

DMX-200 Phase 2a trial

Strong safety and encouraging efficacy signals

Investor presentation

12 July 2017

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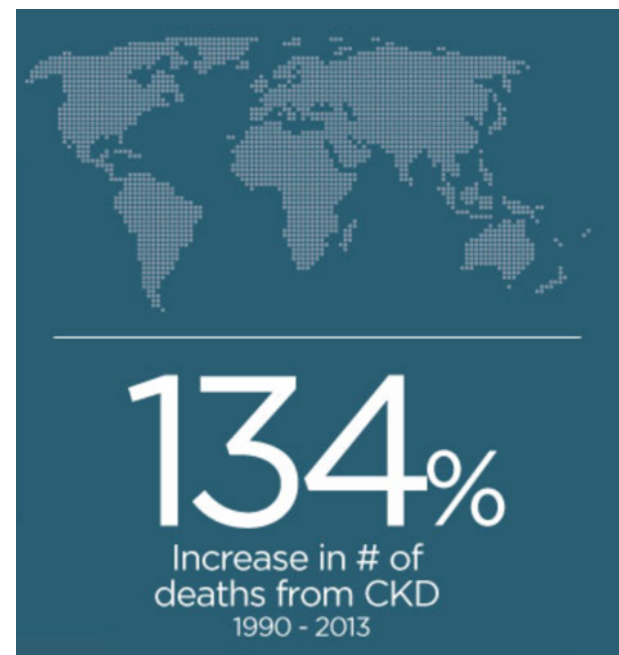
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1. Phase 2a clinical trial for Chronic Kidney Disease (CKD) now complete in 27 patients
2. **Phase 2a results**
 - **primary endpoint of safety and tolerability met**
 - **encouraging efficacy data (secondary endpoint) – deemed clinically meaningful**
3. Data informs dosing and patient population for Phase 2b trial design
4. Relatively low cost and short timeframe of lead clinical program, DMX-200, due to repurposing and Orphan Drug Designation
5. Further drug development and licensing opportunities using Dimerix's patented Receptor- HIT platform technology

Chronic kidney disease (CKD)

- CKD is a growing global health problem affecting over 13% of Australians, 14% of Americans.
- Growing in incidence due to large number of people living with obesity and diabetes.
- Damaged kidneys “leak” proteins into the urine. This is called proteinuria, and itself compounds the damage to the kidneys.
- Proteinuria is the most common symptom of the disease and is a strong indicator of future kidney deterioration.
- Standard of care therapy is focused on reduction of blood pressure.
- Deterioration leads to dialysis and/or transplant, which both have a huge impact on patient quality of life and healthcare budgets.



Source: Global Burden of Disease Study 2013

- DMX-200 is an ‘adjunct’ therapy, which makes the development path less complex.
- Patients continue taking their standard of care medication (irbesartan) and add a second drug to this (propagermanium), which targets inflammation in the kidney.
- Both drugs have been in use for many years, and their safety profile is well understood.
- The combination of these drugs was identified using our Receptor-HIT discovery platform.

