

For Immediate Release

DIMERIX PRESENTATION FOR 2018 BIOSHARES CONFERENCE

MELBOURNE, Australia, 27th July 2018: Dimerix Limited (ASX: DXB), a clinical stage biotechnology company, is pleased to announce that Chief Medical Officer, Associate Professor David Packham will be presenting at the Bioshares Biotech Summit conference in New Zealand today.

The Bioshares conference will be held from 27-28 July and attended by a range of investors, analysts and industry peers, with conference topics exploring current themes and trends in the area of biotechnology.

Associate Professor Packham will present on Dimerix's work in the field of Diabetic Kidney Disease and how the Company is working to provide a new treatment option for what is considered an area of high unmet patient need.

Diabetic Kidney Disease (DKD) is the focus of one of the two Phase 2 trials for which Dimerix has recently received ethics approval, alongside the trial for the orphan disease, Focal segmental glomerulosclerosis (FSGS). DKD is a huge and growing unmet medical need with increasing numbers progressing to dialysis. The Company remains on track to recruit patients into both trials this quarter.

Details of the presentation:

Session title: Drugs are good

Session date/time: Friday 27 July, 1.10pm

A copy of the presentation is appended with this cover note.

For further information, please visit our website at www.dimerix.com or contact the individuals outlined below.

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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.

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 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 ⁽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. This was deemed a "clinically meaningful" result by leading clinicians. Sub set analysis released in November 2017 showed both a statistically significant and clinically meaningful reduction in proteinuria in the diabetic nephropathy cohort of patients

Dimerix has recently received ethics approval to take DMX-200 into two parallel clinical trials to test efficacy. The two trials are comprised of a group of Diabetic Kidney Disease patients; and a separate group of patients with focal segmental glomerulosclerosis (FSGS), a rare disease for which Dimerix has orphan drug designation in the US. The trials are expected to commence in calendar Q3 2018.

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. CKD has a number of different types including Diabetic Kidney Disease (DKD), and Focal Segmental Glomerulosclerosis (FSGS).

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.

Focal segmental glomerulosclerosis (FSGS) is a major cause of proteinuria in children and adolescents, as well as a major cause of kidney failure in adults. FSGS is the leading primary glomerulonephritis causing end stage renal disease (ESRD) in the US. The unmet need is reinforced by Dimerix's Orphan Drug Designation.

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.

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

DMX-200 for Diabetic Kidney Disease

A/Prof David Packham
MBBS(Hons), FRCP, FRACP, ARCP, MD

Chief Medical Officer, Dimerix
Nephrologist

Bioshares Summit
Queenstown, New Zealand
27 July 2018

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Corporate snapshot

ASX code:	DXB
Share price (16 July 18):	\$0.099
Market cap:	\$15.7m
Cash (30 Mar 2018):	\$7.7m
Shares on issue	158.8m

Share price history



Upcoming clinical milestones

- ✓ **18 July** – Ethics approvals for both 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)
- ❑ **CY19Q4** – Preliminary ACTION for DKD data available
- ❑ **CY19Q4** – Preliminary ACTION for FSGS data available

- Prevalence of Type 2 diabetic kidney disease
- Therapeutic options
- Mechanisms of chronic kidney disease progression
- DMX-200
 - Discovery
 - Development plan
- Concluding remarks

- There are 1-1.5 million type 2 diabetics in Australia
- There are 30-84 million type 2 diabetics in the USA
 - 40% have or will develop diabetic kidney disease (DKD)
 - Increasing need for renal replacement therapy (dialysis or kidney transplant)
 - 25 years ago, rare to dialyse patients over 60. Now majority are offered dialysis
 - Peak incidence 75-79 year age group – multiple morbidities
- In Australia:
 - Approximately 1,000 patients with DKD start dialysis each year
 - Approximately 6,000, or 40% of all patients receiving dialysis have type 2 diabetes
 - Annual cost \$80,000 - \$100,000 for dialysis per patient

Increased development of DKD therapeutics

Year of approval for DKD
(all are now generic)

In development



Bristol-Myers Squibb
Captopril (ACE)




MERCK
Losartan (AT1R)




SANOFI
Irbesartan (AT1R)



Dimerix
DMX-200 (AT1R & CCR2)



