For Immediate Release

REMAP-CAP COVID-19 STUDY ANALYSIS UPDATE

- REMAP-CAP recruitment of non-critically-ill patients, paused in February 2022,[1] now closed[2]
- No safety concerns noted for DMX-200
- Efficacy results of the full clinical trial domain being analysed by REMAP-CAP; and will be reported as soon as available

MELBOURNE, Australia, 27 June 2022: Dimerix Limited (ASX: DXB), a biopharmaceutical company with Phase 3 clinical studies in inflammatory diseases currently underway, today confirmed that REMAP-CAP has formally close recruitment of moderate state (non-critically ill) COVID-19 patients to the ACE2 RAS Domain clinical study (including DMX-200) to allow for the full results of this domain to be analysed and reported.[2]

As previously reported, recruitment of critically ill patients to the trial was closed in February 2022, and recruitment of non-critically ill patients was paused pending further analysis of study safety data.[1]

The study closure in non-critically ill patients is not based on any further safety concerns but is instead a pragmatic decision reflecting the REMAP-CAP International Steering Committee's belief that continued recruitment of moderately severe COVID-19 patients would be challenging,[2] particularly given hospitalisation rates of COVID-19 patients appropriate for this study are generally decreasing globally.

The results of this study will be analysed by the REMAP-CAP team and prepared for publication. Dimerix will report the outcome as soon as it has been received from REMAP-CAP.

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. DMX-200 is protected by granted patents in various territories until 2032, with patent applications submitted globally that may extend patent protection to 2042.

In 2020, Dimerix completed two Phase 2 studies: one in FSGS and one in diabetic kidney disease, following a successful Phase 2a trial in patients with a range of chronic kidney diseases in 2017. No significant adverse safety events were reported in any trial, 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.

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.[3] For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney.[4] 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,[5] 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[5]. Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for FSGS. 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 a fast-tracked regulatory pathway to approval. Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

References

[1] ASX release 28Feb2022

[2] REMAP-CAP letter to sites: online: https://www.remapcap.eu/information-for-sites/

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

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

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