Kidney disease contributes to approximately



of all hospitalisations in Australia

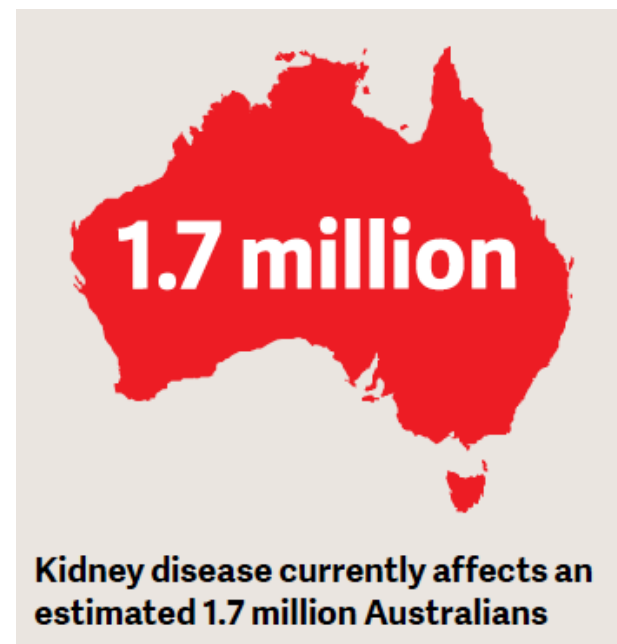
Source: Kidney Health Australia



- 27 patients in an open label dose escalation study across 4 sites in Australia.
- Patients were on stable irbesartan prior to and throughout the study.
- Each patient received an oral dose of DMX-200, which was escalated at four week intervals, unless proteinuria was within normal limits.
- Patients commenced on 10 mg (three times per day) of propagermanium, and were escalated to a maximum of 80mg (three times per day).
- **Primary end point was to determine the safety and tolerability of DMX-200 over a variety of dose ranges, as an adjunct to standard of care drug irbesartan.**
- **Secondary end point was to evaluate the effects of DMX-200 across various biomarkers including proteinuria.**

Phase 2a trial primary endpoint met

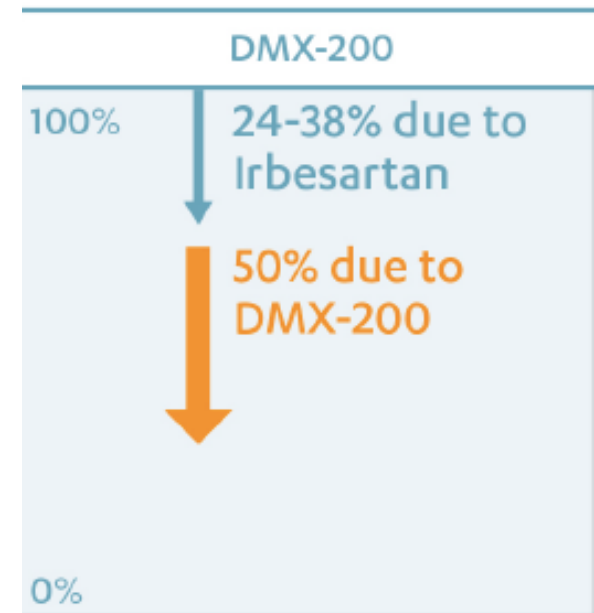
- Primary endpoint met – no serious safety concerns were observed.
- The clinically relevant safety measures were blood pressure (hypertension / hypotension), eGFR (a measure of renal failure) and serum potassium (hyperkalaemia). There were no clinically relevant changes in these primary safety parameters observed.
- Patients were dosed for a median of 28 weeks across the range of doses.
- Three patients withdrew from the study for reasons of anaemia, depression and progression of renal disease, reducing the study size from 27 down to 24 patients.
- DMX-200 was generally well tolerated with an adverse event profile consistent with underlying patient population and associated co-morbidities.



Source: Kidney Health Australia

- 6 of the 24 patients to complete the study achieved >50% reduction in proteinuria during at least one dose level of propagermanium.
- **This is a 50% improvement over and above the patients' stable improvement on standard of care medication (irbesartan*), classifying them as a “responder”.**
- **This result has been deemed clinically meaningful.**

Responders schematic

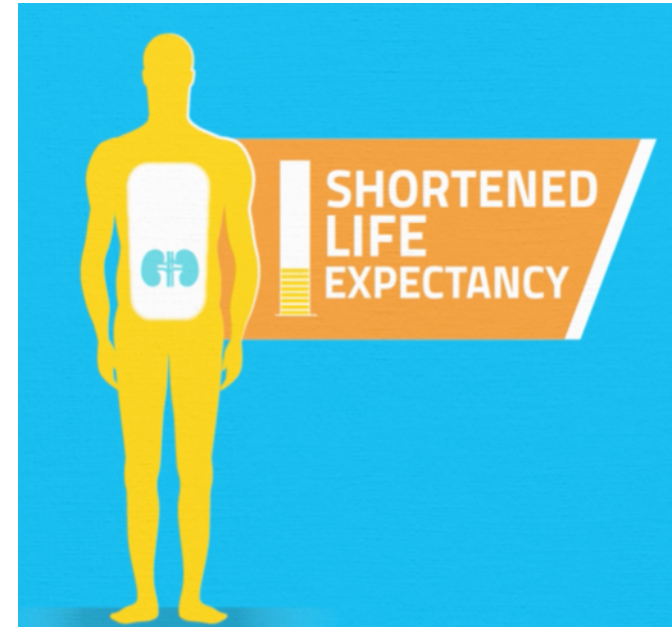


*Double blinded placebo controlled studies in patients with diabetic nephropathy and proteinuria showed irbesartan reduced proteinuria by 24 – 38%