CHEMOCENTRYX
CCX-140 (CCR2)



mesoblast
the regenerative medicine company
Stem cells



Retrophin®
Sparsentan (AT1R & ET_A)



Boehringer
Ingelheim
BI 685509 (sGC)



BAYER
Finerenone (MR)
BAY1142524 (chymase)



AstraZeneca
Dapagliflozin (SGLT2)



janssen
Canagliflozin (SGLT2)

TEIJIN
TMX-049 (XO)

KYOWA KIRIN
Bardoxolone (inflammation)

1990

2000

2010

2020

- Correlates with severity and prognosis
- Are drivers of progressive renal damage
- FDA and EMA: 30% reduction in urinary albuminuria is one mechanism for Accelerated Approval of DKD



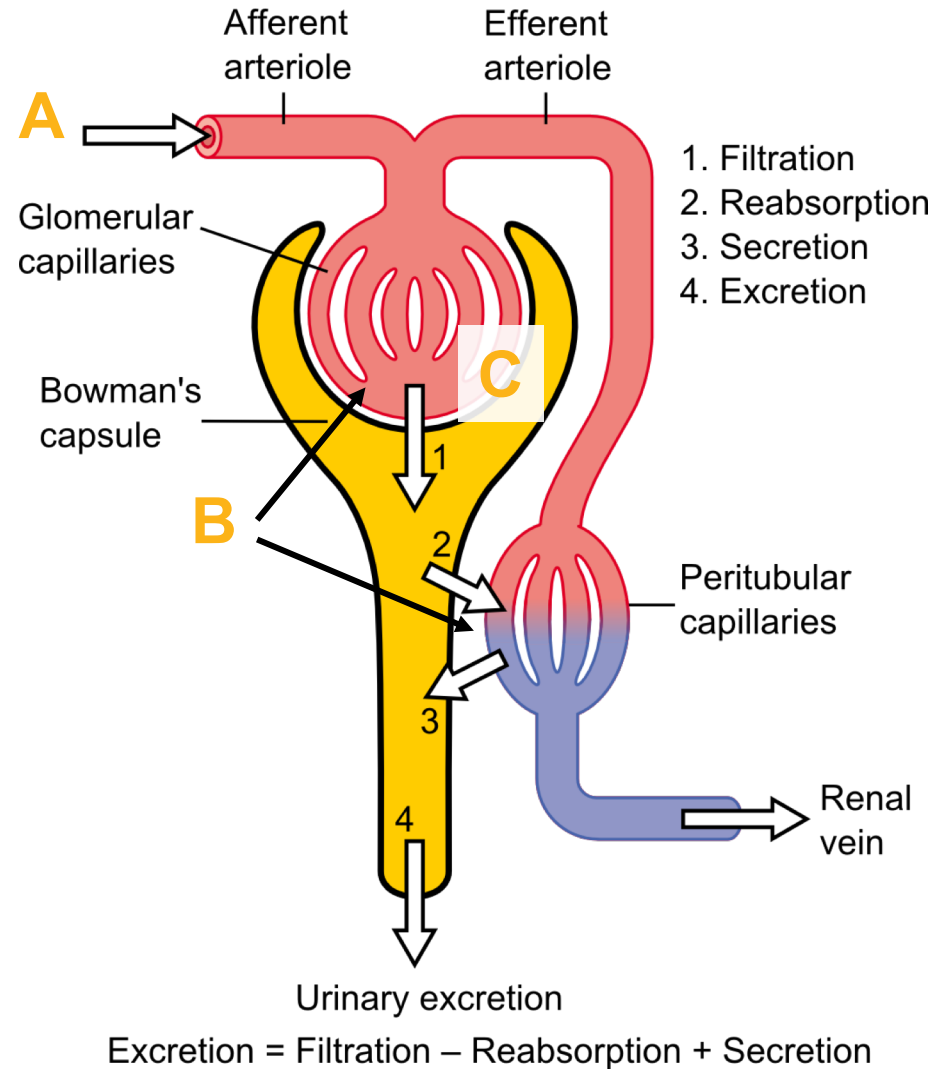
Change in Albuminuria and GFR as End Points for Clinical Trials in Early Stages of Chronic Kidney Disease

