For Immediate Release

DMX-200 RECEIVES UK INNOVATIVE LICENSING AND ACCESS PATHWAY DESIGNATION FOR FSGS

MELBOURNE, Australia, 7 June 2021: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company with multiple Phase 3 opportunities, has been awarded an Innovation Passport and the Innovative Licensing and Access Pathway (ILAP) designation from the UK Medicines and Healthcare products Regulatory Agency (MHRA) for DMX-200 being studied in a Phase 3 study in the serious kidney disease focal segmental glomerulosclerosis (FSGS).

The ILAP is awarded to accelerate the development and access to promising medicines, such as DMX-200, and follows a review of clinical data that demonstrates patients are likely to benefit from the product. Entry with the Innovation Passport into the new ILAP provides a new pathway supporting innovative approaches to the safe, timely and efficient development of medicines to improve patient access. This means patients could benefit much sooner from this treatment and it will be accelerated through the approval process.

"The granting of the Innovation Passport and entry into ILAP comes in addition to the Orphan Drug Designation we already have granted in both US and Europe. These designations ultimately accelerate the review of promising therapies targeting unmet medical needs.

We look forward to working with the MHRA as we progress DMX-200 through the Phase 3 program and to reporting on the program later this year."

Dr Nina Webster, CEO & Managing Director

About ILAP

Launched in January 2021, the ILAP combines the MHRA's globally recognised high standards of quality and safety with improved flexibility to reduce the time it takes for innovative treatments to be available to patients in the UK. The benefits of ILAP include the potential for an accelerated Marketing Authorisation Application (MAA) assessment, a rolling review and a continuous benefit risk assessment, with the goal of early patient access in the UK.

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. Concurrently 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 COPD program towards the clinical stage of development.

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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.

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.