References:

- N Engl J Med (2001) 345:870-878 September 20, 2001 DOI: 10.1056/NEJMoa011489
- Nephrol Dial Transplant (2012) 27: 2255–2263 December 15, 2011 DOI: 10.1093/ndt/gfr696

- *Three further patients, after dosing ceased, saw an increase in proteinuria of 50% or greater, compared to their final measure on treatment.*
- **This increase suggests that DMX-200 may have had a possible benefit in slowing the disease progression in these patients.**
- Only one patient saw a greater than doubling of proteinuria during the study, and was classified by their physician to be showing normal disease progression.



Phase 2a trial outcomes – Special Access Scheme



- Of the 24 patients to complete the study, 11 (45%) applied for and were granted special access to the treatment, upon recommendation of their physician.
- The physicians' recommendation was based on patients meeting one or more of the following criteria:
 - Responders (>50% reduction in proteinuria)
 - Achieving a reduction in proteinuria
 - >50% increase proteinuria 4 weeks after dosing ceased, possibly indicating a benefit in slowing disease progression
- The Australian Therapeutic Goods Administration's Special Access Scheme is a program through which participants in a clinical study can continue to access a drug, following completion of the trial.

Most dialysis patients need treatment at least 3 days a week for 5 hours a session to stay healthy



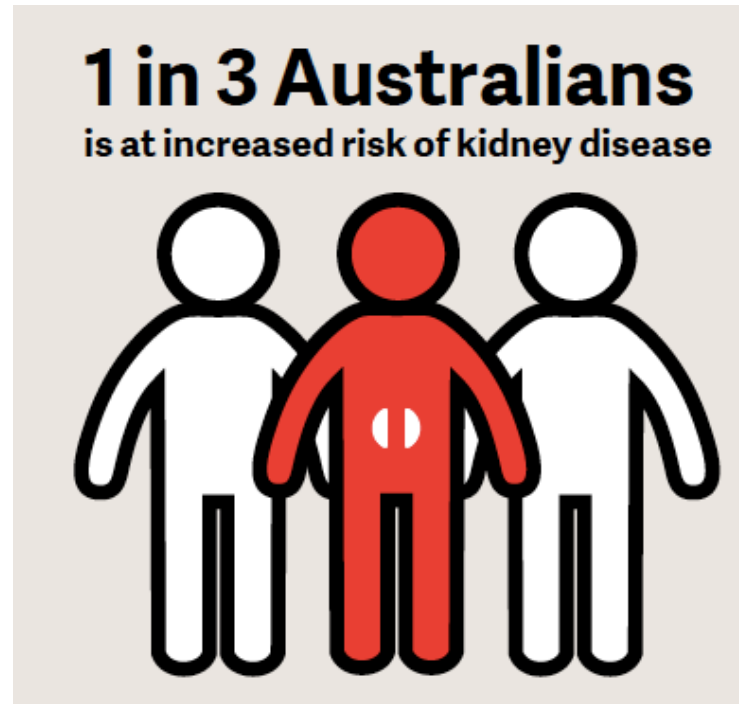
Source: Kidney Health Australia

“These are very encouraging data. DMX-200, and its combination with existing best therapy, appears safe and was well tolerated. A 50% additional 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.”

Associate Professor David Packham, Director of the Melbourne Renal Research Group

David Packham is one of the Principal Investigators on the study. 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).

- Primary end point met – no serious safety concerns were observed.
- Secondary end point encouraging – efficacy – 6 of 24 patients classified as “responders” (>50% reduction in proteinuria clinically meaningful).
- Trial data can now be used to shape phase 2b trial design.
- 11 of 24 patients requesting DMX-200 under TGA’s Special Access Scheme.