A Scientific Workshop Collaboration by the National Kidney Foundation,
the European Medicines Agency
and the U.S. Food and Drug Administration

March 15-16, 2018

Mechanisms of DKD progression

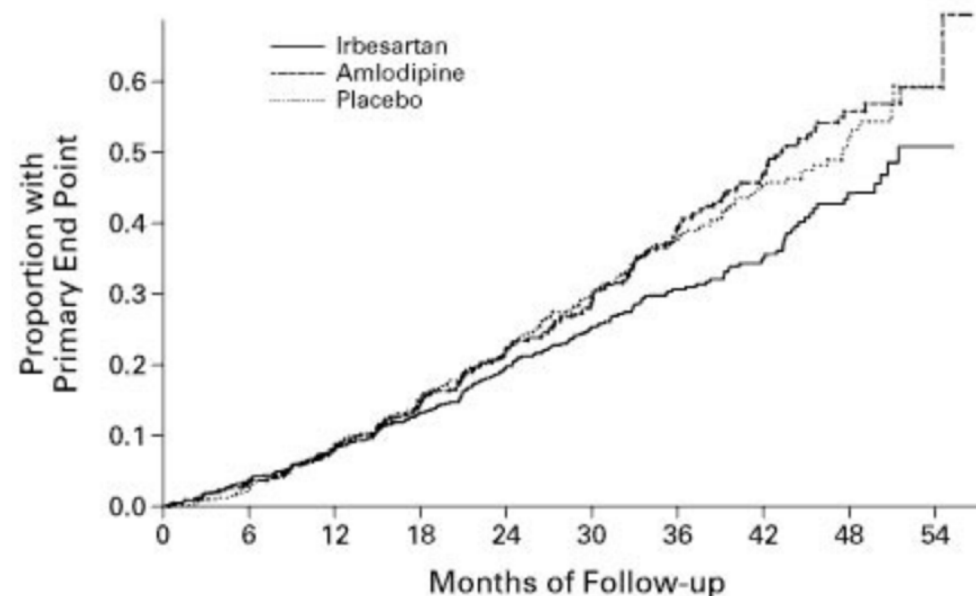
- A. Hyperfiltration
- B. Inflammation/Infiltration
- C. Podocyte damage/loss



A. Hyperfiltration

- **Glomerular** hypertension
- ACE/ARB blockade highly effective: efferent greater than afferent
- Importance of hyperfiltration: IDNT (irbesartan) and REENAL (losartan) studies

IDNT primary end point:
composite of a doubling of
the base-line serum
creatinine concentration,
the onset of end-stage
renal disease, or death
from any cause



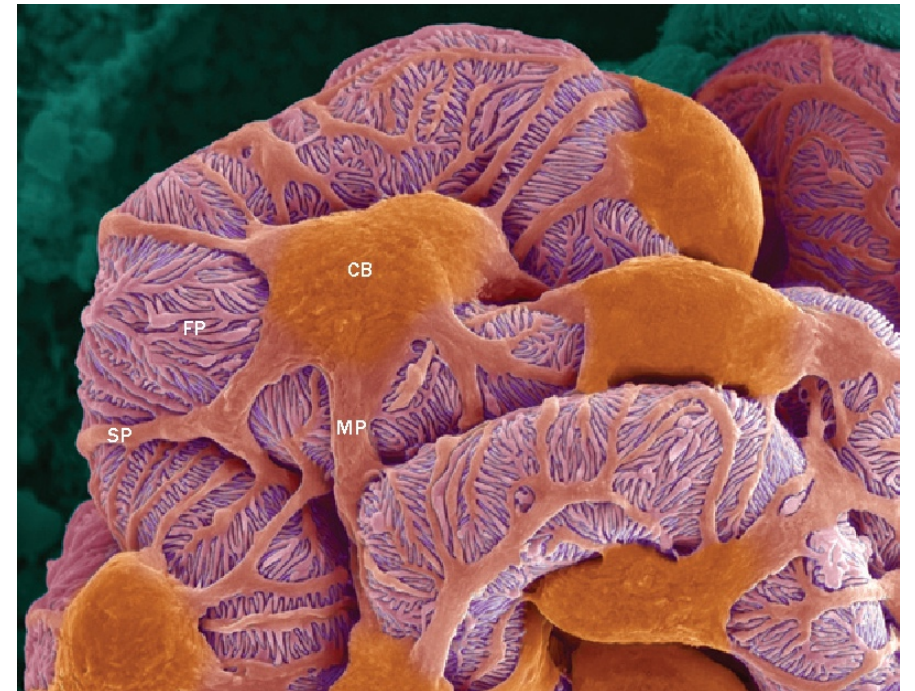
24% decrease in
albuminuria in group
treated with irbesartan
compared to placebo

