**For Immediate Release**

# RECRUITMENT OF ADOLESCENT PATIENTS TO COMMENCE IN ACTION3 PHASE 3 KIDNEY TRIAL

- Adolescent recruitment into ACTION3 to commence at selected specialist paediatric nephrology sites
- Adolescent dose of DMX-200 confirmed using safety and pharmacokinetic (PK) data analysis and of the Part 1 adult cohort of the ACTION3 Phase 3 trial
- Independent Data Monitoring Committee (IDMC) agreement on dose of DMX-200 to be used in adolescent patients (12 – 17 years old) with FSGS is the existing dose used for the adult cohort of the ACTION Phase 3 trial
- This is a significant step towards potentially treating children with FSGS globally, with the paediatric plan in line with US FDA advice[1] and the European Medicines Agency (EMA) approved Paediatric Investigation Plan (PIP)[2]
- FSGS is one of the leading causes of kidney failure in children, with 20% of all presentations of Nephrotic Syndrome in paediatric patients caused by FSGS[3]

MELBOURNE, Australia, 04 July 2024: Dimerix Limited (ASX: DXB) a biopharmaceutical company with late-stage clinical assets in inflammatory diseases, today advised that the Independent Data Monitoring Committee (IDMC) has confirmed the dose of DMX-200 to be used in adolescent patients aged 12-17 years participating in the ACTION3 clinical trial. This allows recruitment of adolescent patients to begin into the ACTION3 Phase 3 global clinical trial in patients with focal segmental glomerulosclerosis (FSGS). The adolescent approved dose is the same as the 120mg adult dose currently being administered in the ACTION3 Phase 3 trial which is given orally and twice daily.

In making this determination the IDMC reviewed the aggregate interim safety and pharmacokinetic data, including simulations in adolescents, from the adult cohort of the ACTION3 Phase 3 trial taken at the first interim analysis point in March 2024. The IDMC noted "*the safety margin [of DMX-200] should allow [the ACTION3 Phase 3] clinical study to proceed in this adolescent population using adult doses*". Approximately 15 specialist paediatric nephrology centres across the UK, USA, Mexico, Brazil and Argentina have been selected to recruit adolescent patients with FSGS.

"The positive recommendation of the IDMC to allow adolescent dosing, further extends the strong safety profile and tolerability of DMX-200 when used in FSGS patients. This is especially important as paediatric FSGS remains an area of high unmet need with limited therapeutic options and a high risk of progression to end-stage kidney disease.

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Undertaking a review by an independent IDMC is consistent with good clinical practice,[4] and was pre-specified in the analysis plan. The primary responsibilities of the IDMC are to review and evaluate the available study data for participant safety, study conduct and progress, and to make recommendations concerning the continuation, modification, or termination of the trial. The study protocol for the ACTION3 Phase 3 clinical trial includes oversight by the IDMC and provides for interim safety reviews and other pre-specified analysis points.

**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).

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 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.[5] For those who are fortunate enough to receive a kidney transplant, approximately 60% 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 limited. FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,[5] and worldwide about 220,000.[7] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[8] 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 release 12Jan2023;*

2 *ASX release 05Jul2023*

3 *Nephcure Kidney International FSGS factsheet (2022); online: https://nephcure.wpenginepowered.com/wp-content/uploads/2021/02/nc.factSheet.FSGS_210106.pdf;*

4 *NHMRC Clinical Trials Data Safety Monitoring Board: https://www.australianclinicaltrials.gov.au/sites/default/files/content/For%20researchers/Data%20Safety%20Monitoring%20Boards_1.pdf*

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

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

7 *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;*

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