A close-up photograph of an elderly person's hand being held by a younger person's hand. The elderly hand is wrinkled and has a white hospital wristband. The younger hand is smoother and is holding the elderly hand gently. The background is a plain, light-colored surface.

Dimerix

DMX-200 for Chronic Kidney Disease

Gold Coast Investment Showcase

20 June 2018

ASX: DXB

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Dimerix has 2 Phase 2 clinical trial programs starting recruiting in Q3 CY2018

1. DMX-200 for **Focal Segmental Glomerulosclerosis (FSGS)**
 - Phase 2a **US Orphan drug designation achieved - path to US drug registration**
 - **Reduced risk of adverse safety events** due to use of known molecules
2. DMX-200 for **Diabetic Kidney Disease (DKD)**
 - **Compelling data from recently completed Phase 2a** study for this more common disease
3. **“Receptor HIT” drug discovery platform**
 - Multiple further pipeline opportunities
 - Collaborative drug discovery and development opportunities

Note: FSGS and DKD are sub indications of Chronic kidney disease (CKD)

Corporate snapshot

| | |
|----------------------------------|---------|
| ASX code: | DXB# |
| Share price (13 June 18): | \$0.105 |
| Market cap: | \$16.3m |
| Cash (30 Mar 2018): | \$7.55m |
| Shares on issue* | 155m |

#Consolidation (20:1) completed 31st October 2017

*Unlisted Performance Shares: 3.75.m; Options (ESOP): 3.47m

Share price history



What is DMX-200?

- DMX-200 is an adjunct therapy. We administer two existing, well known drugs, to achieve a **synergistic effect**
- The two drugs used are:
 - **Propagermanium** – CCR2 antagonist with decades of use in Japan for chronic Hepatitis B
 - **Irbesartan** – existing standard of care, angiotensin receptor blocker. Irbesartan is a blood pressure medication



Dimerix has a granted patent (in the USA and elsewhere) over this method of treatment.

Chronic kidney disease (CKD)

- CKD is a growing global health problem affecting over 10% of the population
- Damaged kidneys “leak” proteins into the urine. This is called **proteinuria**.
- Proteinuria is the most common symptom of the disease and is the **strongest prognostic indicator** of disease progression
- Kidney disease generally gets progressively worse, with patients whose kidneys fail, **requiring dialysis or kidney transplant**



- First line therapy is the use of drugs to reduce blood pressure, which can reduce proteinuria but do not stop progressive kidney failure
- In some types of kidney disease (eg FSGS), patients are given a cocktail of drugs including immunosuppressants and steroids such as prednisone, which have **poor side effects** and require **repeated treatment cycles**
- **There is a huge medical need for a safe treatment which can significantly reduce proteinuria and prolong the life of the kidney**



Will in remission



Relapse from nephrotic syndrome

Focal segmental glomerulosclerosis (FSGS)

- **FSGS** is a very serious disease and is characterized by **rapid progression to end-stage renal disease**
- DMX-200 has **US Orphan Drug Designation for FSGS**

Independent analysts estimate FSGS drug sales in the USA to be worth USD \$1 billion per annum

Diabetic Kidney Disease (DKD)

