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ASX/Media Release

Dimerix Presents Detailed Subgroup Analysis from DMX-200 Phase 2a trial in Chronic Kidney Disease Showing Compelling Efficacy Signals in Diabetic Nephropathy Patients

- **Detailed data from Dimerix's DMX-200 Phase 2a trial in Chronic Kidney Disease (CKD) presented at American Society of Nephrology's (ASN) Annual Kidney Week conference in New Orleans this week**
- ***Post hoc*, detailed data analysis shows efficacy signals in diabetic nephropathy and IgA nephropathy sub-groups**
- **Five of the six (83%) identified responders had a primary diagnosis of diabetic nephropathy**
- **Average Albumin Creatinine Ratio (ACR) reduction of 35.6% (p=0.0063) (above standard of care) was observed in the diabetic nephropathy sub-group, an exceptional result for this indication**
- **Diabetic nephropathy is the single most common cause of chronic kidney disease worldwide, affecting 3% of the population. The findings from this study have the potential to substantially broaden licensing opportunities for DMX-200**
- **DMX-200 Phase 2a data has been used as the basis for the filing of two provisional patent applications.**

MELBOURNE, Australia, 2nd November 2017: Dimerix Limited (ASX: DXB), a clinical stage biotechnology company today announced in-depth, sub-group data from its recently completed DMX-200 Phase 2a trial in Chronic Kidney Disease (CKD) to be delivered at the American Society of Nephrology's (ASN) Annual Kidney Week conference in New Orleans.

The Phase 2a dose escalation study of DMX-200, Dimerix's lead program, examined 27 patients with CKD. 24 patients completed the study, and 3 of the 27 did not complete for reasons unrelated to the study. Top line data, announced in July, showed that DMX-200 met its primary safety endpoint with encouraging, clinically meaningful efficacy data. Six of the 24 patients (25%) to complete the study met the pre-specified criteria of 'responder' as defined by reduction of proteinuria to normal levels, or a 50% reduction in proteinuria, over that being achieved with the current standard of care.

The new data are based on a *post hoc* detailed analysis of individual patients by sub-group. Five of the 6 patient responder sub-group (83%) had a primary diagnosis of diabetic nephropathy and 1 of the 6 responders (17%) had a primary diagnosis of IgA nephropathy. This indicates particularly compelling efficacy signals for the diabetic nephropathy sub-group. The IgA sub-group represents patients suffering from a particularly aggressive kidney disease, and warrants further investigation.

Kathy Harrison, Dimerix CEO said: "Diabetic nephropathy represents the single most common cause of CKD worldwide, affecting an estimated 3% of the US population with a 2014 market value estimated at $US931m in the US alone. Early efficacy signals in this patient sub-group

indicate a potential increase in the commercial value of DMX-200, which we expect should increase its attractiveness for out-licensing."

Associate Professor David Packham, Director of the Melbourne Renal Research Group and one of the trial's Principal Investigators added that "The efficacy signal among patients with Type 2 diabetic nephropathy is remarkable as it is seen on top of the maximum recommended dose of existing best therapy. Because of the unique study design, it is unlikely that consistent changes of this magnitude could be ascribed to a late effect of standard therapy or could have occurred spontaneously without the administration of DMX-200"

DMX-200 Phase 2a data has been used as the basis for the filing of two new provisional patent applications describing the discovery of the optimal dose for the therapy and associated extended release formulation.

Informed by the detailed analysis, Dimerix is in the final stages of designing the protocol for a double-blind, placebo-controlled Phase 2b efficacy trial for DMX-200, which is scheduled to begin patient recruitment in Q1 Calendar 2018 throughout a number of sites in Australia.

Three patient sub-groups have been selected for the Phase 2b trial in consultation with Dimerix's recently appointed Medical Advisory Board (MAB) consisting of respected kidney experts (nephrologists) led by Associate Professor David Packham as Chair.

The three subgroups will consist of patients with diabetic nephropathy; IgA nephropathy and Focal Segmental Glomerulosclerosis (FSGS).

Dimerix has already secured orphan drug designation in the US for DMX-200 in FSGS and has been in discussions with the US Federal Drug Administration (FDA) about filing an Investigational New Drug application in this indication, which will represent a faster route to market. This rare sub-group represents a patient population with high unmet need and will be further evaluated in the Phase 2b study.

As mentioned above, the diabetic nephropathy results are particularly compelling and represent a significant, additional licensing opportunity for Dimerix, given the massive population of Diabetic Nephropathy sufferers world-wide and few therapeutic opportunities.

The IgA nephropathy sub-group represents patients suffering from a particularly aggressive kidney disease, and the results warrant further investigation.

ASN Poster Presentation details

Poster:	The poster presentation is entitled 'A Phase 2a trial of DMX-200: synergistic blockade of AT1R and CCR2 in patients with Chronic Kidney Disease'. A copy of the poster is appended to this announcement.
Presenter:	Professor David Power.
Date/time:	10am on 2nd November (New Orleans time).
Location:	Ernest N. Morial Convention Centre, New Orleans, LA.

The poster is available on the Dimerix web site here:

http://dimerix.com/wp-content/uploads/ASN-2017-Poster.pdf

DMX-200 Phase 2a secondary endpoint efficacy results*

The following overall and sub-group results were achieved for patients on the trial.

In July 2017, with the original data release, we reported:

- 6 out of 24 patients (25%) to complete the study had achieved the pre-specified criteria of 'responder' as defined by achieving reduction of proteinuria to normal levels, or a 50% reduction in proteinuria (measured by the PCR ratio)

Since the original data release in July, *post hoc* analysis has identified:

- 13 of 24 patients who completed the study (54%) achieved at least a 30% reduction in PCR
- 5 of the 6 persons originally announced responder sub-group (83%) had a primary diagnosis of diabetic nephropathy. 1 of the 6 responders (17%) had a primary diagnosis of IgA nephropathy
- 50% (5/10) of patients with a primary diagnosis of diabetic nephropathy were classified as responders
- An average Albumin Creatinine Ratio (ACR**) mean reduction of 35.6% in the Diabetic Nephropathy sub-group which was deemed statistically significant (p=0.0063)
- An average Protein Creatinine Ratio (PCR**) mean reduction of 31.9% in the Diabetic Nephropathy sub-group which was deemed statistically significant (p=0.0088).

Associate Professor David Packham added "A mean reduction of proteinuria levels (measured by PCR) of 32% is not only statistically significant but also very significant clinically. Normally an intervention that reduces proteinuria or albuminuria in these patients by 15% or more is considered likely to impact on renal functional outcomes and potentially significantly delay the need for renal replacement therapies."

* Responses are considered additional to any effect of irbesartan (existing standard of care) on proteinuria levels.
** Protein Creatinine Ratio (PCR) is a measure of proteinuria levels and is a respected indicator of CKD. An alternate measure is the Albumin Creatinine Ratio (ACR).

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About 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

About the DMX-200 program

DMX-200 which successfully completed a Phase 2a clinical trial in humans, 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)].

Dimerix released the results of its Phase 2a clinical trial in humans for DMX-200 in July 2017. The trial met its primary endpoint of safety and tolerability in the participating patient group, which included patients with diabetic nephropathy (10), IgA nephropathy (6), and other proteinuric diseases (11). As a secondary endpoint, DMX-200 was shown to reduce levels of proteinuria in a number of patients, in particular, in the diabetic nephropathy sub-grouping. This was deemed a "clinically meaningful" result by leading clinicians. Preparations for a Phase 2b trial are underway which will test for efficacy and is expected to start by the end of calendar 2017.

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.

[(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.