Immediate Release

DMX-200 RECOMMENDED FOR REGULATORY APPROVAL IN COVID-19 STUDY IN INDIA

Highlights

- DCGI review complete and study formally recommended for regulatory approval
- Multiple clinical sites in India initiated
- Study protocol to recruit 600 participants with COVID-19 overall, with a safety analysis conducted after the first 80 patients
- Study recruitment of DMX-200 in COVID-19 patients hospitalised with respiratory complications will commence in India imminently
- Participant recruitment and dosing expected in next few weeks
- Study subjects will be evaluated for WHO endorsed health score at day 14
- If effective, DMX-200 would likely be COVID-19 strain agnostic based on its mechanism of action

MELBOURNE, Australia, 24 September 2021: Dimerix Limited (ASX: DXB), a clinical-stage drug development company, is pleased to announce that the Indian regulatory agency, the Central Drugs Standard Control Organization (DCGI), met on 02 September 2021 to review the study protocol and has now formally recommended that the DMX-200 clinical study in COVID-19 patients be approved. Multiple clinical sites in India have been initiated and are ready to begin recruitment in the feasibility/Phase 3 clinical study of DMX-200 for the treatment of respiratory complications associated with COVID-19 imminently.

The DCGI approval is the final regulatory agency approval required for commencement of recruitment in the CLARITY 2.0 study and the first patient is expected to be dosed in the next few weeks, once, the approval permit is received. Multiple other sites across India are also expected to initiate and commence recruitment in the coming weeks.

On 23 August 2021, the National Institute of Disaster Management (NIDM) in India has warned of an imminent third wave of COVID that is expected to peak around October, "*…complicated by the new and more virulent mutated variants of SARS Cov-2 that have the ability to escape immunity from earlier infections and in some cases even the prevalent vaccines*".[1] As reported by the BBC in August 2021 , virologist Dr Shahid Jameel commented that "*There is also risk in letting people get infected, even while preventing deaths, and that risk is of long-COVID - long-term problems after recovering from the original infection - which afflicts up to a third of those infected, including asymptomatic patients*".[2]

Dimerix HQ
425 Smith St, Fitzroy 3065
Victoria, Australia
T. 1300 813 321
E. info@dimerix.com

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.

"The University of Sydney NHMRC Clinical Trials Centre is extremely pleased with the DCGI recommendation and to be able to commence recruitment in the CLARITY 2.0 study to investigate DMX-200 in patients with COVID-19 imminently. It is possible the virus, particularly the new variants, will be circulating globally for the foreseeable future. It's essential we continue to investigate new treatments to help reduce the burden of this pandemic.

Vaccines have now been developed that aim to prevent infection or reduce disease severity. However, even with the widespread uptake of vaccines, there will be some who remain susceptible to COVID-19. Improving treatments for patients hospitalised with COVID-19 remains crucial."

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

As announced on 12 May 2021, the study was submitted to DCGI in quarter 1 2021, however the regulatory process was delayed as a result of the devastating wave of COVID infection affecting India earlier in 2021, and the subsequent impact on the DCGI department reviewing study dossiers. As recruitment begins, the expected timing of study results will become clearer, and any change to the current timelines will be advised.

CLARITY 2.0

Study sites ready to recruit

The CLARITY 2.0 protocol, as submitted to the DCGI and recommended for approval, is a seamless feasibility/Phase 3, investigator initiated, prospective, multi-centre, randomised, double blind, placebo-controlled study. The DCGI required an amendment to the submitted protocol to include an analysis conducted after the first 80 patients[3] (referred to as a Phase 2 study in the DCGI minutes), before seamlessly continuing to enrol the full 600 patients diagnosed with COVID-19. 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 longer term outcomes assessed at 26 weeks.

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

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.

"Sadly, the world continues to feel the effects of COVID-19, including here in Australia. We are extremely pleased to be in a position to potentially treat COVID-19 patients suffering debilitating respiratory complications, through both the CLARITY 2.0 study as well as the REMAP-CAP study currently recruiting in Europe.

Whilst COVID-19 is likely to be around for a while yet, if DMX-200 does show benefit in respiratory complications associated with COVID-19, it may also show benefit in respiratory complications associated with other infections too, 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 months."

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 feasibility/Phase 3 studies in COVID-19 patients with respiratory complications. As announced on 03 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 and 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 in August 2021, as well as assess the next study design in diabetic kidney disease patients and finally advance the DMX-700 COPD program towards the clinical stage of development.

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

Dr Nina Webster
Dimerix Limited
Chief Executive Officer & Managing Director
Tel: +61 1300 813 321
E: investor@dimerix.com

Rudi Michelson
Monsoon Communications
Tel: +61 3 9620 3333
Mob: +61 (0)411 402 737
E: rudim@monsoon.com.au

Authorised for lodgement by the Board of the Company

—END—

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.[4] 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.[5] 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%.[4] 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.[6] 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.[7] For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney.[8] 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,[9] 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[9]. 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] National Institute Disaster Management India 2021: https://nidm.gov.in/PDF/pubs/TWPCVR_2021.pdf -

[2] Covid-19: The mystery of rising infections in India's Kerala: https://www.bbc.com/news/world-asia-india-58054124

[3] DCGI 02Sep2021, Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MTUxMA==

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

[5] 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

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

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

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

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