For Immediate Release

DIMERIX COVID-19 PHASE 3 STUDY RECRUITING RAPIDLY IN EUROPE AND UK WITH DSMB ALSO COMPLETED SUCCESSFULLY

- 662 patients with COVID-19 pneumonia now enrolled across Dimerix's ACE2 RAS modulation REMAP-CAP study domain in Europe, a significant increase of ~39% in less than four weeks
- REMAP-CAP Data Safety Monitoring Board (DSMB) review, evaluating the available study data for participant safety, study conduct and progress, has been completed and has recommended the study continue
- Additional study sites anticipated across Italy and France once regulatory approval is received
- If effective in the treatment of COVID-19, DMX-200 may be equally effective across all strains and other infection-related pneumonias[2]

MELBOURNE, Australia, 16 December 2021: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, advises that 662 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 662 subjects, 485 have been recruited in sites across the UK, and represents a 39% increase since 23 November 2021 (ASX Investor Presentation 23 November 2021). DMX-200 has regulatory and ethics approval in both the UK and the Netherlands and is available at sites for administration to patients randomised to the DMX-200 treatment arm. Additional sites in other European countries are anticipated in the coming months, including Italy and France.

A planned, routine review of the ACE2 RAS modulation REMAP-CAP study domain in Europe by an independent REMAP-CAP DSMB has been completed and "*the DSMB did not note any significant or concerning safety issues. The DSMB recommendation is to continue enrolling within the study overall and within the [ACE2 RAS] domain*". A review by an independent DSMB is consistent with good clinical practice in clinical trials.[1] The primary responsibilities of the DSMB are to review and evaluate the available study data for participant safety, study conduct and progress, and to make recommendations concerning the continuation, modification, or termination of the trial.

The company's approach is based on a clear scientific rationale, is unique and potentially complementary to others being investigated globally, and importantly if effective in this study, would likely be effective against any strain as well as potentially other pneumonias with a common mechanism of action.[2]

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Antiviral medications are typically effective at preventing damage caused by a virus when administered within 3-5 days of infection (when many are asymptomatic), as the treatment aims to minimise viral replication.[3] Further, antivirals are usually very specific for a virus and sometimes even the particular strain of the virus. In contrast, DMX-200 does not rely on early inhibition of viral replication but aims to prevent the damaging immune response and lung flooding regardless of vaccination or antiviral treatment. As such, DMX-200 may be beneficial for patients with a wide range of respiratory diseases in addition to the various COVID-19 variants.[2]

COVID-19 Epidemiology

During the week 29 November to 5 December, the WHO reported COVID-19 deaths increased by 10% globally, with over 52,500 new deaths reported during that week alone.[4] The African Region reported the largest increase in new weekly cases (111% increase compared to the previous week) and a corresponding 82% increase in hospital admissions due to COVID-19 during the same period.[4] However, Europe continues to report the highest incidence of COVID-19, with 65% of new cases of COVID-19 and 55% of COVID-19 deaths globally during the week ending 5th December 2021.[4] As of 5 December, nearly 265 million confirmed cases and over 5.2 million deaths have been reported globally.[4]

On 13th December, the World Health Organization's (WHO) provided an update on the variants of concern.[5] In particular, the WHO determined that the overall risk related to the new variant of concern Omicron remains very high, as there was still limited data on the clinical severity of Omicron and the high transmission rates could lead to further surges with severe consequences.[5]

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)

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, can be seen at https://www.remapcap.org/protocol-documents. Should current recruitment rates continue, the study is expected to be fully enrolled by the end of Q1 CY 2022 (ASX Investor Presentation 23 November 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.[6]

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.[6]

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

Dimerix lead drug candidate, DMX-200, is being studied as part of two different investigator-led feasibility/Phase 3 studies in COVID-19 patients with respiratory complications, both of which are actively recruiting. As announced on 3 September 2020, 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.

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.

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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. DMX-200 is protected by granted patents in various territories until 2032.

In 2020, Dimerix completed two Phase 2 studies: one in FSGS and one in diabetic kidney disease, following a successful Phase 2a study in patients with a range of chronic kidney diseases in 2017. No significant adverse safety events were reported in any study, and all studies resulted in encouraging data that could provide meaningful clinical outcomes for patients with kidney disease. 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 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, respiratory distress 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.[7] The market size of Acute Respiratory Distress Syndrome (ARDS) in the seven major markets was expected to grow to US$934.81 million in 2026.[8] However, it is also likely to grow further as a result of the 2020 pandemic. The death rate associated with ARDS is high, with overall mortality between 30 and 40%.[7] 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.[9] 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.[10] For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney.[11] At this time, there are no drugs specifically 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,[12] 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[12]. 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.

References

[1] NHMRC Clinical Trials Data Safety Monitoring Board: https://www.australianclinicaltrials.gov.au/sites/default/files/content/For%20researchers/Data%20Safety%20Monitoring%20Boards_1.pdf

[2] Dysregulation of the CCR2/MCP-1 system has been extensively implicated in the pathogenesis of COVID-19 across all know strains (see Szabo, et al., 2020, Merad, et al., 2020; Xiong, et al, 2020, Wu, et al., 2021). In COVID-19, DMX-200 is hypothesised to work by inhibiting recruitment of activated monocytes to the lung. DMX-200 prevents recruitment of activated monocytes to areas of inflammation by blocking signalling of CCR2. This mechanism of action relates to the host (human) immune response to all infections, rather than a specific virus or strain leading to the conclusion that if DMX-200 is successful in showing benefit for patients with one strain of COVID-19, it would likely be effective against the different COVID-19 strain mutations based on its mechanism of action. The same mechanism of CCR2-mediated lung pathogenesis has been observed in a range of other infection-related pneumonias such as SARS-CoV and other generalised community acquired pneumonias (see Chen, et al., 2009;

Yong, et al., 2016). Therefore, if CCR2 inhibition is effective for patients with COVID-19, the common mechanism of action would likely be effective against any strain as well as potentially other pneumonias with a common mechanism of action.

[3] Brown L et al (2021) Early antiviral treatment in outpatients with COVID-19 (FLARE): a structured summary of a study protocol for a randomised controlled trial: DOI: 10.1186/s13063-021-05139-2

[4] WHO weekly epidemiology report 29Nov – 05Dec 2021: https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---7-december-2021

[5] WHO Weekly operational update on COVID-19 - 13 December 2021: https://www.who.int/publications/m/item/weekly-operational-update-on-covid-19---13-december-2021

[6] https://www.remapcap.org/

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

[8] https://www.prnewswire.com/news-releases/acute-respiratory-distress-syndrome-ards-market-to-reach-usd-934-8-million-by-2026--reports-and-data-300940537.html

[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4261619/

[10] Guruswamy Sangameswaran KD, Baradhi KM. Focal Segmental Glomerulosclerosis (July 2021), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/

[11] DelveInsight Market Research Report (2020); Focal Segmental Glomerulosclerosis (FSGS)- Market Insight, Epidemiology and Market Forecast -2030

[12] Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/