Dimerix

Immediate Release

UPDATE OF DMX-200 STUDY IN COVID-19 PATIENTS IN INDIA

- India remains under horrendous pressure from the current COVID outbreak which is affecting all aspects of normal operations, including those of regulatory agencies
- CLARITY 2.0 coordinators have been directly advised of regulatory delays due to COVID infections at agency level, including a slower than expected approval of trial commencement
- Clinical site activation is continuing in anticipation of imminent regulatory approval for the trial that was previously anticipated during April
- Dimerix confirm that, to date, the company has not received any information or queries that suggest any underlying concerns with the study

MELBOURNE, Australia, 12 May 2021: Dimerix Limited (ASX: DXB), a clinical-stage drug development company, today provided an update on the CLARITY 2.0 study in COVID-19 patients in India.

According to figures from Johns Hopkins University, India recorded more than 750,000 new cases over the weekend, bringing the cumulative total close to 23 million cases and 250,000 deaths across the country to date. Furthermore, the World Health Organization (WHO) has announced that the coronavirus variant first identified in India last year was being classified as a "variant of global concern…with some preliminary studies suggesting increased transmissibility."

Following direct communications with Drug Controller General of India (DCGI - Indian regulatory authority), CLARITY 2.0 project management have been advised that as a result of the devastating wave affecting India, some DCGI and hospital staff are reported to have contracted COVID-19. Due to the significant number of COVID infections, some DCGI review meetings have been postponed and the final permit required for recruitment initiation of the CLARITY 2.0 study anticipated in April has been delayed. Pending DCGI meetings being resumed, all remaining site start up activities will be completed and sites are expected to start recruiting participants shortly. Advice will be provided when final approvals are received, and when dosing is to commence.

> "It is in these times that we can see more acutely how important it is to carry out research in areas that could most benefit from the findings. Despite the many challenges, our investigators, hospital research staff, and central coordinators are courageously continuing to progress COVID-19 research in the midst of a highly pressured situation."
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> *Erika Dempsey, CLARITY 2.0 Clinical Trial Program Manager,*

Beyond the evident pressure on DCGI, at this stage Dimerix is not aware of any material impediment to securing regulatory approval allowing commencement of the CLARITY 2.0 trial.

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"Continuing to complete high-quality research is vital in the fight against COVID-19, but the exponential spread of the virus in India is placing significant strain on the local teams' ability to carry out such research, with a profound impact on collaborating researchers, local hospitals and medical staff.

While the global community is rightly focussing on vaccine distribution and provision, there is an ongoing need for research into improving treatments for patients hospitalised with COVID-19, or at risk of heightened disease severity. We are going to need multiple strategies to contain this virus."

Arlen Wilcox, CLARITY 2.0 Clinical Trial Program Manager

CLARITY 2.0

CLARITY 2.0 is an investigator initiated, prospective, multi-centre, randomised, double blind, placebo-controlled study, commencing with 600 patients diagnosed with COVID-19. The primary endpoint is a 7-point scale of clinical health at treatment day 14, adapted from the endpoint recommended by the WHO for COVID-19 trials (scored from no hospitalisation or ventilation requirement through to death). Participants will be treated for up to 28 days and then assessed for clinical outcomes for a total of 26 weeks.

The study is led by Professor Meg Jardine, Director of the NHMRC Clinical Trials Centre at The University of Sydney, Australia, and conducted in collaboration with Professor Vivek Jha, Executive Director of The George Institute for Global Health, India.

Dimerix recognises and appreciates the support and collaboration of sites and participants in India, coordinated by The George Institute for Global Health, India. 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.

"While the COVID-19 situation in Australia appears to be improving, sadly COVID-19 continues to exert a terrible toll in many parts of the world. We continue to strive towards potentially treating COVID-19 patients suffering debilitating respiratory complications.

Any benefit from DMX-200 for respiratory complications associated with COVID-19, may have implications for a potential benefit in respiratory complications associated with other infections, such as pneumonia and influenza. Thus, this provides an opportunity that could extend well beyond the impact of COVID-19.

We look forward to recruiting participants and to reporting on dosing progress in the coming weeks."

Dr Nina Webster, CEO & Managing Director, Dimerix

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 Phase 3 studies in COVID-19 patients with respiratory complications. 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 and as key milestones are met.

Dimerix continues start-up activities for 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.

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 Diabetic Kidney Disease, Focal Segmental Glomerulosclerosis (FSGS) and Acute Respiratory Distress Syndrome (ARDS), 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 irbesartan, an angiotensin II type I (AT1) receptor blocker and the standard of care treatment for hypertension and kidney disease. DMX-200 is protected by 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. 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). DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.