Immediate Release

FIRST SPECIALIST PAEDIATRIC CLINICAL SITE ACTIVATED, RECRUITMENT UPDATE & KEY APPOINTMENT

- First paediatric site for ACTION3 Phase 3 clinical trial opens for recruitment in Mexico
- An additional 14 specialist paediatric clinical sites to open across Argentina, United Kingdom and United States to support recruitment of paediatric patients
- Patients aged 12-17 years will be recruited as part of ACTION3 Phase 3 clinical trial
- Expert paediatric nephrologist, Dr Howard Trachtman, appointed to Medical Advisory Board
- Recruitment remains on-track with interim analysis still currently expected around mid-CY2025, noting recruitment rates are not linear
- Cash position to fund the ongoing ACTION3 Phase 3 clinical study, which consists of both the randomised adult and the paediatric cohort, remains strong

MELBOURNE, Australia, 12 September 2024: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical asset in kidney disease, is pleased to advise that the first clinical site specialising in paediatric kidney disease was activated today in Mexico. This now allows for the active recruitment of adolescent patients into the ACTION3 Phase 3 clinical trial.

This follows the Independent Data Monitoring Committee (IDMC), and subsequently the FDA and EMA (as part of the Company's Paediatric Investigation Plan (PIP)), confirming that the dose of DMX-200 to be used in adolescent patients aged 12-17 years participating in the trial will be the same dose as provided to adults in the trial (120 mg twice daily)[1]. This determination was based on reviewing the aggregate interim safety and pharmacokinetic data, including simulations in adolescents, from the adult cohort of the ACTION3 Phase 3 trial taken at the first interim analysis point in March 2024 where the IDMC noted "the safety margin [of DMX-200] should allow [the ACTION3 Phase 3] clinical study to proceed in this adolescent population using adult doses".[2]

Of the approximately 170 planned ACTION3 clinical sites, approximately 15 are specialist paediatric kidney centres across the UK, USA, Mexico, Brazil and Argentina that have been selected to recruit a target population of approximately 22 paediatric/adolescent patients with FSGS into the ACTION3 study. Patients in this "adolescent or paediatric cohort" of the ACTION3 Phase 3 clinical trial will also be blinded, randomised (i.e. unknowingly placed on either placebo or DMX-200) and will be followed for a period of two years. Should the paediatric cohort be successful, and DMX-200 be approved in adults, it may allow Dimerix to expand its approval for DMX-200 and market DMX-200 to adolescents in key territories, including the US and Europe. 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.[3]

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

Recruitment remains on-track with 116 patients out of the Part 2 target population of 144 having been randomised into the study, and the timing of the interim analysis expected around mid-2025 remains unchanged. It is important to note recruitment of patients into clinical trials is not linear and, as previously advised, the recruitment rate is expected to grow with the initiation of approximately 100 new trial sites, bringing the total number of clinical sites to approximately 170 globally.

The Company's cash position to fund the ongoing ACTION3 Phase 3 clinical study, which consists of both the randomised adult and the paediatric cohort, remains strong and includes the Company's cash reserves of $22 million at the end of June quarter[4], the anticipated 2024 R&D tax incentive cash rebate of almost $8 million[5] and the anticipated exercise of the $0.154 options (with an expiry of June 2025) that could bring in up to a further $7.6 million. Furthermore, the Company's cash position does not include any potential milestone payments that become due under the Company's existing licensing arrangements or potential up-front payments that may be received as part of future licensing deals. The Company continues to focus on licensing in other available territories including the US, which could represent up to 50% of the global FSGS opportunity alone, and China.

To support the ACTION3 study moving into paediatric patients, Dimerix has appointed Dr Howard Trachtman to the Medical Advisory Board. Dr Trachtman is a graduate of the University of Pennsylvania Medical School and completed a fellowship in paediatric nephrology at Albert Einstein College of Medicine. Dr Trachtman has had an outstanding career to date, including being Chief of the Division of Paediatric Nephrology at the Cohen Children's Medical Center and at NYU Langone Health, and has been the Principal Investigator of multiple NIH and industry-sponsored clinical trials specifically in FSGS patients. Dr Trachtman's clinical research consists of co-authoring over 195 peer reviewed articles in the kidney disease space in the past 15 years. Further, Dr Trachtman is a board member for the Kidney Health Initiative and on the editorial board of multiple journals including Kidney360, Glomerular Diseases, and Paediatric Nephrology.

"The initiation of the first paediatric site in Mexico marks a new milestone for the ACTION3 study and is an important step towards providing a potential new treatment for children with FSGS. We are delighted that we can now draw on the expertise and professional networks of Dr Trachtman as we continue to focus on the recruitment goals of this pivotal study."

Dr David Fuller, Chief Medical Officer, Dimerix

"I am delighted to be extending my relationship with Dimerix for their FSGS program. FSGS remains an area of huge unmet need with similarly poor outcomes in both children and adults. There are still no approved therapies to delay or prevent progression to kidney failure. While DMX-200 remains experimental in this area, it appears very well suited to use in patients of all ages particularly as it is taken orally and is well tolerated. Based on data to date, it is a drug candidate that is certainly worth testing in all patients with FSGS".

Dr Howard Trachtman, NYU School of Medicine, Paediatric Department;
Adjunct Professor of Paediatric Nephrology, University of Michigan

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 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.[6] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[7] 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,[6] and worldwide about 220,000.[8] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[9] 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 *ASX release 04 July 2024*
2 *See ASX Announcement 4 July 2024*
3 *Nephcure Kidney International FSGS factsheet (2022); online: https://nephcure.wpenginepowered.com/wp-content/uploads/2021/02/nc.factSheet.FSGS_210106.pdf;*
4 *Dimerix 4C quarterly update released to market 23 June 2024*
5 *Dimerix Annual Report 2024: see Dimerix website*
6 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/*
7 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*
8 *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;*
9 *Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/*