For Immediate Release

DIMERIX ASSUMES SPONSORSHIP OF U.S. IND FOR NEW FIRST AND BEST-IN-CLASS ASSET DMX-652

Highlights

- Dimerix recently announced that it had acquired DMX-652, a Phase 2-ready renal asset, which has the potential to rapidly advance into a Phase 2 clinical study under an existing open U.S. Investigational New Drug (IND) application[1]
- U.S. IND sponsorship successfully transferred to Dimerix
- Preparations are underway for the DMX-652 Phase 2 clinical trial in the initial indication of acute kidney injury (AKI) associated with cardiac surgery[1]

MELBOURNE, Australia, 17 August 2026 – Dimerix Limited (ASX: DXB, "Dimerix") a clinical-stage biopharmaceutical company developing kidney disease treatments, today announced that it has successfully completed the transfer of the Investigational New Drug application ("IND") in the United States (US) for its acute kidney injury (AKI) asset, DMX-652 from UK based, Mission Therapeutics. Dimerix now has full ownership over the IND and is trial sponsor for the ongoing development of DMX-652 Phase 2 stage AKI asset.

The transfer of the IND represents an important milestone in Dimerix's development of DMX-652 and provides the Company with direct control over clinical development activities for the program in the US. With the encouraging safety and pharmacokinetic data observed in the extensive Phase 1 trial for DMX-652, and its promising pre-clinical data, Dimerix plans to advance DMX-652 into a Phase 2 clinical trial for acute kidney injury during the second half of 2026.

About DMX-652 in Acute Kidney Injury

Acute kidney injury (AKI) is a prevalent and severe clinical syndrome with substantial unmet need. It can arise from several high-risk clinical settings, including cardiac surgery and sepsis, and is characterised by a rapid decline in kidney function, often resulting in high morbidity and mortality. The current addressable high-risk patient population is estimated to be approximately 260,000 across the major markets of the United States, Germany, France, Italy, Spain and the United Kingdom per annum,[2,3] making this indication a potential orphan designation. There are currently no approved therapies for AKI, and the condition is associated with an increased risk of chronic kidney disease and long-term kidney complications.

"IND sponsorship enables the Company to engage directly with the FDA, manage ongoing clinical development activities and timelines, as well as maximise the strategic value of the program as we evaluate opportunities to advance DMX-652 into later-stage clinical development.

We believe DMX-652 has significant potential across a range of mitochondrial dysfunction diseases, creating the opportunity to explore global commercial pathways and potential partnerships that may generate additional sources of income. Securing IND sponsorship positions Dimerix to drive the development of the asset in alignment with our broader pipeline strategy."

Dr Nina Webster, CEO & Managing Director, Dimerix

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

About DMX-652

DMX-652 is a selective inhibitor of USP30, a mitochondrial enzyme that slows the removal of damaged mitochondria. DMX-652 is a small molecule delivered as a once-daily oral capsule and is designed to support mitochondrial quality control in injured kidney cells, a mechanism implicated in the progression of AKI caused by ischaemia (reduced blood flow and oxygen supply), toxins or sepsis, as well as 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 approved by the US Food and Drug Administration (FDA), sufficient GMP-grade 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.

Authorised for lodgement with ASX by the Board of Dimerix.

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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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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.

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.[4] 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,[5] 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 Japan[6].

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 *ASX release 17 July 2026*

2 *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.*

3 *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*

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

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

6 *ASX releases: 14 December 2015, 21 November 2018, 07 June 2021, 30 September 2025*