

DIMERIX EXPANDS PIPELINE WITH ACQUISITION OF PHASE 2 READY ASSET FOR ACUTE KIDNEY INJURY

Highlights

- Dimerix acquires Phase 2-ready asset, DMX-652 - with potential for rapid advancement into a Phase 2 clinical study under an open US Investigational New Drug (IND) application, with initial focus on acute kidney injury (AKI)
- DMX-652 offers potential to address a significant unmet need in AKI - with a global market opportunity estimated to be US\$3.5 billion in 2026,¹ and no currently approved therapies for the disease which is associated with rapid decline in kidney function and high mortality rate
- Strong safety data package - a large Phase 1 clinical trial in 85 healthy participants demonstrated DMX-652 was well tolerated at both a single dose and multiple doses over 14 days, with no serious adverse events related to drug reported
- Promising pre-clinical efficacy data demonstrated to date, with strong scientific reasoning validating DMX-652's mechanism of action
- DMX-652 is first and best-in class drug candidate, with no known clinical stage competitors and a mechanism of action which has the potential to extend across multiple other indications
- Strong strategic alignment with ongoing ACTION3 Phase 3 FSGS rare kidney disease program and Dimerix's broader existing renal-focused pipeline, leveraging Dimerix's existing infrastructure and expertise
- Completion of ACTION3 trial for Dimerix's lead asset, DMX-200 in FSGS; up front acquisition payment for DMX-652 and initiation of Phase 2 clinical trial all funded (see ASX announcement 17 July 2026) with further non-dilutive funding discussions underway

MELBOURNE, Australia, 17 July, 2026 – Dimerix Limited (ASX: DXB, "Dimerix") a clinical-stage biopharmaceutical company developing kidney disease treatments, is pleased to announce that it has acquired DMX-652 for all indications from Mission Therapeutics Limited ("Mission"). The new asset, which expands Dimerix's pipeline in rare kidney disease, is a novel first and best-in-class therapeutic candidate, initially targeting the prevention of acute kidney injury (AKI).

About DMX-652 – expanding Dimerix's leadership in kidney disease

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 assignment of 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, however it's unique mechanism of action may allow it to be progressed into other indications.

The opening of the US IND and the approval of the Phase 2 trial protocol follows successful completion of a Phase 1 clinical trial of DMX-652, in which 85 healthy volunteers received the drug candidate. The trial successfully demonstrated DMX-652 was safe and well tolerated in single doses of up to 200mg a day and multiple doses of up to 100mg a day for 14 days, with a promising pharmacokinetic profile.

Building a focused, rare kidney disease portfolio

The acquisition of DMX-652 aligns with Dimerix's strategy to build a focused pipeline of effective treatments for rare kidney diseases with high unmet medical needs. The DMX-652 program is a complementary addition to the Company's lead asset, DMX-200, which is currently in a fully recruited Phase 3 pivotal trial in focal segmental glomerulosclerosis (FSGS), a rare type of kidney disease. Bringing a complementary asset into the portfolio enables Dimerix to further leverage its core expertise and existing global network of relationships in kidney disease.

The acquisition of DMX-652 broadens Dimerix's renal franchise beyond glomerular disease and FSGS, into acute kidney injury. Dimerix's renal pipeline now includes drug candidates in two high-value indications with differentiated mechanisms and the potential to deliver meaningful value to patients and shareholders.

"Acute kidney injury (AKI) remains one of the most common and serious complications following cardiac surgery, affecting a substantial proportion of patients and contributing to increased morbidity, mortality, prolonged hospitalisation, and a heightened risk of long-term kidney and cardiovascular complications. Despite advances in perioperative care, there are currently no approved therapies specifically indicated to prevent cardiac surgery-associated AKI, representing an area of significant unmet medical need. I believe DMX-652 represents a promising and innovative approach to addressing a major clinical challenge for patients undergoing cardiac surgery."

Univ.-Prof. Dr. med. Alexander Zarbock, Chair and Director of the Department of Anesthesiology, Intensive Care Medicine and Pain Therapy at the University Hospital Münster, Germany

"DMX-652 has demonstrated a compelling clinical profile in Phase 1 development completed by Mission Therapeutics to date. There is a substantial unmet need for novel efficacious therapies for acute kidney disease and DMX-652 represents a unique step forward for these patients. Dimerix's deep domain focus in renal disease and their proven operational expertise make them an excellent partner to further the development and commercialisation of this important drug."

Dr Anker Lundemose, Executive Director, Mission Therapeutics

"DMX-652 represents an exciting and differentiated novel compound, and the acquisition of a Phase 2-ready program in acute kidney disease represents an important step in executing our strategy to expand our renal pipeline. This asset is highly complementary to our Phase 3 FSGS program and broadens our development footprint across the kidney disease continuum, from acute injury through to chronic disease."

Dr Nina Webster, CEO & Managing Director, Dimerix

About 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 100,000-133,000 patients annually in the United States,² making this indication a potential orphan designation. The global market for acute kidney injury treatments is estimated to be worth US\$3.5 billion in 2026 and is forecast to grow to around US\$7.5 billion over the next decade.¹

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.

