For Immediate Release

DIMERIX AND FUSO ENTER INTO AN EXCLUSIVE DEVELOPMENT AND LICENSE AGREEMENT TO COMMERCIALISE DMX-200 IN JAPAN

Investor Webinar 11am AEDT | Tue, 7 January 2025
You are invited to register using this link:
https://us06web.zoom.us/webinar/register/WN_UUz-PxpmT3aGb9NoMI2YFQ

Participants may submit questions at registration or during the session

- FUSO acquires exclusive rights to develop, register and commercialise DMX-200 for the treatment of Focal Segmental Glomerulosclerosis (FSGS) in Japan
- FUSO will be responsible for all clinical trial costs in Japan; Dimerix retains responsibility for clinical trial costs outside of Japan
- Dimerix to receive up to ¥10.5 billion (~AU$107[1] million) in upfront, development and sales milestone payments, plus royalties:
  - ¥300 million (~AU$3.1 million[1]) within 40 days of execution of the agreement
  - ¥400 million (~AU$4.1 million[1]) first development milestone on first clinical site initiation in Japan, anticipated Q1 2025
  - up to ¥3 billion (~AU$30.6 million[1]) in further potential development milestones
  - up to ¥6.8 billion (~AU$69.4 million[1]) in potential sales milestones
  - 15-20% royalties on net sales
- ACTION3 clinical trial approved by the Japanese Pharmaceutical and Medical Device Agency (PMDA), the Japanese regulatory agency
- Sites to open in Japan to support recruitment of ACTION3 clinical trial, with approximately 20 patients to be recruited to support potential approval in Japan
- FUSO is the third license deal executed for DMX-200 following the license deal with Advanz Pharma (announced October 2023)[2] and Taiba (announced May 2024)[3];
  - Collectively the license deals provide up to ~AU$458 million in upfront payments and potential milestone payments, plus royalties on net sales
- DMX-200 is in development in the global ACTION3 Phase 3 clinical trial for the treatment of FSGS, a rare kidney disease, with approximately 1,400 patients having received treatment in Japan in 2023[4]
- Dimerix retains all rights to DMX-200 in all territories other than those covered by the FUSO, Advanz Pharma[2] and Taiba license agreements[3]

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MELBOURNE, Australia, 7 January 2025: FUSO Pharmaceutical Industries, Ltd. ("**FUSO**") and Dimerix Limited (ASX: DXB, "**Dimerix"**), today announced they have entered into an exclusive development and license agreement for the development and commercialisation of Dimerix' Phase 3 drug candidate DMX-200 for the treatment of focal segmental glomerulosclerosis (FSGS) kidney disease in Japan. Dimerix retains all rights to commercialise DMX-200 in all territories other than those covered by the FUSO, Advanz Pharma[2] and Taiba license agreements[3]. DMX-200 is currently in global Phase 3 clinical development, with a blinded interim analysis anticipated in August 2025.[5]

Dimerix will continue to fund and execute the global ACTION3 Phase 3 study for DMX-200 in FSGS patients outside of Japan, and FUSO will be responsible for all development costs, submission and maintenance of the regulatory dossier with the PMDA, as well as all sales and marketing activities in Japan. In exchange for these rights, Dimerix will receive a payment of ¥300 million (~AU$3.1 million[1]) within 40 days of executing the agreement, ¥400 million (~AU$4.1 million[1]) on initiation of the first clinical trial site which is anticipated in Q1 2025, plus potential development and commercialisation milestones of up to ¥9.8 billion (~AU$100 million[1]).[6] In addition, Dimerix is eligible to receive royalties of between fifteen to twenty percent on net sales of DMX-200 if successfully commercialised (all contracted financial terms are denominated in Japanese Yen).

"We, FUSO, are greatly honoured to be involved in the development of a new drug for FSGS, as there are currently no approved drugs for the treatment of FSGS. It is a truly valuable opportunity for us to partner with Dimerix, which also has an innovative technology called Receptor-HIT, and we will work together with Dimerix to do our best to quickly deliver safe and effective new drugs to patients suffering from FSGS."

Mikio Toda, President and Representative Director, FUSO Pharmaceutical Industries, Ltd.

"We are delighted to partner with FUSO for the commercialisation of DMX-200 in Japan. FUSO brings a wealth of experience in pharmaceutical development and sales and marketing across Japan, and with a proven record in sales and marketing products for patients with renal disease. This partnership reflects a confidence not only in the significant potential for DMX-200 in FSGS patients but also in Dimerix' capabilities in the development of DMX-200. FUSO's expertise and resources will be invaluable in supporting Dimerix to advance our shared goal of developing and commercialising DMX-200 and bringing hope to those patients desperately in need of treatment options."

Dr Nina Webster, CEO & Managing Director, Dimerix

Dimerix and FUSO will form a Joint Steering Committee to align the development and commercialisation of DMX-200 in FSGS in Japan. Any data and regulatory filings generated by FUSO may be used by Dimerix for the development and commercialization of DMX-200 outside of the territory. FUSO also has a right to negotiate a license to develop and commercialize DMX-200 in any additional indications in the licensed territory that Dimerix may achieve for the compound. The agreement otherwise contains terms common for an arrangement of this kind, including termination provisions that, amongst other matters, allows for FUSO to terminate on 180 days' notice.[6]

Dimerix continues to pursue and progress licensing opportunities with potential partners outside the licensed territories, including in the United States of America and Mainland China.

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

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Authorised for lodgement with ASX by the Board of Dimerix

-ENDS-

About ACTION3 FSGS CLINICAL STUDY **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 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).

About FUSO Pharmaceutical Industries, Ltd.

Based on the concept of "Supporting Life, Nurturing Life", FUSO Pharmaceutical Industries, Ltd. has been engaged in the development, manufacture and sale of basic pharmaceutical products that are essential for medical treatment, such as dialysis solutions for artificial kidneys, infusions and injections, and products related to infertility treatment. As a specialty pharmaceutical company in the field of dialysis and renal/urology that developed Japan's first dialysis fluid, FUSO has contributed to the popularisation and development of dialysis treatment. FUSO will continue to fulfil their mission of ensuring a stable supply of dialysis solutions, infusions and injections that are essential for medical treatment, and contributing to people's health by developing pharmaceuticals and infertility products that address unmet medical needs of patients.
For more information, please visit FUSO's website at www.fuso-pharm.co.jp/en/

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

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1 *Based on exchange rate of 100 Japanese Yen = 1.02 AUD as at 06 Jan 2025*

2 *ASX release 5 October 2023*

3 *ASX release 27 May 2024*

4 *Rare Disease Information Center: Number of recipients of special medical expenses (designated intractable disease) certificates: https://www.nanbyou.or.jp/entry/5354*

5 *ASX release 30 January 2025*

6 *Only in the event that Dimerix prohibits FUSO from conducting an activity in Japan that subsequently prevents FSGS marketing approval in Japan, and Fuso subsequently terminates on 45 days notice, Dimerix shall either issue to FUSO Dimerix ordinary shares equal to the amount received by Dimerix in upfront and development milestones or pay the amount in cash, or a combination of the two.*

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/*