Dimerix

For Immediate Release

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

- The sixth 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 emerging strong safety profile of DMX-200
- The next scheduled IDMC meeting is planned for Q4/2025

MELBOURNE, Australia, 22 May 2025: 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 sixth 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, supporting the emerging strong safety profile of DMX-200.

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."
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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 is 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).

For further information, please visit our website at www.dimerix.com or contact:

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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, serious kidney disorder characterized by progressive scarring (sclerosis) in parts of the glomeruli—the kidney's filtering units. This scarring leads to proteinuria, progressive loss of kidney function, and often end-stage renal disease. FSGS is increasingly understood to have an inflammatory component, with monocyte and macrophage activation contributing to glomerular injury. In the United States, more than 40,000 people are estimated to be living with FSGS, including both adults and children.[2] There are no therapies specifically approved for FSGS anywhere in the world, and disease management relies on non-specific immunosuppressive and supportive therapies. In patients with progressive or treatment-resistant FSGS, the average time from diagnosis to end-stage kidney disease can be as short as five years. Even among those who undergo kidney transplantation, disease recurrence occurs in up to 60% of cases,[3] underscoring the urgent need for new, disease-modifying treatments. 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 *NHMRC Clinical Trials Data Safety Monitoring Board: www.nhmrc.gov.au/sites/default/files/documents/reports/data-safety-monitoring-boards.pdf*

2 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/*

3 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*