**For Immediate Release**

# ACTION3 PHASE 3 FSGS CLINICAL TRIAL MILESTONE RECRUITEMENT UPDATE

- A total of 200 adult patients have now been randomised and dosed in Dimerix' ACTION3 Phase 3 clinical trial in FSGS patients, representing ~70% of adult patients to be dosed in the 2-year trial
- Recruitment of patients into the trial remains on track to complete dosing of all 286 adult patients in the second half of calendar year 2025[1]
- A total of 43 patients have now also completed the full 2-year ACTION3 study treatment period and have subsequently entered into the Company's Open Label Extension study
- Dimerix continues to focus on recruitment into the ACTION3 Phase 3 clinical trial of both adults and paediatric patients, as well as licensing opportunities with potential partners in territories not already licensed

MELBOURNE, Australia, 13 June 2025: Dimerix Limited (ASX: DXB) a biopharmaceutical company with late-stage clinical assets in inflammatory diseases, is pleased to provide an update on the progress of the Company's ACTION3 Phase 3 clinical trial in patients with focal segmental glomerulosclerosis (FSGS).

**PATIENT RECRUITMENT**

A total of 200 adult patients, out of a total recruitment target of ~286 adult patients, have now been recruited and dosed in the trial. This represents a significant milestone being achieved and represents ~70% of the total trial adult patient cohort. Based on anticipated recruitment rates at each site, full recruitment of patients into the trial is on track to complete in the second half of calendar year 2025.[1] The ACTION3 Phase 3 clinical trial has activated over 190 clinical sites in 22 countries around the world. To date, feedback from the trial sites on patient participation has been very positive. In addition, the trial has successfully passed six reviews of the trial safety data by the Independent Data Monitoring Committee (IDMC).

"The opening of so many sites across the world and the recruitment of patients into our Phase 3 clinical trial in this rare type of kidney disease has been phenomenal, and I am extremely grateful for the dedication and hard work of our clinical team and the investigators at the trial sites, as well as the bravery of the patients and their families. We are also pleased to see so many patients rollover into the Company's Open Label Extension Study. The next few months are extremely exciting for the Company as we approach the final stages of patient recruitment in this trial, and I look forward to updating the market in due course on further developments."

*Dr Nina Webster, Chief Executive Officer & Managing Director, 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 randomised to receive either DMX200 (120 mg capsule twice daily) or placebo.

The single Phase 3 trial in FSGS patients 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).

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 working to improve the lives of patients with inflammatory diseases, including kidney 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 respiratory disease. 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.

**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, serious kidney disorder characterized by progressive scarring (sclerosis) in parts of the glomeruli—the kidney's filtering units. This scarring leads to proteinuria, progressive loss of kidney function, and often end-stage renal disease. FSGS is increasingly understood to have an inflammatory component, with monocyte and macrophage activation contributing to glomerular injury. In the United States, more than 40,000 people are estimated to be living with FSGS, including both adults and children.[2] There are no therapies specifically approved for FSGS anywhere in the world, and disease management relies on non-specific immunosuppressive and supportive therapies. In patients with progressive or treatment-resistant FSGS, the average time from diagnosis to end-stage kidney disease can be as short as five years. Even among those who undergo kidney transplantation, disease recurrence occurs in up to 60% of cases,[3] underscoring the urgent need for new, disease-modifying treatments. 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 FDA Meeting Outcomes, ASX release 28 April 2025

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*