For Immediate Release

SUCCESSFUL COMPLETION OF PLANNED IDMC REVIEW OF ACTION3 PHASE 3 FSGS KIDNEY TRIAL

- The seventh scheduled Independent Data Monitoring Committee (IDMC) review, evaluating the available study data for participant safety, study conduct and progress, has been successfully completed
- The IDMC recommends the ACTION3 clinical trial continue unchanged, with no changes to design or safety monitoring
- The IDMC has again noted no safety concerns to date, consistent with their prior reviews and the existing and emerging strong safety profile of DMX-200
- 271 patients (268 adult and 3 paediatric) randomised/dosed in the ACTION3 Phase 3 clinical trial as at 18 November 2025
- The next scheduled IDMC meeting is planned for CYQ2/2026

MELBOURNE, Australia, 19 November 2025: Dimerix Limited (ASX: DXB a biopharmaceutical company with a Phase 3 clinical asset in kidney disease, today confirmed that the Independent Data Monitoring Committee (IDMC) successfully concluded a seventh review of the ACTION3 phase 3 clinical trial safety data. Following its routine scheduled review, the IDMC raised no safety concerns and recommended the continuation of the clinical trial as planned. This endorsement further validates the emerging strong safety profile of DMX-200 and reinforces its potential as a well-tolerated treatment option in a space where safety remains a key differentiator.

Undertaking a review by an IDMC is consistent with good clinical practice,[1] and was pre-specified in the study protocol. 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 clinical trial includes oversight by an IDMC as well as provision for planned and regular interim safety reviews, the seventh of which has now been successfully completed.

"The IDMC's recommendation underscores the strong and emerging safety profile of DMX-200, highlighting its potential to offer a differentiated treatment option without the added burden of side effects commonly associated with high-dose steroids and immunosuppressants. This positions DMX-200 as a potential compelling asset in the FSGS treatment landscape, offering meaningful hope to patients with limited options and representing a significant commercial opportunity in an underserved market."

Dr David Fuller, Chief Medical Officer, Dimerix

Dimerix HQ
425 Smith St, Fitzroy 3065
Victoria, Australia
T. 1300 813 321
E. info@dimerix.com

About ACTION3 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). Once the ARB dose is stable, patients are then randomised to receive either DMX-200 (120 mg capsule, twice daily) or placebo.

The single Phase 3 trial in FSGS patients has two 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:

Dr Nina Webster
Dimerix Limited
Chief Executive Officer & Managing Director
Tel: +61 1300 813 321
E: investor@dimerix.com

Jane Lowe
IR Department
Tel: +61 411 117 774
E: jane.lowe@irdepartment.com.au

Follow us on **LinkedIn** and **X**

Authorised for lodgement by the Board of the Company

—END—

About Dimerix Limited

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 focused on developing its proprietary Phase 3 product candidate DMX-200, 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's 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. For more information, please visit the company's website at www.dimerix.com and follow on X and LinkedIn.

About DMX-200

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 2042, in addition to Orphan Drug Designation granted by the FDA in the United States.

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.[2] 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,[3] 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, along with those factors outlined in the most recent Dimerix Limited Annual Report.

References

1 *NHMRC Clinical Trials Data Safety Monitoring Board: www.nhmrc.gov.au/sites/default/files/documents/reports/data-safety-monitoring-boards.pdf*

2 *Nephcure FSGS Facts (https://nephcure.org/)*

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