DATA COLLECTION COMPLETE FOR FIRST INTERIM ANALYSIS IN ACTION3 PHASE 3 CLINICAL TRIAL FOR FSGS KIDNEY DISEASE

MELBOURNE, Australia, 27 February 2024: Dimerix Limited (ASX: DXB, "**Dimerix"**), is pleased to confirm that data from the first 72 patients randomised in the ACTION3 Phase 3 trial of DMX-200 in patients with focal segmental glomerulosclerosis (FSGS) has successfully been collected ahead of the first interim efficacy and safety analysis and review by the independent Data Safety Monitoring Committee (IDMC) in March 2024.

The Company expects to report on the Part 1 analysis outcome on, or before, 15th March 2024, following the planned IDMC meeting.

"We are absolutely delighted to have reached this important milestone. I would like to thank all of our patients for agreeing to be part of this trial to date, as well as our CRO and our amazing Dimerix team. We are now only a matter of days away from our Part 1 analysis outcome and, on the presumption of success, are continuing to prepare for Part 2 of the Phase 3 study. Success in Part 1 would signal that DMX-200 is performing better than placebo in reducing proteinuria, an important marker of kidney disease progression, in a larger cohort of patients than our prior Phase 2 study and validates our strategy and our prioritisation of this potentially valuable program."

Dr Nina Webster; CEO & Managing Director, Dimerix

In line with best practice for blinded Phase 3 clinical trials, the interim analysis data are only reviewed by the IDMC. Dimerix, the regulatory authorities including the United States Food and Drug Administration (FDA), and the trial investigators are blinded to treatment allocations, grouped safety and efficacy data for the ongoing trial and the data inputs into this interim analysis.

It is expected that the full ACTION3 Phase 3 trial will enrol in total approximately 286 patients, with a second interim analysis planned after the first 144 patients complete approximately 35 weeks. ACTION3 is the only Phase 3 study active in patients with FSGS, in a disease with no approved products.

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

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Authorised for lodgement with ASX by the Board of Dimerix

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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 a second interim analysis point built in that is 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.[1] For those who are fortunate enough to receive a kidney transplant, approximately 60% 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 limited.

FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,[1] and worldwide about 220,000.[3] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[4] 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 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/*

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

3 *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;*

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