For Immediate Release

ACTION3 INVESTIGATIONAL NEW DRUG APPLICATION APPROVED IN CHINA

- Investigational New Drug (IND) application for DMX-200 approved by National Medical Products Administration (NMPA), the Chinese regulatory agency
- No bridging* studies are required in the Chinese population prior to recruitment
- Open IND in China may support partnering discussions across the region
- Clinical sites on mainland China are intended for Part 2 of the FSGS ACTION3 Phase 3 clinical trial currently recruiting in 11 other countries
- DMX-200 is being investigated in the pivotal global ACTION3 Phase 3 clinical trial; Part 1 analysis outcome is expected to be reported on or around 15 March 2024[1]
- FSGS is a rare disease that causes kidney scarring and can lead to end-stage kidney disease
- Total FSGS market in China alone valued at US$2.2 billion by 2027[2], driven by over 100,000 patients in Mainland China with FSGS[3]

MELBOURNE, Australia, 28 November 2023: Dimerix Limited (ASX: DXB) ("Dimerix" or the "Company"), a clinical-stage biopharmaceutical company with late-stage clinical assets, today announced that the Chinese National Medical Products Administration (NMPA) Center for Drug Evaluation (CDE) has approved an Investigational New Drug (IND) application to commence recruitment for ACTION3 Phase 3 study of DMX-200, for focal segmental glomerulosclerosis (FSGS) kidney disease. The study is already recruiting across 70 clinical sites in 11 countries globally. Dimerix intends on opening sites in additional countries, including China, following the Part 1 analysis expected on or around 15 March 2024.[1]

Importantly, the IND approval confirms that no further manufacturing, nonclinical or clinical (*bridging) studies are required prior to recruitment of Chinese patients in ACTION3 – which are often required for other product candidates as a prerequisite. The open IND will likely further support partnering discussions in the region. The full study will enrol 286 patients with FSGS globally, including some in mainland China. Positive data from the ACTION3 study may support a future marketing authorisation application for DMX-200 (or Qytovra® in some territories) in China. A subset of 144 patients (Part 2) enrolled in the study from all countries, including Mainland China, is to be incorporated in an interim analysis towards Accelerated/Conditional Marketing Approval in regions where early access to medicines is possible.

"The NMPA approval is a milestone event that allows the ACTION3 study to commence enrolment in the world's second largest pharmaceutical market and provide a new clinical trial option for FSGS patients in China. We are delighted that no bridging study in a Chinese population is required, which would allow the study to commence in China more efficiently after first analysis outcome. FSGS remains an area of high unmet medical need with no approved therapies for this indication. We look forward to reporting the outcome of the study's first analysis in March 2024."

Dr David Fuller, Dimerix Chief Medical Officer

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

The single Phase 3 trial in FSGS patients, which has has two interim analysis points built in, 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 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,[7] 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 *Current independent Data Safety Monitoring Board (DSMB) scheduled meeting*

2 *Focal Segmental Glomerulosclerosis: Global Strategic Business Report (March 2023) https://www.researchandmarkets.com/reports/5309873/focal-segmental-glomerulosclerosis-global*

3 *Personal communications from potential partners (2022) FSGS sales forecasts in China*

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/*