



Immediate Release

DIMERIX APPOINTS NEW DMX-200 MEDICAL ADVISORY BOARD AHEAD OF CLINICAL STUDY READ-OUT

Highlights

- Medical Advisory Board comprised of leading global nephrology experts, with extensive experience with FDA and other global regulatory bodies;
- Professor Hiddo Heerspink (EU), a specialist in the research of novel treatment approaches to slow the onset of renal disease including biomarker development, FDA engagement and the use of drugs such as SGLT2 inhibitors, will lead the advisory board in the position of Chair;
- Additional members of the Medical Advisory Board are all eminent experts in renal disease treatment and development of therapeutics, and include Professor Alessia Fornoni (US), Professor Jonathan Barratt (UK), Assoc. Professor Lesley Inker (US) and Dr Muh Geot Wong (AU);
- Medical Advisory Board members will advise on data analysis and interpretation of the two Phase 2 studies currently underway, as well as assist in the design of the pivotal clinical study;
- FSGS Phase 2a study last patient dosing is scheduled in June 2020, and top line data anticipated shortly thereafter;
- Diabetic Kidney Disease Phase 2 study last patient dosing is scheduled in July 2020, and top line data anticipated shortly thereafter.

MELBOURNE, Australia, 06 March 2020: Dimerix Limited (ASX: DXB), a clinical-stage drug development company, today announced an update to their Medical Advisory Board (MAB) for the DMX-200 renal program ahead of both Phase 2 clinical studies due to complete mid-2020. The eminent and globally recognised MAB will assist with the analysis and interpretation of data from the two Phase 2 clinical studies expected mid-2020, as well as assist with the design of future studies, including the pivotal Phase 3 study for Focal Segmental Glomerulosclerosis (FSGS) for which Dimerix received guidance from the FDA during a face-to-face meeting in November 2019.

External Medical Advisory Board Members:

- Professor Hiddo Heerspink, PhD (Chair)
- Professor Alessia Fornoni, MD, PhD, FASN
- Professor Jonathan Barratt, MD, PhD, FRCP
- Associate Professor Lesley Inker, MD, MS, FRCP
- Dr Muh Geot Wong, MBBS, PhD, FRCP

Further background on each of the Advisory Board members can be found in the appendix following this release.

Dimerix is a biopharmaceutical company developing innovative new therapies in areas with unmet medical needs.

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“We are honoured to have attracted such respected and experienced nephrologists to join this global Medical Advisory Board for our DMX-200 renal program, particularly as we approach the outcomes of our current clinical trials,” Nina Webster, CEO and Managing Director commented. “The MAB will help drive forward the clinical potential of our DMX-200 product candidate and provide clear disease-specific guidance on the analysis and planning of our lead clinical program. The MAB members' insights and guidance will prove invaluable as we design and advance our future program.”

Dimerix has two Phase 2 studies currently underway: DMX-200 for FSGS; and DMX-200 for Diabetic Kidney Disease, and an asset in pre-clinical development: DMX-700 for COPD. The two Phase 2 clinical studies are both double-blind, randomised, placebo-controlled, crossover studies, evaluating the safety and efficacy of DMX-200 in patients who are receiving a stable dose of Irbesartan, the current standard of care for both FSGS and Diabetic Kidney Disease. The Phase 2 trial outcomes in FSGS and in Diabetic Kidney Disease are both anticipated mid-2020, both of which represent a major clinical milestone for Dimerix. Furthermore, patients from the current phase 2 studies, as well as the 2017 Phase 2a study, are continuing treatment with DMX-200 via the Therapeutic Goods Association's (TGA) compassionate use Special Access Scheme (SAS) following completion of the study protocol and recommendation by their respective physicians.

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

—END—

Appendix – Medical Advisory Board members

Professor Hiddo Heerspink, PhD

Hiddo Lambers Heerspink is the Professor of Clinical Trials and Personalized Medicine at the University Medical Center Groningen, the Netherlands, specializing in the research of novel treatment approaches to slow the onset of diabetic cardiovascular and renal disease. He received his PhD from the medical faculty of the University Medical Center Groningen. He then worked as a post-doctoral fellow at The George Institute in Sydney, Australia.

Professor Heerspink has published over 300 papers on the design and interpretation of renal trials, and has been lead or senior author in many of the recent seminal papers in nephrology including analysis of the trials leading to approval of a new class of compounds, the sodium reuptake inhibitors, for patients with diabetic kidney disease. Professor Heerspink has been involved with the operations and design of many clinical trials that have resolved some of the largest questions in the field of nephrology, and has been instrumental in interactions between industry, researchers and regulatory agencies in the validation of surrogate endpoints for renal trials.

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Professor Alessia Fornoni, MD, PhD, FASN

Professor Fornoni is Professor of Medicine and Molecular and Cellular Pharmacology at the University of Miami Miller School of Medicine. She is the Chief of the Katz Family Division of Nephrology and Hypertension and serves as and Director and Chair of the Peggy and Harold Katz Drug Discovery Center. Professor Fornoni received an MD. and a PhD in medical pharmacology from the University of Pavia, Italy.

Through her pioneering work on insulin signaling, cholesterol metabolism and sphingolipid-related pathways, Professor Fornoni has uncovered novel pathogenetic mechanisms and therapeutic approaches for glomerular disorders and she has gained experience in drug development as Global Head of Discovery in Cardiovascular and Metabolism at Hoffman-La Roche in Basel. Based on her inventions, she funded several startup companies focused on finding a cure for patients affected by chronic kidney diseases.

