For Immediate Release

FDA CONFIRMS PROTEINURIA AS ACCEPTABLE PRIMARY ENDPOINT FOR DMX-200 FOR FULL MARKETING APPROVAL IN US

Key Outcomes from Dimerix Meeting with the US FDA in March 2025:

Primary Endpoint for Full Approval

- FDA confirmed that a proteinuria-based endpoint could be the basis for full marketing approval of DMX-200 in the US
- FDA further confirmed that suitable proteinuria primary endpoints could include either:
  - the proportion of patients achieving a defined proteinuria reduction compared to the placebo arm after 2-years of treatment; or
  - the percentage change in proteinuria from baseline after 2-years of treatment
- The new "percent change in proteinuria from baseline primary endpoint" proposed by the FDA aligns with existing DMX-200 preclinical and clinical efficacy results including:
  - **Animal Models:** Statistically significant reduction of proteinuria shown in key animal models of renal disease[1]
  - **Phase 2a clinical trial:** DMX-200 demonstrated a 24% change in proteinuria from baseline, and a 17% placebo-adjusted reduction in proteinuria from baseline after 16-weeks of treatment[2]
  - **Part 1 interim analysis of the ACTION3 Phase 3 clinical trial (reported March 2024)**: whereby it was confirmed that there was a reduction in proteinuria in the DMX-200 treatment arm compared to the placebo arm after 35-weeks of treatment, and hence the Phase 3 clinical trial was to continue unchanged[3]
- No additional changes are anticipated to the ACTION3 study design because both eGFR and proteinuria data are being collected for a total of 2 years
- 183 out of 286 patients have currently been randomised/dosed in the ACTION3 Phase 3 clinical trial

Accelerated Approval

- FDA confirmed that they remain open to discussion on endpoints that could support a potential Accelerated Approval application and verify clinical benefit

MELBOURNE, Australia, 28 April 2025: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical asset, DMX-200, in a rare kidney disease, today announced a highly positive development regarding its ACTION3 Phase 3 clinical trial. The formal meeting minutes from the collaborative and productive Type C meeting with the US Food and Drug Administration (FDA) held in March 2025 confirm the FDA's acceptance of proteinuria as an appropriate primary endpoint for full (or traditional) marketing approval in the United States (US) for DMX-200 in Focal Segmental Glomerular Sclerosis (FSGS).

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The FDA agreed with Dimerix' proposal that proteinuria could be considered as an appropriate primary endpoint for full marketing approval in the US, and proposed that suitable proteinuria endpoints could include 1) a statistically significant increase in the proportion of patients achieving a defined proteinuria reduction compared to the placebo arm after 2-years of treatment as proposed by the PARASOL working group (dichotomous variable, e.g. below 0.7 g/g), or 2) a statistically significant reduction in proteinuria from baseline (percent change) compared to the placebo arm after 2-years of treatment (continuous variable), along with a justification for what constitutes a meaningful difference between treatment arms. The FDA noted that this justification should be data driven and provided well in advance of the completion of the trial. The FDA further proposed that, if using proteinuria as a primary endpoint, the existing eGFR slope change endpoint should be pre-specified as a secondary endpoint. Proteinuria is known to demonstrate less variability than eGFR for clinical trials and could therefore reduce risk for potential downstream marketing approval in the US.

The outcome of this meeting with the FDA is a significant and positive result for DMX-200, given Dimerix' prior pre-clinical and clinical analysis has already demonstrated encouraging effects on change in proteinuria levels from baseline.[1,2,3]

> "The agreement with the FDA on proteinuria as an appropriate primary endpoint for full marketing approval for DMX-200 in our phase 3 trial is an exceptional outcome, particularly given that DMX-200 has previously demonstrated positive effects on this endpoint in both pre-clinical and clinical studies. As part of our study design, both eGFR and proteinuria data are being collected for a total of 2 years however the FDA response on proteinuria potentially gives us an opportunity for earlier market entry by working with both PARASOL and FDA on an accelerated approval proteinuria endpoint for use in FSGS. There remains a high unmet need for new treatments for this progressive disease, and studies such as ACTION3 provide hope for those patients desperately in need of treatment options."
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> *Dr Nina Webster, CEO & Managing Director, Dimerix Limited*

Based on discussion during the meeting, Dimerix is working with the PARASOL working group to generate additional analysis of existing PARASOL data to further assess what may represent an appropriate and meaningful endpoint for accelerated approval in the population of patients with FSGS treated in the ACTION3 study and the quantitative relationship with the final primary (confirmatory) endpoint of the ACTION3 study. This additional work may provide the justification to support an accelerated approval endpoint, which will be discussed with the FDA prior to any potential submission.

Dimerix will also undertake a blinded statistical powering analysis[4] of the ACTION3 clinical trial once the additional PARASOL work is complete and the primary and secondary endpoints have been pre-specified in the protocol and aligned with the FDA. The PARASOL analytical work is expected to take approximately three to six months.

The feedback and collaborative discussions with the FDA reflect a very positive and constructive interaction for Dimerix, clarifying the use of proteinuria as an alternative endpoint for full marketing approval of DMX-200. This Type C meeting, and the timely issuance of the minutes, further confirms the drive by both Dimerix and the Division of Cardiology and Nephrology at the FDA towards the goal of bringing potential new treatments for patients with FSGS.

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).

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.[5] 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,[6] 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 *Ayoub MA, et al. (2015) PLoS ONE 10(3): e0119803*

2 *Repeated measures mixed model analysis; top line data was reported as grouped analysis on 29 July 2020; study design was not powered for statistical significance*

3 *Interim Phase 3 analysis data does not guarantee a statistically significant outcome at the end of the trial, ASX release 11 March 2024*

4 *Quarterly Appendix 4C and Activities Report released 23 July 2025*

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

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