Immediate Release

FIRST ETHICS AND REGULATORY APPROVALS RECEIVED FOR DMX-200 PHASE 3 STUDY IN FSGS KIDNEY PATIENTS

- First ethics and regulatory approval received for ACTION3 Phase 3 FSGS study in Australia
- >50% sites selected globally to conduct study Part 1 to first interim analysis point
- Recruitment and screening expected to commence this quarter

MELBOURNE, Australia, 21 October 2021: Dimerix Limited (ASX: DXB), a biopharmaceutical company with multiple near-term Phase 3 clinical studies in inflammatory diseases, has received Australian ethics and regulatory approval for its pivotal Phase 3 clinical trial, ACTION3, to evaluate the efficacy and safety of DMX-200 against a placebo in patients with Focal Segmental Glomerulosclerosis (FSGS) kidney disease. Dimerix anticipates recruitment and screening to commence during the quarter ending December 2021.

The single Phase 3 study in FSGS patients has built in two interim analysis points designed to capture evidence of both proteinuria and kidney function (eGFR slope) during the study, aimed at generating sufficient evidence to support accelerated marketing approval.

Dimerix has selected more than half of the anticipated ~75 global sites across multiple territories to conduct Part 1 of the Phase 3 study (first interim analysis point), five of which are in Australia. Clinical sites will be initiated country by country, based on a number of factors including speed of regulatory and ethics submissions and reviews. Submissions in other territories, including the US and Europe, are anticipated in the quarter ending December 2021.

"Our preparations to initiate sites globally are well underway and receiving this first ethics and regulatory approval is a significant milestone for the company. We expect recruitment to begin this quarter and look forward to reporting on recruitment progress and our first interim analysis in due course.

Following the encouraging Phase 2a study data reported in 2020, we are excited to deliver on the DMX-200 program for FSGS patients who currently have few treatment options."

Dr Nina Webster, CEO & Managing Director, Dimerix

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About FSGS

Focal Segmental Glomerulosclerosis (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.[1] For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney.[2] 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,[3] 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[3]. Because of the rare nature of the disease, Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe and has been granted access to the MHRA Innovative Licencing and Access Pathway in the UK. This is a special status granted to a drug to treat a rare disease or condition; the designation means that DMX-200 clinical development and regulatory pathway can potentially be fast-tracked and receive tax and other concessions to help it get to market such as 7 years (FDA) and 10 years (EMA) of market exclusivity if regulatory approval is received.

Dimerix continues to drive the Phase 3 pivotal study of DMX-200 in FSGS, assess the next study design in diabetic kidney disease patients and advance the DMX-700 COPD program towards clinical stage development.

Orphan Drug Designation

Dimerix has received Orphan Drug Designation for DMX-200 in both the US (ASX:14 December 2015) and Europe (ASX: 21 November 2018), and the equivalent Innovative Licensing and Access Pathway (ILAP) designation in the UK (ASX: 07 June 2021), for the treatment of FSGS. These designations provide regulatory and financial benefits to help bring new drugs to market faster, including reduced fees during the product development phase, protocol assistance from the regulatory authorities, and 7-year (US) and 10-year (Europe) market exclusivity following product approval.

Two Phase 3 Clinical Studies in Respiratory Complications Associated with COVID-19

Dimerix lead drug candidate, DMX-200, is also 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 (ASX: 03 September 2020), with support from UniQuest.

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

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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.

ESG Statement: *Dimerix is committed to integrating Environmental, Social and Governance (ESG) considerations across the development cycle of its programs, processes and decision making - being alert and responsive to the challenges and opportunities of doing business responsibly and sustainably.*

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 patients with COVID-19 in two separate studies: REMAP-CAP and CLARITY 2.0.

References

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

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

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