Dimerix

**For Immediate Release**

# NEW DMX-200 CLINICAL TRIAL IN DIABETIC KIDNEY DISEASE PATIENTS

- Dimerix has entered into an agreement with Australian Centre for Accelerating Diabetes Innovations (ACADI) to conduct clinical trial of DMX-200 in diabetic kidney disease patients
- ACADI was established through MRFF funding from the Australian Government's Targeted Translation Research Accelerator program, delivered by MTPConnect[1,2]
- Diabetic kidney disease is one of three ACADI priority areas[2]
- The global diabetic kidney disease market size was valued at US$2.49 billion in 2021 and is estimated to rise to US$3.34 billion by 2028[5]
- Encouraging data seen in Dimerix Phase 2 study (2020) suggests greater albuminuria reductions may be observed over a longer study treatment duration[3]
- Clinical trial protocol being finalised – expected to be 12-24 months study of proteinuria and eGFR (kidney function), with an interim analysis, and is expected to commence Q4 2022
- ACADI is led by Associate Professor Elif Ekinci, an investigator on the DMX-200 Phase 2 study completed in 2020
- Dimerix will be the sponsor organisation and will have oversight in this trial

MELBOURNE, Australia, 7 June 2022: Dimerix Limited (ASX: DXB), a biopharmaceutical company with Phase 3 clinical studies in inflammatory diseases currently underway, today announced that it has entered into an agreement with The Australian Centre for Accelerating Diabetes Innovations (ACADI) to progress DMX-200 into a new clinical trial in patients with diabetic kidney disease. This new trial provides another potential market opportunity for Dimerix in addition to its other Phase 3 trials underway.

ACADI was established in January 2022 through MRFF funding from the Australian Government's Targeted Translation Research Accelerator program, delivered by MTPConnect.[1,2] ACADI will accelerate innovations to improve the lives of people with or at risk of diabetic kidney disease. The Centre was awarded $10 million over four years from the Australian Government's Medical Research Future Fund (MRFF), in addition to $13.3 million in cash and in-kind contributions from 70 partners across the country. Improving outcomes in diabetic kidney disease is one of three ACADI priority areas.[2] ACADI is led by Associate Professor Elif Ekinci from the University of Melbourne, an investigator on the Dimerix DMX-200 Phase 2 study completed in 2020.

"Diabetes is the key cause of kidney disease leading to dialysis and need for transplantation. Unfortunately, diabetic kidney disease is one of the most difficult complications of diabetes to treat and comes at a massive cost to the person living with diabetes and to our health care systems.
We are delighted to be partnering with Dimerix to find new and potentially more effective treatments for people living with diabetic kidney disease. ACADI is pleased to see innovative therapies being researched and developed in an area of unmet need."

*Associate Professor Elif Ekinci, ACADI Centre Director*
*Endocrinologist, Sir Edward Weary Dunlop Principal Research Fellow in Metabolic Medicine and Dame Kate Campbell Fellow at the University of Melbourne*



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The clinical trial protocol is currently being finalised and is expected to be 12-24 months study of proteinuria and eGFR (kidney function) in patients with diabetic kidney disease, with an interim analysis. The study plans to recruit across Australia and is expected to commence Q4 2022.

"The results of our Phase 2 study in diabetic kidney disease were reported in the 2021 financial year, with 30% of all participants falling below the threshold for diabetic kidney disease diagnosis by the end of the study – a fantastic outcome for those patients. It also appeared that protein levels in the urine appeared to be continuing to trend downwards at the end of both DMX-200 treatment periods, which indicated that a longer study treatment duration was warranted.
With our Phase 3 ACTION3 FSGS study now well underway globally, we are delighted to be partnering with Associate Professor Ekinci and her team at ACADI to progress this opportunity in diabetic kidney disease".

*Dr Nina Webster, Dimerix CEO & Managing Director*

**About Diabetic Kidney Disease**

There were 23 million diagnosed diabetics in the US in 2017,[4] and the incidence of diabetes is estimated to grow by 54% by the year 2040, due to an aging population, obesity and increasing diabetes prevalence in younger age groups.[6] The prevalence of obesity has nearly tripled between 1975 and 2020. In 2020, 39% of the global population was overweight, with approximately 30% of these clinically obese. If the number of obese cases continue at this pace, by 2030, half of the global adult population would be overweight or obese.[5] The global diabetic nephropathy market size was valued at US$2.49 billion in 2021 and is estimated to rise to US$3.34 billion by 2028.[5] A third of people with diabetes develop diabetic kidney disease, the leading cause of end-stage kidney disease (ESKD) requiring dialysis or kidney transplant and a major risk factor for cardiovascular disease and premature death.[6]

There is no cure for diabetic kidney disease and current treatment options are ineffective, as the kidneys deteriorate towards failure.[6] The current treatment options include medications to reduce high blood pressure or glucose content in the blood, dialysis or kidney transplant. The progressive nature of kidney disease inevitably results in poor outlook for patients, as it most often results in total kidney failure and a poor quality of life.

In addition, Dimerix continues to drive the Phase 3 ACTION3 pivotal study of DMX-200 in FSGS; support both feasibility/Phase 3 studies driven by the REMAP-CAP and CLARITY 2.0 teams for DMX-200 in COVID-19 patients; and advance the DMX-700 COPD program towards clinical stage development.

For further information, please visit our website at www.dimerix.com or contact:


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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.[7] For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney.[8] 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,[9] 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[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] MTP Connect Announcement 14Jan2021: https://www.mtpconnect.org.au/programs/TTRA/ResearchCentres/ACADI

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[3] ASX release 27Sep2021

[4] US National Diabetes Statistics Report, 2017. [ONLINE] Available at https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf

[5] Global Diabetic Nephropathy Market and Competitive Landscape Report (2021); cited at https://www.fortunebusinessinsights.com/diabetic-nephropathy-market-102012

[6] ACADI Priority One: Diabetic Kidney Disease; https://medicine.unimelb.edu.au/research/acadi/our-projects/priority-1

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[8] DelveInsight Market Research Report (2020); Focal Segmental Glomerulosclerosis (FSGS)- Market Insight, Epidemiology and Market Forecast -2030

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