Dimerix

For Immediate Release

DIMERIX PLANS FOR NEXT STUDY IN DIABETIC KIDNEY DISEASE PATIENTS

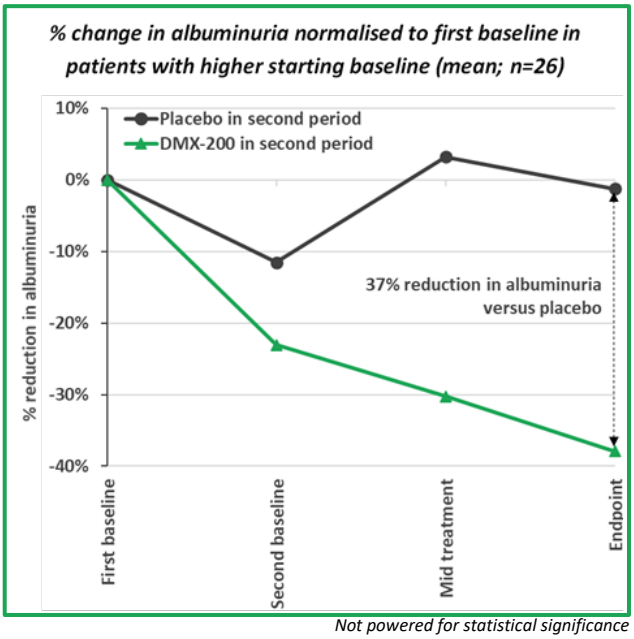
- Medical Advisory Board completes formal assessment of renal data in diabetic kidney disease
- DMX-200 treatment effect seen in patients at the end of the two-period cross-over study
- A 37% mean reduction in albuminuria was observed on DMX-200 versus placebo and a 38% mean reduction in albuminuria from study entry (first baseline) in the cohort of patients with higher albuminuria in the second period of the cross-over study (n=26)
- A 22% mean reduction in albuminuria was observed on DMX-200 versus placebo and a 27% mean reduction in albuminuria from study entry (first baseline) across the full patient cohort in the second period of the cross-over study (n=40)
- Planning of further clinical study in diabetic kidney disease patients underway

MELBOURNE, Australia, 28 January 2021: Dimerix Limited (ASX: DXB), a clinical-stage biopharmaceutical company, today announced additional positive efficacy data from the Phase 2 study in diabetic kidney disease patients that reported top line data in September 2020, looking at the overall treatment effect in patients at the end of the cross-over study, as well as plans to further progress development of DMX-200 in diabetic kidney disease.

DMX-200 positive treatment effect

An exploratory subgroup analysis was conducted in patients during the second treatment period, where a 37% reduction in albuminuria in patients receiving DMX-200 versus placebo (Figure 1) in those patients with a starting albuminuria baseline greater than 500 mg/g (38% reduction versus baseline; n=26). A 22% mean reduction in albuminuria was observed in patients on DMX-200 versus placebo (Figure 2) when normalised to first baseline (27% reduction versus baseline; n=40). Importantly, these reductions in albuminuria are in addition to any reduction that occurred on the background therapy of an angiotensin receptor blocker.

Figure 1



Not powered for statistical significance

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

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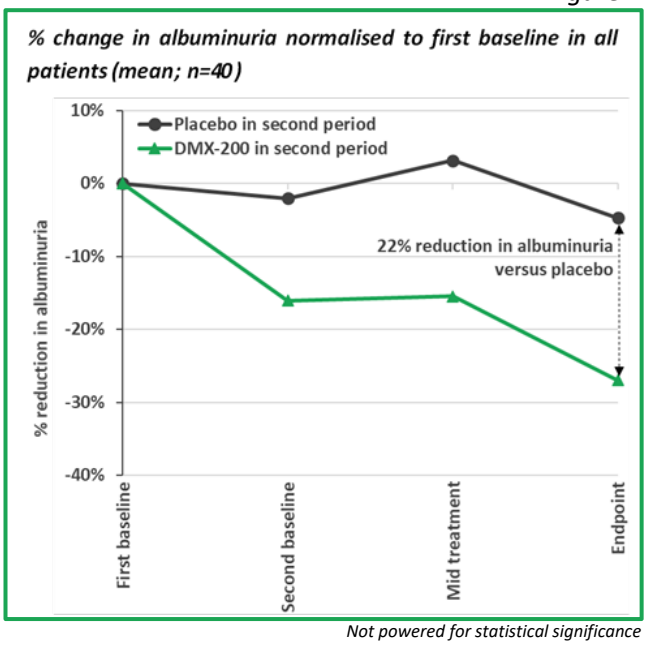
Figure 2



Not powered for statistical significance

These data support the mechanism of action of DMX-200, which aims to reduce inflammation, being effective in diseases where active inflammatory processes are driving disease progression and are also consistent with Dimerix' observations from the prior open-label study (completed in 2017) where diabetic patients achieved a 36% reduction in albuminuria compared to baseline after 26 weeks of treatment with DMX-200.

