For Immediate Release

SIGNIFICANT MILESTONE ACHIEVED WITH FIRST PATIENT RECRUITED INTO DMX-200 PHASE 3 ACTION3 FSGS KIDNEY CLINICAL TRIAL

- A significant milestone has been achieved with the first patient recruited in ACTION3 phase 3 pivotal clinical trial of DMX-200 in the treatment of focal segmental glomerulosclerosis ('FSGS') kidney disease
- FSGS is a rare disease with no existing registered treatment options specifically for sufferers
- FSGS is a significant market opportunity - end stage renal failure represented an estimated cost of US$55 billion per annum to the US healthcare system in 2021[1]
- The trial is being performed at 75 sites across 12 different countries[2]
- All activated sites are currently proactively screening for suitable patients
- The first interim analysis is anticipated in the first half of 2023[3]
- The trial has 2 interim data analysis points, the second of which may enable accelerated marketing approval[4]
- The primary endpoint is the reduction in protein in the urine and its relationship to kidney function (eGFR slope) compared to placebo[5]
- Granted patent protection for DMX-200 to at least 2032, with potential to extend to 2042[6]
- Orphan drug designation received, allowing potential fast track of commercialisation if successful[8,9,10]

MELBOURNE, Australia, 31 May 2022: Dimerix Limited (ASX: DXB), a biopharmaceutical company with Phase 3 clinical studies in inflammatory diseases, is pleased to announce the recruitment of the first patient to its DMX-200 phase 3 trial in patients with FSGS kidney disease. The ACTION3 Phase 3 trial will recruit across 75 sites in 12 different countries globally, with ethics and regulatory submissions having been made in all 12 countries and all activated sites proactively screening for suitable patients.[7]

"This is a significant step forward for Dimerix with recruitment of the first patient into our key Phase 3 ACTION3 FSGS kidney clinical trial. We also expect first dosing in the trial to commence imminently. The potential commercial opportunity for Dimerix in this space is very material, given over US$55 billion is estimated to having been spent on end stage renal failure in the US Healthcare system alone in 2021 and the US Government has issued incentives for physicians to delay patient progression to renal failure as a priority.[1] If successful, our drug candidate could make a huge difference globally to patients with this illness and given we have orphan drug designation status, a potential fast track to commercialisation is available - highlighting the compelling nature of this trial for the Company."

Dr Nina Webster, CEO & Managing Director, Dimerix Limited

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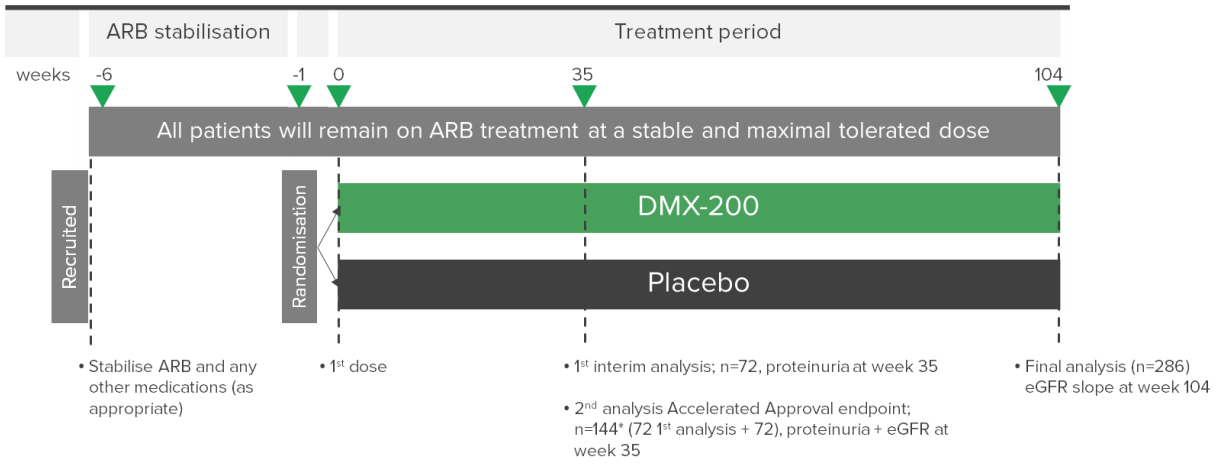
The single Phase 3 trial in FSGS patients has two interim analysis points built in that are designed to capture evidence of proteinuria and kidney function (eGFR slope) during the trial, aimed at generating sufficient evidence to support accelerated marketing approval.[4] Part 1 of the trial will conclude after the first interim analysis, once 72 patients have completed 35 weeks treatment, and is expected to occur in the first half of 2023 (subject to recruitment).



The trial will continue seamlessly into Part 2 of the trial. Patients recruited into the trial will need to demonstrate a minimum of 6 weeks stable dosing of an angiotensin receptor blocker prior to randomisation and dosing with DMX-200 or placebo.[2]

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, 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).

Orphan Drug Designation

Dimerix has received Orphan Drug Designation for DMX-200 in both the US[8] and Europe[9], and the equivalent Innovative Licensing and Access Pathway (ILAP) designation in the UK[10], for the treatment of FSGS. These designations provide regulatory and financial benefits to help bring new drugs to market faster, including reduced fees during the product development phase, protocol assistance from the regulatory authorities, and 7-year (US) and 10-year (Europe) market exclusivity following product approval.

Two additional new patent applications for DMX-200, titled 'Treatment of Inflammatory Diseases' (PCT/AU2022/050249)[6] and 'Compositions Comprising a Chemokine Receptor Pathway Inhibitor' (PCT/AU2022/050013)[6], were filed globally (with a priority date of 25 March 2021 and 14 January

2022). If granted, the patent application, PCT number, will extend and broaden the protection for DMX-200 until at least March 2041 and January 2042 respectively (DMX-200 granted patents currently provide protection until at least 2032).

Dimerix has multiple assets in commercially attractive and growing markets that have a high unmet need, no current marketed competition, and with a potential fast pathway to market. Dimerix continues to drive the FSGS Phase 3 program, further progress the diabetic kidney disease and COPD programs, as well as support the investigator-led COVID-19 programs.

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), 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.[11] For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney.[12] 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,[13] and worldwide about 210,000. The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year[13]. 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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