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Immediate Release

NATIONAL REGISTRY OF RARE KIDNEY DISEASES TO ENHANCE ACTION3 PHASE 3 TRIAL AND MULTIREGION TRIAL SITE UPDATE

- Dimerix collaborates with UKs National Registry of Rare Kidney Diseases (RaDaR) to enhance patient recruitment in the ACTION3 Phase 3 clinical trial, targeting 286 patients in total globally
- RaDaR to provide a further new source of patient referrals for potential participation in the ACTION3 clinical trial across the UK
- IND approved by Thai FDA, with recruitment expected to initiate across Thailand in the coming weeks
- Recruitment remains on-track with blinded interim analysis for the first 144 patients currently expected around mid-CY2025

MELBOURNE, Australia, 16 September 2024: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical asset in kidney disease, today advised that it has entered into a collaboration with the UK's National Registry of Rare Kidney Diseases (RaDaR) to prospectively identify suitable FSGS patients for the ACTION3 Phase 3 clinical trial. RaDaR is a UK Kidney Association initiative, led by Professor Danny Gale from University College London, and is designed to collate information across patients diagnosed with certain rare kidney diseases, including FSGS.[1]

RaDaR is the largest, rare kidney disease registry in the world and holds records of over 34,500 rare kidney disease patients recruited from 109 hospitals across the UK. RaDaR is run by the UK Kidney Association and was established with funding from the Medical Research Council, Kidney Research UK, Kidney Care UK, and the Polycystic Kidney Disease Charity.[1]

Under terms of the collaboration, RaDaR will identify UK patients with FSGS who meet the ACTION3 Phase 3 clinical trial inclusion criteria. RaDaR staff will then contact these patients and provide those that express interest in participation with contact details for their closest ACTION3 clinical trial site. Dimerix believes this collaboration will further enhance the recruitment rates in the UK for its ACTION3 Phase 3 clinical trial.

> "We are very pleased to be working with RaDaR on this collaboration, as it represents a unique way to connect with FSGS patients across the United Kingdom for potential trial participation. The UK has an excellent renal research infrastructure and RaDaR has a strong track record of assisting companies who are working towards bringing new treatments for rare renal diseases, such as FSGS, recruit patients."
>
> *Dr David Fuller, Chief Medical Officer, Dimerix*

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"Data from the RaDaR registry show that people with rare kidney diseases such as FSGS have a substantially higher risk of needing treatment for kidney failure than do other people in the population with chronic kidney disease.[2] Many patients who participate in RaDaR are aware of this and are interested in finding more about participating in research trials that might help to address this important area of unmet medical needed. We are therefore very happy to be able to work with Dimerix to contact RaDaR participants who might be eligible for their Phase 3 study in FSGS to help them to find out about this study and decide whether to participate in it."

Prof Daniel Gale, Professor of Nephrology UCL Department of Renal Medicine; Chair UK Rare Diseases Committee UK Kidney Association

The ACTION3 clinical trial is currently recruiting across 16 of the 19 planned countries. The full study recruitment target is 286 patients. Regulatory agencies in different parts of the world often have different regulatory and ethics requirements for opening clinical sites, hence the opening of clinical sites is often staggered from country to country. Pleasingly, Dimerix also received approval for its Investigational New Drug Application (IND), which is a prerequisite for trial initiation, from the Thai Food and Drug Administration (FDA) this week and expects clinical sites to initiate recruitment in Thailand in the coming weeks.

About ACTION3 FSGS Phase 3 Study

The Phase 3 study, which is titled "Angiotensin II Type 1 Receptor (AT1R) & Chemokine Receptor 2 (CCR2) Targets for Inflammatory Nephrosis", 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.

The single Phase 3 trial in FSGS patients will follow 286 patients across 2 years, with a further blinded interim analysis built in which is planned after the first 144 patients reach 35 weeks of treatment, designed to capture evidence of proteinuria and kidney function (eGFR slope) during the trial, aimed at generating sufficient evidence to support marketing approval.

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).

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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 kidney 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 respiratory disease. 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 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.[3] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[4] 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 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.[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.[6] 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.

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References

1 *See RaDaR website: https://ukkidney.org/rare-renal/homepage*
2 *Wong K et al (2024) Effects of rare kidney diseases on kidney failure: a longitudinal analysis of the UK National Registry of Rare Kidney Diseases (RaDaR) cohort, The Lancet, Volume 403, Issue 10433, 1279 - 1289*
3 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/*
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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 *Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/*

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