Immediate Release

FIRST PAEDIATRIC PATIENT RECRUITED FOR ACTION3

- The first paediatric patient for the ACTION3 Phase 3 clinical trial has been recruited at a specialist site in the United Kingdom
- A total of 19 specialist paediatric clinical sites across Argentina, Mexico, United Kingdom and United States will recruit patients into ACTION3 Phase 3 clinical trial to support recruitment of paediatric patients (12-17 years old)
- The DMX-200 complete paediatric development plan aims to collect sufficient data for potential marketing approval in children over 1 year old in accordance with the FDA and EMA expectations[1]
- FSGS is one of the leading causes of kidney failure in children, with 20% of all presentations of Nephrotic Syndrome in paediatric patients caused by FSGS[2]
- ACTION3 recruitment remains on-track with interim data collection currently anticipated August 2025 and full study recruitment anticipated late Q3/2025

MELBOURNE, Australia, 16 January 2025: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical asset in kidney disease, is pleased to advise that the first paediatric patient for ACTION3 has been recruited at a site in Manchester, UK. This represents a significant milestone being achieved in recruiting paediatric patients aged 12-17 years old into ACTION3 to support potential marketing approval in this population.

The dose of DMX-200 to be used in paediatric patients aged 12-17 years participating in the trial will be the same dose as provided to adults in the trial (120 mg twice daily).[3] This determination was based on reviewing the aggregate interim safety and pharmacokinetic data, including simulations in paediatric patients (12-17 years old), from the adult cohort of the ACTION3 Phase 3 trial taken at the first interim analysis point in March 2024 where the IDMC noted “the safety margin [of DMX-200] should allow [the ACTION3 Phase 3] clinical study to proceed in this paediatric population using adult doses”.[4]

Approximately 19 of the planned >170 study sites are specialist paediatric kidney centres across the UK, USA, Mexico and Argentina, and have been selected to recruit paediatric patients (12-17 years old) with FSGS into the ACTION3 study. Patients in this paediatric cohort of the blinded ACTION3 Phase 3 clinical trial will also be randomised (i.e. unknowingly placed on either placebo or DMX-200) and will be followed for a period of two years. Should the paediatric cohort aged 12-17 years old be successful, and DMX-200 be approved in adults, it may allow Dimerix to expand its approval for DMX-200 and market DMX-200 to paediatric in key territories, including the US and Europe. FSGS is one of the leading causes of kidney failure in children, with 20% of all presentations of Nephrotic Syndrome in paediatric patients caused by FSGS.[5]

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The DMX-200 paediatric development plan aims to collect sufficient data for potential marketing approval in children over 1 year old in accordance with the FDA and EMA expectations and with key components including:

- Paediatric patients from 12 to 17 years of age to be included in current ACTION3 study in patients with FSGS – in line with US FDA[6] and European EMA advice[1]
- In silico modelling, simulation and extrapolation of paediatric data from ACTION3 will be undertaken in order to support a confirmatory small open-label study in children from 1 to 11 years of age[1]

> *"The recruitment of the first paediatric patient for ACTION3 is highly significant, being the first step towards providing a potential new treatment for children with FSGS. The study is entering a very exciting phase as we open the last remaining study sites and work towards full recruitment later this year, as well as the blinded interim analysis anticipated in August 2025."*
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> *Dr David Fuller, Chief Medical Officer, Dimerix*

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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 has 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 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).

About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company working to improve the lives of patients with inflammatory diseases, including kidney 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 respiratory disease. 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.

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.[7] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[8] 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.[9] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[10] 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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4 *See ASX Announcement 4 July 2024*
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6 *ASX release 12 January 2023*

7 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/*
8 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*
9 *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;*
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