For Immediate Release

DIMERIX RECEIVES INITIAL UPFRONT PAYMENT FROM FUSO

- Dimerix has received the upfront payment of ¥300 million (~AU$3.2 million[1]) from FUSO Pharmaceutical Industries, Ltd. (FUSO)
- Dimerix anticipates a further ¥400 million (~AU$4.1 million[2]) from FUSO on the first development milestone being achieved (i.e. the first clinical site initiation in Japan) anticipated in the next 6-12 weeks
- Dimerix remains eligible for further potential development milestones of up to up to ¥3 billion (~AU$30.6 million[2]) and potential sales milestones of up to ¥6.8 billion (~AU$69.4 million[2]), plus 15 – 20% royalties on any net sales[3]
- Trial Sites have been identified, and progress is being made towards opening those sites in Japan to support recruitment of ACTION3 clinical trial
- FUSO remain responsible for all clinical trial costs in Japan
- FUSO is the third license deal executed for DMX-200 following the license deal with Advanz Pharma (announced October 2023)[4] and Taiba (announced May 2024)[5];
    - Collectively the license deals provide up to ~AU$458 million[6] in total upfront payments and potential milestone payments, plus royalties on net sales
- Dimerix retains all rights to DMX-200 in all territories other than those covered by the FUSO[3], Advanz Pharma[4] and Taiba license agreements[5]
- Dimerix continues to focus on licensing opportunities with potential partners in territories not already covered, including the major markets of US and China

MELBOURNE, Australia, 4 March 2025: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical asset in kidney disease, today announced that it has received the initial payment of ¥300 million (AU$3.2 million[1]) in line with the recently announced license agreement with FUSO Pharmaceutical Industries[3], Ltd. (FUSO). Under the agreement, FUSO has been granted exclusive rights to commercialise DMX-200 for FSGS in Japan. However Dimerix retains all rights to commercialise DMX-200 in all territories other than those covered by the FUSO, Advanz Pharma[4] and Taiba license agreements[5].

Under the FUSO agreement, Dimerix may become eligible to receive: ¥400 million (~AU$4.1 million[2]) on the first development milestone being achieved (i.e. the first clinical site initiation in Japan) which is still anticipated to occur in Q1 2025; further potential development milestone payments of up to ¥3.4 billion (~AU$30.6 million[2]); potential sales milestones of up to ¥6.8 billion (~AU$69.4 million[2]); as well as being eligible to 15-20% royalties on net sales of DMX-200 if successfully commercialised (all contracted financial terms are denominated in Yen). No royalties or similar costs are payable by Dimerix to third parties, which means that any revenue from FUSO will flow through to pre-tax profit for Dimerix.

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Dimerix now has three high quality partners across multiple territories, providing strong support for Dimerix in advancing and commercialising DMX-200 as a potential new treatment for FSGS. Collectively across all licences, Dimerix may become eligible for up to ~AU$458 million[6] in total upfront payments and potential milestone payments, plus royalties on net sales

Dimerix continues to focus on licensing opportunities with potential partners in territories other than those covered by the FUSO[3], Advanz Pharma[4] and Taiba license agreements[5], including the major markets of US and China.

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 randomized to receive either DMX200 (120 mg capsule twice daily) or placebo.

The single Phase 3 trial in FSGS patients has 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

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 disease that attacks the kidney's filtering units, where blood is cleaned (called the 'glomeruli'), causing irreversible scarring. This leads to permanent kidney damage and eventual end-stage failure of the organ, requiring dialysis or transplantation. For those diagnosed with FSGS the prognosis is not good. The average time from a diagnosis of FSGS to the onset of complete kidney failure is only five years and it affects both adults and children as young as two years old.[7] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[8] At this time, there are no drugs specifically approved for FSGS anywhere in the world, so the treatment options and prognosis are limited.

FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,[7] and worldwide about 220,000.[9] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[10] 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

1 *Before tax, based on XE exchange rate of 100 Japanese Yen = 1.07 AUD as at 03 Mar 2025*
2 *Based on XE exchange rates & further terms outlined in ASX Announcement on 07 Jan 2025*
3 *ASX release 07 January 2025*
4 *ASX release 5 October 2023*
5 *ASX release 27 May 2024*
6 *Based on XE exchange rates & further terms outlined in ASX Announcements on 5 October 2023, 27 May 2024 and 07 January 2025;*
7 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/*
8 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*
9 *Delve Insight Market Research Report (2022): Focal segmental glomerulosclerosis (FSGS) – Market Insight, Epidemiology and market forecast – 2032; https://www.delveinsight.com/report-store/focal-segmental-glomerulosclerosis-fsgs-market;*
10 *Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/*