B. Inflammation, infiltration and fibrosis

- Correlates with severity and prognosis of DKD
- Drivers of progressive renal damage
- Therapeutic attempts to prevent, modify or halt progression
- Recent studies in sulodexide, bardoxolone, atrasentan
- Activation of chemokine receptor 2 (CCR2) attract activated monocytes into kidney

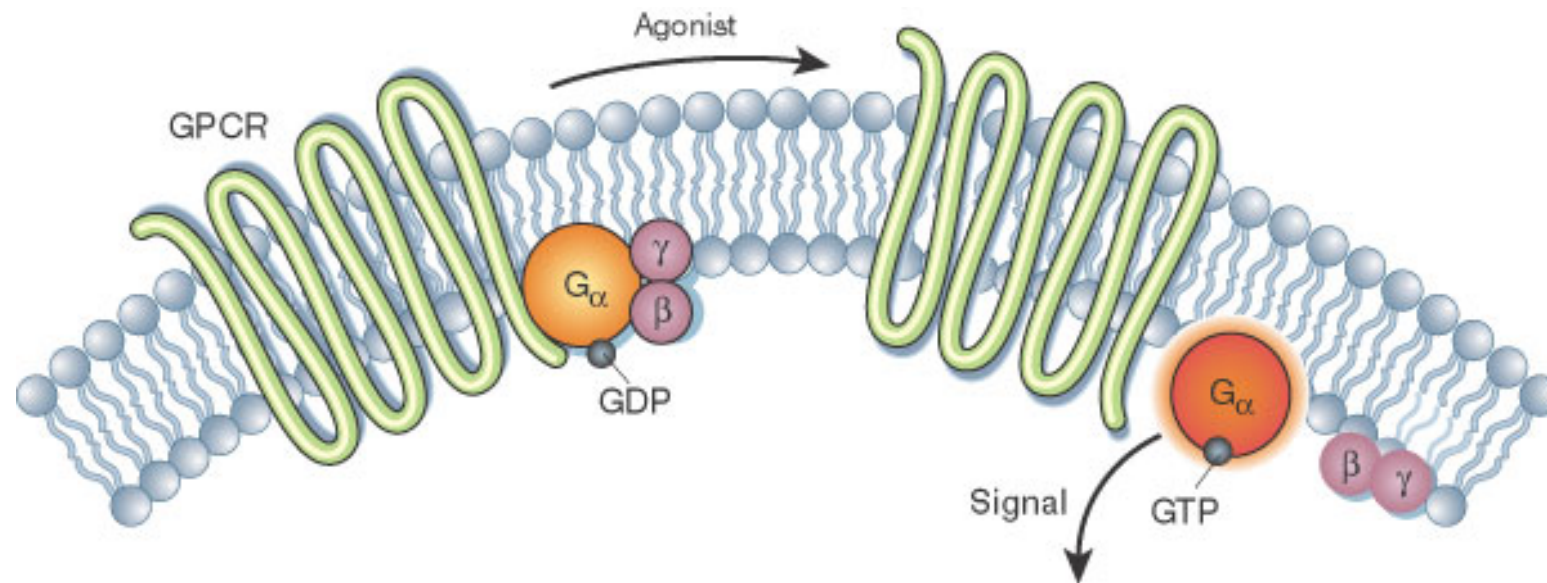
C. Podocyte loss

- Specialised cells unable to regenerate
- Loss correlates with severity and prognosis
- Loss drives progressive renal damage
- Express both AT1R and CCR2 receptors



