DIMERIX SUCCESSFULLY PASSES EFFICACY INTERIM ANALYSIS IN ACTION3 PHASE 3 STUDY FOR FSGS KIDNEY DISEASE

Highlights

- ACTION3 Phase 3 trial successfully passes first interim analysis using proteinuria efficacy endpoint
- DMX-200 is currently performing better than placebo in reducing proteinuria (using a statistical measure[1]) in patients with FSGS in a significantly larger cohort than our prior Phase 2 study[2]
- Passing this early interim analysis suggests a statistically significant and clinically meaningful result in reducing proteinuria at the end of the study may be possible [2,3]
- IDMC has again noted no safety concerns to date, which is entirely consistent with the existing and growing strong safety profile of DMX-200
- The IDMC recommended the ACTION3 clinical trial continue unchanged
- ACTION3 clinical trial will now formally expand into Part 2 of the study
- New clinical sites will now be opened in additional countries, including China, to further enhance recruitment
- Dimerix will now focus on the execution of potential licensing deals for available jurisdictions including in the US and China
- Focal Segmental Glomerulosclerosis (FSGS) is a rare disease that causes kidney scarring and can lead to end-stage kidney disease
- Total FSGS market size driven by approximately 220,000 FSGS sufferers across the 7 major markets[4] and premium orphan drug pricing[5]

MELBOURNE, Australia, 11 March 2024: Dimerix Limited (ASX: DXB, "**Dimerix"**), today announced that the ACTION3 Phase 3 trial of DMX-200 in patients with focal segmental glomerulosclerosis (FSGS) was successful in the pre-specified interim analysis of the proteinuria (efficacy) endpoint from the trial's first 72 randomised patients. The analysis indicates that, using a statistical measure,[1] DMX-200 is performing better than placebo in terms of reducing proteinuria (a surrogate marker of kidney disease progression[6]) in patients with FSGS. This analysis is extremely valuable as it is based on a significantly larger cohort than the prior Dimerix Phase 2 study which was conducted in 8 patients.[2]

An interim analysis incorporating a futility assessment (where certain data are assessed early to determine whether or not the drug is having a desired effect) is included to ensure a trial does not continue unnecessarily if there is no efficacy signal.[3] Therefore passing this first interim analysis (a futility assessment) is important as it suggests that it is possible DMX-200 may achieve a statistically significant and clinically meaningful result at the end of the study.[2]

ACTION3 Phase 3 clinical trial continues as planned

After notifying the Company of the interim analysis results, the trial's Independent Data Monitoring Committee (IDMC) additionally stated that it had no safety concerns relating to DMX-200 and formally recommended the trial continue as planned.

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In line with best practice for blinded Phase 3 clinical trials, the interim analysis data are only reviewed by the unblinded IDMC members. Dimerix, the regulatory authorities including the United States Food and Drug Administration (FDA), and the trial investigators are blinded to treatment allocations, grouped safety and efficacy data for the ongoing trial and the data inputs into this interim analysis. It is expected that the full trial will enrol approximately 286 patients, with a second interim analysis planned after the first 144 patients complete approximately 35 weeks' treatment.

"It is very pleasing to see that the Phase 3 clinical trial of DMX-200 was successful in the pre-specified interim futility analysis for efficacy in the first 72 patients. The positive signal suggests that treatment with DMX-200 may indeed result in a clinically meaningful improvement in kidney function when added to the standard of care in patients with FSGS. With limited treatment options currently available, there remains a significant unmet need for more efficacious and durable therapies for FSGS."

Professor Jonathan Barratt, Nephrologist, Mayer Professor of Renal Medicine: University of Leicester, Co-Chair UK Glomerulonephritis Clinical Study Group, Medical Advisory Board Member for Dimerix

The ongoing Phase 3 is a double-blind, randomised (1:1) trial and is currently being conducted across multiple study sites in 11 countries, with the primary endpoints currently being both eGFR and proteinuria. Proteinuria (the measure of how much protein is in the urine), is used along with the estimated glomerular filtration rate (eGFR) in both the classification of kidney diseases and the effectiveness of therapies. Proteinuria can serve as an indicator of renal disease, and the degree of proteinuria correlates with disease progression.[6] To date, the study has randomised and dosed 94 patients with FSGS.

"Passing this first interim analysis for DMX-200 is a key milestone for Dimerix and our FSGS program. It demonstrates that DMX-200 is performing better than placebo in reducing proteinuria in a much larger cohort than our prior 8-patient Phase 2 study, and this validates our strategy and our prioritisation of this potentially valuable program in a disease where there are no FDA approved therapies. We now look forward to rapidly expanding this study, which will include recruiting children down to 12 years old as well as adults."

Dr David Fuller; Chief Medical Officer, Dimerix

A collaborative international effort has been established (project PARASOL) that aims to define the quantitative relationships between short-term changes in biomarkers (proteinuria and GFR) and long-term outcomes to further support the use of alternative proteinuria-based endpoints as a basis for accelerated and traditional approval in FSGS kidney disease. Dimerix intends to support this working group once industry has been invited to participate, given these outcomes may support and/or influence the final ACTION3 endpoints and statistical analysis plan.

Dimerix has received a significant amount of partnering interest from pharma companies globally, with its first licence agreement entered into with Advanz Pharma in October 2023 for Europe, Canada, Australia and New Zealand, and valued at up to $230 million plus royalties on sales. Dimerix has received several non-binding term sheets for other regional deals, with multiple parties currently in the data room conducting due diligence and negotiating a potential licensing agreement for various territories. Following the successful first interim analysis, Dimerix will focus on the execution of potential licensing deals for those available jurisdictions including in the US and China.

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

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Authorised for lodgement with ASX by the Board of Dimerix

-ENDS-

About ACTION3 FSGS CLINICAL STUDY **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 a second interim analysis point built in that 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).

About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company working to improve the lives of patients with inflammatory diseases, including both kidney and respiratory 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 Chronic Obstructive Pulmonary Disease (COPD).

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 blood pressure 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 potential 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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6 *Haider M, Aslam A (2023) Proteinuria; PMID: 33232060 online https://pubmed.ncbi.nlm.nih.gov/33232060/*

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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;*

10 *Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/*