For Immediate Release

BLINDED ASSESSMENT OF ACTION3 STATISTICAL ASSUMPTIONS COMPLETE

Key Highlights:

- An external statistical blinded review of ACTION3 data has achieved its objective by confirming that the study remains appropriately statistically powered (>90%) to demonstrate a treatment effect for the primary study endpoint of proteinuria; meaning that if DMX-200 continues to reduce proteinuria in trial patients as anticipated, then there is a >90% chance that the study will successfully show a statistically significant proteinuria treatment effect at the trial's conclusion
- To maximise the likelihood of a successful study outcome and regulatory success, Dimerix and its commercialisation partners will continue the ACTION3 Phase 3 Study to the final proteinuria endpoint
- As previously announced, the FDA has agreed that proteinuria is an appropriate endpoint for full regulatory approval for DMX-200 in ACTION3
- Evidence from the PARASOL working group, together with the recent FDA approval of an FSGS therapy in the US based on the proteinuria endpoint, further supports proteinuria as the primary study endpoint for ACTION3
- The Company remains well positioned to continue focussing on advancing the ACTION3 Phase 3 clinical trial, as well as the advanced licensing discussions with potential partners in territories not already licensed

Study Progress:

- The ACTION3 Phase 3 clinical trial adult cohort is fully recruited, with 333 patients; the last patient is expected to receive their last dose in March 2028[1]
- Recruitment of pediatric patients aged 12-17 years old 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[1]
- As previously reported, the ACTION3 Phase 3 study passed a formal futility analysis of the proteinuria endpoint in March 2024[2] demonstrating the drug was performing better than placebo at that point in time; and a further 7 Independent Data Monitoring Committee (IDMC) reviews to date have not identified safety issues or requested changes to the protocol.[3]

MELBOURNE, Australia, 28 April 2026: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical asset in kidney disease, today announced that the blinded review of ACTION3 Phase 3 study data to confirm statistical assumptions of the primary endpoint has been successfully completed. This blinded review confirms that the ACTION3 study remains appropriately statistically powered to detect the treatment effect for the proteinuria primary endpoint. Having the ACTION3 Phase 3 study with >90% statistical power for its primary endpoint means that if DMX-200 continues to reduce proteinuria in trial patients as anticipated, then there is a >90% chance that the study will successfully show a statistically significant proteinuria treatment effect at the trial's conclusion.

Evolving FSGS landscape knowledge guides decision making

In parallel to the blinded review, Dimerix and its commercial partners assessed the changes to the Focal Segmental Glomerulosclerosis (FSGS) landscape and potential endpoints since initiation of the ACTION3 study in 2022, all of which support proteinuria as the primary endpoint. Specifically, the PARASOL working group outcomes provided evidence of proteinuria as a candidate surrogate endpoint for FSGS; FDA provided positive feedback to Dimerix confirming that the proteinuria endpoint is appropriate for the full approval of DMX-200; and, earlier this month, FDA approved a new treatment for FSGS based on proteinuria as an endpoint.

A key finding from PARASOL working group analysis was that proteinuria required smaller sample sizes and demonstrated less variability than eGFR for FSGS clinical trials and could therefore reduce risk for potential downstream marketing approval in the US. Collectively, the PARASOL working group analysis, the National Registry of Rare Kidney Diseases UK (RaDaR) analyses,[4] Kaiser Permanente analyses,[5] third party FSGS study data, and FSGS key opinion leaders all suggest that measuring proteinuria change from baseline is a far more statistically achievable endpoint for DMX-200 than eGFR endpoints and may substantially reduce the risk for traditional approval.

Given that any application for accelerated approval based on proteinuria would likely require that the ACTION3 use an eGFR-based confirmatory endpoint, which would increase costs, lengthen study timeline and necessitate the splitting of alpha,[6] potentially reducing the probability of success for the final endpoint, Dimerix and its commercial partners have concluded that conducting an interim analysis required for an Accelerated Approval application would not now be the most strategic and optimal course for the trial.

Proteinuria as primary endpoint may substantially reduce ACTION3 execution risk

The FDA has previously confirmed that the proposed primary endpoint of percent reduction in proteinuria compared to placebo is suitable to support traditional approval of DMX-200 via the 505(b)(1) pathway, should the findings of the ACTION3 be positive, with change in eGFR as a secondary endpoint.

"The understanding of the FSGS disease and appropriate surrogate clinical endpoints has evolved significantly since the initiation of the ACTION3 study and justified a comprehensive review of all considerations. The conclusion of this review has resulted in a strategic decision being made and is a good outcome for Dimerix and our partners, as it provides much needed clarity and insights on the DMX-200 regulatory pathway in our major commercial territories. By focussing on proteinuria, it significantly reduces the clinical and commercial risk for traditional approval.

Given the successful blinded interim futility analysis in 2024, we know that DMX-200 was performing better than placebo in reducing proteinuria at that point in time, and with seven independent data monitoring committee reviews completed, we are confident that DMX-200 is well tolerated.

The outcome of this review and the decision to proceed to completion of ACTION3 to support traditional approval helps us strengthen the probability of ACTION3 success and ultimately deliver a potential new therapy for patients with FSGS while also reducing risk and adding value for Dimerix shareholders and partners."

Dr David Fuller, Chief Medical Officer, Dimerix

"The move to having proteinuria as the ACTION3 primary endpoint for traditional approval increases the likelihood of a successful marketing approval and avoids the very real risks associated with use of eGFR endpoints. The required additional activities, cost and increased risk associated with accelerated approval would not be value generating in our view."

Dr Jeff Castelli, Chief Development Officer, Amicus Therapeutics

About ACTION3 FSGS Phase 3 Study

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.

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:

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**

Authorised for lodgement by the Board of Dimerix

—END—

About Dimerix Limited

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 2045, in addition to Orphan Drug Designation granted in the United States, Europe, UK and Japan[7]. For more information, please visit the company's website at www.dimerix.com and follow on X and LinkedIn.

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.[8] 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,[9] 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 *ASX release 10 March 2026*
2 *ASX release 11 March 2024,*
3 *ASX release 19 November 2025*
4 *RaDaR registry: https://www.ukkidney.org/audit-research/data-permissions/data/radar-database*
5 *Munis M et al (2026), Real-world eligibility for FSGS clinical trials: insights from a US health system; Clinical Kidney Journal, 19(2); https:/doi.org/10.1093/ckj/sfaf377*
6 *Alpha is the preset threshold to demonstrate statistical significance, often 0.05 for 2-tailed test or 0.025 for 1-tailed test; when the p value is below alpha, the result is statistically significant*
7 *ASX releases: 14 December 2015, 21 November 2018, 07 June 2021, 30 September 2025*
8 *Nephcure FSGS Facts (https://nephcure.org/)*
9 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*