Immediate Release

DIMERIX RECEIVES APPROVAL FOR PAEDIATRIC INVESTIGATION PLAN FROM THE EMA

- Positive Opinion on Paediatric Investigation Plan (PIP), a major achievement towards a potential treatment for children with FSGS kidney disease
- PIP agreed with European Medicines Agency for paediatric development of DMX-200 in FSGS
- 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[1]
- The PIP plan aims to ensure sufficient data for marketing approval in children is obtained through studies run in accordance with the European Medicines Agency expectations:
  - Paediatric patients from 12 to 17 years of age to be included in current ACTION3 study in patients with FSGS – in line with US FDA advice[2]
  - In silico modelling, simulation and extrapolation of paediatric data from ACTION3 to support a confirmatory small open-label study in children from 1 to 11 years of age
  - Safety package accepted and no further non-clinical studies are required.
- ACTION3 first interim analysis (Part 1), which will assess proteinuria reduction of the first 72 adult patients on DMX-200 versus placebo at week 35, is anticipated in Q1 2024[3]
- Total FSGS market size across the 7 major markets estimated to be >US$3 billion by 2032 driven by approximately 220,000 FSGS sufferers across the 7 major markets[4] and premium orphan drug pricing[5]
- DMX-200 has previously received Orphan Drug Designation with the FDA, EMA and UK, allowing potential fast track of commercialisation if successful [6,7,8]

MELBOURNE, Australia, 05 July 2023: Dimerix Limited (ASX: DXB), a biopharmaceutical company with Phase 3 clinical studies in inflammatory diseases, today announced that the Paediatric Committee (PDCO) of the European Medicines Agency (EMA) accepted its Paediatric Investigation Plan (PIP) for the development of DMX-200 for focal segmental glomerulosclerosis (FSGS) following the PDCO meeting on 23 June 2023.

A PIP is a mandatory development plan aimed at ensuring that the necessary data is obtained to support the registration and use of new medicines for children in the European Union (EU). 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 EU. The positive final opinion from PDCO ensures that the Company's clinical studies, including its Phase 3 clinical study of DMX-200 in FSGS, will be run in accordance with PDCO expectations for future product approval in children.

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

The 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 be included in current ACTION3 study in patients with FSGS, in line with US FDA advice, and in silico modelling, simulation and extrapolation of paediatric data from ACTION3 will be used to support a confirmatory small open-label study in paediatric patients from 1 to 11 years of age.

A successful clinical trial in paediatrics will allow Dimerix to file for an additional market authorisation(MAA) in Europe, thereby potentially expanding market access in a paediatric population where no treatment for FSGS exists and associated healthcare costs are high.

> "This approval from the PDCO of the EMA will allow Dimerix to develop DMX-200 for paediatric patients, including adolescents in the current ACTION3 study. DMX-200 represents a potentially safe and effective new treatment option in these patients where there is a substantial unmet clinical need. We look forward to including adolescent patients in our existing ACTION3 study and to working with parents and children aged 1-11 years old following a positive outcome to ACTION3."
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> *Dr Nina Webster, CEO & Managing Director, Dimerix*

Focal Segmental Glomerulosclerosis 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.[9] The single Phase 3 study 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 study, aimed at generating sufficient evidence to support accelerated marketing approval. Part 1 of the study will conclude after the first interim analysis, once 72 patients have completed 35 weeks treatment. The study will continue seamlessly into Part 2 of the study, which has the potential to include adolescents with FSGS.

> "Paediatric nephrologists are desperate for new treatments for their patients, with no drugs registered for paediatric FSGS patients anywhere in the world and very new drugs under investigation for children. We are actively engaged with networks of paediatric nephrologists and patient advocacy groups to generate high-quality data to support the registration of DMX-200 in this typically underserved population".
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> *Dr Ash Soman, Chief Medical Officer, Dimerix*

FSGS Phase 3 Study - ACTION3

ACTION3
FSGS CLINICAL 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 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 will be randomized to receive either DMX-200 (120 mg capsule twice daily) or placebo.

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 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), 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.

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.[4] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[Error! Bookmark not defined.] 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 *Nephcure Kidney International FSGS factsheet (2022); online: https://nephcure.wpenginepowered.com/wp-content/uploads/2021/02/nc.factSheet.FSGS_210106.pdf*

2 ASX release 12Jan2023

3 *ASX release 04May2023*

4 *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;*

5 *IQVIA Report (2018), Orphan Drugs in the United States: Growth Trends in Rare Disease Treatments;*

6 *ASX:14Dec2015;*

7 *ASX: 21Nov2018*

8 *ASX: 07Jun2021*

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

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*