For Immediate Release

DMX-200 ACTION3 PHASE 3 TRIAL COMPLETES RECRUITMENT

- Recruitment successfully completed in Dimerix' ACTION3 Phase 3 clinical trial[1], which has recruited and dosed its target 286th adult patient
- 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
- Of the 286 adult patients dosed in the trial, 69 have already completed the full 2-year treatment period and of those, 65 entered voluntarily into the Open Label Extension (**OLE**) study, representing 94% OLE uptake
- 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]
- Following the successful outcome of the PARASOL collaboration data analysis (**PARASOL Findings**), Dimerix and its U.S. partner, Amicus Therapeutics, intend to seek feedback from the FDA on the proposed clinical trial endpoints, prior to a blinded analysis of ACTION3 data[3]
- Recruitment of pediatric patients remains ongoing as an independent cohort in the trial, and if successful, may allow Dimerix to expand its application for DMX-200 to adolescents in key territories
- Dimerix continues to maintain a strong cash position to fund its operations, including the ongoing ACTION3 Phase 3 clinical trial as well as assess new R&D opportunities

MELBOURNE, Australia, 15 December 2025: 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 the planned recruitment and dosing of the 286th adult patient[1].

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.

In accordance with the trial protocol, patients were first recruited and then stabilised on background medications before undergoing a second screening. Only those who successfully passed this re-screening were randomised to receive either the DMX-200 or placebo. As per standard practice, patients currently recruited and in the stabilisation phase will be allowed to continue in the study (if still eligible) and, once dosed, will confirm the anticipated last patient and last dose date.

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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.[4] 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[5]) in patients with FSGS at that point in time.[6]

> "We are pleased to announce that the recruitment, randomisation and dosing of the 286th patient in the ACTION3 Phase 3 trial has successfully completed, reflecting the commitment and operational excellence of the Dimerix team and our clinical partners. Achieving this milestone in a rare disease setting reflects our ability to execute efficiently in complex environments. With patient data now being collected across a 2-year treatment period, we are progressing towards a number of key value-inflection points. With the successful achievement of the study's target recruitment, this positions Dimerix and our commercial partners to continue to advance toward regulatory submission and potential commercialisation. 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.

Next Steps in the U.S.

Dimerix and its U.S. partner, Amicus Therapeutics, intend to seek feedback from the FDA on the 104-week endpoints and potential submission for accelerated approval.

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

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.[7] 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,[8] 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 *Subject to blinded analysis of statistical powering anticipated Q42025*
2 *ASX release 19 November 2025*
3 *ASX release 08 October 2025*
4 *ASX release 11 March 24*
5 *Haider M, Aslam A (2023) Proteinuria; PMID: 33232060 online https://pubmed.ncbi.nlm.nih.gov/33232060/*
6 *Interim analysis data does not guarantee a statistically significant outcome at the end of the trial*
7 *Nephcure FSGS Facts (https://nephcure.org/)*
8 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*