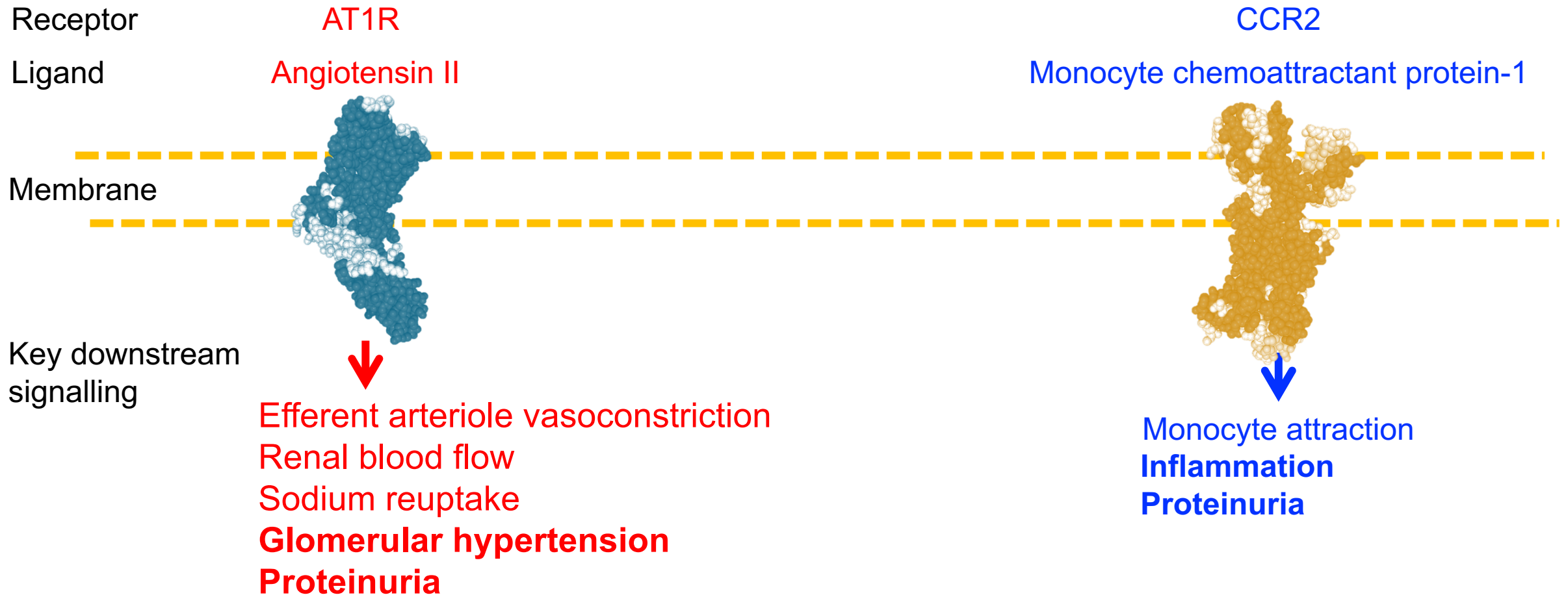
DMX-200 acts through GPCRs

- G-Protein Coupled Receptors are the target of 30-40% of all known drugs
- Robert Lefkowitz and Brian Kobilka won the 2012 Nobel Prize for chemistry for studies of G protein–coupled receptors



