Dimerix

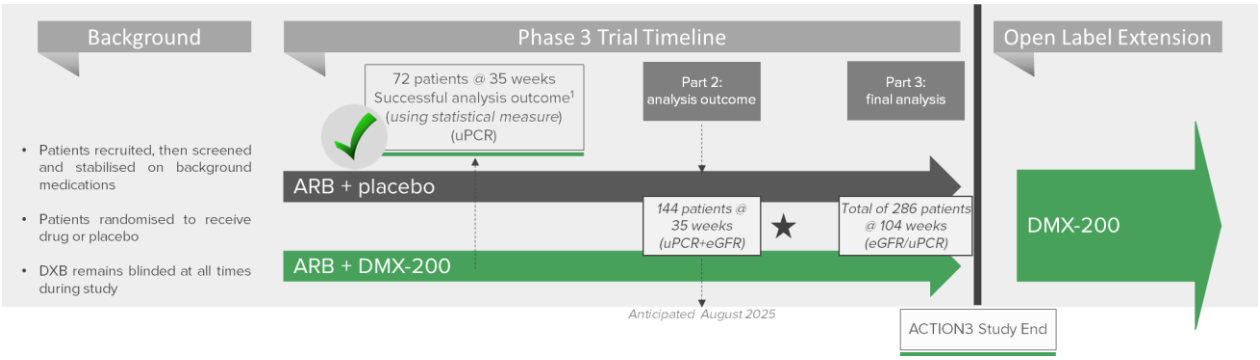
Immediate Release

DMX-200 FSGS ACTION3 PHASE 3 TRIAL PART 2 RECRUITMENT COMPLETE

Highlights

- Significant milestone achieved with the 144th patient recruited, randomised & dosed into the DMX-200 ACTION3 Phase 3 global clinical trial; representing 50% of total trial recruitment
- Full study recruitment of 286 adult patients is anticipated in Q3/2025 (calendar year)
- Planned blinded interim data collection anticipated in August 2025, following 35 weeks' dosing of the first 144 patients[1], with the Part 2 interim analysis outcome expected shortly thereafter once laboratory and statistical analysis is complete
- The potential for accelerated (or conditional) approval submissions will be assessed based on the outcome of this analysis and discussions with the appropriate regulatory authorities such as the FDA in the US[1]
- The Phase 3 trial has now undergone 5 separate Independent Data Monitoring Committee reviews including a formal futility assessment (Part 1 Analysis Outcome[2]) and with no safety concerns identified
- To date, 14 patients have completed the full 2-year ACTION3 clinical trial and have elected to continue into the additional 2 year Open Label Extension study
- DMX-200 is the most advanced FSGS asset in a Phase 3 clinical trial globally and is attracting strong interest from potential commercial partners
- Orphan drug designation received, allowing potential fast track of commercialisation if successful[3,4,5]

MELBOURNE, Australia, 30 December 2024: Dimerix Limited (ASX: DXB) a biopharmaceutical company with late-stage clinical assets in inflammatory diseases, today confirmed that the first 144 patients have been randomised in its DMX-200 ACTION3 Phase 3 clinical trial in patients with FSGS kidney disease. Following enrolment into the study, patients are required to complete the background medication stabilisation period, before being randomised to receive either DMX-200 or placebo. With randomisation of the first cohort of 144 patients completed on 27 December 2024 (US time), the blinded interim analysis for this cohort is now scheduled for August 2025, with the Part 2 interim analysis outcome expected to be announced shortly thereafter once laboratory and statistical analysis is complete.[1] The trial continues to recruit patients for the final phase of the trial (target recruitment of 286 patients in total).



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 144 patients into our DMX-200 ACTION3 Phase 3 FSGS kidney clinical trial is a major milestone for Dimerix, and this triggers the current planned blinded data collection in August 2025, after 35 weeks treatment, with the Part 2 interim analysis outcome expected to be announced shortly thereafter. Based on current projections we expect to complete recruitment for the full study in Q3/2025. Subject to ongoing guidance and correspondence with the appropriate authorities, the Company may be able to apply for accelerated (or conditional) approval of DMX-200 in some key territories which could, if approved, enable commercial launch of DMX-200 prior to the completion of the 2 year double blind ACTION3 Phase 3 clinical trial. We know FSGS patients today face poor outcomes with limited treatment options, and upon trial success, DMX-200 could be a significant advancement in the treatment of FSGS providing hope to the FSGS community."

Dr Nina Webster, CEO & Managing Director, Dimerix Limited

Importantly, patients, physicians and Dimerix staff will remain blinded to patient allocation (i.e. which patients are receiving DMX-200 and which are receiving placebo) at all times during study, including at the second interim analysis timepoint, which will assess the statistical powering of the ACTION3 study and confirm study continuation as per protocol based on safety and efficacy assessments[1]. The potential for accelerated (or conditional) approval submissions, following the Part 2 interim analysis outcome and any required unblinding, will be assessed based on recommendations of the IDMC and discussions with the appropriate regulatory authorities such as the FDA in the US.[1]

The Phase 3 study, which is titled "Angiotensin II Type 1 Receptor (AT1R) & Chemokine Receptor 2 (CCR2) Targets for Inflammatory Nephrosis", 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. DMX-200 is the most advanced FSGS asset in a Phase 3 clinical trial globally and is attracting strong interest from potential commercial partners.

Open Label Extension Study

In addition, given a number of territories around the world require compulsory access to the experimental treatment for patients as they complete a clinical trial, following the successful Part 1, Dimerix now has an open label extension (OLE) study in place. The OLE study will allow all patients access to DMX-200 once they have completed the ACTION3 clinical trial and follow them for a further 2 years. This provides further study risk mitigation and long-term data. To date, 14 patients have completed the 2 year ACTION3 phase 3 study and have elected to continue into the OLE. It is anticipated that the OLE study is to be funded through current cash reserves as well as future licensee milestone payments under the existing partnering arrangements.

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[3] and Europe[4], and the equivalent Innovative Licensing and Access Pathway (ILAP) designation in the UK[5], 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

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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 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.[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 limited. 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 Dimerix June 2024 Activities Report, released to market 23 July 2024
2 ASX: 11Mar2024
3 ASX:14Dec2015
4 ASX: 21Nov2018
5 ASX: 07Jun2021
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