

**For Immediate Release****ASX/Media Release****Dimerix Investor Update**

**MELBOURE, Australia; 11 April 2017:** Dimerix Limited (ASX: DXB), a clinical stage biotechnology company committed to discovering and developing new therapeutic treatments identified using its proprietary screening assay, today published a copy of its latest investor presentation. The presentation highlights a number of clinical and corporate milestones including:

- Dimerix is on track to release final data for its Phase 2 Part A study in Chronic Kidney Disease in July 2017
- Interim study data released in November 2016 was positive and well received by clinicians in the sector
- The data released to date compares favourably with other larger pharmaceutical and drug research companies active in the same market sector
- The company will initiate a Phase 2 Part B study in the second half of 2017
- Dimerix believes if the Phase 2 Part A data scheduled for release in July 2017 is positive, it will be supportive of a potential licensing or partnering.

Dimerix Chief Executive Officer Kathy Harrison will make two investor presentations this week in Melbourne on Tuesday 11 April and in Sydney on Wednesday 12 April. A copy of the presentation is attached.

The company's lead compound is an innovative treatment that combines two existing pre-approved drugs and has been granted Orphan Drug Designation status in the United States.

Orphan Drug Designation gives the drug seven years exclusive marketing in the US along with a range of regulatory and financial support measures designed to expedite development.

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**Dimerix Bioscience Pty Ltd**

Dimerix Limited's 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](http://www.dimerix.com)

### **DMX 200**

DMX-200 is being developed as an adjunct therapy, adding propagermanium 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<sup>(1)</sup>.

### **The DMX-200 Phase II Trial**

The trial is a single arm, open label study in adult patients with chronic kidney disease (with proteinuria). The primary end points are the incidence and severity of adverse events and the clinically significant changes in the safety profile of participants. The secondary end points are obtained from statistical analysis of biomarker data at each time point including change from baseline, and the proportion of responders defined as those participants achieving normalisation of proteinuria (proteinuria within normal limits) or those participants achieving a 50 per cent reduction in proteinuria.

The trial has two parts. Part A is a dose escalation trial recruiting up to 30 patients and completed enrolment at the end of November 2016. All patients recruited to the trial will be on stable irbesartan therapy, and will be treated with propagermanium dosed orally three times per day. Each patient will commence on 30mg PPG/day and the dose increased each 28 days to a maximum of 240mg/day, or until proteinuria is absent or reduced to a level the clinician considers acceptable. The Company expects to complete Part A in mid 2017.

Part B is an expansion study, in which up to 30 patients will be given the optimal dose identified from Part A.

### **Chronic Kidney Disease**

Chronic kidney disease can result from diabetes, high blood pressure and diseases that cause inflammation specifically in the kidneys. Proteinuria is the most common manifestation of the disease. As the disease progresses it can lead to end-stage renal disease (ESRD) where the kidneys fail. The only treatment for ESRD is a kidney transplant or regular blood-cleansing treatments called dialysis. More than 26 million people suffer from the disease in the United States.

<sup>(1)</sup> 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, Pflieger KD. PLoS One. 2015 Mar 25;10(3):e0119803. doi: 10.1371/journal.pone.0119803.



# A clinical phase company with a powerful drug discovery technology

Investor Update  
11-12 April 2017

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**Patient Need** - working to help people with chronic kidney disease (CKD), a disease that has no cure but **affects over 10% of the population**

**Lead candidate DMX-200** - in **Phase 2 clinical trials** for CKD, with **data due from Part A of our two part trial in July 2017**

**Market Need** - *Initially* targeting patients with a specific form of kidney disease: Focal Segmental Glomerularsclerosis (FSGS), a condition with limited treatment options that are often ineffective and poorly tolerated.

- The market for FSGS treatment is estimated to be **US\$1B** in the US

**Orphan Drug Designation** approved by the FDA for FSGS which provides:

- **Seven years exclusive marketing** in the US
- Regulatory and financial support measures which can **accelerate development**

**Patented Receptor-HIT platform technology** - the powerful technology which identified DMX-200 and enables a **pipeline of opportunities**

Chronic kidney disease can lead to kidney failure, cardiovascular disease and premature death

Proteinuria, or excess protein in the urine, is the most common symptom of the disease and is indicative of decreased renal functioning

Current treatments for CKD include a cocktail of drugs such as immunosuppressants and steroids, which have high toxicity profiles and efficacy as low as 25%

- Kidney disease is a major global health problem, affecting 26 million people in the US
- The total US Medicare spending on patients with End Stage Renal Disease (ESRD) was **US \$32.8 billion** in 2014
- Due to poor efficacy and tolerability of existing treatments, a **significant response** in 25% of patients with a safe and well tolerated drug would be a **great clinical outcome**

# DMX-200 – lead product candidate



**Drug**                      Combination of two approved drugs (irbesartan and propagermanium) to target inflammatory root cause of kidney disease

**Planned indication(s)**                      Initial indication FSGS, expansion to CKD

**Potential advantages**                      Safety of approved drugs with efficacy tailored by their synergistic effect

**Potential market size**                      Estimated US\$1BILLION in the US alone

**Development status**                      US FDA Orphan Drug Designation (ODD)  
Phase 2A near complete, Phase 2B planned  
Only single Phase 3 required under ODD  
Orphan Drug designation gives seven years exclusive marketing and regulatory and financial support measures which can accelerate development

## Milestones achieved

- Australian, US and Japanese patents** for lead candidate granted
- Orphan Drug Designation in the USA for FSGS
- Positive meeting with FDA – achievable path to registration
- Completed patient enrollment in Phase 2 Part A study
- Positive interim Phase 2 data
- On track to report Part A in July 2017



## DMX-200 Program

Expected timeframe	Milestone
1H 2017	Manufacture of commercial propagermanium formulation
1H 2017	Commence clinical PK study with commercial formulation
June 2017	Engage with NephCure Accelerating Cures Institute
July 2017	<b>Report Phase 2 dose escalation (Part A) – July 2017</b>
2H 2017	Commence Phase 2 Part B
End 2018	Complete Phase 2

## Other News Drivers

### Milestone

Further pre-clinical studies for Non-Alcoholic Steatohepatitis (NASH)

Research collaborations and assay licensing opportunities

## G-Protein Coupled Receptors (GPCRs)

- **Large family of cell surface receptors** which control most physiological process including **blood pressure, inflammation, and cellular division**
- **Over 30%** of all prescription drugs target GPCR's
- **Signalling between complexes** is essential for many cellular functions
- Drugs developed without understanding GPCR complexes may cause **unwanted and unexplained side effects**
- FDA has agreed with Dimerix that understanding GPCR complexes is a critical factor in **developing safe new drugs**

## Dimerix' Receptor-HIT platform

- Patented tool that enables identification and characterisation of GPCR complexes
- Can be used to identify new uses and treatments for existing drugs, drive the discovery of new drugs, and identify entirely new therapeutic pathways

**Global pharmaceutical companies need access to Dimerix's Receptor-HIT technology to develop safe new drugs**









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