For Immediate Release

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DIMERIX ANNOUNCES POSITIVE TOP-LINE RESULTS IN PHASE 2a CLINICAL STUDY OF DMX-200 IN FSGS

Highlights

- Primary and secondary endpoints met in the Phase 2a study of DMX-200 in FSGS patients
- DMX-200 was found to be generally safe and well-tolerated in FSGS patients
- 86% of patients demonstrated a reduction of proteinuria with DMX-200 versus placebo
- A 29% reduction in proteinuria was observed across all patients receiving DMX-200 compared to placebo
- 29% of patients achieved a >40% reduction in proteinuria on DMX-200 compared to placebo
- Multiple patients from both FSGS and diabetic kidney disease studies continue on DMX-200 via TGA Special Access Scheme
- Statistically powered Phase 2 study in diabetic kidney disease results due in 4 - 6 weeks

MELBOURNE, Australia, 29 July 2020: Dimerix Limited (ASX: DXB), a clinical-stage drug development company, today announced positive top-line results from the Phase 2a ACTION study of DMX-200 for the treatment of focal segmental glomerulosclerosis (FSGS), a rare kidney disorder without an approved pharmacologic treatment that often leads to end-stage kidney failure. The study administered 240mg of oral DMX-200 to patients with FSGS already taking a stable 300 mg dose of the angiotensin receptor blocker irbesartan. The 240mg daily dose was administered as a 120mg capsule twice daily, which is an improved, more convenient transition from an 80mg capsule administered three times a day in the previous Phase 2a study in patients with chronic kidney disease.

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Ten patients were enrolled in the study, with seven patients meeting all pre-defined criteria required for inclusion in the final analysis in accordance with the protocol. The primary endpoint for the study was safety, as measured by the number and severity of adverse events and clinically significant changes in the patient safety profile with the use of DMX-200 compared to placebo in participants with FSGS who are receiving irbesartan. The preliminary safety findings show DMX-200 was generally safe and well-tolerated, with no variation in the incidence or severity of adverse events between treatment with DMX-200 or placebo. There were no patient withdrawals from the study and there were no serious adverse events related to the drug reported.

The secondary endpoints were the proportion of patients who achieved a response during treatment with DMX-200 compared to placebo as well as the percent change from baseline in 24-hour proteinuria after 16 weeks of treatment with DMX-200 as compared to placebo. Importantly, 86% (6/7) of patients demonstrated a reduction in proteinuria on treatment versus placebo, with an average 29% change from baseline in 24-hour proteinuria compared to placebo following treatment with DMX-200 based on protein/creatinine ratio (PCR) grouped analysis (an average reduction of 119mg/mmol (1052mg/g) proteinuria on DMX-200 versus an average reduction of 1mg/mmol (8.84mg/g) proteinuria on placebo). Furthermore, 29% (2/7) of the patients achieved a >40% reduction in proteinuria during treatment with DMX-200 compared to placebo.

Unlike other investigational drugs currently in development for FSGS, patients stayed on the standard of care angiotensin receptor blockade. As a result, the reduction in proteinuria observed from DMX-200 is in addition to any reduction in proteinuria expected from background therapy that would have occurred prior to starting on DMX-200.

The Phase 2a study was a double-blind, randomised, placebo-controlled, crossover study designed to evaluate the safety and preliminary signs of efficacy of DMX-200 in patients with FSGS who are receiving a stable dose of standard of care, irbesartan. Patients must have been receiving irbesartan for at least 12 weeks prior to being included in the trial. As previously announced, each participant in the study received 16 weeks DMX-200 preceded or followed by 16 weeks placebo, separated by a 6-week washout period.

Whilst this initial Phase 2a study in patients with FSGS was of a short duration and was not powered for statistical significance, it was designed to derive maximum insight from a small number of patients, while retaining the ability for a flexible number of patients to complete the study. As such, the study delivered encouraging data, which supports further development of DMX-200 in FSGS.

“I believe that the results of this Phase 2a FSGS study, together with the positive outcomes of the Company’s prior Phase 2a study in Chronic Kidney Disease, further validates Dimerix’ lead candidate, DMX-200, in sclerotic kidney diseases. The positive signals suggest that treatment with DMX-200 may indeed result in clinically meaningful improvements in kidney function when added to the standard of care in patients with FSGS. To have 86% of patients see a benefit on DMX-200 versus placebo in a disease is very impressive. I am very excited at what this may mean for future studies in patients with FSGS," commented Dr Hiddo Heerspink, Chair of the Dimerix Medical Advisory Board.

Investigator on the study and Head of the Melbourne Renal Research Group, Associate Professor David Packham, commented “These are tremendous top line results and certainly very encouraging for all FSGS sufferers. I look forward to further analysis over the next several weeks, which I expect will equally be fascinating and informative.”

"We are very pleased with the top-line results from the study, which suggest DMX-200 could be a significant advancement in the treatment of FSGS," said Dr Nina Webster, CEO and Managing Director of Dimerix. "FSGS patients today face poor outcomes with limited medical options, and we continue to progress our proposed development pathway forward that could deliver the first approved pharmacologic treatment to the FSGS community. In the meantime, we will soon be reporting on the larger diabetic kidney disease Phase 2 study that we hope will further support the growing evidence of DMX-200 efficacy in treating kidney diseases."

It is anticipated that additional analyses of these FSGS data will be available in due course, following availability of additional data and review by the Medical Advisory Board.

In the meantime, multiple patients from both the FSGS and the diabetic kidney disease study continue on treatment with DMX-200 through the TGA’s Special Access Scheme following respective study completion.

Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for the treatment of FSGS. Dimerix established with the respective regulatory agencies that “the intention to treat FSGS with DMX-200 was justified based on preliminary non-clinical data which showed a reduction in the number of podocytes lost and an improvement in proteinuria.” Furthermore, as stated by the respective regulatory agencies, the orphan designation indicates that “Dimerix has provided sufficient justification that if approved, [DMX-200] is likely to be of significant benefit to those affected by the condition” and that “[DMX-200] would provide a clinically relevant advantage as an alternative to any currently marketed products”. Orphan designation also provides regulatory and financial benefits to help bring DMX-200 to market in the US and Europe faster, including reduced fees during the product development phase, protocol assistance from the regulatory authorities, and 7-year (US) and 10-year (Europe) market exclusivity following product approval.

Dimerix is also awaiting the Phase 2 study results in diabetic kidney disease, which completed dosing in late July and has an expected data read-out in 4 - 6 weeks. In addition to the ongoing Phase 2 diabetic kidney disease study, the study in patients with COVID-19, and DMX-700 in Chronic Obstructive Pulmonary Disease, Dimerix continues to undertake planning for its proposed global Phase 3 pivotal program in FSGS.

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

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Conference call details

- Time: 11:00 (AEST) Wednesday 29 July
- Conference ID: 10009009

Access the call by pre-registration (preferred option) or by direct dial-in (delays possible):

1. **Pre-registration** Participants can pre-register by navigating to: **https://s1.c-conf.com/diamondpass/10009009-invite.html** Registered participants will receive their dial in number upon registration to enter the call automatically on the day.			
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Authorised for lodgement by the Board of the Company

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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. In addition to this announcement, Dimerix is currently developing its proprietary product DMX-200 for Diabetic Kidney Disease, Focal Segmental Glomerulosclerosis (FSGS) and Acute Respiratory Distress Syndrome (ARDS). 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 hypertension and kidney disease. DMX-200 is protected by 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.

DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

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 it 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.

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.