**For Immediate Release**

# ACUTE RESPIRATORY DISTRESS SYNDROME IN COVID-19 PATIENTS PROTOCOL PUBLISHED

- REMAP-CAP domain protocol including DMX-200 to treat Acute Respiratory Distress Syndrome in patients with COVID-19 now finalised and available online
- Protocol will be submitted to regulatory authorities in jurisdictions with high recruitment rates allowing Dimerix to now submit IND, or equivalents, to support recruitment of patients to the DMX-200 study arm
- GMP supply of DMX-200 released from contract manufacturer ready for shipment to sites
- Three Phase 2 clinical studies completed by Dimerix all show positive efficacy in patients with active inflammatory renal disease, supporting mechanism of action in inflammatory processes
- DMX-200 mode of action expected to block MCP-1 driven inflammation in COVID-19, based on Dimerix clinical data

MELBOURNE, Australia, 09 November 2020: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, is pleased to announce that the renin angiotensin system (RAS) domain protocol that includes assessment of DMX-200 and an angiotensin receptor blocker (ARB), has been formally approved by the 42-member REMAP-CAP International Trial Steering Committee and is now publicly available online. The randomised, open label study domain protocol can be seen at https://www.remapcap.org/protocol-documents. The study enrols patients admitted to hospital with acute illness due to suspected or proven COVID-19, including patients admitted to an Intensive Care Unit (ICU).

The RAS domain will assess the efficacy of DMX-200 administered together with an angiotensin receptor blocker (ARB) for up to 10 days, compared to no RAS inhibitor, and ARB alone or an angiotensin converting enzyme (ACE) inhibitor alone. The study will investigate the effect of DMX-200 and an ARB on in-hospital mortality as well as the number of days on a respirator while admitted to an ICU in the 21 days following treatment. The study is designed so that when positive data is seen in an initial cohort of patients, the treatment can be rapidly and seamlessly extended into additional trial sites around the world. As the study is an adaptive design, there is no fixed number of total patients enrolled, however there are a number of interim analyses built into the protocol to assess patients assigned to DMX-200.

Dimerix's clinical drug candidate, DMX-200, was selected by investigators for inclusion in the global REMAP-CAP study for patients with Acute Respiratory Distress Syndrome (ARDS) associated with COVID-19. 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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Dimerix has completed three Phase 2 studies in renal disease to date that have each delivered positive data and that support the mechanism of action of DMX-200 being effective in diseases where active inflammatory processes are driving disease progression, and specifically where monocyte chemoattractant protein (MCP)-1 is driving inflammation. DMX-200 inhibits the cellular receptor that is activated by MCP-1. The most recent renal data translates to reduced inflammation and subsequent fibrosis (scarring) in the kidneys, and this supports the mechanism expected in COVID-19 where MCP-1 is believed to be a major driver of the inflammatory phase following infection.

An Investigational New Drug (IND) submission, or equivalent, will be submitted in selected countries with sites already recruiting patients into other REMAP-CAP trial domains, including the EMA (Europe), MHRA (UK) and Health Canada, referencing the study protocol which has already been submitted to relevant regulatory authorities. Simultaneously, Dimerix will work with REMAP-CAP to ship DMX-200 to those countries that will initiate treatment first. Dimerix's global contract manufacturer recently released the pharmaceutical grade (GMP) batch of DMX-200 for supply to the REMAP-CAP study.

In September, Dimerix was awarded $1 million from the Australian Government's BTB program to support the inclusion of DMX-200 in the REMAP-CAP global study.

"REMAP-CAP was designed to find optimal treatments for severe pneumonia both in non-pandemic and pandemic settings," stated Professor Steve Webb, Professor of Critical Care Research, School of Public Health and Preventive Medicine, Monash University and Chair of the REMAP-CAP International Trial Steering Committee. "When COVID-19 began, REMAP-CAP pivoted to its pandemic mode, as per its original intent, to incorporate additional potential treatment regimens specifically targeting COVID-19 and to expand enrolment to COVID-19 patients."

"There is a compelling biologic rationale to imbed DMX-200 into the RAS domain of the REMAP-CAP COVID trial, where its potential therapeutic effects may combine with those of angiotensin receptor blockers to reduce the organ support requirements, including ventilation, and death in patients hospitalized with COVID-19. REMAP-CAP is working closely with Dimerix to rapidly obtain the necessary regulatory approvals as the next step in this program," said Dr Patrick Lawler, REMAP-CAP RAS Domain Specific Working Group Chair and Clinician-Scientist at Toronto General Hospital.

"We are extremely pleased to support this global initiative investigating the potential of multiple therapies to treat COVID-19 patients dying of ARDS. We acknowledge the time and effort that the REMAP-CAP team have spent in preparing a well-designed and robust clinical study domain to assess the effect of our compound in these patients," said Dr Nina Webster, CEO & Managing Director of Dimerix. "We have now completed three Phase 2 studies that show efficacy in a group of patients with active inflammatory disease and are all supportive of our inclusion in this ARDS study as well as progressing DMX-200 into a Phase 3 clinical study in FSGS in the first half of 2021."

For Dimerix to be included in a global trial of this magnitude generates an enormous value creation opportunity for the Company and its shareholders. Importantly, if DMX-200 does show some benefit in ARDS associated with COVID-19, it may also show benefit in ARDS associated with other infections too, such as pneumonia and influenza. Thus, this provides an opportunity that could extend well beyond the impact of COVID-19.

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 study is coordinated by the Australian and New Zealand Intensive Care Research Centre, collaborating with more than 30 partner organisations globally to enrol over 7,000 patients at approximately 260 sites across 16 countries.

In addition to the DMX-200 in ARDS associated with COVID-19, Dimerix continues to preparation 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.

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), 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.