Immediate Release

MAJOR MILESTONE REACHED WITH FIRST REGULATORY APPROVAL IN EUROPE RECEIVED FOR DMX-200 PHASE 3 STUDY IN FSGS KIDNEY PATIENTS

- **Major milestone achieved with first European regulatory approval received from the Danish Medicines Agency for ACTION3 Phase 3 FSGS study in Denmark**
- **Represents first regulatory study approval for DMX-200 in kidney patients outside of Australia/New Zealand and a significant step forward for the global Phase 3 clinical trial**
- **97% sites selected globally to conduct Part 1 of the study to first interim analysis point**
- **Site initiation and training underway in preparation for recruitment at sites globally**

MELBOURNE, Australia, 01 February 2022: Dimerix Limited (ASX: DXB), a biopharmaceutical company with multiple near-term Phase 3 clinical studies in inflammatory diseases, has reached a significant milestone with the receipt of the first regulatory approval in Europe (for Denmark) 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. This is the first time DMX-200 has been approved for use in kidney patients by a regulator outside of Australia/New Zealand. Recruitment in Denmark will commence once ethics approval is received.

The single Phase 3 study in FSGS patients has two interim analysis points built in that are 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 73 of the planned 75 global sites (97%) across 12 countries to conduct Part 1 of the Phase 3 study (first interim analysis point), and 15 of those 75 sites are in Europe. Recruitment for the study is expected to commence imminently, starting with Australia, following site initiation including staff training.

ACTION3
FSGS CLINICAL STUDY

FSGS Phase 3 Study - ACTION3

The Phase 3 study, which is titled **"A**ngiotensin II Type 1 Receptor (AT1R) & **C**hemokine Receptor 2 (CCR2) **T**argets for **I**nflammat**o**ry **N**ephrosis" – or ACTION3 for short, is a pivotal (Phase 3), multi-centre, randomised, double-blind, placebo-controlled study of the efficacy and safety of DMX-200 in patients with FSGS who are receiving a stable dose of an angiotensin II receptor blocker (ARB). Once the ARB dose is stable, patients, aged 18 to 80 years, will be randomized to receive either DMX-200 (120 mg capsule twice daily) or placebo.

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Further information about the study can be found on ClinicalTrials.gov (Study Identifier: NCT05183646) or Australian New Zealand Clinical Trials Registry (ANZCTR) (Study Identifier ACTRN12622000066785).

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[4] and Europe[5] and has been granted access to the MHRA Innovative Licencing and Access Pathway in the UK.[6] 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.

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, as well as progress the next study design in diabetic kidney disease patients and finally advance the COPD program towards the clinical stage of development.

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/

[4] ASX 14 December 2015

[5] ASX: 21 November 2018

[6] ASX: 07 June 2021