For Immediate Release

CLARITY 2.0 STUDY PROGRESSES IN PATIENTS WITH COVID-19

- Approval for the CLARITY 2.0 study received from Central Independent Ethical Review Board, a submission required as part of the regulated approval process for Indian clinical trial activities
- Dossiers submitted to regulatory authorities in India for CLARITY 2.0 study
- Patient recruitment expected to initiate in April.

MELBOURNE, Australia, 10 March 2021: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, is pleased to provide an update on the CLARITY 2.0 study in patients with COVID-19.

CLARITY 2.0

Submitted to regulatory authorities

DMX-200 is included in a large 600 patient feasibility/Phase 3 study led by Professor Meg Jardine from the NHMRC Clinical Trials Centre at The University of Sydney, Australia, and in collaboration with Professor Vivek Jha and The George Institute for Global Health India. The study, called CLARITY 2.0, is aimed at COVID-19 patients at an earlier stage of respiratory complications, prior to the onset of Acute Respiratory Distress Syndrome (ARDS), which is being studied in the REMAP-CAP study. CLARITY 2.0 is an investigator initiated, prospective, multi-centre, randomised, double blind, placebo-controlled study, with the primary endpoint being a 7-point clinical health at treatment day 14, adapted from the categorical scale, recommended by the WHO for COVID-19 trials (scored from no hospitalisation or ventilation requirement through to death). Participants will be treated for up to 28 days and then followed up for a total of 26 weeks.

The Indian regulatory process differs from other territories, with a streamlined parallel regulatory and ethics submission process. The CLARITY 2.0 team has now received approval by Central Independent Ethical Review Board, which is required to obtain final approval from the Indian regulatory authority. Multiple clinical study sites have been engaged, and recruitment will initiate once the regulatory approval is obtained, anticipated in April.

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

Dimerix lead drug candidate, DMX-200, is part of two different investigator-led Phase 3 studies in COVID-19 patients with respiratory complications. Dimerix was awarded $1 million from the Australian Government for one of these studies from the highly competitive Medical Research Future Fund, an endorsement that reflects the strong scientific rationale for DMX-200 in this setting. Despite the introduction of vaccines that aim to reduce the symptoms caused by COVID-19, many respiratory symptoms will still need to be addressed in many individuals and countries accordingly. Global recruitment of patients in such studies appears to remain steady.

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.

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 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:

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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.

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. Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

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.

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 per cent, 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.

Diabetic Kidney Disease (DKD)

There were 23 million diagnosed diabetics in the US alone in 2017, and the incidence of diabetes is estimated to grow by 54% by the year 2040. Approximately 40% of all diabetics suffer from kidney disease, which is a progressive disease leading to kidney failure and dialysis – and many of them do not know it yet. So sadly, diabetes has a large – and growing – population. With the incidence of diabetes growing so rapidly globally, so too will the incidence of kidney disease. This is a rapidly growing market, for which there is no cure for DKD, and current treatment options are ineffective as the kidneys deteriorate towards failure. Dimerix reported statistically and clinically significant outcomes in a Phase 2 study in diabetic kidney disease patients in September 2020.

The diabetic kidney disease market is reported to be a US$5.8 billion per annum (AU$8 billion) market and is estimated to grow at 5.1% a year by 2022. We believe our addressable market is at least US$1.1 billion (AU$1.5 billion), a market that is growing as diabetes incidence rises.

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. Because there is no direct cure for ARDS the treatment is focused on supporting the patient while the lung heals. The goals of this supportive care are to keep enough oxygen in the blood to prevent further damage to the body and to treat whatever caused ARDS in the first place.

Chronic Obstructive Pulmonary Disease

COPD is a progressive and life-threatening lung disease. The most common cause of COPD is exposure to tobacco smoke (either active smoking or secondary smoke) however, COPD is also caused by exposure to indoor and outdoor air pollution, occupational dusts and fumes and long-term asthma. COPD is the fourth-leading cause of death in the world and although treatments exist to improve the symptoms of COPD, there is currently no way to slow progression of the condition or cure it. Moreover, among the top five causes of death globally, this disease is the only one with increasing mortality rates. In 2016, the Global Burden of Disease Study reported a prevalence of 251 million cases of COPD globally, and it was estimated that 3.17 million deaths were caused by the disease in 2015, which equates to 5% of all deaths globally in that year (WHO Factsheet – Chronic Obstructive Pulmonary Disease). The global COPD treatment market was valued at US$14 billion in 2017 and is projected to increase at a compound annual growth rate of 4.9% to 2026.