Immediate Release

DSMB CHANGE TO REMAP-CAP COVID-19 STUDY

- REMAP-CAP independent Data Safety Monitoring Board (DSMB) conducted a scheduled interim safety assessment on available data to determine if the treatments in the RAS study domain were safe in patients with both severe and moderate COVID-19
- DSMB has communicated safety concerns related to the use of angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARB) in patients with severe COVID-19
- The DSMB made no comment on the safety of the ARB + DMX-200 intervention
- The DSMB recommended that recruitment of patients with severe COVID-19 to all available interventions in this domain be suspended, and REMAP-CAP will temporarily pause enrolment of patients with moderate COVID-19 into this domain to allow review of additional data prior to potentially resuming enrolment
- Complete assessment of data from patients with severe disease will be undertaken and will be reported as soon as available
- The preliminary finding is unlikely to impact the CLARITY 2.0 study of DMX-200 and an ARB in patients with moderate COVID-19 respiratory complications
- The preliminary finding does not impact the ACTION3 study of DMX-200 in FSGS patients, where ARBs are part of existing standard of care[1]

MELBOURNE, Australia, 28 February 2022: Dimerix Limited (ASX: DXB), a biopharmaceutical company working to improve the lives of patients with inflammatory diseases, today confirmed that it had received initial outcomes from the investigator-led REMAP-CAP International Trial Steering Committee (ITSC), on the ACE2 renin angiotensin system (RAS) modulation study domain, recruiting patients with both severe (patients receiving organ support in ICU) and moderate (patients in ICU not receiving organ support) COVID-19.

The REMAP-CAP ACE2 RAS study domain randomised patients to receive one of:

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

On 24 February 2022 (European time), the Independent Data Safety Monitoring Board (DSMB) conducted an assessment to determine if the treatment arms in the RAS study domain were safe and/or effective. Of the 779 patients recruited into the study domain, 564 patients were assessed across the four treatment arms in this planned analysis.

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The DSMB has communicated to REMAP-CAP that a concerning safety signal was observed in critically ill patients in the study arms where patients were receiving an ACE inhibitor or an ARB, and has recommended that recruitment of patients in the severe illness severity state of the domain be suspended. Given DMX-200 is administered to patients on the background of an ARB, the DSMB has recommended that the ARB and DMX-200 arm also be suspended in these critically ill patients. These safety concerns of the ACE inhibitor and the ARB were not reported for patients in moderate state, and the domain will likely continue to recruit these patients for the study including those patients on DMX-200, after a brief pause in recruitment to fully assess the available safety data. Analysis of all study outcomes for all randomized patients with severe disease will begin shortly and be released when the data are available.

The REMAP-CAP study uses adaptive analysis to examine the study data, and continually assesses if a treatment in the study is safe and effective, and considers whether any of the study drugs should be stopped to avoid giving patients an ineffective therapy, particularly if there are side effects.

After further review of all available data, the study may continue treating patients, including with those receiving an ARB and DMX-200, until it reaches a pre-specified statistical threshold for determining efficacy among patients who are moderately ill with COVID-19. Given the DSMB have only identified the safety signal in patients with severe COVID-19 requiring organ replacement in an Intensive Care Unit, this finding is unlikely to impact on the CLARITY 2.0 study of DMX-200 and an ARB in moderate COVID-19 patients with respiratory complications. Importantly, this finding has no relevance to Dimerix's ACTION3 study in patients with the kidney disease FSGS where ARBs are a safe and longstanding part of the current standard of care for patients with residual proteinuria.[1]

The company's approach to treating COVID-19 with the CCR2 pathway inhibitor DMX-200 is based on a clear scientific rationale, is unique and potentially complementary to others being investigated globally, and importantly if effective in this study of patients with moderate COVID-19, would likely be effective against any strain as well as potentially other community acquired pneumonias with a common mechanism of action.[2]

Dimerix continues to progress DMX-200 in 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 advance the DMX-700 program in COPD 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 Focal Segmental Glomerulosclerosis (FSGS), respiratory complications associated with COVID-19 and Diabetic Kidney Disease, 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 an angiotensin II type I receptor (AT1R) blocker - the standard of care treatment for hypertension and kidney disease.[1] DMX-200 is protected by granted patents in various territories until 2032, with additional applications submitted that may extend the protection to 2042 if granted.

DMX-200 has demonstrated encouraging data that could provide meaningful clinical outcomes for patients with kidney disease across 4 clinical studies to date[3]. DMX-200 is also under investigation as a potential treatment for patients with COVID-19 in two separate studies: REMAP-CAP and CLARITY 2.0.

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 results 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.[4] The global ARDS market is expected to grow at 10.1% (CAGR) between 2022 and 2029 and is expected to reach over US$18 billion by 2029.[5] Increasing prevalence and incidence of acute lung injury, wide range of risk factors for ARDS and acceleration in patient pool of COVID-19 with ARDS acts as driver for the ARDS market. The death rate associated with ARDS is high, with overall mortality between 30 and 40%.[4] 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.[6] 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.

References

[1] KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases, v100(4S); October 2021

[2] Based on Szabo, et al., 2020; Merad, et al., 2020; Xiong, et al, 2020; Wu, et al., 2021; Chen, et al., 2009; Yong, et al., 2016

[3] ASX releases: 12Jul17, 18Oct17, 27Mar18, 29Jul20, 14Sep20, 27Oct20, 28Jan21, 24Mar21, 03Jun21, 07Jun21, 19Jul21

[4] REMAP-CAP background: https://www.remapcap.org/background

[5] DataBridge Market Research 2022, https://www.databridgemarketresearch.com/reports/global-acute-respiratory-distress-syndrome-ards-market

[6] Bice, T et al, (2013) Cost and Healthcare Utilization in ARDS – Different from Other Critical Illness?, Semin Respir Crit Care Med. 2013; 34(4): 529–536.