For Immediate Release

DIMERIX RECEIVES INPUT FROM FDA ON ACTION3 PHASE 3 CLINICAL TRIAL ENDPOINTS

- In written feedback, the U.S. Food and Drug Administration (FDA) reconfirmed that percent reduction of proteinuria at 2 years is an appropriate endpoint for full approval of DMX-200 in the ACTION3 trial
- In addition, the FDA has requested further information and documentation prior to undertaking the planned blinded statistical powering analysis of the ACTION3 trial
- Dimerix expects to provide this information and documentation to the FDA shortly and it is anticipated that the blinded analysis will now occur in early 2026

MELBOURNE, Australia, 24 December 2025: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical asset in kidney disease, today announces that it has received feedback from the U.S. FDA on the clinical appropriateness of proteinuria reduction as an endpoint for full approval of DMX-200 in the ACTION3 Phase 3 trial in patients with focal segmental glomerulosclerosis (FSGS) under the 505(b)(1) pathway.

The FDA has 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.

In this feedback, the FDA requested further information and documentation to ensure trial integrity is maintained, prior to proceeding with the blinded statistical powering analysis. Dimerix expects to provide this information and documentation to the FDA shortly.

Next Steps in the U.S.

Dimerix will submit the requested information and documentation to the FDA prior to undertaking the planned blinded statistical powering analysis and the required ACTION3 clinical study protocol updates, with that blinded analysis now anticipated to occur early 2026.

About ACTION3 FSGS CLINICAL STUDY 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.

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

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

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Authorised for lodgement by the Board of Dimerix

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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. DMX-200 was 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. 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.[1] 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,[2] 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 *Nephcure FSGS Facts (https://nephcure.org/)*

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