Dimerix

For Immediate Release

COVID-19 STUDY INCORPORATING DMX-200 OPENS MORE SITES IN EUROPE AND UK

- 167 patients with COVID-19 pneumonia enrolled across the ACE2 RAS modulation REMAP-CAP study domain in Europe
    - 43 sites currently recruiting domain in UK, Netherlands, and Italy
- DMX-200 has regulatory study approval in both UK and Netherlands, with additional study sites anticipated to recruit DMX-200 patients in Italy following submission in July 2021
- DMX-200 available at clinical sites for patients randomised to the DMX-200 treatment arm
- Supply of DMX-200 distributed to UK and Netherlands from a central depot in Germany

MELBOURNE, Australia, 02 August 2021: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, advises that 167 patients have now been recruited into the feasibility/Phase 3 ACE2 renin angiotensin system (RAS) modulation study domain in patients with COVID-19 pneumonia, which incorporates DMX-200. Of those 167 subjects enrolled across 43 clinical sites, 106 have been recruited in sites across the UK, 60 in the Netherlands and 1 in Italy and represents an ~7-fold increase over the past 3-months. DMX-200 has regulatory approval in both the UK and the Netherlands and is available at sites for administration to patients randomised to the DMX-200 treatment arm.

Even as vaccination rates increase, it is anticipated that a significant proportion of the population will still be susceptible to COVID-19 because they are either resistant to the vaccine, cannot be vaccinated or choose not to be vaccinated. Therefore, it is still likely that many patients will get infected and will end up with COVID respiratory complications and potentially long-COVID (symptoms that extend long beyond recovery from the virus). As such, there remains a great need for treatments for patients with COVID.

According to the World Health Organisation (WHO), 195 million COVID cases have been reported to date, including 3.9 million (+10% on prior week) in the past 7 days. This coincides with an increase in the number of deaths globally, with 70,000 reported in the last 7 days (+21% on prior week) and over 4.2 million in total. Europe is currently bracing for a fourth wave anticipated as the territory enters Autumn.

ACE2 RAS modulation domain design

In the REMAP-CAP approved ACE2 RAS study domain, participants who meet platform entry criteria will be randomised to receive one RAS blockade treatment arm or a control:

- **ARB in combination with DMX-200**
- Angiotensin receptor blocker (ARB)
- Angiotensin converting enzyme (ACE) inhibitor
- No RAS inhibitor (no placebo)

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The feasibility/Phase 3 study is a multi-centre, randomised, standard of care vs multi-active comparators platform study in patients with COVID-19. The overarching REMAP-CAP study incorporating DMX-200 is funded by the European Union through the H2020 Project called "Rapid European COVID-19 Emergency Research response," which uses the acronym "RECOVER".

The study domain protocol, which aims to recruit approximately 200 patients per treatment arm (~600 patients across all treatment arms), can be seen at https://www.remapcap.org/protocol-documents. Should current recruitment rates continue, the study is expected to be fully enrolled Q4 CY 2021, with preliminary data available soon thereafter.

REMAP-CAP

DMX-200 is included in the investigator-led feasibility/Phase 3 study in patients with COVID-19 pneumonia, driven by a consortium of global trialists, clinicians and experts through the study sponsor, REMAP-CAP.

The study, endorsed by the World Health Organization (WHO), has initiated a master protocol across over 300 clinical sites across eight global regions. REMAP-CAP has investigated 48 active treatments for COVID-19, mostly repurposed and novel medicines, including for registration purposes. The study has now recruited over 7,000 patients with suspected or proven COVID-19 overall.

Two 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. For one of these studies, Dimerix was awarded $1 million from MTPConnect's Biomedical Translation Bridge (BTB) program provided by the Australian Government's Medical Research Future Fund, with support from UniQuest.

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. Importantly, if DMX-200 does show benefit in patients with COVID-19, it may also show benefit in respiratory complications associated with other infections, such as pneumonia and influenza. Thus, this provides an opportunity that could extend well beyond the impact of COVID-19.

Dimerix continues to progress the 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.

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 rare disease that attacks the kidney's filtering units, where blood is cleaned (called the 'glomeruli'), causing irreversible scarring. This 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 and it affects both adults and children as young as two years old. For those who are fortunate 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.