Professor Fornoni brings an extensive history of translational excellence for patients with renal disease, and has previously served as a member of the DMX-200 medical advisory board.

Professor Jonathan Barratt, MD, PhD, FRCP

Professor Barratt is the Mayer Professor of Renal Medicine in the Department of Cardiovascular Sciences at the University of Leicester and Honorary Consultant Nephrologist at the University Hospitals of Leicester NHS Trust, UK. Professor Barratt qualified as an MD from the University of Manchester and obtained his PhD in Molecular Immunology at the University of Leicester. He leads the Renal Research Group within the College of Life Sciences, University of Leicester and supervises a laboratory and clinical research team focussed on a bench to bedside approach to improving our understanding of the pathogenesis of IgA nephropathy a common global cause of kidney failure. Professor Barratt has run and been involved in a wide range of clinical trials in a range of renal diseases and is the IgA nephropathy Rare Disease Group lead for the UK National Registry of Rare Kidney Diseases (RaDaR) and a member of the steering committee for the International IgA Nephropathy Network.

Professor Barratt brings a detailed mechanistic and translational research skillset to the DMX-200 advisory board, including understanding the standards of clinical care in the UK, as well as extensive experience in supporting interactions between sponsors and the FDA and EMA.

Associate Professor Lesley Inker, MD, MS, FRCPC

Associate Professor Inker is an attending physician and the director of the Kidney and Blood Pressure Center in the Division of Nephrology at Tufts Medical Center, and an associate professor at Tufts University School of Medicine, USA. She received her MD and completed residency at McMaster School of Medicine, Hamilton, Ontario, CA. Associate Professor Inker's clinical interests are general nephrology, detection and treatment of CKD, assessment of kidney function, and her research interests are in epidemiology and outcomes related to CKD. Her major research interest is in the estimation and measurement of glomerular filtration rate (GFR) and in defining alternative endpoints for CKD progression trials based on GFR decline and changes in albuminuria. She is the co-principal investigator of the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) , served as one of the analytical team directors for the recent joint workshop with NKF, the FDA and EMA on End Points for Clinical Trials in Early Chronic Kidney Disease and, is an investigator in the NIDDK CKD-Biomarker Consortium, a collaborative effort to discover and validate new markers for CKD.

Associate Professor Inker brings a strong background in the rigorous evidentiary requirements for GFR estimates and their use in trials, and biomarkers, and an extensive background in the clinical care of patients with kidney disease in North America.

Dr Muh Geot Wong, MBBS, PhD, FRCP

Dr Wong is a Renal Physician and Head of the Renal Clinical trials at the Royal North Shore hospital, Sydney, Australia. He is also a senior research fellow at the Kolling Institute and the George Institute of Global Health and a senior clinical lecturer at UNSW Sydney. Dr Wong received his MD from Manipal University, India, and his PhD from the University of Sydney, Australia. His main area of research is in understanding the pathomechanisms of kidney tubulointerstitial fibrosis, strategies in delaying CKD progression, and biomarkers in predicting progressive kidney disease, especially in diabetic kidney disease. He is also passionate in translation medicine and is involved in the

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analyses of the IDEAL trial and currently involved in multicentre international trials at the George Institute including TESTING and SONAR trial.

Dr Wong has an outstanding record in the translation of new medicines into therapeutics for patients with renal disease with extensive experience in the APAC region, and has been an investigator involved with the current DMX-200 clinical trials for patients with FSGS and DKD.

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 both Diabetic Kidney Disease and Focal Segmental Glomerulosclerosis (FSGS). DMX-200 was 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 irbesartan, an angiotensin II type I (AT1) receptor blocker and the standard of care treatment for kidney disease. DMX-200 has granted patents in various territories until 2032.

In 2017, Dimerix completed its first Phase 2a study in patients with a range of chronic kidney diseases. No significant adverse safety events were reported, and all study endpoints were achieved. In a subsequent sub-group analysis, significant clinical efficacy signals were seen in the diabetic group.

DMX-200 administered to patients already taking stable irbesartan reduced proteinuria levels by a further 36%. This reduction in proteinuria is highly correlated with improved renal function and delay in kidney failure and dialysis. The compelling results from this study prompted the decision to initiate two different clinical studies in 2018: one for patients with Diabetic Kidney Disease; and the second for patients with another form of kidney disease, Focal Segmental Glomerulosclerosis (FSGS).

FSGS is a serious and rare disease that attacks the kidney's filtering units (glomeruli) causing serious scarring which leads to permanent kidney damage and kidney failure and for which there is a recognised medical need for a new or improved treatment. FSGS affects both children and adults.

DMX-200 for FSGS has been granted Orphan Drug Designation by the FDA and EMA. 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 an abbreviated regulatory pathway to approval.

About DMX-700

COPD is a progressive and life-threatening lung disease. The primary cause of COPD is exposure to tobacco smoke (either active smoking or secondary smoke), however is also caused by exposure to indoor and outdoor air pollution, occupational dusts and fumes and long-term asthma. COPD is the fourth-leading cause of death in the world and although treatments exist to improve the symptoms of COPD, there is currently no way to slow progression of the condition or cure it. Moreover, among the top five causes of death globally, this disease is the only one with increasing mortality rates. The global COPD treatment market was valued at US\$14 billion in 2017 and is projected to increase at a compound annual growth rate of 4.9% to 2026.

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Initial studies have been completed, and Dimerix has completed a key step in securing ownership over what it believes is an important new drug discovery by lodging a provisional patent application for DMX-700. Over the next 12 months Dimerix will conduct further proof of concept studies to perform the value added verification in support of a robust product development pathway and patent position.

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