For Immediate Release

DIMERIX TO CONDUCT BLINDED ASSESSMENT OF ACTION3 STATISTICAL ASSUMPTIONS

- Dimerix to conduct a blinded review of ACTION3 data to confirm statistical assumptions for the primary endpoint late March 2026
- The ACTION3 Phase 3 study has previously passed a formal analysis for futility of the proteinuria endpoint in March 2024, as well as 7 Independent Data Monitoring Committee (IDMC) Reviews with no safety issues identified or changes to the protocol requested[1]
- The blinded review aims to provide further confidence that, statistically, the study remains powered to demonstrate a treatment effect for the primary study endpoint
- The blinded review will use methods prespecified in the Statistical Analysis Plan and submitted to the FDA, with results expected to be available in April 2026

MELBOURNE, Australia, 16 March 2026: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical asset in kidney disease, today announced that it will conduct a blinded review of ACTION3 Phase 3 study data to confirm statistical assumptions of the primary endpoint during March 2026, using methods specified in the study's Statistical Analysis Plan previously submitted to the US Food and Drug Administration (FDA) .

The FDA has previously confirmed that the proposed primary endpoint of percent reduction in proteinuria compared to placebo is suitable to support traditional approval of DMX-200 via the 505(b)(1) pathway, should the findings of the ACTION3 be positive, with change in eGFR as a secondary endpoint.

The purpose of a blinded review, conducted by an independent third party, in a clinical trial is to provide confidence that the study is tracking within the original statistical assumptions and confirm that the study remains able to show a benefit of DMX-200 compared to placebo, without knowledge of treatment assignments or treatment effect, thus maintaining study integrity. Before a clinical trial begins, it is designed based on certain assumptions — for example, how much variation there is in measurements and between patients. This review of the variation serves to confirm that the study is still powered to detect the treatment effect for the primary endpoint.

"This review is an important step for the Company. With the FSGS landscape having evolved since the initiation of the ACTION3 study, we are focused on ensuring the program remains appropriately powered to meet its primary endpoint. In particular, the emphasis on proteinuria as a primary measure is expected to strengthen the probability of success. We believe this review follows a clear and disciplined pathway as we advance the study and remain committed to delivering value for patients and shareholders. I look forward to providing an update to market in due course."

Dr Nina Webster, CEO & Managing Director, Dimerix

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Dimerix anticipates undertaking this blinded review in late March 2026, in line with the revised study protocol and the prespecified methods outlined in the ACTION3 Statistical Analysis Plan submitted to the FDA.

About ACTION3 FSGS Phase 3 Study

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.

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[2]. 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.[3] 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,[4] 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 19 November 2025*
2 *ASX releases: 14 December 2015, 21 November 2018, 07 June 2021, 30 September 2025*
3 *Nephcure FSGS Facts (https://nephcure.org/)*
4 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*