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Dimerix

Immediate Release

CLARITY 2.0 COVID-19 STUDY OUTCOME

Highlights

- CLARITY 2.0 investigator-led study in COVID-19 patients has completed first analysis
- DMX-200 was found to be generally safe and well-tolerated in COVID-19 patients
- Primary Endpoint: At Day 14, 92% of participants did not require hospitalisation and had no limitation on activities (Score of 1 on the Clinical Health Score Scale) in both arms; no formal statistical analyses of efficacy were completed given the small sample size
- Secondary Outcomes: 1) the median time to oxygen free status was 4 days in the DMX-200 group and 5 days in the placebo group; 2) The median length of hospital stay was 6 days in the DMX-200 group and 6 days in the placebo group, with no formal statistical analyses of efficacy completed
- Dimerix remains focussed on its flagship program, the Phase 3 ACTION3 pivotal study of DMX-200 in Focal Segmental Glomerulosclerosis (FSGS) which is actively recruiting globally[1]

MELBOURNE, Australia, 13 December 2022: Dimerix Limited (ASX: DXB) a biopharmaceutical company with late-stage clinical assets in inflammatory diseases, today confirmed that the CLARITY 2.0 investigator-led study of DMX-200 in COVID-19 patients has reported top line data. In total, 49 patients were recruited into the study, with 25 receiving DMX-200 and 24 receiving a placebo for 28 days. All patients were treated concurrently with an angiotensin receptor blocker (ARB). Protocol adherence was high and medication adherence complete.

DMX-200 appeared to be safe and well-tolerated, with no notable variation in the incidence or severity of adverse events between treatment with DMX-200 or placebo. There were no serious adverse events related to the drug reported. The safety data findings are entirely consistent with existing and growing strong safety profile of DMX-200.

The cohort was low risk, highly vaccinated and with high rates of other COVID-19 treatments. The median age was 37 years and 92% had received prior COVID-19 vaccination. In addition, 69% of patients received concomitant corticosteroid treatment, a therapy now proven effective in the treatment of hospitalised COVID-19.

At Day 14, 92% of participants did not require hospitalisation and had no limitation on activities (score of 1 on the Health Score Scale) in both arms (Primary Endpoint), and 4% in each group were not hospitalised but had limitation on activities (score of 2 on the Health Score Scale). Given the low-risk patient population recruited, there was interest in exploring alternative endpoints including time to oxygen free status defined as the time to a score of 3 or less. The median time to oxygen free status was 4 days in the DMX-200 group and 5 days in the placebo group. The median length of hospital stay was 6 days in the DMX-200 group and 6 days in the placebo group. The study was halted early due to recruitment challenges driven in part by falling rates of hospitalised COVID-19.

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"Although we faced multiple challenges in executing this study, it is pleasing to see the improved outcomes from COVID-19 overall that are associated with high vaccination rates and the uptake of proven therapies"

Professor Meg Jardine, CLARITY 2.0 Steering Committee Chair

In November 2022, the CLARITY group also published the results of their CLARITY 1.0 clinical study of angiotensin receptor blockers versus placebo,[2] and noted that ARBs alone did not improve outcomes in patients hospitalised with mild COVID-19, but that there was no overall signal of harm over the 28 days of treatment.

"To date, we have completed four clinical studies in the kidney disease space, all providing consistent and encouraging safety and efficacy data in kidney disease to support our ACTION3 Phase 3 study in FSGS. It is extremely pleasing to see, once again, no reason to doubt the safety profile exhibited by DMX-200 in these COVID-19 patients.

The scientific rationale for using DMX-200 in COVID related respiratory conditions was sound, and whilst it is very pleasing to see that 92% of all patients in the study made a full recovery, we recognise that there were insufficient patient numbers to provide any statistical significance. We also recognise that this was the first study of DMX-200 in any respiratory condition, which is a very different cohort of patients compared to kidney disease.

Dimerix remains very focussed on its flagship program, the Phase 3 ACTION3 pivotal study of DMX-200 in Focal Segmental Glomerulosclerosis. We are excited by the progress made and very much look forward to reporting on the upcoming key milestones for this program."

Dr Nina Webster, CEO & Managing Director, Dimerix Limited

As an investigator-led trial, the study has been a relatively low-cost source of clinical data for Dimerix. Dimerix proactively supported the study driven by the CLARITY 2.0 team in providing information for the regulatory submissions and in supplying DMX-200 to the study sites.

Dimerix has multiple assets in commercially attractive and growing markets that have a high unmet need, no current marketed competition, and with a potential fast pathway to market. Dimerix continues to drive the FSGS Phase 3 program, as well as further progress the diabetic kidney disease and COPD programs.

CLARITY 2.0 Rationale

The use of DMX-200 in this study was based on a clear scientific rationale, being 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.[3]

The CLARITY study was 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.

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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.[4] For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney.[5] 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,[6] 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[6]. 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 31May2022

2 Jardine M et al (2022) Angiotensin receptor blockers for the treatment of covid-19: pragmatic, adaptive, multicentre, phase 3, randomised controlled trial, BMJ 2022; 379, doi: https://doi.org/10.1136/bmj-2022-072175

3 Based on Szabo, et al., 2020; Merad, et al., 2020; Xiong, et al, 2020; Wu, et al., 2021; Chen, et al., 2009; Yong, et al., 2016

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

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

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

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