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For Immediate Release

SECOND INTERNATIONAL STUDY TO INCLUDE DMX-200 IN COVID-19 PATIENTS

- DMX-200 has been selected for inclusion into a new Investigator initiated feasibility/Phase 3 study, CLARITY 2.0, led by Professor Meg Jardine from the University of Sydney
- CLARITY 2.0 is the second international COVID-19 study to include DMX-200, providing further opportunity for the evaluation of DMX-200 as a potential treatment for respiratory complications associated with the COVID-19 disease
- The CLARITY 2.0 study will recruit COVID-19 patients at an early stage of respiratory complications, prior to the onset of Acute Respiratory Distress Syndrome (ARDS) being studied in the REMAP-CAP study.

MELBOURNE, Australia, 30 November 2020: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, is pleased to announce that its lead candidate DMX-200 is entering a second clinical study in COVID-19 patients led by Professor Meg Jardine (NHMRC Clinical Trials Centre at The University of Sydney, Australia) and conducted in collaboration with Professor Vivek Jha and The George Institute for Global Health (India).

The Dimerix candidate CCR2-inhibitor, DMX-200, was selected by the Lead Investigators of the Controlled evaLuation of Angiotensin Receptor Blockers for COVID 19 respiraTorY disease (CLARITY) study, for a partner study, CLARITY 2.0, to evaluate DMX-200 treatment in patients diagnosed with COVID-19 who are intended for hospital admission. Dimerix has entered into an agreement with the University of Sydney's NHMRC Clinical Trials Centre (CTC) to initiate the investigator-led study, under which Dimerix will provide the DMX-200 and matched placebo study medication.

The CLARITY 2.0 vanguard (feasibility)/Phase 3 study will assess the safety and effectiveness of DMX-200 administered together with an angiotensin receptor blocker (ARB), on clinical outcomes of approximately 600 participants in India who have tested positive for COVID-19. CLARITY 2.0 is a prospective, multi-centre, randomised, double blind, placebo-controlled study, with the primary endpoint being the 7-point clinical health score developed by the World Health Organization (WHO) for Coronavirus Disease 2019 (COVID-19) trials (scored from no hospitalisation or ventilation requirement through to death) at treatment day 14. Participants will be treated for up to 28 days and then followed up for a total of 26 weeks.

The DMX-200 therapy is aimed at reducing damage from inflammatory immune cells by blocking their signalling and limiting subsequent movement in the lungs, or other tissues, damaged by the virus. Global experts see DMX-200 as a compelling potential treatment option to limit inflammation in the lungs during infection of the SARS-CoV2 virus.

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"The SARS-CoV-2 virus downregulates and suppresses certain anti-inflammatory effects and that may tip the local lung environment towards inflammation and fibrosis and might be why the virus has such a devastating effect on lung tissue," said Professor Meg Jardine. "We generally see that people with chronic health conditions that include inflammatory drivers, such as chronic kidney disease, diabetes, cardiovascular disease and obesity, are also those who are more vulnerable to respiratory complications if they contract the SARS-CoV2 virus. Some of those inflammatory drivers interact with the blood pressure system which is why some common blood pressure medications may improve outcomes in COVID-19 disease. Early results suggest that DMX-200 may have stronger anti-inflammatory effects when used in combination with these blood pressure medications. The CLARITY and CLARITY 2.0 studies are designed to answer whether these blood pressure medications, used alone or in combination with DMX-200, may alter the course of COVID-19 disease and provide a better outcome for patients."

"Unfortunately, the threat of COVID-19 outbreaks are likely to remain with us for some time," said Dr Nina Webster, CEO and Managing Director of Dimerix. "Our lead candidate, DMX-200, has demonstrated efficacy across three different studies in patients with active inflammatory disease, and we are very pleased to support a second research study in COVID-19 patients as well as progressing DMX-200 into a Phase 3 clinical study in the rare kidney disease Focal Segmental Glomerulosclerosis (FSGS) in the first half of 2021. Dimerix recognises and appreciates the support and collaboration of India within the expanse of research into SARS-CoV-2 and COVID-19. If, DMX-200 in combination with an ARB is proven effective for the treatment of COVID-19, and is approved for an indication within this setting, Dimerix is committed to an upscale of opportunity for treatment, including a fair and ethical supply of DMX-200 within India in line with industry standards."

In September, Dimerix was awarded $1 million from the Australian Government's Biomedical Translation Bridge (BTB) program to support the inclusion of DMX-200 in the REMAP-CAP global study in COVID-19 patients with ARDS, a more progressed and severe respiratory disease stage. REMAP-CAP is a global World Health Organization (WHO)-endorsed study designed to rapidly generate evidence for treatments in patients with respiratory distress associated with COVID-19.

The inclusion of DMX-200 in a second study in COVID-19 patients represents a further opportunity for the evaluation of DMX-200 as a potential treatment for patients with COVID-19 disease and presents Dimerix with a further opportunity to realise the full value of DMX-200 to the Company and its shareholders. Importantly, if DMX-200 does show some lessening of the severity and duration of symptoms associated with COVID-19 disease, it may also show benefit in the treatment of other respiratory infections such as influenza, providing an opportunity that could extend well beyond the impact of COVID-19.

In addition to research with DMX-200 in respiratory diseases associated with COVID-19, Dimerix continues to prepare for a Phase 3 study in FSGS patients, assess the next steps for diabetic kidney disease and the development of DMX-700 in Chronic Obstructive Pulmonary Disease.

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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), as well as 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. In a subsequent sub-group analysis, significant clinical efficacy signals were seen in the diabetic group. DMX-200 administered to patients already taking stable irbesartan reduced proteinuria levels by a further 36%. This reduction in proteinuria is highly correlated with improved renal function and delay in kidney failure and dialysis. 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.

It is estimated that 40% of people with diabetes have kidney disease and many may not know it yet. With the incidence of diabetes growing so rapidly globally, so too will the incidence of kidney disease. This is a rapidly growing market, with few treatment options at this time. Dimerix reported statistically and clinically significant outcomes in a Phase 2 study in diabetic kidney disease patients in September 2020.

FSGS is a serious and rare disease that attacks the kidney's filtering units (glomeruli) causing serious scarring which leads to permanent kidney damage and kidney failure and for which there is a recognised medical need for a new or improved treatment. FSGS affects both children and adults. Dimerix reported positive Phase 2a data in FSGS patients in July 2020 and is currently preparing for a Phase 3 program.

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.