Dimerix

For Immediate Release

Teleconference at 11am today 4 June (AEST)
Conference ID: 10007545
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GLOBAL REMAP-CAP PLATFORM TRIAL PROTOCOL TO INCLUDE DMX-200 IN COVID-19 PATIENTS

- **DMX-200 selected for inclusion in the REMAP-CAP global study protocol for Acute Respiratory Distress Syndrome (ARDS) caused by COVID-19**
- **The REMAP-CAP clinical study is endorsed by the World Health Organisation (WHO)[1] and funded by a consortium of government and non-government organisations[2]**
- **Subject to regulatory and ethics approval in each territory, Dimerix will supply drug product from its existing GMP batch of DMX-200**
- **Dimerix has lodged provisional patent applications in addition to the existing granted patents in all key jurisdictions for use of any CCR2 inhibitor, including DMX-200, in ARDS**
- **DMX-200 Phase 2 clinical studies in kidney disease continue on track and on budget, with read-out anticipated mid-2020**

MELBOURNE, Australia, 04 June 2020: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, today announced that DMX-200 has been selected for inclusion in the protocol as a new treatment arm in the global Randomised, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia (REMAP-CAP) program aimed at treating patients with Acute Respiratory Distress Syndrome (ARDS) as a result of COVID-19. The REMAP-CAP program is endorsed by the World Health Organisation (WHO)[1], and designated as a Pandemic Special Study[1].

REMAP-CAP (and the companion platform REMAP-COVID) is an international adaptive platform trial run by a network of leading experts, institutions, and research groups collaborating on a global level. The program is studying a number of diverse interventions (https://www.remapcap.org/coronavirus) in hospitalized patients with proven or suspected COVID-19, enrolling in both ICU and non-ICU settings.

[1] *WHO endorsement: https://www.remapcap.org: Pandemic Appendix to the Core Protocol p.16*
[2] *Funding: available at https://www.remapcap.org/partners*

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Pandemic Special Study Designation

The REMAP-CAP program has been tasked with helping answer crucial questions during a declared pandemic. This designation ensures that knowledge translation of clinical trial results can occur directly with policymakers and public health officials for rapid implementation around the globe as required. It ensures that results generated from REMAP-CAP during a declared pandemic can be translated in an efficient and transparent manner to benefit affected patients, providing a collaborative pathway to global clinical practice. Furthermore, REMAP-CAP has been named by the Chief Medical Officers of the United Kingdom as a key clinical trial for COVID-19 (https://www.remapcap.org/coronavirus).

The study has several existing treatment domains including anti-viral, immune-modulation and immunoglobulin treatment arms. Now, REMAP-CAP are actively developing a domain within REMAP-CAP/COVID to study the effects of renin angiotensin system inhibition, which includes DMX-200. The study aims to, subject to appropriate regulatory and ethics approval in each territory (for example an IND submission is approved by the FDA in the US), compare directly the treatment effect of a number of study treatment options on the clinical outcomes of COVID-19 patients requiring hospital care. Upon regulatory approval, DMX-200 could be the only investigational new drug in the study since all of the other selected candidates are a repurposing of existing approved drugs with potential for COVID-19. DMX-200 has been selected based on the strong scientific rationale and unique potential to treat COVID-19 related issues that is supported by multiple publications (*see references at document end*). Details on the study design will become available following regulatory submission and approval.

Given the REMAP-CAP study is an adaptive design, patient numbers are not specified at the outset, rather are migrated to study arms showing promising efficacy signals. The overall REMAP-CAP study, currently registered as a Phase 4 study, plans to include over 7,000 patients at its >200 already initiated study sites across Asia-Pacific, Europe and North America. Dimerix will work closely with REMAP-CAP to rapidly obtain the necessary regulatory and ethics approvals, before providing DMX-200 to sites from its existing pharmaceutical grade manufactured supply. This global study is supported by several funding agencies worldwide (https://www.remapcap.org/partners) and Dimerix expects to be responsible for providing DMX-200 to the study.

“Overall, we see this trial as biologically compelling, operationally feasible, and potentially of tremendous clinical impact for a condition with high morbidity and mortality and for which few effective therapies are available” said Dr Patrick Lawler, REMAP-CAP RASi Domain Specific Working Group Chair and Clinician at Toronto General Hospital.

“We are extremely pleased to be in a position to support this global initiative investigating the potential of multiple therapies to treat COVID-19 patients dying of ARDS” said Dr Nina Webster, CEO & Managing Director of Dimerix. “Dimerix is uniquely positioned to support the global effort in identifying COVID-19 treatments, as well as having two Phase 2 renal clinical studies completing mid-2020.”

