Dimerix

**Immediate Release**

# PHASE 3 DMX-200 COVID-19 STUDY EXPANDS INTO AUSTRALIA

- CLARITY 2.0 feasibility/Phase 3 study expanded to recruit patients with COVID-19 in Australia
- Six sites initially planned across New South Wales, Victoria and Queensland
- Study approved in India and open for recruitment
- If successful, DMX-200 would likely be effective against the different COVID-19 strain mutations based on its mechanism of action
- Strong balance sheet to support Dimerix clinical studies

MELBOURNE, Australia, 15 October 2021: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, has entered into an agreement with the NHMRC Clinical Trials Centre (CTC) at the University of Sydney to expand the CLARITY 2.0 clinical study to sites in Australia testing the Dimerix-developed drug candidate DMX-200 in COVID-19 patients with respiratory complications. An initial six sites will begin recruitment for the feasibility/Phase 3 study across New South Wales, Victoria and Queensland once regulatory and ethics approval is received.

There are an estimated 26,448 active COVID-19 cases in Australia, and approximately 1,500 patients currently hospitalised.[1] These numbers are expected to increase as border restrictions change over the coming months.[2] Vaccines are critically important to reduce the severity of symptoms and spread of the disease. However, even as vaccination rates increase, it is anticipated that a significant proportion of the population will remain susceptible to COVID-19 because they are not vaccinated or do not get an adequate protective response from the vaccines. Therefore, it is still likely that a large number of people will get infected, with many ending up with COVID respiratory complications and potentially long-COVID, which refers to symptoms that extend long beyond recovery from the virus. As such, there remains a great need for treatments for patients with COVID-19 within Australia.

"A safe, affordable, and effective oral treatment would be a huge advance in the fight against COVID-19. Even with the widespread uptake of vaccines, there will be some who remain susceptible to the virus. Improving treatments for patients hospitalised with COVID-19 remains crucial.

We are delighted to be part of a team working towards a treatment that could benefit COVID-19 patients globally."

*Professor Meg Jardine, Director of the NHMRC Clinical Trial Centre, University of Sydney*



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The CLARITY 2.0 study, which is already approved and open for recruitment in India, will recruit an aggregate of 600 patients across both India and Australia. The NHMRC CTC will be the local sponsor in Australia, led by Professor Meg Jardine. Additional countries that could recruit patients for the study is also being investigated.

The company's approach is based on a clear scientific rationale, 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.

**Record Balance Sheet Strength**

The Company's balance sheet is the strongest it has been in the Company's history, having received $24 million from the recent Share Purchase Plan (SPP) and two tranche Placement from institutional and strategic investors. As stipulated in the prospectus, the capital raisings will support the clinical programs including the pivotal Phase 3 study in FSGS patients. The oversubscriptions SPP funds enable Dimerix to support inclusion of DMX-200 in those additional CLARITY 2.0 territories as well as advance DMX-700 through pre-clinical development and towards the clinic.

*CLARITY 2.0*

The CLARITY 2.0 protocol is a seamless feasibility/Phase 3, investigator initiated, prospective, multi-centre, randomised, double blind, placebo-controlled study. The primary endpoint will be an 8-point clinical health score measured on treatment day 14. The clinical health score is adapted from the categorical scale recommended by the WHO for COVID-19 trials and ranks health states from being discharged with no limitations through to death. Participants will be treated for up to 28 days with long-term outcomes of treatment assessed at 26 weeks.

**6 clinical sites in Australia planned**

The study in both Australia and India is led by Professor Meg Jardine, Director of the NHMRC Clinical Trials Centre at The University of Sydney, Australia.

**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 supports both studies driven by the REMAP-CAP and CLARITY 2.0 teams including supply of DMX-200. Dimerix looks forward to reporting on progress as key milestones are met.

Dimerix continues to drive the Phase 3 pivotal study of DMX-200 in FSGS, a rare kidney disorder without an approved pharmacologic treatment that often leads to end-stage kidney failure, following first ethics submission, as announced to the ASX on 25 August 2021, as well as assess the next study design in diabetic kidney disease patients and finally advance the DMX-700 COPD program towards clinical stage 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. 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 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 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.[3] 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.[4] 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%.[3] 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.[5] 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.

Dimerix recognises and appreciates the support and collaboration of The George Institute for Global Health India within the expanse of research into SARS-CoV-2 and COVID-19. If DMX-200 in combination with an ARB is proven effective for the treatment of COVID-19 and is approved for an indication within this setting, Dimerix is committed to an upscale of opportunity for treatment including a fair and ethical supply of DMX-200 within India in line with industry standards.

***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.[6] For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney.[7] 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,[8] 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[8]. 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


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