For Immediate Release

ASX/Media Release

Dimerix Reports Positive Results from Phase 2a Trial of DMX-200 in Chronic Kidney Disease

- **DMX-200 Phase 2a clinical trial meets primary safety endpoint and demonstrates encouraging efficacy in a clinically meaningful number of patients**
- **25% of patients achieved a greater than 50% reduction in proteinuria, beyond that achieved with the highest dosage of current standard of care therapy**
- **45% of patients granted ability to continue ongoing treatment under Special Access Scheme upon recommendation of their advising physician, confirming confidence in the treatment**
- **Study data informs dosing and patient targeting parameters to progress the DMX-200 Phase 2b efficacy study in 2017**

Investors are invited to join a conference call, tomorrow – Thursday, 13th July at 12pm AEST to discuss the results with CEO, Kathy Harrison

MELBOURNE, Australia, 12th July 2017: Dimerix Limited (ASX: DXB), a clinical-stage biotechnology company today announced positive safety and efficacy data (primary endpoint met) following its now completed 27 patient Phase 2a Proof of Concept, Dose Escalation Study in Chronic Kidney Disease (CKD) for lead program, DMX-200. Dimerix will now progress with the design for the planned Phase 2b DMX-200 study.

The primary endpoint of the Phase 2a study - demonstrating safety and tolerability - has been met. In addition, encouraging efficacy signals have been demonstrated, with 25% of patients showing a reduction in excess protein in the urine (proteinuria) of over 50%, beyond that achieved with the highest dosage of current standard of care therapy (irbesartan.).

Associate Professor David Packham*, one of the Principal Investigators in the study and Director of the Melbourne Renal Research Group, said "These are very encouraging data. DMX-200, and its combination with existing best therapy, appears safe and was well tolerated. An incremental 50% fall in proteinuria is a 'high bar' to set in studies of this type and the observation of this efficacy endpoint in 25% of the patients certainly warrants further clinical investigation in a larger, more targeted, population.'

Dimerix CEO Kathy Harrison said, "We are delighted that this study has resulted in such positive outcomes. The clinically meaningful reductions in proteinuria are highly encouraging and support the rationale behind the program. Given this is a "hard to treat" patient group, we now have a very strong indication that the treatment is having a significant impact in slowing the progression of Chronic Kidney Disease.

"CKD is a complex disease and a silent epidemic. Driven by factors like increasing incidence of diabetes, it now affects 1.7 million Australians and 26 million Americans each year" she said. "It is a progressive disease, which means that without treatment, a patient's proteinuria levels will tend to get worse over time. If we can further demonstrate in our studies that DMX-200 reduces those levels and prevents progression to the need for blood dialysis, we will have a very viable therapy and a huge leap forward in treatment options for patients over the current highest standard of care."

DMX-200 Phase 2a trial overview

DMX-200 is an adjunct therapy program for Chronic Kidney Disease (CKD) involving patients stably treated with irbesartan (current standard of care) and additionally treating them with propagermanium. The Phase 2a trial enrolled 27 patients in an open label trial, with patients being recruited at four sites in Australia.

The primary endpoint was the safety and tolerability of the CCR2 antagonist, propagermanium, over a wide variety of dose ranges when added to stable treatment of the Angiotensin Receptor Type 1 (AT_1R) antagonist, irbesartan, in patients with proteinuria.

The secondary endpoint was the effect of propagermanium on various biomarkers, including proteinuria.

Approach

All patients were on a stable dose of irbesartan for three or more months prior to enrolment, and throughout the study.

Patients received escalating doses of propagermanium (10, 20, 30, 50, 80 mg three times per day) at four-week intervals unless proteinuria fell to within normal limits. Participants remained on their maximum dose for a further 8 weeks. Proteinuria was re-quantified 4 weeks after discontinuation of propagermanium. The patients were aged between 36 and 87 years. Primary diagnoses included diabetic nephropathy, IgA nephropathy, and other proteinuric diseases.

Top line results

Results showed no serious safety concerns were observed in patients on irbesartan when treated with 10-80 mg of propagermanium three times daily. Consistent with the nature of the patient population, three patients withdrew from the study for the following reasons: emergence of anaemia secondary to a gastrointestinal bleed, depression and progression of renal disease. Of the 24 patients that completed dosing, 6 (25%) achieved greater than 50% reduction in proteinuria during at least one dose level of propagermanium.

Full data will be released in a key scientific forum in due course.

