Dimerix

Immediate Release

CLARITY 2.0 RECEIVES ETHICS APPROVAL IN AUSTRALIA PHASE 3 COVID-19 STUDY

- First ethics approval received for CLARITY 2.0 feasibility/Phase 3 study in patients with COVID-19 in Australia
- Six sites planned to recruit across New South Wales, Victoria and Queensland
- Recruitment and dosing expected to commence in Australia in January
- Study previously approved in India[1] and open for recruitment
- If effective in the treatment of COVID-19, DMX-200 may be equally effective across all strains and other infection-related pneumonias[6]

MELBOURNE, Australia, 23 December 2021: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, confirmed CLARITY 2.0 has received Australian ethics approval from the Research Ethics and Governance Office Ethics Committee representing the clinical sites for the feasibility/Phase 3 clinical trial of DMX-200 in patients with COVID-19 respiratory complications. The CLARITY team anticipates initiating recruitment across New South Wales, Victoria and Queensland in January.[2]

The study approval comes as COVID-19 case numbers and hospitalisations rise significantly across Australia, which may influence recruitment rates.[3] There are an estimated 33,140 active COVID-19 cases in Australia, and approximately 850 patients currently hospitalised.[3] These numbers are expected to increase as restrictions ease.[4]

The CLARITY 2.0 study, which is already approved[1] and open for recruitment in India,[5] will recruit an aggregate of 600 patients across both India and Australia. The NHMRC Clinical Trials Centre (CTC) will be the local sponsor in Australia, led by Professor Meg Jardine. Additional countries that could recruit patients for the study are also being investigated.

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.[6]

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.[7] 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.[6]

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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.

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, in collaboration with Professor Vivek, Jha, Director of The George Institute, India.

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 and 22 December 2021, for one of these studies Dimerix was awarded $1.1 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.[8] 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.[9] 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%.[8] 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.[10] 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.[11] For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney.[12] 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,[13] 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[13]. 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 ASX 24 September 2021
2 ASX 15 October 2021
3 Australian Government Health Department: https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/coronavirus-covid-19-case-numbers-and-statistics - cited 14 Oct 2021
4 Prime Minister of Australia statement 01Oct21: https://www.pm.gov.au/media/next-steps-reopen-world
5 ASX 25 October 2021
6 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.
7 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
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