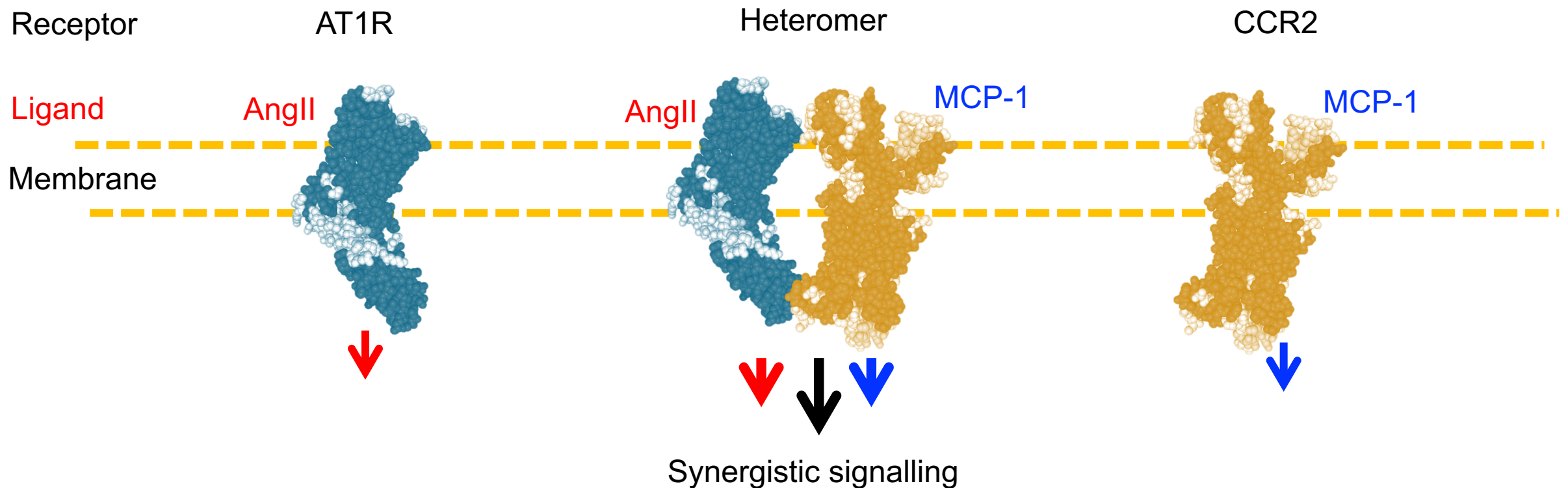
AT1R and CCR2 receptors

- AT1R and CCR2 are GPCRs expressed on podocytes and other kidney cells
- Activation promotes kidney damage

