Immediate Release

FDA CONFIRMS INCLUSION OF PAEDIATRIC PATIENTS IN ACTION3 STUDY OF DMX-200 FOR FSGS

- FDA confirms inclusion of adolescent children (12-17 years old) in ACTION3 global Phase 3 FSGS study is appropriate, increasing the total addressable market for DMX-200 if approved
- FSGS is one of the leading causes of kidney failure in children, with 20% of all child nephrotic syndrome cases caused by FSGS[1]
- Dimerix is also in discussion with the European Medicines Agency (EMA) regarding a Paediatric Investigation Plan (PIP), which is a regulatory requirement prior to seeking market approval in Europe, the outcome of which is expected in calendar year 2023
- 90 adult patients currently recruited in ACTION3 phase 3 pivotal clinical trial of DMX-200 in the treatment of focal segmental glomerulosclerosis ('FSGS') kidney disease
- 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]
- All activated sites will continue to recruit suitable patients for Part 2 of the ACTION3 trial[2]
- Total global FSGS market was valued at US$12.6 billion in 2022[3] with a CAGR of 8.2%, 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, 12 January 2023: Dimerix Limited (ASX: DXB) a biopharmaceutical company with late-stage clinical assets in inflammatory diseases, today confirmed the outcomes of a meeting with the US Food and Drug Administration (FDA) to discuss the paediatric plan for DMX-200 in Focal Segmental Glomerulosclerosis (FSGS) patients under 18 years old.

The FDA has consistently recommended the evaluation of DMX200 in paediatric patients, and at the meeting, the FDA confirmed that the inclusion of paediatric patients aged 12 years or older (adolescent) was appropriate in the current global ACTION3 Phase 3 study of DMX-200 for patients with FSGS, which recognises the appropriate safety profile exhibited by DMX-200. No change in dose or regime is required for this population. Importantly, the meeting also provided clarity on the remaining development of DMX-200 required for paediatric patients younger than 12 years old with FSGS through to market approval, broadening the label indication and pool of patients for treatment if approved.

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"The FDA have consistently encouraged Dimerix to develop DMX-200 for children given the very poor prognosis in this disease and lack of targeted therapies. This formal meeting with the FDA gave us a valuable opportunity to discuss our paediatric plans for DMX-200 in the US.
We are very pleased to be able to open the study to adolescent patients later in the year, which may provide a viable treatment option for these younger patients, if approved. The inclusion of patients aged 12 and above will also increase the total pool of patients that could be recruited into Part 2 of the ACTION 3 study – potentially accelerating the rate of recruitment for the study.
This initial discussion regarding adolescent enrolment in the ACTION3 study builds on the numerous constructive discussions we have had with key regulatory agencies worldwide. Following this meeting, we will continue discussions with the FDA to support development of new therapies in this population of adolescent patients who have very few therapeutic options currently available or in development".

Dr Nina Webster, CEO & Managing Director, Dimerix Limited

FSGS is a rare disease that attacks the kidney's filtering units causing irreversible scarring. This leads to permanent kidney damage and eventual end-stage kidney failure, requiring dialysis or transplantation. FSGS affects both adults and children as young as two years old,[9] and for those who are fortunate enough to receive a kidney transplant, 60% of patients have reoccurring FSGS after first kidney transplant.[10] Furthermore, FSGS is one of the leading causes of kidney failure in children, with 20% of child nephrotic syndrome cases caused by FSGS.[1] At this time, there are no drugs specifically approved for FSGS anywhere in the world, leading to limited treatment options and poor prognosis.

About ACTION3 Phase 3 clinical study

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), 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:

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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 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. 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.

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.[9] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[1] 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,[3] 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.[1] 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 15Dec2022*

3 *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*

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

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