**For Immediate Release**

# FIRST ACTION3 CLINICAL SITE ACTIVATED IN JAPAN & FIRST MILESTONE PAYMENT TRIGGERED

- First site in Japan for ACTION3 Phase 3 clinical trial opens for recruitment
- First Development Milestone Payment of ¥400 million (~AU$4.3 million[1]) triggered from Japanese partner, FUSO Pharmaceutical Industries Ltd. with payment expected within 30 days
- Sites opening in Japan to support recruitment of ACTION3 clinical trial, with approximately 20 patients to be recruited to support potential approval in Japan[1]
- FUSO is one of four regional licensing deals executed for DMX-200
  - Collectively the license deals provide up to ~AU$1.4 billion[2] in total upfront payments and potential milestone payments, plus royalties on net sales
- Dimerix continues to focus on ACTION3 Phase 3 clinical trial delivery and licensing opportunities with potential partners in territories not already licensed

MELBOURNE, Australia, 30 May 2025: Dimerix Limited (ASX: DXB) a biopharmaceutical company with late-stage clinical assets in inflammatory diseases, today confirmed that the first clinical trial site in Japan is now open for recruitment, triggering the first development milestone payment of ¥400 million (~AU$4.3 million[1]) to Dimerix from FUSO Pharmaceutical Industries Ltd, the exclusive licensee of DMX-200 for FSGS in Japan.

Similar to other territories, the clinical trial approval process is sequential in Japan. Importantly, the opening of the first clinical trial site was the final step required prior to recruiting patients in Japan, following prior approval by the Japanese Pharmaceutical and Medical Device Agency (PMDA, the Japanese regulatory agency), receiving ethics approval and the Clinical Trial Agreements with the clinical sites being finalised and agreed.

> "Opening the first clinical site in Japan is another major step forward for our global ACTION3 clinical program, as we aim to bring much needed and new treatments to patients with FSGS around the world. This milestone reflects the strength of our data to date, the rigor of our clinical trial design, and the expertise from our local partner in Japan, FUSO."
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> *Dr Nina Webster, Chief Executive Officer & Managing Director, Dimerix*

FUSO will be responsible for clinical development costs in Japan, submission and maintenance of the regulatory dossier with the PMDA, as well as all sales and marketing activities in Japan, while Dimerix will continue to fund and execute the global ACTION3 Phase 3 study for DMX-200 in FSGS patients outside of Japan. The Company expects to receive the First Development Milestone Payment of ¥400 million (~AU$4.3 million[1]) within 30 days from FUSO.



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## About ACTION3 FSGS Phase 3 Study

The Phase 3 study, which is titled **"A**ngiotensin II Type 1 Receptor (AT1R) & **C**hemokine Receptor 2 (CCR2) **T**argets for **I**nflammat**o**ry **N**ephrosis", or ACTION3 for short, is a pivotal (Phase 3), multi-centre, randomised, double-blind, placebo-controlled study of the efficacy and safety of DMX200 in patients with FSGS who are receiving a stable dose of an angiotensin II receptor blocker (ARB). Once the ARB dose is stable, patients will be randomised to receive either DMX200 (120 mg capsule twice daily) or placebo.

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).

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**

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 focussed on developing its proprietary Phase 3 product candidate DMX-200 (QYTOVRA® in some territories), 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' 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.

**About DMX 200**

DMX 200 is the adjunct therapy of 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 any exclusivity period that may apply in key territories. In 2020, Dimerix completed two Phase 2 studies: one in FSGS and one in diabetic kidney disease, following a successful Phase 2a trial in patients with a range of chronic kidney diseases in 2017. No significant adverse safety events were reported in any trial, and all studies resulted in encouraging data that could provide meaningful clinical outcomes for patients with kidney disease.

**About FSGS**

FSGS is a rare, serious kidney disorder characterized 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.[3] There are no therapies specifically approved for FSGS anywhere in the world, 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,[4] underscoring the urgent need for new, disease-modifying treatments. Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX 200 in both the US and Europe for FSGS. Orphan Drug Designation is granted to support the development of products for rare diseases and qualifies Dimerix for various development incentives including: seven years (FDA) and ten years (EMA) of market exclusivity if regulatory approval is received, exemption from certain application fees, and a fast-tracked regulatory pathway to approval. Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

**References**

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1 *ASX release 7 Jan 2025, using XE exchange rate of 100 Japanese Yen = 1.07 AUD as at 29 May 2025, before tax*

2 *Based on XE exchange rates & further terms outlined in ASX Announcements on 5 October 2023, 27 May 2024, 07 January 2025, and 01 May 2025;*

3 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/*

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