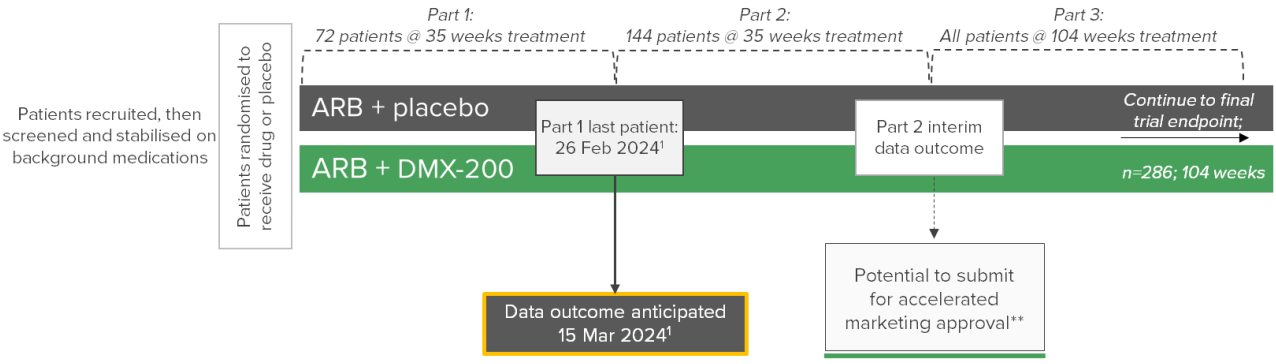
Immediate Release

DMX-200 FSGS ACTION3 PHASE 3 KIDNEY TRIAL PART 1 OUTCOME SET FOR Q1 2024

Highlights

- A significant milestone has been achieved with the last patient randomised in the first 72 patient cohort, global Phase 3 FSGS study
- This now drives the first interim data outcome (Part 1), expected to be reported on, or around, 15 March 2024[1]
- 133 patients having entered the screening and/or stabilisation process, with 72 patients now randomised to receive drug or placebo
- The trial has two interim data 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]
- The Dimerix Phase 3 ACTION3 trial is being conducted at over 70 clinical sites across 11 different countries[6]
- All activated sites will continue to recruit patients for Part 2 of the ACTION3 trial
- Orphan drug designation received, allowing potential fast track of commercialisation if successful[7,8,9]

MELBOURNE, Australia, 24 July 2023: Dimerix Limited (ASX: DXB) a biopharmaceutical company with a Phase 3 clinical study in inflammatory diseases, today confirmed that the first 72 patients have been randomised in its DMX-200 ACTION3 phase 3 trial in patients with FSGS kidney disease. Following recruitment, patients were required to complete the background medication stabilisation period and subsequent re-screening, before being randomised to receive either drug or placebo. With randomisation of the first cohort of patients complete, the final data collection is scheduled on 26 February 2024, with the Part 1 interim outcome expected to be announced on, or around, 15th March 2024.[1] The trial continues to recruit patients for Part 2 of the trial.[2]



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

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

"The randomisation of the first 72 patients into our key Phase 3 ACTION3 FSGS kidney clinical trial is a major milestone for Dimerix. The first patient in the trial was randomised in July 2022, meaning Part 1 randomisation of patients in a rare disease has taken only 12 months. We are delighted to be able to now provide clarity on the anticipated Part 1 data timing.
FSGS patients today face poor outcomes with limited medical options, and on success, DMX-200 could be a significant advancement in the treatment of FSGS as well as the first approved treatment available to the FSGS community."

Dr Nina Webster, CEO & Managing Director, Dimerix Limited

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 interim analysis outcome, expected on or around 15 March 2024[1], would see the Company announce a clinically significant and statistical meaningful improvement in proteinuria in patients on DMX-200 vs 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).

Orphan Drug Designation

Dimerix has received Orphan Drug Designation for DMX-200 in both the US[7] and Europe[8], and the equivalent Innovative Licensing and Access Pathway (ILAP) designation in the UK[9], 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.

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**

Authorised for lodgement by the Board of the Company

—END—

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.[10] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[11] 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,[10] 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 *ASX investor presentation 29Mar2022*
7 *ASX:14Dec2015*
8 *ASX: 21Nov2018*
9 *ASX: 07Jun2021*
10 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/*
11 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*