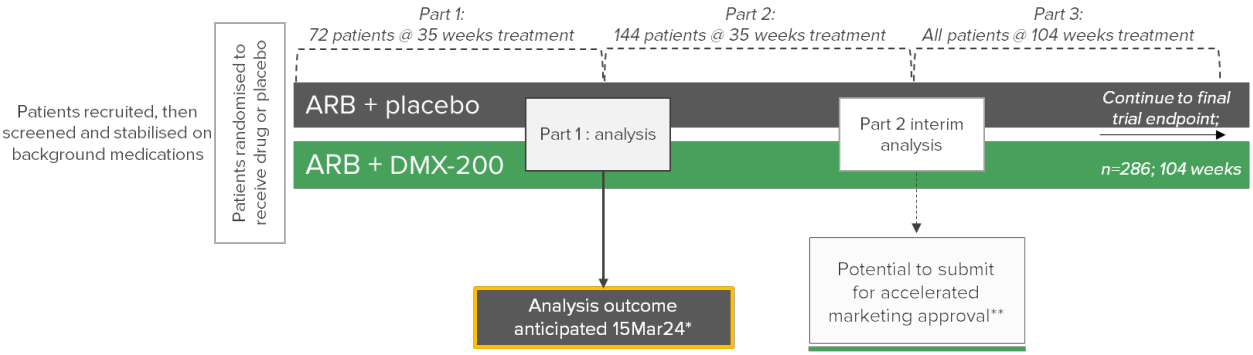
For Immediate Release

DIMERIX RECEIVES REGULATORY APPROVAL TO EXPAND ACTION3 PHASE 3 FSGS KIDNEY TRIAL INTO MALAYSIA

- Regulatory approval in Malaysia received from National Pharmaceutical Regulatory Agency (Malaysia regulatory authority) for ACTION3 Phase 3 study in FSGS kidney disease
- Sites planned for Part 2 of the study, expanding ACTION3 global access to FSGS patients post first analysis
- Part 1: Last patient data collection for Phase 3 study scheduled for 26 February 2024
- Part 1: First analysis expected to be reported on, or around, 15 March 2024[1]
- The trial has two interim analysis points, the second of which may enable accelerated marketing approval[2]
- FSGS is a rare disease with no existing long term treatment options specifically for sufferers[3]
- Total FSGS market size across the 7 major markets estimated to be >US$3 billion by 2032 driven by approximately 220,000 FSGS sufferers across the 7 major markets[4] and premium orphan drug pricing[5]

MELBOURNE, Australia, 22 September 2023: Dimerix Limited (ASX: DXB) a biopharmaceutical company with late-stage clinical assets in inflammatory diseases, today announced it has received regulatory approval from the National Pharmaceutical Regulatory Agency to expand its Phase 3 ACTION3 clinical trial into Malaysia, in addition to the ethics approval previously received. Dimerix intends on opening sites in additional countries, including Malaysia, following the Part 1 analysis expected on or around 15 March 2024.[1]



"Expanding the country access and number of sites is an important milestone as we plan progression of the study into Part 2 in 2024, to enable patients globally to participate for our ACTION3 Phase 3 study in FSGS patients. Malaysia is one of several key countries we are looking to expand into, and we look forward to reporting on those additional countries as we approach the outcome of our Part 1 analysis in March 2024."

Dr Ash Soman, Chief Medical Officer, Dimerix

Dimerix is a biopharmaceutical company developing innovative new therapies in areas with unmet medical needs.

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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 DMX-200 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 DMX-200 (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 accelerated marketing approval. A successful outcome in the first analysis, expected on or around 15 March 2024[1], would see the Company announce that, based on available data, the study is on track to see a clinically and statistical meaningful improvement in proteinuria in patients on DMX-200 versus placebo and that the trial is continuing to Part 2.

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, for Focal Segmental Glomerulosclerosis (FSGS) kidney disease, and is also developing DMX-700 for Chronic Obstructive Pulmonary Disease (COPD). 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.

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.[6] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[7] At this time, there are no drugs specifically approved for FSGS anywhere in the world, so the treatment options and prognosis are poor.

FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,[6] and worldwide about 220,000.[4] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[3] 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 *ASX 25Aug2021*

3 *Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/*

4 *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;*

5 *IQVIA Report (2018), Orphan Drugs in the United States: Growth Trends in Rare Disease Treatments;*

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

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