Protein in the urine continues to trend downwards on DMX-200

At the end of the current study, it was further noted that albuminuria levels appeared to be continuing to trend downwards at the end of both DMX-200 treatment periods, which also suggests greater albuminuria reductions may be observed with a longer study treatment duration. This is consistent with effects seen in other late-stage clinical studies including in Dapagliflozin (*doi:10.1111/dom.12654*), Canagliflozin (*doi:10.1681/ASN.2020050723*) and Finerenone (*doi:10.1056/NEJMoa2025845*) and in the previous Dimerix study of DMX-200 in patients with diabetic kidney disease completed in 2017.

Importantly, other medications taken during the study, including SGLT2 inhibitors, did not appear to affect the efficacy outcomes of DMX-200.

The Medical Advisory Board has now concluded its formal assessment of the Phase 2 renal data in diabetic kidney disease. Importantly, these encouraging data support the ongoing development of DMX-200 in diabetic kidney disease, and based on the Phase 2 data, a further study assessing the effect of DMX-200 in diabetic kidney disease patients over a longer period is warranted.

Further study in diabetic kidney disease patients planned

Given the effect of DMX-200 on albuminuria levels appears to be continuing to trend downwards, while the placebo does not, which is consistent with other studies in diabetic kidney disease patients, a longer study will allow the natural history of diabetic kidney disease patients to be contrasted against possible longer-term effects of DMX-200. Dimerix is now assessing the study design in diabetic kidney disease patients.

"The trends observed in this relatively short study warrants further investigation, and I look forward to working with Dimerix on the design of this next stage of development," commented Dr Hiddo Heerspink, Chair of the Dimerix Medical Advisory Board.

Phase 2 Study Design

The Phase 2 study was a double-blind, randomised, placebo-controlled, cross-over study designed to evaluate the safety and efficacy of DMX-200 in patients with diabetic kidney disease who were receiving a stable dose of standard of care, irbesartan. In this study, efficacy was measured by a surrogate biomarker of protein in the urine, known as albuminuria, and which is typically used as a measure of kidney disease progression. Higher levels of albuminuria are reflective of more advanced disease and an expectation of a faster decline in kidney function. Conversely, a reduction in the amount of albumin in the urine reflects a slowing of the progression of kidney failure.

Patients remain on DMX-200 through Special Access Scheme

Dimerix is also pleased to report that the first patient with kidney disease to be treated with its drug candidate, DMX-200, on compassionate grounds (Therapeutic Goods Administration - Special Access Scheme) will celebrate four years of on-going treatment in February 2021. This patient received the first dose of DMX-200 under the Special Access Scheme in February 2017, has been on continuous therapy, and thus has apparent treatment related benefits since that time. Multiple kidney disease patients have since accessed DMX-200 under the Special Access Scheme.

In parallel, Dimerix continues to undertake planning for the proposed Phase 3 pivotal program in FSGS, a rare kidney disorder without an approved pharmacologic treatment that often leads to end-stage kidney failure, as well as further progress two Phase 3 studies of DMX-200 in COVID-19 patients, and finally advance the COPD program towards the clinical stage of development.

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

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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 Diabetic Kidney Disease, Focal Segmental Glomerulosclerosis (FSGS) and Acute Respiratory Distress Syndrome (ARDS), as well as 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 which reduces inflammation when 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). DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

It is estimated that 40% of people with diabetes have kidney disease and many may not know it yet. With the incidence of diabetes growing so rapidly globally, so too will the incidence of kidney disease. This is a rapidly growing market, with few treatment options at this time. Dimerix reported statistically and clinically significant outcomes in a Phase 2 study in diabetic kidney disease patients in September 2020.

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. Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

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 most common 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 PCT patent application for DMX-700. Dimerix DMX-700 development plan continues to progress towards the clinical phase, with some further in vivo assessment in an appropriate COPD model to confirm target engagement, pharmacokinetics and pharmacodynamics in support of a robust product development pathway and patent position.