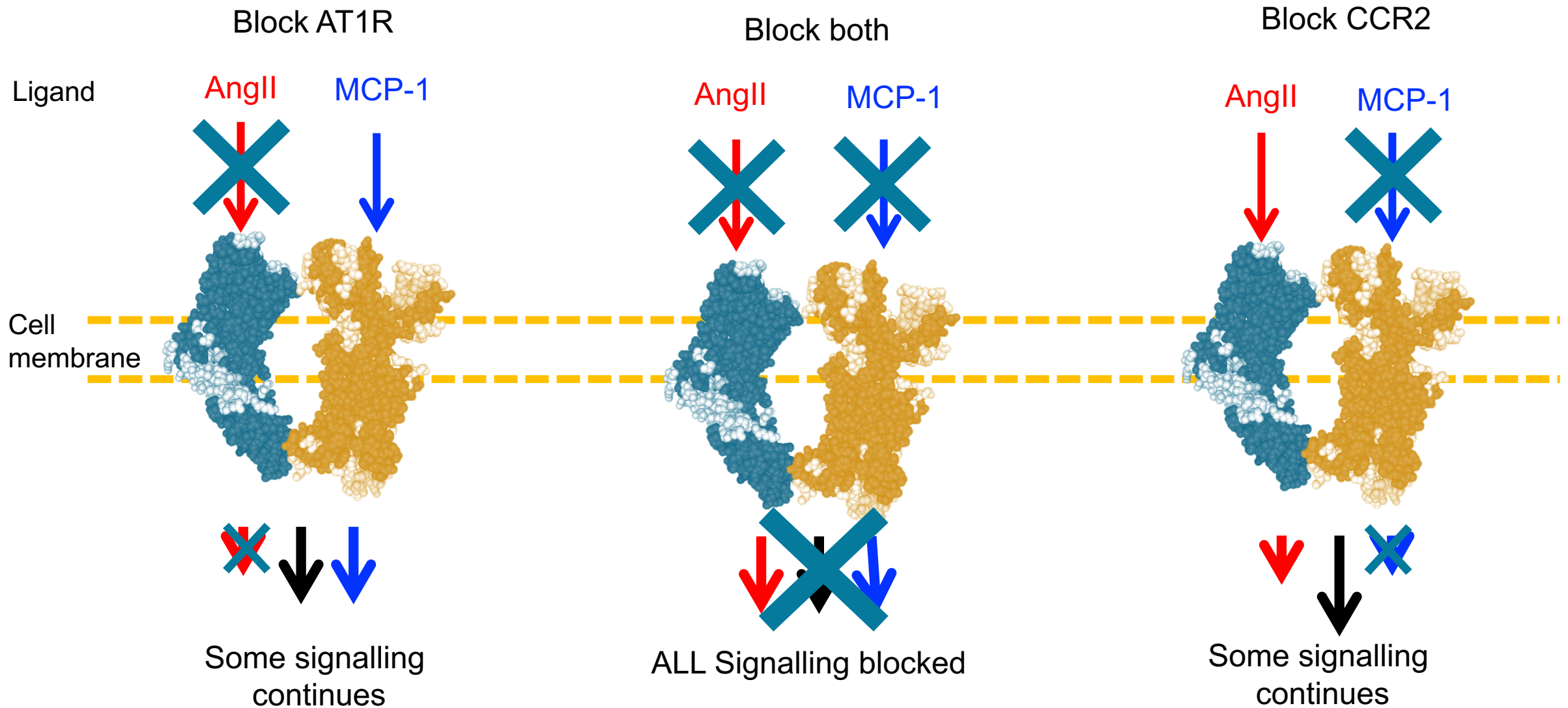


Heteromerisation of AT1R and CCR2

- AT1R and CCR2 are GPCRs expressed on podocytes and other kidney cells
- AT1R and CCR2 signal as monomers **and** heteromers
- Synergy identified with DXB platform technology



Inhibition AT1R & CCR2 heteromers



*Simultaneous inhibition of AT1R & CCR2 will
have a greater than additive renal benefit
compared to inhibition of each receptor alone*

What is DMX-200?

Co-administration of 2 drugs to achieve a **synergistic** renal effect

- Irbesartan - angiotensin receptor blocker (ARB)
 - Small molecule
 - Global approval as anti-hypertensive, and FDA (USA) approval for diabetic kidney disease
- Propagermanium (PPG) - CCR2 antagonist
 - Small molecule
 - PDMA (Japan) approval for chronic hepatitis B