Special Access Scheme

Upon the recommendation of their physician, 11 (45.8%) of the patients who completed the study applied for and were accepted into the Australian Therapeutic Goods Administration's Special Access Scheme to enable continued access to the drug after completion of the study. This result demonstrates the physicians' confidence that DMX-200 was having a positive effect on their patients. The physicians' recommendation was based on patients meeting one or more of the following criteria:

- Patients were either classified as a responder as defined above, or;
- A reduction in proteinuria was observed, which the physician considered encouraging, or;
- A 50% or greater increase in proteinuria in the follow-up period which occurred after last dose, suggesting that DMX-200 may have had a possible benefit in slowing the disease progression in these patients.

Next steps

Preparations are well underway to design the Phase 2b efficacy study for DMX-200. Using the inputs from this Phase 2a study, Dimerix will now finalise design of the patient inclusion criteria, dosing and timetable, which is expected to start by the end of 2017.

Investors are invited to join a conference call to be hosted by Kathy Harrison, CEO at 12.00pm (AEST) on Thursday, 13th July 2017. The call will cover today's release of positive Phase 2a clinical trial results from the DMX-200 program in patients with Chronic Kidney Disease.

To access the call**: Dial 1800 123 296**, **Conference ID: 5074 2992**

Toll free numbers:

Australia	1800 123 296
Canada	1855 5616 766
China	4001 203 085
Hong Kong	800 908 865
India	1800 3010 6141
Japan	0120 477 087
New Zealand	0800 452 782
Singapore	800 616 2288
United Kingdom	0808 234 0757
United States	1855 293 1544

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About the DMX-200 program

DMX-200 is being developed as an adjunct therapy, adding propagermanuim to a stable dose of irbesartan. Irbesartan is an off-patent angiotensin II type I receptor blocker indicated for the treatment of hypertension and nephropathy in Type II diabetic patients. Propagermanium (PPG) is a chemokine receptor (CCR2) blocker, which has been used for the treatment of Hepatitis B in Japan and is available in the USA for its anti-inflammatory properties. DMX-200 has been shown to improve the outcome of chronic kidney disease by reducing proteinuria by more than 50 per cent in animal models [(1)].

About Chronic Kidney Disease

Chronic Kidney Disease (CKD) is a disorder in which patients show progressive loss of renal function usually accompanied by excess protein in the urine (proteinuria). Levels of proteinuria predict rate of decline of renal function (higher levels = more rapid decline). In part this is believed to reflect direct toxicity, or damage, to the kidneys by proteinuria itself. This establishes a cycle of worsening renal function leading in turn to increasing proteinuria and further kidney damage. Many CKD patients progress to a need for renal replacement therapy or dialysis and / or experience excessive morbidity and mortality from cardiovascular-related diseases.

The prevalence of CKD is rising and as such there is urgent need for treatments that can benefit CKD patients, including reducing proteinuria. In most cases of CKD residual proteinuria continues even with optimal use of existing therapies. Accordingly, therapies designed to further reduce, or abolish, proteinuria, are eagerly sought.

The rationale behind the DMX-200 program is to provide patients with a therapy that can reduce proteinuria in addition to that achieved with standard best therapy. The unmet need of CKD patients is reinforced by Dimerix's Orphan Drug Designation.

Dimerix Bioscience Pty Ltd

Dimerix Limited's (ASX: DXB) wholly owned subsidiary Dimerix Bioscience Pty Ltd is a clinical-stage pharmaceutical company committed to discovering and developing new therapeutic models identified using its proprietary assay, termed Receptor-Heteromer Investigation Technology (Receptor-HIT). This assay enables the identification of pairs of receptors that function in a joint manner (interact) when ligands, small molecule drugs, peptides or antibodies, bind to them.

The Receptor-HIT technology was used to identify DMX-200 in an internal drug development program, initially for the treatment of a subset of patients with chronic kidney disease. In addition to its own therapeutic programs, the company also earns revenue by providing this technology to global pharmaceutical companies.

For more information see www.dimerix.com

(1) Functional interaction between angiotensin II receptor type 1 and chemokine (C-C motif) receptor 2 with implications for chronic kidney disease. Ayoub MA, Zhang Y, Kelly RS, See HB, Johnstone EK, McCall EA, Williams JH, Kelly DJ, Pfleger KD. PLoS One. 2015 Mar 25;10(3):e0119803. doi: 10.1371/journal.pone.0119803.

* David Packham is one of the investigators on the study, and is the Director of the Melbourne Renal Research Group, a specialist clinical research facility for nephrology studies. David has more than 30 years experience in clinical research and has conducted in excess of 50 studies. His formal qualifications include his basic medical degree from the University of London (1981) and his subsequent Doctorate of Medicine from the University of Melbourne (1989). David assists Dimerix as a paid consultant in relation to DMX-200 and has a minor shareholding in the company.