For Immediate Release

DMX-200 RECEIVES ORPHAN DRUG DESIGNATION IN JAPAN

- Orphan Drug Designation for DMX-200 reflects the high medical need for DMX-200 as a potential new treatment option for patients living with Focal Segmental Glomerulosclerosis (FSGS) in Japan
- Orphan Drug Designation aims to reduce economic burden and regulatory hurdles for development of rare disease treatments, thereby accelerating the availability of new therapies for patients[1]
    - Provides for extended market exclusivity period of 10 years[1]
    - Provides for price premiums[1]
- ACTION3 Phase 3 clinical trial is currently recruiting in Japan, with approximately 20 patients to be recruited to support potential marketing approval in Japan[2]
- Dimerix commercial partner, FUSO Pharmaceutical Industries, Ltd., has exclusive rights to develop, register and commercialise DMX-200 for the treatment of FSGS in Japan
- 243 patients to date have been randomised/dosed in the ACTION3 Phase 3 clinical trial globally[3]

MELBOURNE, Australia, 30 September 2025: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical asset in kidney disease, today announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has granted its lead asset, DMX-200 with Orphan Drug designation (ODD) in Focal Segmental Glomerulosclerosis (FSGS), a rare type of kidney disease. DMX-200 is a small molecule inhibitor of the chemokine receptor 2 (CCR2), currently in a pivotal Phase 3 study, ACTION3, in FSGS patients.

Achieving ODD in Japan marks a major milestone for Dimerix's Phase 3 rare disease program. ODD is a system for supporting and promoting the development of drugs that are not sufficiently researched and developed due to smaller patient numbers. In Japan, drugs can be designated as orphan drugs if they treat diseases affecting fewer than 50,000 patients and there is a high medical need.[1]

"This Orphan Drug Designation reflects the urgent medical need for DMX-200 as a potential new treatment option for patients living with FSGS in Japan. This successful designation is a testament to the expertise and commitment of our commercial partner in Japan, FUSO.
With this designation now in place in Japan, as well as in the US and in Europe, we believe we are well positioned to execute on our global strategy to bring patients with FSGS one of the first, if not the first, FSGS treatment, pending success of our Phase 3 trial and subsequent regulatory filings."

Dr Nina Webster, CEO & Managing Director, Dimerix

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The designation provides significant benefits for DMX-200, including financial incentives through grants and tax credits, regulatory assistance via priority consultation and review processes, and market advantages with a 10-year market exclusivity period as well as pricing premiums. These benefits collectively enhance the commercial potential of Dimerix's program whilst simultaneously ensuring timely access for FSGS patients with limited treatment options.

About ACTION3 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 is stable, patients are then randomised to receive either DMX-200 (120 mg capsule, twice daily) or placebo.

The single Phase 3 trial in FSGS patients has two interim analysis points built in that are 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).

For further information, please visit our website at www.dimerix.com or contact:

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Authorised for lodgement by the Board of the Company

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About Dimerix Limited

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company working to improve the lives of patients with inflammatory diseases, including kidney diseases. Dimerix is currently focused on developing its proprietary Phase 3 product candidate DMX-200, for Focal Segmental Glomerulosclerosis (FSGS) kidney disease, and is also developing DMX-700 for respiratory disease. DMX-200 and DMX-700 were both identified using Dimerix's proprietary assay, Receptor Heteromer Investigation Technology (Receptor-HIT), which is a scalable and globally applicable technology platform, enabling the understanding of receptor interactions to rapidly screen and identify new drug opportunities. For more information, please visit the company's website at www.dimerix.com and follow on X and LinkedIn.

About DMX-200

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 by the FDA in the United States.

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.[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.

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, along with those factors outlined in the most recent Dimerix Limited Annual Report.

References

1 *Japanese Ministry of Health, Labour and Welfare, Orphan Drug Designation: https://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/orphan_drug.html*

2 *ASX release 7 January 2025*

3 *As at 29 September 2025, including 240 adults and 3 children*

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

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