Dimerix

Immediate Release

NEPHROTIC SYNDROME STUDY NETWORK TO ENHANCE ACTION3 PHASE 3 TRIAL RECRUITMENT IN UNITED STATES

- Dimerix collaborates with the University of Michigan's NEPTUNE MATCH study to support participant recruitment and biomarker profiling
- NEPTUNE MATCH network provides a new source of patient referrals for potential participation in the ACTION3 clinical trial across the USA
- Biomarker profiling among the NEPTUNE MATCH participants to help identify those FSGS patients who meet the inclusion/exclusion criteria and may benefit from a treatment with a mechanism of action such as DMX-200
- The ACTION3 Phase 3 clinical trial aims to recruit approximately 286 patients globally with focal segmental glomerulosclerosis (FSGS), a rare disease categorized within nephrotic syndrome
- Interim analysis is currently planned after the first 144 patients reach 35-week treatment, expected around mid-2025

MELBOURNE, Australia, 01 November 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 University of Michigan's Nephrotic Syndrome Study Network of Rare Kidney Diseases (NEPTUNE) to assist with biomarker profiling and prospectively identifying patients with FSGS most likely to benefit, for the ACTION3 trial via their proprietary NEPTUNE MATCH network.

Based at the University of Michigan in the United States, under the leadership of Dr Matthias Kretzler, NEPTUNE is a leading network for precision medicine in glomerular diseases. NEPTUNE has enrolled more than 1100 participants, from 32 participating sites over the last 16 years. The overarching goal of NEPTUNE is to collate comprehensive, long-term clinical and molecular data into a resource for better understanding nephrotic syndrome complexities, including FSGS. The NEPTUNE Match precision medicine platform aims to connect patients to the best matching clinical trials based on their disease biomarker profile. With Dimerix joining the NEPTUNE Match precision trial network, NEPTUNE will help identify patients with FSGS across the United States who meet the inclusion/exclusion criteria, may benefit from a treatment with a mechanism of action such as DMX-200 and refer those patients to the closest ACTION3 clinical trial site, should they wish to participate. Dimerix will also now have the opportunity to collaborate with NEPTUNE to jointly address key research questions using the comprehensive NEPTUNE knowledge network of patients with FSGS.

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

"We are delighted to collaborate with Dimerix and support the ACTION3 study by identifying potential participants who are likely to benefit through our biomarker profiling. This is aligned with NEPTUNE's aim of matching patients to therapies that can effectively treat specific disease mechanisms affecting them. Treatments for rare kidney diseases, in general, remain a high unmet need, and we look forward to the outcome of the ACTION3 study for patients with FSGS"

Dr Matthias Kretzler, Co-Chair Project PARASOL, Warner-Lambert/Parke-Davis Professor, Internal Medicine-Nephrology University of Michigan

"This is an extremely important collaboration for the ACTION3 trial as NEPTUNE is the recognised global leader in rare kidney disease research. The Neptune Match program has a track record of successfully assisting recruitment into trials and should boost our recruitment rate for the ACTION3 trial in the USA while the biomarker work will provide further invaluable insights into the mechanism of action and response to DMX-200 in patients with FSGS."

Dr David Fuller, Chief Medical Officer, Dimerix

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

—END—

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.

The single Phase 3 trial in FSGS patients has 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 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).

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.[1] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[2] 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,[1] and worldwide about 220,000.[3] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[4] 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 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/*

2 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*

3 *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;*

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