Phase 2 Clinical Trial in Cardiac Surgery-Associated AKI

The initial Phase 2 target indication, cardiac surgery-associated AKI (CS-AKI), is a predictable complication, linked to cardiopulmonary bypass and valve surgeries. These procedures can result in kidney injury, related to ischaemia (resulting in oxygen starvation) followed by reperfusion (re-oxygenation) during on-pump surgeries.

The proposed Phase 2 clinical trial is a multicentre, double-blind, randomised, placebo-controlled study, evaluating the safety and efficacy of DMX-652 in approximately 160 patients at high risk of AKI following cardiac surgery, with the primary endpoint being AKI incidence at 7 days post-surgery. Clinical trial ethics approval and clinical site initiation is anticipated in H2 CY2026, with dosing of the first patient anticipated in H1 CY2027, with an interim data readout anticipated during 2027.³

Patent Protection

Under the acquisition, the composition of matter patent family for DMX-652 (PCT/EP2021/064897) will be assigned to Dimerix, with anticipated expiry in 2041, as well as the exclusive license to further background patents and patent applications required for freedom to operate (PCT/GB2016/050851, PCT/GB2019/050608). In addition to patent protection, DMX-652 may be eligible to receive exclusivity for a minimum of 5 years, post-marketing approval, with the potential to extend up to 7 years exclusivity in US and 10 years in Europe upon any successful orphan drug designation.

Terms of the Agreement

Under the terms of the agreement, Dimerix will have sole ownership and control development of DMX-652. In return, Dimerix will pay a US\$5 million upfront acquisition payment to UK based Mission Therapeutics within 30 days of signing; up to US\$47 million deferred acquisition payment payable on upon success of predefined clinical development milestones; US\$40 million on product marketing approval; US\$25 million on approval in a second indication; and up to US\$175 million on certain success-based sales milestones. Dimerix will pay 8-10% royalty on global net sales if made by Dimerix, or 2.5%-5% on net sales if made by a third-party sub-licensee. All contracted financial terms are denominated in U.S. dollars. In the event Dimerix elects not to proceed with development, Mission has the first right to negotiate for return of the acquired assets.

Potential catalysts

As Dimerix advances its pivotal ACTION3 Phase 3 trial for DMX-200 toward what could be a major value-creating event if successful, the Company is simultaneously strengthening its growth profile through the progression of DMX-652 into Phase 2 clinical development. Progress and positive outcomes from DMX-652 development program have the potential to create substantial shareholder value, diversify Dimerix's clinical pipeline, and deliver multiple near- and medium-term catalysts for ASX investors.

Funding

Dimerix confirms that it is funded through to completion of the ACTION3 Phase 3 trial in DMX-200, as well as initiation of the Phase 2 clinical trial in DMX-652 through:

- Existing cash reserves;
- ~AU\$14 million upfront payment to be received from Everest Medicines for commercial rights to Greater China, South Korea and Southeast Asia;¹ and
- AU\$10 million through the binding Loan Agreement, with any draw-down to take place at the Company's discretion.

Negotiations to access up to a further AU\$40 million in non-dilutive funding, anticipated to be on substantially similar terms to the loan facility, are progressing and such funding would extend the Company's cash runway beyond the DMX-200 ACTION3 Phase 3 clinical trial, while supporting Dimerix in building a sustainable development pipeline of assets in rare and/or renal disease.^{4, 5} For further information on the funding agreement, please see ASX announcement dated 17 July 2026.

Authorised for lodgement with ASX 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 rare 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 Mission Therapeutics

Mission Therapeutics is a world leader in discovering and developing novel therapeutics which promote the removal of dysfunctional mitochondria, promoting cell health and function. Mission is currently developing small molecule drug, MTX325 (targeting the CNS) which, through inhibition of the mitochondrial DUB enzyme USP30, promotes clearance of dysfunctional mitochondria – consequently improving overall cellular health.

Mission is backed by blue chip investors including Pfizer Venture Investments, Sofinnova Partners, Roche Venture Fund, SR One, IP Group and Rosetta Capital.

About DMX-200 in FSGS

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 Japan⁶.

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, including but not limited to those factors outlined in the most recent Dimerix Limited Annual Report.

References

- 1 Internal market analysis based on meta-analysis of 21 market reports (2026) ; Includes China and Japan markets, label expansion into sepsis-associated AKI (SA-AKI) and contrast-associated AKI
- 2 Ostermann M, Lumlertgul N, Jeong R, et al. Acute kidney injury, (2025) *Lancet* 405:241–56. [https://doi.org/10.1016/s0140-6736\(24\)02385-7](https://doi.org/10.1016/s0140-6736(24)02385-7)
- 3 Subject to recruitment
- 4 Funding subject to a definitive agreement(s) being executed (which is expected to include customary conditions precedent)
- 5 Based on current anticipated spend and activities; should activities or spend change, this could materially impact the cash runway of the Company
- 6 ASX releases: 14 December 2015, 21 November 2018, 07 June 2021, 30 September 2025
- 7 Nephcure FSGS Facts (<https://nephcure.org/>)
- 8 *Front. Immunol.*, (July 2019) | <https://doi.org/10.3389/fimmu.2019.01669>