

DMX-200 ACTION3 PHASE 3 TRIAL: FIRST 100 PATIENTS COMPLETE DOUBLE-BLIND TREATMENT

Highlights

- Significant operational milestone reached with first 100 patients having completed the full 2-year double-blind treatment period in Dimerix's ACTION3 Phase 3 trial of DMX-200 in FSGS
- Each patient who completes the 2-year blinded trial progressively reduces operational and execution risk associated with long-duration trial retention and treatment adherence
- Following completion of the trial, patients can elect to continue into the Open Label Extension (OLE) study, with 93% of patients electing to do so to date
- OLE study provides access to DMX-200 treatment, regardless of whether that patient was on placebo or DMX-200 during the trial and will generate important and additional long-term safety and efficacy data, which can be used by Dimerix to support future regulatory activities
- ACTION3 Phase 3 trial remains ongoing, with patients continuing treatment and follow-up as planned

MELBOURNE, Australia, 16 October 2026: Dimerix Limited (ASX: DXB, "Dimerix") a clinical-stage biopharmaceutical company developing kidney disease treatments, is pleased to announce a significant operational milestone in its pivotal ACTION3 Phase 3 study of DMX-200 in focal segmental glomerulosclerosis (FSGS), with the first 100 patients enrolled having successfully completed the full 2-year double-blind treatment period.

The completion of the first 100 patients represents an important execution milestone for the ACTION3 study and is a significant achievement given the rarity of FSGS and the recruitment challenges associated with rare diseases. As patients continue to successfully complete the full double-blind treatment period, the remaining execution risk associated with long-duration treatment adherence, participant retention and successful trial execution reduces.

Importantly, 93 of these 100 patients have elected to continue into the Open Label Extension (OLE) study, representing a continuation rate of 93%. The OLE study provides participants access to treatment with DMX-200 following completion of the double-blind phase, regardless of whether that patient was on placebo or DMX-200 during the trial. The OLE study enables the collection of important additional long-term safety and clinical outcome data which can be used to support future regulatory activities.

"The completion of the first 100 patients represents another important milestone for the ACTION3 Phase 3 program. Having 100 patients now complete the 2-year double-blind treatment phase is not only an important clinical milestone, but also a significant operational achievement, for a global study of this size and duration. Each patient who reaches this point contributes to reducing execution risk for the ACTION3 program.

We remain grateful to the patients, their families, investigators and study coordinators whose dedication continues to advance this important program for people living with FSGS."

Dr Nina Webster, CEO & Managing Director, Dimerix

For personal use only

About **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 was stable, patients were randomised to receive either DMX-200 (120 mg capsule twice daily) or placebo.

The ACTION3 adult cohort is fully recruited with 333 patients randomised and dosed globally. Recruitment has been completed across 219 sites in 21 countries including the United States, Europe, Japan, China, Australia and New Zealand. The final adult patient commenced treatment in March 2026, transitioning the study from recruitment into treatment and follow-up. The final adult patient is expected to complete dosing in March 2028. Recruitment of paediatric patients aged 12-17 years continues as an independent cohort within the ACTION3 program and may support future expansion into adolescent indications in key territories.

The single Phase 3 trial in FSGS patients is 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).

Potential catalysts

As Dimerix advances its pivotal, fully recruited ACTION3 Phase 3 trial for DMX-200 toward what is anticipated to be a major value-creating event if successful, the Company has simultaneously strengthened its growth profile through the recent acquisition of a second asset, DMX-652 and its ongoing advancement into Phase 2 clinical development for acute kidney injury (AKI). Progress and positive outcomes from the DMX-652 development program have the potential to create substantial additional shareholder value, diversify Dimerix's clinical pipeline, and deliver multiple near- and medium-term catalysts for investors.

Authorised for lodgement by the Board of Dimerix

—END—

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 Dimerix on [LinkedIn](#) and [X](#)

About Dimerix

Dimerix Limited (ASX: DXB) is a clinical-stage biopharmaceutical company focused on developing new therapies for kidney diseases with significant unmet medical need. The Company's lead program, DMX-200, is currently in Phase 3 clinical development for focal segmental glomerulosclerosis (FSGS), a serious and life-threatening rare kidney disease with limited treatment options. In addition, Dimerix is advancing a Phase 2 program in acute kidney injury (AKI), further strengthening its pipeline in high-need renal indications. With a growing network of five commercial partners supporting global development and future market access, Dimerix is committed to expanding its reach and delivering innovative treatments to as many patients as possible worldwide while creating long-term value for shareholders. For more information, please visit the company's website at www.dimerix.com.

About DMX-200 in 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.

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 in the United States, Europe, UK and Japan³.

About DMX-652 in Acute Kidney Injury

Acute kidney injury (AKI) is a prevalent and severe clinical syndrome of substantial unmet need. It can arise from several high-risk clinical settings including, most notably, cardiac surgery and sepsis and is characterised by a rapid decline in kidney function (within hours), often resulting in high morbidity and mortality. The current addressable patient population is estimated to be approximately 260,000 across the major markets of United States, Germany, France, Italy, Spain and United Kingdom per annum,^{4,5} making this indication a potential orphan designation. AKI represents a significant clinical burden. There are no approved therapies for AKI, which is associated with rapid kidney function decline within hours, increased risk of chronic kidney disease and long-term kidney complications.

DMX-652 is a selective inhibitor of USP30 - a mitochondrial enzyme that slows the removal of damaged mitochondria. DMX-652, which is a small molecule delivered as an oral once daily capsule, is designed to support mitochondrial quality control in injured kidney cells, a mechanism indicated in the progression of AKI caused by ischaemia (lack of blood flow resulting in oxygen starvation), toxins or sepsis related causes, as well as in other renal and non-renal indications. The DMX-652 acquisition includes the composition of matter patent, an open IND in the US with a Phase 2 clinical trial protocol which has received approval to proceed by the US Food and Drug Administration (FDA), as well as sufficient pharmaceutical grade (GMP) drug product for the Phase 2 trial and all manufacturing methodology. The Phase 2 trial is designed to investigate DMX-652's potential to prevent kidney injury and preserve renal function.

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 Nephcure FSGS Facts (<https://nephcure.org/>)
- 2 *Front. Immunol.*, (July 2019) | <https://doi.org/10.3389/fimmu.2019.01669>
- 3 ASX releases: 14 December 2015, 21 November 2018, 07 June 2021, 30 September 2025
- 4 Demirjian S, Bashour CA, Shaw A, et al. Predictive Accuracy of a Perioperative Laboratory Test–Based Prediction Model for Moderate to Severe Acute Kidney Injury After Cardiac Surgery. *JAMA* 2022;327:956–64. <https://doi.org/10.1001/jama.2022.1751>.
- 5 Hobson C, Ruchi R, Bihorac A. Perioperative Acute Kidney Injury. *Crit Care Clin* 2017;33:379–96. <https://doi.org/10.1016/j.ccc.2016.12.008>