indeed result in clinically meaningful improvements in kidney function in FSGS patients.

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

"A treatment, such as DMX-200, that has a good combination of strong clinical safety records and a demonstrated proteinuria lowering capability and data that has the potential to delay the onset of end-stage kidney failure would be a significant benefit to patients.
While a setback for Travere, and patients needing a treatment for FSGS, the delay to Accelerated Approval for Sparsentan does not change the DMX-200 program as we work towards a treatment for patients that have no other therapeutic options and face poor outcomes with limited medical options.
We continue to progress our proposed development pathway forward that could deliver the first approved pharmacologic treatment to the FSGS community."

Dr Nina Webster, CEO & Managing Director

Dimerix continues to undertake planning for the proposed 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 global Phase 3 studies in patients with COVID-19, 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

—END—

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.

Respiratory Complications associated with COVID-19

Patients hospitalised with COVID-19 typically have acute lung dysfunction due to the human immune response to the virus. However, while the long-term effects on the lung from COVID-19 remain largely unknown, it is widely accepted that COVID-19 will result in acute injury in the same way as previous coronavirus infections such as SARS and MERS. As such, it is likely to result in chronic lung fibrosis in many patients, leading to poor quality of life, high ongoing hospitalisation requirements and ultimately a poor prognosis.

Globally, and prior to COVID-19, ARDS affected more than 3 million people a year in 2019 accounting for 10-15% of intensive care unit admissions, and approximately 200 000 patients each year in the United States. The market size of Acute Respiratory Distress Syndrome (ARDS) in the seven major markets was US$917.81 million in 2017. This has grown significantly because of the 2020 pandemic. The death rate associated with ARDS is high, with overall mortality between 30 and 40%. The estimated average costs of treatment in an ICU unit with artificial ventilation total approximately US$100,000 per patient, with the average length of stay in ICU as a result of ARDS being 25 days, and the average length of hospitalisation being approximately 47 days. However, there are also significant costs associated with additional post-discharge treatment. There is no known prevention of ARDS currently available, nor is there any known cure.

FSGS

FSGS is a very rare disease; and a particularly heart-breaking one. FSGS attacks the kidney's filtering units, where blood is cleaned (called the 'glomeruli'), causing irreversible scarring, which 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: sadly, it affects both adults and children as young as two years old. For those who are lucky 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.