Immediate Release

DIMERIX RECEIVES APPROVAL FOR PAEDIATRIC INVESTIGATION PLAN FROM THE UK MHRA

- The UK Medicines and Healthcare products Regulatory Agency (MHRA) has approved the Company's DMX-200 Paediatric Investigation Plan (PIP) for the UK
- This is a major achievement towards potentially treating children with FSGS kidney disease globally, with the paediatric plan in line with US FDA advice[1] and the European Medicines Agency (EMA) approved PIP[2]
- The UK PIP aims to ensure that sufficient data are generated in the Company's ACTION Phase 3 study to allow for marketing approval for children should it be successful:
  - Paediatric patients (i.e. children) from 12 to 17 years of age are now to be included in current ACTION Phase 3 study in patients with FSGS in the UK
  - Same plan to achieve paediatric label indication now agreed across the FDA, EMA and MHRA
- FSGS is one of the leading causes of kidney failure in children, with 20% of all presentations of Nephrotic Syndrome in paediatric patients caused by FSGS[3]

MELBOURNE, Australia, 1 May 2024: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company with late-stage clinical assets, today announced that the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA) has accepted its Paediatric Investigation Plan (PIP) for the development of DMX-200 for focal segmental glomerulosclerosis (FSGS). The Company's ACTION Phase 3 study will now be opened up to include children from ages 12-17 in the UK.

A successful clinical trial in paediatrics would allow Dimerix to file for an extension to any market authorisation (MAA) in UK, thereby potentially expanding market access in a paediatric population where no treatment for FSGS exists and associated healthcare costs are high. The approved PIP in the UK aligns with the previously approved European EMA PIP[2] and the US FDA's advice[1]. FSGS is one of the leading causes of End Stage Renal Disease (ESRD) in children and is associated with up to 20% of all new cases of Nephrotic Syndrome in children each year.[4]

A PIP in the UK is a mandatory development plan aimed at ensuring that the necessary data are obtained to support the registration and use of new medicines for children in the UK. The PIP addresses the entire paediatric development program for DMX-200 in FSGS and provides a clear framework for the development and registration of DMX-200 for paediatric patients with FSGS in the UK. This positive and final opinion from the MHRA ensures that the Company's clinical studies, including its ACTION Phase 3 clinical study of DMX-200 in FSGS, will be run in accordance with the MHRA's expectations to allow for potential future product approval in children should it be successful.

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

The Company's UK PIP covers all studies needed for registration of DMX-200 in the paediatric population and no safety concerns were raised. The safety package was accepted, and no further non-clinical studies are required. Paediatric patients from 12 to 17 years of age will now be included in the current ACTION Phase 3 study for patients with FSGS in the UK. In addition, in silico modelling, simulation and extrapolation of paediatric data from the ACTION Phase 3 study will also be used to support a confirmatory small open-label study in paediatric patients from 1 to 11 years of age.

> "It is pleasing to see that the MHRA approved PIP aligns extremely well with the European EMA PIP and the US FDA advice. Our single Phase 3 clinical study, having successfully passed its first efficacy interim analysis is now being rapidly expanded to include new adult and paediatric sites, which will now allow recruiting children down to 12 years old as well as adults."
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> *Dr David Fuller; Chief Medical Officer, Dimerix*

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. All patients in the study are also eligible for enrolment in an open-label extension study for a further 2 years of treatment with DMX-200.

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:

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

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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 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.[5] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[6] 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,[5] and worldwide about 220,000.[7] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[8] 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 release 12Jan2023;*

2 *ASX release 05Jul2023*

3 *Nephcure Kidney International FSGS factsheet (2022); online: https://nephcure.wpenginepowered.com/wp-content/uploads/2021/02/nc.factSheet.FSGS_210106.pdf;*

4 *Nephcure FSGS factsheet 2022: https://2eu46v1q93c11mayx1nfvwg6-wpengine.netdna-ssl.com/wp-content/uploads/2021/02/nc.factSheet.FSGS_210106.pdf;*

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*

7 *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;*

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