Immediate Release

FIRST PATIENT ENTERS DMX-200 OPEN LABEL EXTENSION STUDY AFTER SUCCESFULLY COMPLETING ACTION3 PHASE 3 TRIAL

- First patient enters DMX-200 Open Label Extension (OLE) study after successfully completing the ACTION3 Phase 3 clinical trial
- The OLE study allows patients who have successfully completed the ACTION3 Phase 3 clinical trial, to optionally start or continue a 2 year treatment of DMX-200 in an open label (unblinded) setting
- All patients in the OLE study will receive DMX-200, regardless of whether they received DMX-200 or placebo during the randomised and blinded phase of the ACTION3 Phase 3 clinical trial
- The OLE study will allow additional long-term data to be collected on DMX-200, to support future potential regulatory filings
- 116 patients have currently been randomised/dosed in the ACTION3 Phase 3 clinical trial

MELBOURNE, Australia, 10 September 2024: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical asset in kidney disease, today announced that the first patient has successfully completed the ACTION3 Phase 3 clinical trial, including the initial follow-up period, and has chosen to enter the global open-label extension (OLE) study. The OLE study is optional for all qualifying patients who have completed the ACTION3 Phase 3 clinical trial and offers a 2 year treatment with DMX-200. The OLE study will evaluate the longer term safety and efficacy of DMX-200 treatment in patients with focal segmental glomerulosclerosis (FSGS) in an open label (unblinded) setting and will run in conjunction with the Company's existing blinded ACTION3 Phase 3 global clinical trial.

All patients in the OLE study will receive DMX-200, regardless of whether they received drug or placebo during the ACTION3 Phase 3 clinical trial. All patients in the OLE study will continue on the background standard of care blood pressure medication, angiotensin receptor blocker (ARBs) and will be treated for 2 years with DMX-200. Further information on Open Label Extension studies is outlined later in this announcement.

What is an Open Label Extension (OLE) study?

When a promising new drug is being tested for a serious problem, doctors and patients generally want the drug to be available outside the period of the randomised controlled trial. As there is inevitably a delay between the completion of the trial and the potential marketing approval, participants often want to continue treatment.[1] Compassionate use schemes, such as the Special Access Scheme in Australia, which are programs that allow patients to access non-approved medications, are not considered research and as such data cannot be collected. In contrast, a properly designed and conducted OLE study can provide rigorous information on long term safety and tolerability of potential new drugs, as well as enable those patients who participated in the study to remain on drug.[1] This in turn can benefit the licensing application for the drug by providing longer term data that would otherwise not be available until after the licence was approved.

All participants in the open label extension study are given the study drug, regardless of whether they were on drug or placebo during the blinded phase of the Phase 3 study, and so both they and the investigators know they are receiving the active drug (i.e. the open label study is "unblinded").

What data are collected during DMX-200 Open Label Extension study

Data are collected periodically throughout the study. At the end of the OLE treatment period, the change in urine protein to creatinine ratio (UPCR) and the change in estimated glomerular filtration rate (eGFR), which are markers of drug efficacy, will be evaluated. Further, a comparison between those patients who were given placebo and those patients who received DMX-200 in the ACTION3 Phase 3 trial will also be made at the end of the OLE study.

The initiation of the open label extension study is another important milestone as we advance DMX-200 as a potential treatment to address the significant unmet need of patients with FSGS. The Open Label Extension study will provide us with additional longer term information regarding treatment with DMX-200, and we are pleased to be able to provide the active drug to all patients who complete the ACTION3 Phase 3 trial, irrespective of treatment arm. We are delighted that the investigators, participants and regulatory authorities endorse us moving forward into this important longer term study, supported by the strong safety profile to date of the drug.

We acknowledge the FSGS patients and their families who continue to inspire us, as well as our investigators, partners and collaborators who provide invaluable assistance in our product development efforts. Working together with the renal community, we strive towards bringing this potential new and much-needed therapeutic solution for people living with FSGS."

Dr David Fuller, Chief Medical Officer, Dimerix

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Authorised for lodgement by the Board of the Company

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About ACTION3 FSGS Phase 3 Study

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 DMX200 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 DMX200 (120 mg capsule twice daily) or placebo.

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

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 Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company working to improve the lives of patients with inflammatory diseases, including both kidney and respiratory diseases. Dimerix is currently focussed on developing its proprietary Phase 3 product candidate DMX-200 (QYTOVRA® in some territories), for Focal Segmental Glomerulosclerosis (FSGS) kidney disease, and is also developing DMX-700 for Chronic Obstructive Pulmonary Disease (COPD). DMX-700 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.

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 addition to any exclusivity period that may apply in key territories. 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.

About 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.[2] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[3] At this time, there are no drugs specifically approved for FSGS anywhere in the world, so the treatment options and prognosis are limited. FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,[2] and worldwide about 220,000.[4] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[5] 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

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

3 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*

4 *Delve Insight Market Research Report (2022): Focal segmental glomerulosclerosis (FSGS) – Market Insight, Epidemiology and market forecast – 2032; https://www.delveinsight.com/report-store/focal-segmental-glomerulosclerosis-fsgs-market;*

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