Immediate Release

CLARITY 2.0 COVID-19 STUDY CONCLUDES RECRUITMENT

Highlights

- CLARITY 2.0 investigator-led study in COVID-19 patients concludes recruitment
- 49 patients were recruited into the CLARITY 2.0 study
- Safety and efficacy results of the clinical trial currently being analysed by CLARITY team and will be reported as soon as available
- If effective, DMX-200 may be beneficial for patients with a wide range of respiratory diseases in addition to the various COVID-19 variants[1]
- 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[2]

MELBOURNE, Australia, 18 August 2022: Dimerix Limited (ASX: DXB) a biopharmaceutical company with Phase 3 clinical studies in inflammatory diseases currently underway, today confirmed that the CLARITY 2.0 led study of COVID-19 patients has concluded recruitment to allow this study to be analysed and reported. An interim safety analysis was planned after the first 80 patients recruited in India. Given additional patient recruitment would likely not change the data outcomes relating to safety and efficacy, recruitment was closed prior to the 80 patients which will enable the faster reporting of results. In total, 49 patients were recruited into the study.

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

The results of this study will be analysed by the CLARITY team. Dimerix will report the outcome as soon as it has been received from CLARITY.

Dimerix remains focussed on its flagship program, the Phase 3 ACTION3 pivotal study of DMX-200 in Focal Segmental Glomerulosclerosis (FSGS); advancing the diabetic kidney disease program towards the next clinical study, and planning the first clinical study for the DMX-700 chronic obstructive pulmonary disease (COPD) program.

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

"Dimerix was pleased to support both the CLARITY and REMAP-CAP studies into the treatment of COVID-19 disease using DMX-200 based on its compelling mechanism of action and demonstrated safety profile, particularly as there were few viable therapeutic options for treatment of COVID. With the recruitment now concluded, the current data can be assessed for positive signs of proof of concept. If a positive signal is substantiated, Dimerix may then assess the next steps to progress towards the ultimate therapeutic outcome for these patients. With both COVID studies now under data review by the investigators, Dimerix' continues to focus on our lead Phase 3 FSGS program, and further pipeline development."

Dr Nina Webster, Dimerix CEO & Managing Director

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.[1]

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.[3] 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.[1]

The CLARITY 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, Director of The George Institute, India.

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

Follow us on **LinkedIn** and **Twitter**

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 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

2 ASX release 31May2022

3 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

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/