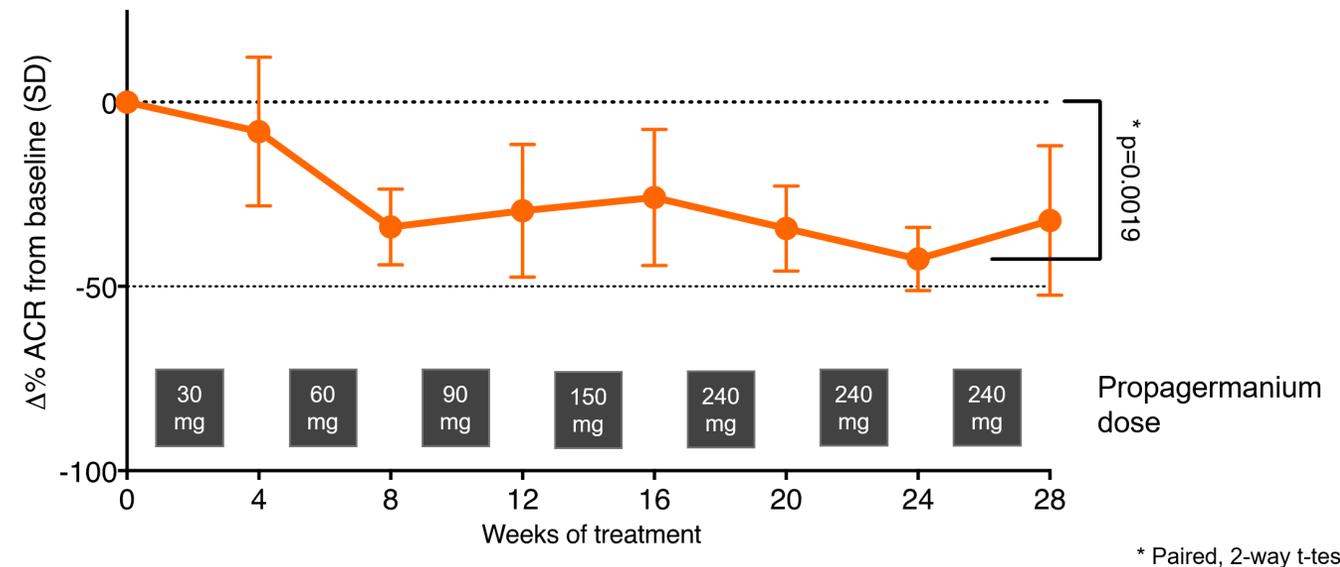
- **DKD** is the single most common cause of CKD worldwide and is associated with significant increase in cardiovascular morbidity and mortality
- US prevalence is estimated as **3% of the population (9 million patients)**

The North American and global markets are expected to reach \$1.3 billion and \$2.9 billion in 2020 (respectively)

Comparable companies in the US with developments in FSGS are capitalised at more than \$500 million

- When introduced, the current standard of care medication (irbesartan) was a step change in the treatment of chronic kidney disease patients
- In 2001 irbesartan was studied in a large group of type 2 diabetics. It was shown to reduce proteinuria levels by 24%
- Dimerix's 2017 Phase 2a study showed a further 35.6% reduction of proteinuria levels

Diabetic proteinuria mean reduction 35.6% n=10



Our Phase 2a results represent a quantum leap in the way proteinuria levels can be managed. We are now moving into a further two Phase 2 studies to confirm our results in FSGS and DKD patients.

- Both trials are **randomised, double blind placebo-controlled, crossover studies**
- **“Crossover” trial design** means that **all** patients receive both placebo and DMX-200 on the trials, in randomised order
- These studies will investigate **AT1R** and **CCR2 Targets for Inflammatory Nephrosis**, and have been titled **ACTION**.
- **ACTION FOR FSGS:** Phase 2a trial will study the effects of DMX-200 in around 10 patients with FSGS - endpoints including safety and a number of efficacy (proteinuria reduction)
- **ACTION FOR DKD:** Phase 2b trial will study the effects of DMX-200 in around 40 patients with DKD - primary end point change in 24hr albumin creatinine ratio (ACR) based on identified patient responses in the Phase 2a study

DMX-200 Timelines



Completed activities

| Activity | 2015 | 2016 | 2017 | H1 2018 | H2 2018 | H1 2019 | H2 2019 | 2020 |
|---|--|-------------|-------------------|--|---|---------|---------|--------------------------------------|
| Phase 2a CKD “all comers” study | Completed activities | | | | | | | |
| FSGS + DKD CRO appointment, ethics submissions, lead site | | | | Completed activities | | | | |
| Phase 2a in FSGS | | | | | Current development activities | | | |
| Phase 2b in DKD | | | | | Current development activities | | | |
| Orphan Drug Designation | US Completed activities | | | | Europe Current development activities | | | |
| Regulatory Authority engagement | US pre IND Completed activities | | | | European authority and US IND filing Current development activities | | | |
| Intellectual Property | Australian patent ★ | US patent ★ | Japanese patent ★ | Ongoing examination in Europe and new applications for dose and formulation Current development activities | | | | |
| Single pivotal FSGS Phase 3 | | | | | | | | Dimerix or partner future activities |
| Licensing opportunities | FSGS, DKD, core patents Current development activities | | | | | | | |

