Dimerix

For Immediate Release

Teleconference at 11:00am (AEST) Monday 14 September

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DIMERIX REPORTS POSITIVE PHASE 2 STUDY RESULTS OF DMX-200 IN DIABETIC KIDNEY DISEASE

Key points

- A statistically significant difference in albuminuria reduction was observed in patients receiving DMX-200 versus placebo with a higher starting baseline albuminuria, and is consistent with prior studies:
  - 18% (*p*= .03) reduction in albuminuria in patients with >500mg/g (57mg/mmol) starting albuminuria (n=26) in addition to standard of care;
  - 64% of patients with the higher starting albuminuria level demonstrated a reduction in albuminuria versus placebo, with 56% achieving a clinically significant >25% reduction above that achieved by standard best therapy.
- No significant difference between treatment with DMX-200 and placebo across full patient cohort
- DMX-200 was found to be generally safe and well-tolerated in diabetic kidney disease patients
- Data supportive of progression to the next stage of development in diabetic kidney disease

MELBOURNE, Australia, 14 September 2020: Dimerix Limited (ASX: DXB), a clinical-stage drug development company, today announced positive results in a Phase 2 clinical trial in individuals with diabetic kidney disease to support further development of its DMX-200 drug candidate.

The Phase 2 study was a double-blind, randomised, placebo-controlled, crossover study designed to evaluate the safety and efficacy of DMX-200 in patients with diabetic kidney disease 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. Each participant in the study received 12 weeks DMX-200 preceded or followed by 12 weeks placebo, separated by a 6-week washout period. Unlike some other investigational drugs currently in development for kidney diseases, patients stayed on the standard of care angiotensin receptor blockade throughout the study. As a result, the reduction in albuminuria observed from DMX-200 is in addition to any reduction in albuminuria expected from background therapy that would have occurred prior to starting on DMX-200.

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A total of 45 patients were enrolled in the study, with 40 patients meeting all pre-defined criteria required for inclusion in the final analysis in accordance with the protocol. The study administered 240mg of oral DMX-200 to patients with diabetic kidney disease already taking a stable 300 mg dose of the angiotensin receptor blocker irbesartan.

The primary endpoint was the percent change from baseline in 24-hour albuminuria after 12 weeks of treatment with DMX-200 as compared to placebo. Although a statistically significant difference in reduction of albuminuria for the primary endpoint was not seen, with overall analysis showing no conclusive benefit of DMX-200 compared to placebo across the entire cohort of diabetic kidney disease patients (2% difference), analysis showed statistically and clinically significant variation in treatment response for patients with higher levels of albuminuria at study baseline.

A statistically significant trend was observed between treatment effect in patients that entered the study with a baseline albuminuria value above 57mg/mmol (500mg/g), a recognised clinically relevant threshold for treatment of kidney disease, compared to those with lower baseline levels of albuminuria below 57mg/mmol (study inclusion criteria was 30mg/mmol, which is also a recognised threshold for treatment). Analysis across this population demonstrated that those with a starting level of higher than 57mg/mmol demonstrated an average 18% reduction in albuminuria on DMX-200 versus placebo (p= .03; n=26). Although all prior studies also had the 30mg/mmol inclusion criteria, this is the first exploratory study that enrolled diabetic patients with baseline albuminuria below 100mg/mmol.

This top line disease burden-specific treatment effect is consistent with the recent Phase 2a study in patients with focal segmental glomerulosclerosis (FSGS), where all patients had a starting baseline albuminuria of over 179mg/mmol who showed a 29% fall in proteinuria against placebo, and the previous Phase 2a study completed in 2017 data in chronic kidney disease study that showed a 36% fall in albuminuria in a group of patients with diabetic kidney disease against baseline and who also all had a starting baseline over 100mg/mmol.

In the sub-group above 57mg/mmol starting albuminuria there was a compelling 64% of patients with a reduction in albuminuria level and 56% achieving a greater than 25% reduction in albuminuria versus placebo. Top line data of all patients on study suggests that 25% demonstrated a greater than 30% reduction in albuminuria on treatment with DMX-200 versus placebo.

The safety findings show DMX-200 was safe and well-tolerated, with no notable variation in the incidence or severity of adverse events between treatment with DMX-200 or placebo. There were three patient withdrawals from the study (none related to the study drug) and there were no serious adverse events related to the drug reported. The safety data findings are entirely consistent with existing safety data on DMX-200.

