

SUCCESSFUL COMPLETION OF PLANNED IDMC REVIEW OF ACTION3 PHASE 3 FSGS KIDNEY TRIAL

- The fifth scheduled Independent Data Monitoring Committee (IDMC) review, evaluating the available study data for participant safety, study conduct and progress, has been successfully completed
- The IDMC recommends the ACTION3 clinical trial continue unchanged, with no changes to design or safety monitoring
- The IDMC has again noted no safety concerns to date, consistent with their prior reviews and the existing and growing strong safety profile of DMX-200
- The next scheduled IDMC meeting is planned for Q2/2025

MELBOURNE, Australia, 20th November 2024: Dimerix Limited (ASX: DXB) a biopharmaceutical company with late-stage clinical assets in inflammatory diseases, today confirmed that the Independent Data Monitoring Committee (IDMC) successfully concluded a fifth review of the ACTION3 phase 3 clinical trial safety data. Following this routine, scheduled review, the IDMC has noted no safety concerns and recommended that the clinical trial continue as planned.

Undertaking a review by an IDMC is consistent with good clinical practice,¹ and was pre-specified in the study protocol. The primary responsibilities of the IDMC are to review and evaluate the available study data for participant safety, study conduct and progress, and to make recommendations concerning the continuation, modification, or termination of the trial. The study protocol for the ACTION3 clinical trial includes oversight by an IDMC as well as provision for interim safety reviews, the fifth of which has now been successfully completed.

“This encouraging recommendation of the IDMC confirms the strong emerging safety profile of DMX-200 and suggests that DMX-200 does not add a burden of side effects to patients, compared to commonly used treatments such as high dose steroids and immunosuppressants. DMX-200 represents a real hope for the many patients suffering from FSGS kidney disease who currently have limited treatment options.”

Dr David Fuller, Chief Medical Officer, Dimerix

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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 FSGS Phase 3 Study

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.

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).

1 NHMRC Clinical Trials Data Safety Monitoring Board:
www.nhmrc.gov.au/sites/default/files/documents/reports/data-safety-monitoring-boards.pdf