DMX-200 for FSGS and DKD

- ✓ **Ongoing** – Partnering discussions for FSGS and DKD
- ✓ **CY18Q2** – Principal Investigator and CRO engaged for ACTION studies
- ❑ **CY18Q2** – Ethics applications for ACTION studies
- ❑ **CY18Q3** – Sites open and commencement of patient recruitment for ACTION studies
- ❑ **CY18Q3** – European orphan drug application for FSGS (already granted in the US)
- ❑ **CY18Q4** – European regulatory engagement for FSGS development path
- ❑ **CY19Q1** – Commercial manufacturing data available for regulatory filings
- ❑ **CY19Q3** – Preliminary ACTION for DKD data available
- ❑ **CY19Q4** – Preliminary ACTION for FSGS data available

DMX-200 Intellectual Property – a licencing opportunity

- Dimerix has **granted patents** in the **USA, Australia and Japan** covering our lead program DMX-200 (US patent no. 9,314,450); and pending applications in Europe and other major jurisdictions including
- The 9,314,450 patent covers the **use of CCR2 antagonists** in conjunction with, or sequential to, administration of **angiotensin receptor blockers (ARBs)**, inclusive of treatment of CKD – **potentially a license opportunity to any company developing a CCR2 antagonist to be used with an ARB**
- Additional patent applications filed for formulation and dosage regimes for DMX-200
- The therapeutic use patent expires in **2032**



The Director of the United States
Patent and Trademark Office

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

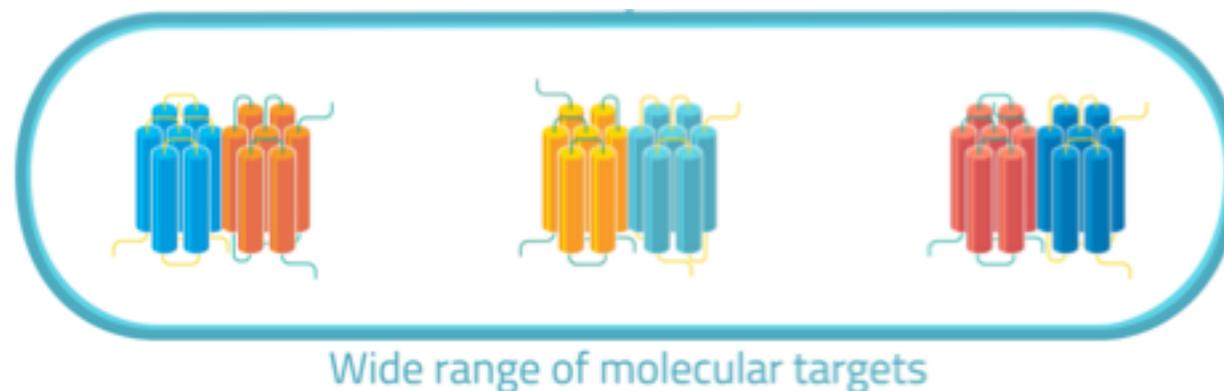
Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America, and if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States of America, or importing into the United States of America, products made by that process, for the term set forth in 35 U.S.C. 154(a)(2) or (c)(1), subject to the payment of maintenance fees as provided by 35 U.S.C. 41(b). See the Maintenance Fee Notice on the inside of the cover.

David J. Kappas

Director of the United States Patent and Trademark Office

Receptor-HIT

- Patented tool that enables understanding of receptor interactions
- Particularly suited to G-Protein Coupled Receptors (GPCRs) – most targeted receptor class for drug discovery
- Can identify **new uses** for existing drugs and drive the **discovery** of new drugs and research programs



Global pharmaceutical companies need access to Receptor-HIT technology to develop safe new drugs

1. Strong track record in delivering regulatory, patent and clinical milestones
2. Two Phase 2 trials in kidney diseases about to commence, as a follow up to last year's Phase 2a trial, where compelling clinical data was seen
3. Significant market opportunity – across the areas of FSGS (orphan disease) and DKD
4. Funded to progress Phase 2 trials to significant inflection points



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