

DIMERIX RECEIVES INITIAL UPFRONT PAYMENT FROM ADVANZ PHARMA

- Dimerix has received the initial upfront payment of €6.5 million (AU\$10.7 million¹) from Advanz Pharma
- Dimerix remains eligible for potential development and sales milestones of up to €132 million (~AU\$219 million¹), plus tiered, escalating, mid-teen to twenty percentage royalties on net sales
- Dimerix retains all rights to DMX-200 in all other territories, and the company continues to pursue licensing opportunities with potential partners outside the licensed territories
- FSGS is a rare disease that causes kidney scarring and can lead to end-stage kidney disease
- DMX-200 is in development in the global ACTION3 Phase 3 clinical trial; first analysis outcome expected to be reported on, or around, 15 March 2024²

MELBOURNE, Australia, 6 November 2023: Dimerix Limited (ASX: DXB) (“Dimerix” or the “Company”), a clinical-stage biopharmaceutical company with late-stage clinical assets, today announced that it has received the initial payment of €6.5 million (AU\$10.7 million¹) in line with the recently announced license agreement with Advanz Pharma, marking a pivotal milestone in the company’s growth and development. Under the agreement, Advanz has been granted exclusive rights to commercialise DMX-200 for FSGS in the European Economic Area, the UK, Switzerland, Canada, Australia, and New Zealand.³ Dimerix has retained all commercial rights to DMX-200 outside the Advanz territories, as well as all other indications globally.

Dimerix may receive development and sales milestone payments of up to €132 million (approximately AU\$219 million¹), as well as being eligible to receive tiered, escalating, mid-teen to twenty percentage royalties on net sales of DMX-200 if successfully commercialised (all contracted financial terms are denominated in Euros). No royalties or similar costs are payable by Dimerix to third parties, which means that any revenue from Advanz will flow through to pre-tax profit.

About  **ACTION3** FSGS Phase 3 Study
FSGS CLINICAL STUDY

The Phase 3 study, which is titled “**A**ngiotensin II Type 1 Receptor (AT1R) & **C**hemokine Receptor 2 (CCR2) **T**argets for **I**nflammatory **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).

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

Rudi Michelson
Monsoon Communications
Tel: +61 3 9620 3333
Mob: +61 (0)411 402 737
E: rudim@monsoon.com.au

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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 both kidney and respiratory 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 Chronic Obstructive Pulmonary Disease (COPD). DMX-700 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 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.⁴ For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.⁵ 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 80,000,⁴ and worldwide about 220,000.⁶ The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.⁷ 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 exchange rate of 1 EUR = 1.66 AUD as at 31 October 2023, and non-refundable unless an unremedied material breach of contract occurs*
- 2 *Current independent Data Safety Monitoring Board (DSMB) scheduled meeting*
- 3 *ASX release 05Oct2023*
- 4 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis, online: <https://www.ncbi.nlm.nih.gov/books/NBK532272/>*
- 5 *Front. Immunol., (July 2019) | <https://doi.org/10.3389/fimmu.2019.01669>*
- 6 *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>;*
- 7 *Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online <https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/>*