About DMX-200 in Acute Respiratory Distress Syndrome in Patients 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.

Dimerix has been working on DMX-200 as a renal therapy to reduce damage from inflammatory cells by blocking their signalling and limiting subsequent onset of fibrosis, a process that was discovered by Dimerix in Professor Kevin Pfleger's laboratory at the Harry Perkins Institute of Medical Research and the University of Western Australia. Based on the known effects in the lung of COVID-19, DMX-200 may also benefit ARDS patients with COVID-19 by reducing the inflammatory response in the lungs and thus reducing inflammation and subsequent fibrosis. Specifically, there are multiple credible publications recently reporting a SARS-CoV-2 (the virus causing COVID-19) induced elevation of MCP-1, the pro-inflammatory ligand acting on CCR2, the receptor targeted by DMX-200 (*see references at document end*).

Dimerix has secured ownership over what it believes is an important new drug discovery, including by lodging four different provisional patent applications for the use of any CCR2 inhibitor in ARDS. The new provisional patent applications, titled "Treatment for Virus Induced Acute Respiratory Distress Syndrome" or "Treatment for Acute Respiratory Distress Syndrome" were filed in the US in May 2020, and if granted, would expire post 2040. These new independent applications are in addition to the current protection afforded by Dimerix' core patent family (including granted patents in the US and other jurisdictions) which claims the utility of CCR2 antagonists (DMX-200) given concurrently with angiotensin receptor blockers (ARBs) in various chronic inflammatory conditions, including in the lung and the kidney.

Detailed information about the REMAP-CAP trial can be found at ClinicalTrials.gov Identifier: NCT02735707 and information about REMAP-CAP at https://www.remapcap.org.

Dimerix has two further Phase 2 studies currently underway: DMX-200 for FSGS; and DMX-200 for Diabetic Kidney Disease, and an asset in pre-clinical development, DMX-700 for chronic obstructive pulmonary disease (COPD). The two kidney Phase 2 clinical studies being conducted at sites across Australia both remain on budget and on track, with data read-out expected mid-2020. The new COVID-19 opportunity has no impact on the status or development plans for the renal program.

For further information, please visit our website at www.dimerix.com or contact:

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Conference call details

Time: 11:00 (AEST) Thursday 4 June
Conference ID: 10007545

Access the call by pre-registration (preferred option) or by direct dial-in (delays possible):

1. **Pre-registration**
Participants can pre-register by navigating to: **https://s1.c-conf.com/diamondpass/10007545-invite.html**
Registered participants will receive their dial in number upon registration to enter the call automatically on the day.

2. Dial-in directly (toll free)			
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References

1. Yong Xiong, Yuan Liu, Liu Cao, Dehe Wang, Ming Guo, Ao Jiang, Dong Guo, Wenjia Hu, Jiayi Yang, Zhidong Tang, Honglong Wu, Yongquan Lin, Meiyuan Zhang, Qi Zhang, Mang Shi, Yingle Liu, Yu Zhou, Ke Lan & Yu Chen (2020), 'Transcriptomic characteristics of bronchoalveolar lavage fluid and peripheral blood mononuclear cells in COVID-19 patients', Emerging Microbes & Infections, vol. 9, pp. 761-770.
2. Williams AE, José RJ, Mercer PF, et al. (2017), 'Evidence for chemokine synergy during neutrophil migration in ARDS; Thorax, vol.72, pp. 66-73.
3. Yao Shen, Diane Wang & Xiangdong Wang (2011), 'Role of CCR2 and IL-8 in acute lung injury: a new mechanism and therapeutic target', Expert Review of Respiratory Medicine, vol. 5, pp. 107-114.
4. Merad, M., Martin, J.C. (2020), 'Pathological inflammation in patients with COVID-19: a key role for monocytes and macrophages', Nat Rev Immunol, vol. 20, pp. 355–362.

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. In addition to this announcement, Dimerix is currently developing its proprietary product DMX-200 for both Diabetic Kidney Disease and Focal Segmental Glomerulosclerosis (FSGS). DMX-200 was 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 kidney disease. DMX-200 has 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).

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.

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.

DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

About DMX-700

COPD is a progressive and life-threatening lung disease. The primary cause of COPD is exposure to tobacco smoke (either active smoking or secondary smoke), however it 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. 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.

Initial studies have been completed, and Dimerix has completed a key step in securing ownership over what it believes is an important new drug discovery by lodging a provisional patent application for DMX-700. Over the next 12 months Dimerix will conduct further proof of concept studies to perform the value-added verification in support of a robust product development pathway and patent position.