Dimerix

For Immediate Release

DIMERIX CONFIRMS PHASE 3 FSGS KIDNEY DISEASE STUDY DESIGN APPROPRIATE FOR CHINA

- National Medical Products Administration (NMPA), the Chinese regulatory agency confirms single Phase 3 design appropriate to support trials and potential registration in China
- Clinical sites on mainland China intended for Part 2 of the FSGS Phase 3 clinical trial; which is currently recruiting in Hong Kong and Taiwan
- The investigational new drug (IND) application will now be submitted for Mainland China
- FSGS is a rare kidney disease with no existing approved treatment options specifically for sufferers[1]
- Total Chinese FSGS market alone valued at US$2.2 billion by 2027[2], driven by over 100,000 FSGS sufferers diagnosed in China alone[3]
- ACTION3 FSGS Phase 3 trial continues to recruit globally, with first interim data expected Q12024

MELBOURNE, Australia, 03 July 2023: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical study in inflammatory disease, today confirmed that the Chinese regulatory agency, National Medical Products Administration (NMPA) has provided a written response on the proposed Focal Segmental Glomerulosclerosis (FSGS) Phase 3 study design. The NMPA reviewed a dossier that summarised Dimerix' proposed Phase 3 clinical program for FSGS and its supporting data in the form of non-clinical studies, the manufacturing and process controls and all existing Phase 1 and Phase 2 renal clinical data accumulated to date.

The written response from the NMPA acknowledged that the overall ACTION3 design was acceptable for China, and that Dimerix may not be required to conduct any further clinical studies before proceeding with the ACTION3 study in the Chinese population.

"With over 100,000 patients estimated to be diagnosed in China[3], and no approved treatments, there is very high unmet medical need for new therapeutic options for this disease, which makes studies like this one critical.

This formal response from the NMPA is the first step towards ensuring that the proposed FSGS development program meets with Chinese regulatory expectations for clinical trial and marketing approval, in addition to that feedback we have already received from the US and Europe."

Dr Nina Webster, CEO & Managing Director, Dimerix

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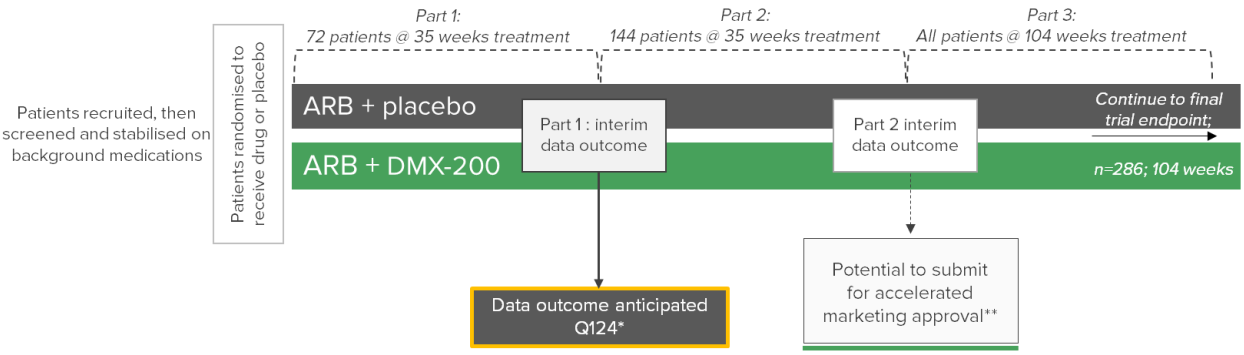
Phase 3 trial

The ACTION3 Phase 3 trial is actively recruiting across clinical sites globally, including in Taiwan and Hong Kong. Once patients have successfully completed the background medication stabilisation period and subsequent re-screening, they are then randomised to receive either drug or placebo. The trial continues to recruit patients for any screen failure, drop out or do not comply with the clinical trial protocol and to support Part 2 of the trial. Those patients who fail the inclusion/exclusion criteria during this screening and stabilisation process are not dosed.



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 potential accelerated marketing approval. Part 1 interim analysis of the trial data will conclude once 72 patients have completed 35 weeks treatment, anticipated Q1 2024.

The Phase 3 trial, 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 trial 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, aged 18 to 80 years (broadening to 12 to 80 years following first successful interim analysis[4]), will be randomized to receive either DMX-200 (120 mg capsule twice daily) or placebo.

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.[5] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[6] 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,[1] and across the seven major markets about 220,000.[2] The illness has a global compound

annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[1] Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for FSGS.[7] 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.

Further information about the trial 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 developing innovative new therapies in areas with unmet medical needs for global markets. Dimerix is currently developing its proprietary product DMX-200, for Focal Segmental Glomerulosclerosis (FSGS) and Diabetic Kidney Disease, and is 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 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.

References

1 *Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/*
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 *ASX release 12Jan2023*
5 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/*
6 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*
7 *ASX releases: 14Dec15, 21Nov18, 07Jun21*