Dimerix

For Immediate Release

DMX-200 ACTION3 PHASE 3 TRIAL OVER-RECRUITS: LAST PATIENT RECEIVES FIRST DOSE

- 333 patients have been randomised and dosed in the ACTION3 Phase 3 clinical study, which is now closed to further recruitment of adult patients
- Recruitment of paediatric patients remains ongoing as an independent cohort in the trial as agreed with regulators
- Target recruitment and dosing of 286 adult patients was completed in December 2025[1]
- Full 2-year study is expected to complete in March 2028
- Patients who had been consented at the time the study reached n = 286 randomised were allowed to progress to randomisation and dosing, resulting in this over-recruitment[1]
- The ACTION3 Phase 3 trial explores the efficacy and safety of DMX-200 in FSGS patients when dosed in combination with standard-of-care blood pressure medication over 2 years
- The study has now successfully passed seven scheduled Independent Data Monitoring Committee (IDMC) reviews with no changes to the protocol required or safety concerns identified[2]
- The Company remains well positioned to continue focussing on advancing the ACTION3 Phase 3 clinical trial, as well as licensing opportunities with potential partners in territories not already licensed

MELBOURNE, Australia, 10 March 2026: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical asset in kidney disease, today announces that the ACTION3 Phase 3 trial of DMX-200 in patients with focal segmental glomerulosclerosis (FSGS) has now successfully completed dosing the last adult patient recruited into the study, bringing the final enrolment to 333 adult patients.

As per standard practice, patients that were in the screening process at the time the 286th adult patient was reached were allowed in the study if still eligible. With the last patient randomised now having been randomised and dosed, the final date for the full 2 year treatment period ending will be March 2028.

The ACTION3 Phase 3 study 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 a blood pressure medication known as an angiotensin II receptor blocker (ARB). Once the ARB dose is stable, patients are then randomised to receive either DMX-200 (120 mg capsule, twice daily) or placebo for a 2-year treatment period. The single Phase 3 trial in FSGS patients is designed to capture evidence of proteinuria reduction and kidney function (eGFR slope) during the trial, aimed at generating sufficient evidence to support marketing approval.

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Notably, in March 2024, Dimerix announced that the ACTION3 Phase 3 trial of DMX-200 in patients with focal segmental glomerulosclerosis (FSGS) was successful in the pre-specified interim analysis of the proteinuria (efficacy) endpoint from the trial's first 72 randomised patients.[3] The analysis indicated that, using a statistical measure, DMX-200 was performing better than placebo in reducing proteinuria (a surrogate marker of kidney disease progression[4]) in patients with FSGS at that point in time.[5]

> "I am delighted with the achievement of such a significant milestone in the Company's clinical development of DMX-200 in FSGS patients. By allowing patients who had been progressing through the screening process at the time 286 patients had been randomised and dosed, we have naturally recruited beyond the targeted 286 adult patients. This will ultimately support the statistical powering of the study endpoints. With this significant catalyst being achieved, we look forward to progressing towards a number of potential key value-inflection points. Dimerix and our current commercial partners are well positioned to continue to advance toward regulatory submission and potential approval and commercialisation of DMX-200. We are sincerely grateful to the patients and their families for their vital contribution to this important program."
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> *Dr Nina Webster, CEO & Managing Director, Dimerix*

The ACTION3 trial opened 219 sites for recruitment across 21 countries, including US, Europe, UK, Japan, China, Hong Kong, Taiwan, Malaysia, Australia and New Zealand.

The Company remains well positioned to continue focussing on advancing its licensing opportunities with potential partners in territories not already licensed.

Next Steps in the U.S.

Following the successful outcome of the PARASOL collaboration data analysis on eGFR and proteinuria endpoints (**PARASOL Findings**), Dimerix plans to conduct a blinded statistical powering analysis of the primary endpoint in the ACTION3 study in line with FDA guidance[6].

About ACTION3 FSGS CLINICAL STUDY **FSGS Phase 3 Study**

The Phase 3 study, which is titled "Angiotensin II Type 1 Receptor (AT1R) & Chemokine Receptor 2 (CCR2) Targets for Inflammatory Nephrosis", 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).

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 Dimerix

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About Dimerix Limited

DMX-200 is 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 2045, in addition to Orphan Drug Designation granted in the United States, Europe, UK and Japan[7]. For more information, please visit the company's website at www.dimerix.com and follow on X and LinkedIn.

About FSGS

FSGS is a rare, serious kidney disorder characterised 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.[8] There are no therapies specifically approved for FSGS in the U.S., 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,[9] underscoring the urgent need for new, disease-modifying treatments.

Dimerix Forward Looking Statement

This release includes forward-looking statements that are subject to risks and uncertainties. Although management believes that the expectations reflected in the forward-looking statements are reasonable at this time, Dimerix can give no assurance that these expectations will prove to be correct. Readers are cautioned not to place undue reliance on forward-looking statements. Actual results could differ materially from those anticipated. Reasons may include risks associated with drug development and manufacture, risks inherent in the regulatory processes, delays in clinical trials, results of clinical trials, contractual risks, risks associated with patent protection, future capital needs or other general risks or factors, including but not limited to those factors outlined in the most recent Dimerix Limited Annual Report.

References

1 ASX release 15 December 2025
2 ASX release 19 November 2025
3 ASX release 11 March 24

4 *Haider M, Aslam A (2023) Proteinuria; PMID: 33232060 online https://pubmed.ncbi.nlm.nih.gov/33232060/*
5 *Interim analysis data does not guarantee a statistically significant outcome at the end of the trial*
6 *ASX release 08 October 2025*
7 *ASX releases: 14 December 2015, 21 November 2018, 07 June 2021, 30 September 2025*
8 *Nephcure FSGS Facts (https://nephcure.org/)*
9 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*