Source: *Kidney Health Australia*








- Human pharmacokinetics study on track to complete 2H CY2017.
- Phase 2b – to explore efficacy in refined patient population using optimal doses identified in Phase 2a study, compared with placebo.
- Ongoing discussions with big pharma and key opinion leaders.
- Full data to be presented in a leading clinical forum in due course.

12 months news flow

- Completion of commercial dosage form
- Completion of human pharmacokinetic study
- Commencement of Phase 2b study
- Presentation of 2a data in a scientific forum
- Filing Orphan Drug designation in Europe (2018)
- Meetings with European Regulatory Advisors (2018)

DMX-200 Development & licensing timeline



Activity	Q2 2017	Q3 2017	Q4 2017	2018	2019	2020
Phase 2a						
Manufacture of commercial tablet						
Human PK study - commercial tablet						
Phase 2b						
End of Phase 2 consultation with FDA						
Single pivotal Phase 3						
Licensing opportunities						



Current development activities



Future development activities



Retrophin[®]

- **NASDAQ: RTRX**
- **Market cap : ~US\$ 674million**
- Phase 2 asset, sparsentan, for treating FSGS – a **dual angiotensin endothelin receptor blocker**



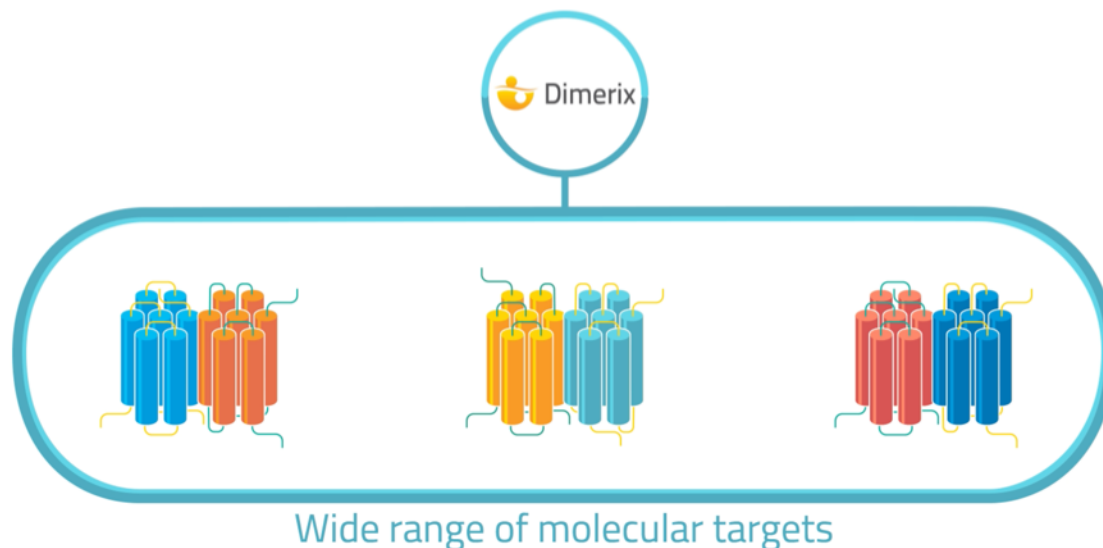
CHEMOCENTRYX

- **NASDAQ: CCXI**
- **Market Cap: ~US\$ 355 million**
- Completed Phase 2 for CCX140 in diabetic nephropathy – a **CCR2 antagonist**
- Vifor licensed CCX-140 from ChemoCentryx with Phase 2 data for use *outside the US* for \$50m upfront

Limited competition in a large market

Receptor-HIT

- Patented tool that enables understanding of receptor interactions
- Particularly suited to 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

Corporate Snapshot

ASX Code:	DXB
Share Price (5 Jul 17):	\$.011
Market cap:	\$20.6m
Cash (31 Mar 2017):	\$2.8m
Shares on issue*:	1,829.9m

Major Shareholders

Mr Peter Meurs	17.33
Yodambao Pty Ltd	5.11
Mrs Wishney Sritharan Krishnarajah	2.47
White Family	2.21
SRV Custodians Pty Ltd	2.07
Pfleger Family	1.70
Jampaso Pty Ltd (Williams Family)	1.51

Share price history





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