For Immediate Release

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

- Scheduled independent Data Safety Monitoring Board (DSMB) review, evaluating the available study data for participant safety, study conduct and progress, has been successfully completed
- The DSMB recommends the ACTION3 clinical trial continue unchanged
- DSMB has noted no safety concerns to date, which is entirely consistent with the existing and growing strong safety profile of DMX-200
- The trial has two interim data analysis points, the second of which may enable accelerated marketing approval[1]
- ACTION3 Part 1 interim analysis, which will assess proteinuria reduction of the first 72 patients on DMX-200 versus placebo at week 35, is anticipated in the latter half of calendar year 2023[2]
- Patient recruitment continues to progress well, with 96 enrolled patients as at 08 February 2023 (up 100% since 27 October 2022) across 70 active sites
- FSGS is a rare kidney disease with no existing approved treatment options specifically for sufferers[3]
- Total global FSGS market was valued at US$12.6 billion in 2022[4] with a CAGR of 8.2%, driven by approximately 220,000 FSGS sufferers across the 7 major markets[5] and premium orphan drug pricing[6]

MELBOURNE, Australia, 09 February 2023: Dimerix Limited (ASX: DXB) a biopharmaceutical company with late-stage clinical assets in inflammatory diseases, today confirmed that an independent Data Safety Monitoring Board (DSMB) has successfully concluded a review of the ACTION3 phase 3 clinical trial. Following the routine, scheduled review, the DSMB has noted no safety concerns and recommended that the clinical trial continue as planned.

Undertaking a review by an independent DSMB is consistent with good clinical practice,[7] and was pre-specified in the analysis plan. The primary responsibilities of the DSMB 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 a DSMB as well as provision for interim reviews, the first of which has now been successfully completed.

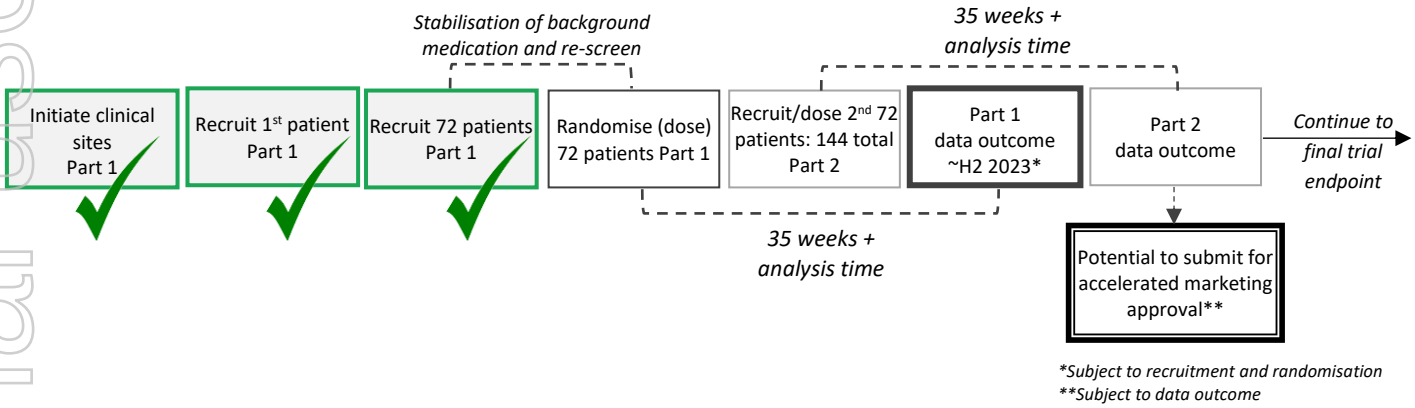
> "The DSMB's positive recommendation is a key milestone, which enables us to continue patient enrolment as planned and to complete the trial as soon as possible. The outcome from this DSMB analysis is entirely consistent with existing and growing strong safety profile of DMX-200.
> We have seen strong recruitment momentum across the study, and we look forward to reporting on the results of the interim analysis once the first 72 patients reach 35 weeks treatment."
>
> *Dr Ash Soman, Chief Medical Officer, Dimerix*

Dimerix HQ
425 Smith St, Fitzroy 3065
Victoria, Australia
T. 1300 813 321
E. info@dimerix.com

Phase 3 trial

The ACTION3 Phase 3 trial is actively recruiting across clinical sites globally, with 96 patients having now been recruited to its DMX-200 Phase 3 trial in patients with FSGS kidney disease as at 7 February 2023 (versus 48 as at 27 October 2022[8]). Once patients have completed the background medication stabilisation period and subsequent re-screening, they are then randomised to receive either drug or placebo. The trial continues to recruit patients for any screen failure, drop out or do not comply with the clinical trial protocol and to support Part 2 of the trial.[1]

The single Phase 3 trial in FSGS patients has two 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 accelerated marketing approval.[1] Part 1 interim analysis of the trial data will conclude once 72 patients have completed 35 weeks treatment.



The Phase 3 trial, 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 trial of the efficacy and safety of DMX-200 in patients with FSGS who are receiving a stable dose of an angiotensin II receptor blocker (ARB). Once the ARB dose is stable, patients, aged 18 to 80 years (broadening to 12 to 80 years following first successful interim analysis[9]), will be randomized to receive either DMX-200 (120 mg capsule twice daily) or placebo.

Further information about the trial 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:

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

—END—

About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company developing innovative new therapies in areas with unmet medical needs for global markets. Dimerix is currently developing its proprietary product DMX-200, for Focal Segmental Glomerulosclerosis (FSGS), respiratory complications associated with COVID-19 and Diabetic Kidney Disease, and is developing DMX-700 for Chronic Obstructive Pulmonary Disease (COPD). 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. Receptor-HIT is licensed non-exclusively to Excellerate Bioscience, a UK-based pharmacological assay service provider with a worldwide reputation for excellence in the field of molecular and cellular pharmacology.

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 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. DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

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.[10] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[11] At this time, there are no drugs specifically approved for FSGS anywhere in the world, so the treatment options and prognosis are poor.

FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,[10] and worldwide about 220,000.[5] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[3] 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 *ASX 25Aug2021*
2 *AGM investor presentation 29Nov2022*
3 *Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/*
4 *DataBridge Market Research (2022) Global Focal Segmental Glomerulosclerosis Drugs Market – Industry Trends and Forecast to 2030; https://www.databridgemarketresearch.com/reports/global-focal-segmental-glomerulosclerosis-drugs-market*
5 *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;*
6 *IQVIA Report (2018), Orphan Drugs in the United States: Growth Trends in Rare Disease Treatments;*
7 *NHMRC Clinical Trials Data Safety Monitoring Board: https://www.australianclinicaltrials.gov.au/sites/default/files/content/For%20researchers/Data%20Safety%20Monitoring%20Boards_1.pdf*
8 *4C ASX release 27Oct22*
9 *ASX release 12Jan2023*
10 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/*
11 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*