Immediate Release

FDA IND APPROVAL FOR THE ACTION3 PHASE 3 CLINICAL TRIAL OF DMX-200 IN FSGS

- FDA IND approved for ACTION3 Phase 3 clinical study, paving the way for patient recruitment in the United States
- United States is one of 12 countries to recruit patients for Part 1 of the ACTION3 clinical study
- The trial is being conducted at 75 sites across 12 countries,[1] with 19 of those sites in the US
- All activated sites are proactively screening for suitable patients
- The study has 2 interim data analysis points, the second of which may enable accelerated marketing approval[2]
- The first interim analysis is anticipated in the first half of 2023[3]

MELBOURNE, Australia, 9 May 2022: Dimerix Limited (ASX: DXB), a biopharmaceutical company with Phase 3 clinical studies in inflammatory diseases, is pleased to announce it received approval from the US Food and Drug Administration (FDA) on 6 May 2022 (US time) to proceed with the Phase 3 study of DMX-200 in patients with focal segmental glomerulosclerosis (FSGS) in the United States. The Investigational New Drug (IND) application for the ACTION3 clinical study is now active, paving the way for patient recruitment in the United States.

The ACTION3 Phase 3 study will recruit across 75 sites in 12 different countries globally, with 19 of those clinical sites having been selected in the US. Ethics and regulatory submissions have been made in all 12 countries, with all activated sites proactively screening for suitable patients.

Dimerix CEO & Managing Director, Dr Nina Webster, commented "FDA approval of our IND for the Phase 3 FSGS study is an important milestone, as it includes regulatory review of all manufacturing, nonclinical and clinical data that we have generated for the DMX-200 program to date, and we are delighted to be in a position to recruit patents as we strive towards finding new and much needed treatments for patients with FSGS".

FSGS Phase 3 Study - ACTION3

The single Phase 3 study in FSGS patients, which is already recruiting in other territories globally, has two interim analysis points built in that are designed to capture evidence of proteinuria and kidney function (eGFR slope) during the study, aimed at generating sufficient evidence to support accelerated marketing approval[42] Part 1 of the study will conclude after the first interim analysis, once 72 patients have completed 35 weeks treatment, and is expected to occur in the first half of 2023 (subject to recruitment).[3]

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The study will continue seamlessly into Part 2 of the study. Patients recruited into the study will need to demonstrate a minimum of 6 weeks stable dosing of an angiotensin receptor blocker prior to randomisation and dosing with DMX-200 or placebo.

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 will be randomized to receive either DMX-200 (120 mg capsule twice daily) or placebo.

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).

Dimerix continues to drive the Phase 3 pivotal study of DMX-200 in FSGS, support both feasibility/Phase 3 studies driven by the REMAP-CAP and CLARITY 2.0 teams for DMX-200 in COVID-19 patients, assess the next study design in diabetic kidney disease patients and advance the DMX-700 COPD program towards clinical stage development.

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

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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 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.

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.[5] For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney.[6] 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,[7] 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[7]. 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 investor presentation 29Mar2022*

2 *ASX 25Aug2021*

3 *ASX investor presentation 23Nov2021*

4 *ASX 25Aug2021*

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

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

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