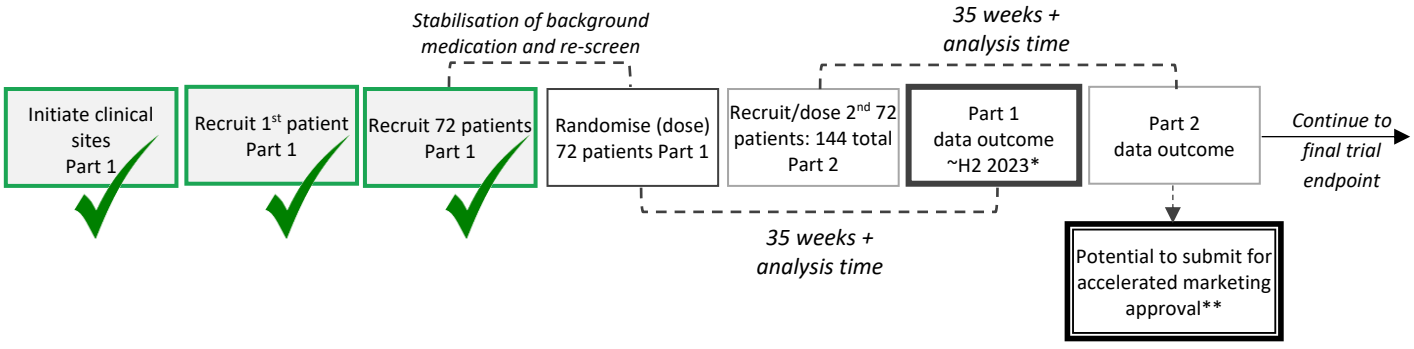
**Immediate Release**

# DMX-200 FSGS ACTION3 PHASE 3 KIDNEY TRIAL PART 1 RECRUITMENT ACHIEVED

## Highlights

- A significant milestone has been achieved with the first 72 patients (Part 1) now recruited in ACTION3 phase 3 pivotal clinical trial of DMX-200 in the treatment of focal segmental glomerulosclerosis ('FSGS') kidney disease
- FSGS is a rare disease with no existing registered treatment options specifically for sufferers[1]
- Total global FSGS market was valued at US$12.6 billion in 2022[2] with a CAGR of 8.2%, driven by approximately 220,000 FSGS sufferers across the 7 major markets[3] and premium orphan drug pricing[4]
- All recruited patients complete background medication stabilisation period before being re-screened and randomised to receive either drug or placebo
- Part 1 interim analysis, which will assess proteinuria reduction in patients on DMX-200 versus placebo at week 35, is anticipated in the latter half of 2023[5]
- The trial has two interim data analysis points, the second of which may enable accelerated marketing approval[6]
- The trial is being performed at over 70 clinical sites across 11 different countries[7]
- All activated sites will continue to recruit suitable patients for Part 2 of the ACTION3 trial, also allowing for any screen failures or patient dropouts
- Orphan drug designation received, allowing potential fast track of commercialisation if successful[9,10,11]

MELBOURNE, Australia, 15 December 2022: Dimerix Limited (ASX: DXB) a biopharmaceutical company with multiple late-stage clinical assets in inflammatory diseases, today confirmed that recruitment of the first 72 patients to its DMX-200 ACTION3 phase 3 trial in patients with FSGS kidney disease had been achieved. Once patients have completed the background medication stabilisation period and subsequent re-screening, they are then randomised to receive either drug or placebo. The trial will immediately continue to recruit patients for Part 2 of the trial, as well as to allow for any screen failures and/or patients who drop out or do not comply with the clinical trial protocol.[6]




*Subject to recruitment and randomisation
**Subject to data outcome



Dimerix HQ
425 Smith St, Fitzroy 3065
Victoria, Australia
T. 1300 813 321
E. info@dimerix.com

Part 1 of the trial will conclude after the first interim analysis, once 72 patients have completed 35 weeks of treatment, and is expected to occur in the latter half of 2023. The ACTION3 Phase 3 trial is recruiting across over 70 sites in 11 different countries.[8]

> "The recruitment of the first 72 patients into our key Phase 3 ACTION3 FSGS kidney clinical trial is a significant and exciting milestone for Dimerix. The Dimerix team and the clinical sites have been working extremely hard behind the scenes, with several hundred FSGS patients having been pre-screened against the clinical trial inclusion criteria to enrol those 72 patients. We are delighted that the time from first patient recruited to the 72nd patient was only 7 months, and we now eagerly await the results of the interim analysis once these patients have been dosed. We also look forward to the strong recruitment momentum achieved to date continuing into Part 2 of the trial."
>
> *Dr Nina Webster, CEO & Managing Director, Dimerix Limited*

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.[2] Part 1 interim analysis of the trial data will conclude once 72 patients have completed 35 weeks treatment.

With Part 1 recruited, the trial will continue to recruit and randomise a further 72 patients at all activated clinical sites for Part 2 of the trial effective immediately, to reach a total of 144 patients for the second potential Accelerated Approval data analysis. Patients recruited into the trial will need to demonstrate a minimum of 6 weeks stable dosing of an angiotensin receptor blocker prior to randomisation and dosing with DMX-200 or placebo.

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, will be randomized to receive either DMX-200 (120 mg capsule twice daily) or placebo.

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).

**Orphan Drug Designation**

Dimerix has received Orphan Drug Designation for DMX-200 in both the US[9] and Europe[10], and the equivalent Innovative Licensing and Access Pathway (ILAP) designation in the UK[11], for the treatment of FSGS. These designations provide regulatory and financial benefits to help bring new drugs to market faster, including reduced fees during the product development phase, protocol assistance from the regulatory authorities, and 7-year (US) and 10-year (Europe) market exclusivity following product approval.

Dimerix has multiple assets in commercially attractive and growing markets that have a high unmet need, no current marketed competition, and with a potential fast pathway to market. Dimerix

continues to drive the FSGS Phase 3 program, further progress the diabetic kidney disease and COPD programs, as well as support the investigator-led COVID-19 programs.

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


Follow us on **LinkedIn** and **Twitter**

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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), respiratory complications associated with COVID-19 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. Receptor-HIT is licensed non-exclusively to Excellerate Bioscience, a UK-based pharmacological assay service provider with a worldwide reputation for excellence in the field of molecular and cellular pharmacology.

**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. DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

***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.[12] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[13] 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,[12] and worldwide about 220,000.[3] 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. 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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