Further investigation is underway exploring the relationship between treatment effect in this study and other patient factors, including inflammatory biomarkers, concomitant medications or legacy effect, and these data will be published in due course. Findings from this in-depth analysis of the study data will be used to inform the design of future clinical studies of DMX-200 in kidney diseases, including diabetic kidney disease. A legacy effect implies continued additional benefit after a trial participant has ceased taking active drug and can be an indicator that the drug may be having a lasting effect on the function of the kidney, thereby modifying the disease.

As with our previous studies, these data suggest that DMX-200 does provide benefit to patients that have progressed in kidney disease severity, and thus have a higher inflammatory response within the kidney. This is also consistent with the proposed mechanism of action of DMX-200 whereby patients with higher baseline levels of albuminuria, and so inflammatory processes, responded to treatment with larger magnitudes than those with lower initial levels of these inflammatory drivers.

The study has delivered data that is consistent with prior data, and which adds to the growing body of evidence to support development of DMX-200 in indications where activation of CCR2, the receptor targeted by DMX-200, is driving inflammatory processes and disease progression. In parallel to the results announced today, Dimerix continues to undertake planning for its proposed Phase 3 pivotal program in FSGS, a rare kidney disorder without an approved pharmacologic treatment that often leads to end-stage kidney failure for which Dimerix announced positive clinical study results in July 2020.

“A treatment, such as DMX-200, that has a good combination of strong clinical safety records and a demonstrated albuminuria lowering capability and data that has the potential to delay the onset of end-stage kidney failure would be a significant benefit to patients,” said Professor Simon Roger, Lead Investigator, clinical nephrologist and Director of the Renal Research Group in Sydney. “With limited treatment options currently available and many patients who do not adequately respond to angiotensin receptor blockers, there remains a significant unmet need for more efficacious and durable therapies for diabetic kidney disease and FSGS.”

“Whilst the study did not show a statistically significant difference in its primary endpoint, the effects in people with baseline albuminuria of over 500mg/g provides informative insight that certainly warrants further analysis,” commented Dr Hiddo Heerspink, Chair of the Dimerix Medical Advisory Board. “I am very keen to see the collective assessment across all of the kidney studies conducted to date, as well as the additional data analysis when it becomes available, and using this to inform the future studies in patients with kidney disease. I am looking forward to working with Dimerix on finalising the design of the FSGS clinical study.”

“The confirmation of a clinically significant fall in albuminuria in patients with Type 2 Diabetes and high levels of residual albuminuria indicting poor prognosis undoubtedly warrants further investigation, focusing on this most at risk group with high levels of residual albuminuria despite best

therapy," commented Associate Professor David Packham. "The potential for a legacy effect is intriguing, especially as early data analysis suggests a similar effect in the recently reported ACTION FSGS trial, and I look forward to the outcomes of the additional data analysis."

"Following on from our positive Phase 2a data in FSGS patients in July, as well as our prior Phase 2a study in chronic kidney disease in 2018, these results provide further supporting and consistent data demonstrating that DMX-200 may benefit patients with inflammatory diseases, including diabetic kidney disease, FSGS and ARDS", said Dr Nina Webster, CEO and Managing Director of Dimerix. "This is now the third study completed by Dimerix that shows efficacy in a group of patients with active inflammatory disease and is supportive of our plan to progress DMX-200 into a Phase 3 clinical study in FSGS in the first half of 2021, in parallel to partnering discussions and ultimately further testing in later stage diabetic kidney disease patients. The collective Phase 2 data is invaluable in informing the design and execution of our single Phase 3 registration study in FSGS and further increases our confidence that DMX-200 will prove a valuable therapeutic option to patients suffering FSGS and who currently have no approved or effective medication."

This mechanism of increased treatment effect at higher levels of inflammatory disease burden is also consistent with the planned use of DMX-200 for the treatment of Acute Respiratory Distress Syndrome (ARDS) caused by COVID-19 where high concentration of MCP-1 in lung fluid is correlated with poor patient outcomes and where DMX-200 may have the maximum effect.

In the meantime, multiple patients from both the FSGS and the diabetic kidney disease study, as well as the previous Phase 2 study in 2017, continue on treatment with DMX-200 through the TGA's Special Access Scheme following respective study completion.

In addition to the diabetic kidney disease and FSGS renal programs, Dimerix continues to work on a study in patients with Acute Respiratory Distress Syndrome associated with COVID-19, and DMX-700 in Chronic Obstructive Pulmonary Disease.

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

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Conference call details

Time: 11:00am (AEST) Monday 14 September
Conference ID: 10009865

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/10009865-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.