

FIRST PATIENT COMPLETES FOUR YEARS IN DMX-200 CLINICAL PROGRAM

Highlights

- Significant milestone achieved as first patient completes 2-years in the DMX-200 Open Label Extension (OLE) study, in addition to completing the 2-year ACTION3 Phase 3 trial
- The milestone marks four years of continuous participation in the DMX-200 clinical development program, highlighting sustained patient engagement and providing important long-term safety and efficacy data for DMX-200 in patients with FSGS
- The OLE study allows patients who complete the ACTION3 Phase 3 clinical trial to receive DMX-200 for up to two years in an open-label (unblinded) setting, regardless of whether they received DMX-200 or placebo during the randomised, blinded phase of the trial
- Patients who complete the OLE study will be offered continued access to DMX-200 through the Post-Trial-Access (PTA) scheme once ethics approval for the scheme has been achieved
- Currently over 90% of eligible patients who have completed the ACTION3 Phase 3 trial have elected to continue into the two-year OLE study
- The Company's ACTION3 Phase 3 trial remains ongoing, with the adult cohort fully recruited and patients continuing treatment and follow up visits as planned

MELBOURNE, Australia, 5 October 2026: Dimerix Limited (ASX: DXB, "Dimerix"), a clinical-stage biopharmaceutical company developing treatments for kidney disease, is pleased to announce that the first patient has successfully completed the Company's two-year Open Label Extension (OLE) study of DMX-200 in focal segmental glomerulosclerosis (FSGS), marking four years of continuous participation in the DMX-200 clinical development program.

The milestone follows the patient's successful completion of the two-year blinded ACTION3 Phase 3 clinical trial and subsequent participation in the optional two-year OLE study.

OLE Study and Four Years of Clinical Study Participation

The OLE study, under which the first patient was treated in September 2024¹ (ASX: 10 September 2024) is designed to collect additional long-term safety and efficacy data in patients who successfully complete the ACTION3 Phase 3 trial and elect to continue treatment. All participants in the OLE study receive DMX-200, regardless of whether they received DMX-200 or placebo during the blinded phase of the ACTION3 study. Data from the OLE study may support future regulatory and commercial activities for DMX-200.

Strong Participation in the Open Label Extension Study

Importantly, of the 96 patients who have completed the ACTION3 Phase 3 trial to date, 89 have elected to join the OLE study, representing a continuation rate of 93%. The high level of participation in the OLE study (which is completely optional for patients following their participation in the ACTION3 Phase 3 trial) reflects the commitment of patients, investigators and study sites to the ACTION3 program and DMX-200.

Post-Trial Access Program

Following completion of the OLE study, patients will be offered the opportunity to continue receiving DMX-200 through a post-trial access program, once ethics approval for the scheme has been achieved. Dimerix, and its commercial partners, are in the process of seeking ethics approval for the PTA program in each territory that recruited ACTION3 patients. Continued treatment in the PTA program would follow approximately four years of participation in the DMX-200 clinical development program, including both the blinded ACTION3 Phase 3 study and the subsequent two-year OLE study. Long-term participation and continuation in clinical programs such as the OLE study or PTA Program can support the collection of additional safety information while providing the benefit of continuity of treatment for eligible patients.

ACTION3 Study Continues as Planned

The global ACTION3 Phase 3 program remains ongoing, with patients continuing treatment and follow-up as planned. The OLE study continues to enrol eligible participants who complete the blinded phase of the ACTION3 Phase 3 trial, further expanding the long-term safety database for DMX-200 which may support future regulatory and commercial activities for DMX-200.

“The completion of four years of study participation by the first patient in our DMX-200 clinical program represents an important milestone for both Dimerix and the broader FSGS community. Long-term participation of this nature reflects the commitment of patients, their families and clinical investigators, and provides an opportunity to gather valuable longer-term information on DMX-200.

We are particularly encouraged that over 90% of eligible patients completing the ACTION3 study have elected to continue into the Open Label Extension study and are excited to potentially offer patients who complete the OLE study the option to continue treatment through a post-trial access program.

We are grateful to all participants in the ACTION3 program and remain focused on advancing DMX-200 as a potential treatment option for patients living with FSGS, a disease for which there remains a significant unmet medical need.”

Dr Nina Webster, CEO & Managing Director, Dimerix

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 DMX-652 and its ongoing advancement into Phase 2 clinical development. 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

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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 second asset, DMX-652, via 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.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.

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 Japan⁴.

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,^{5,6} 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

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- 1 ASX release 10 September 2024
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