Irbesartan

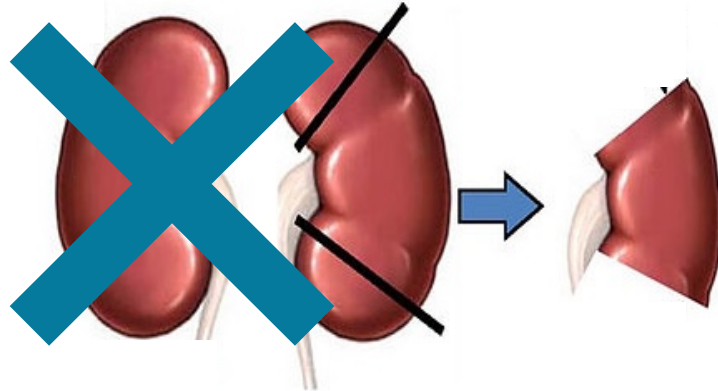


Propagermanium

+

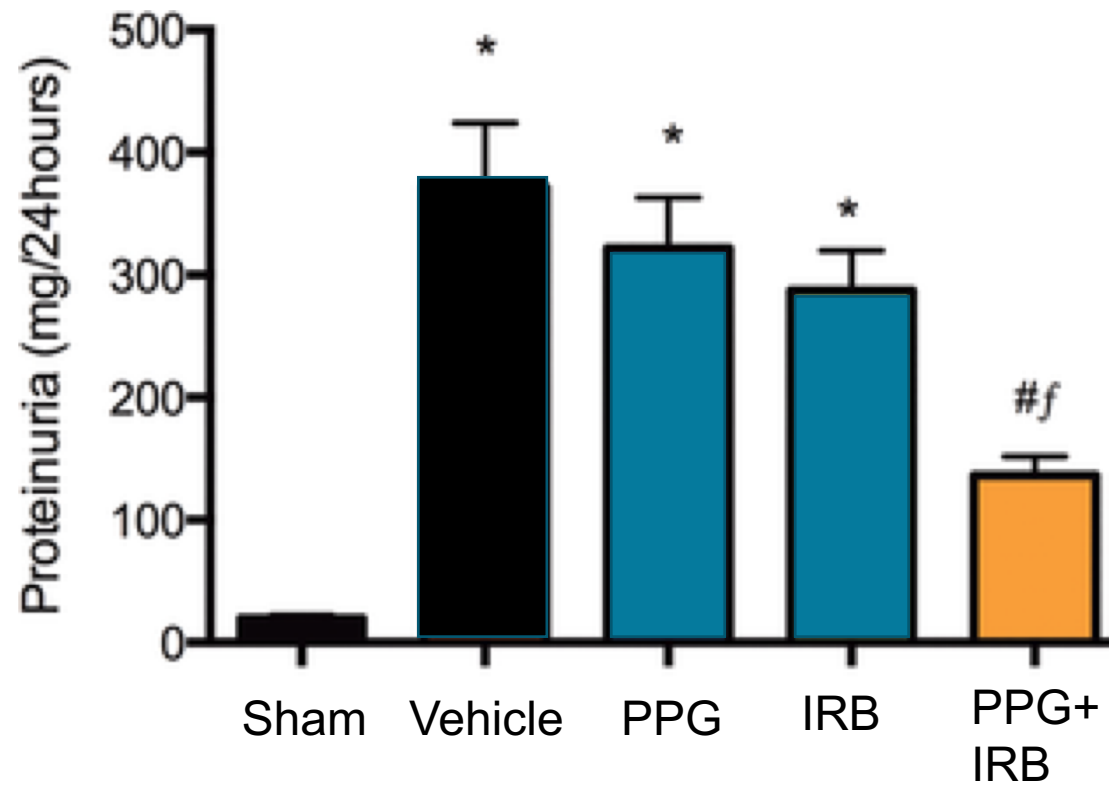


Surgically remove 5/6th of the rodent kidney

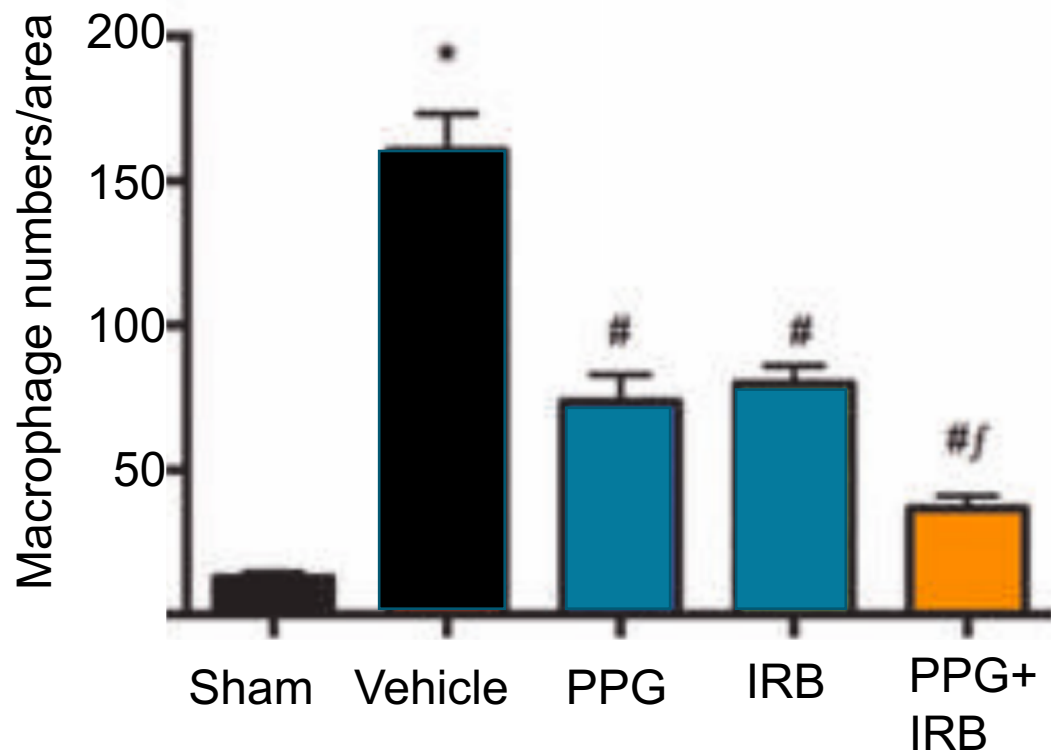


- Hyperfiltration
 - Glomerular hypertension
 - Interstitial inflammation
 - Fibrosis
 - Podocyte loss
-
- Proteinuria
 - Progressive renal failure

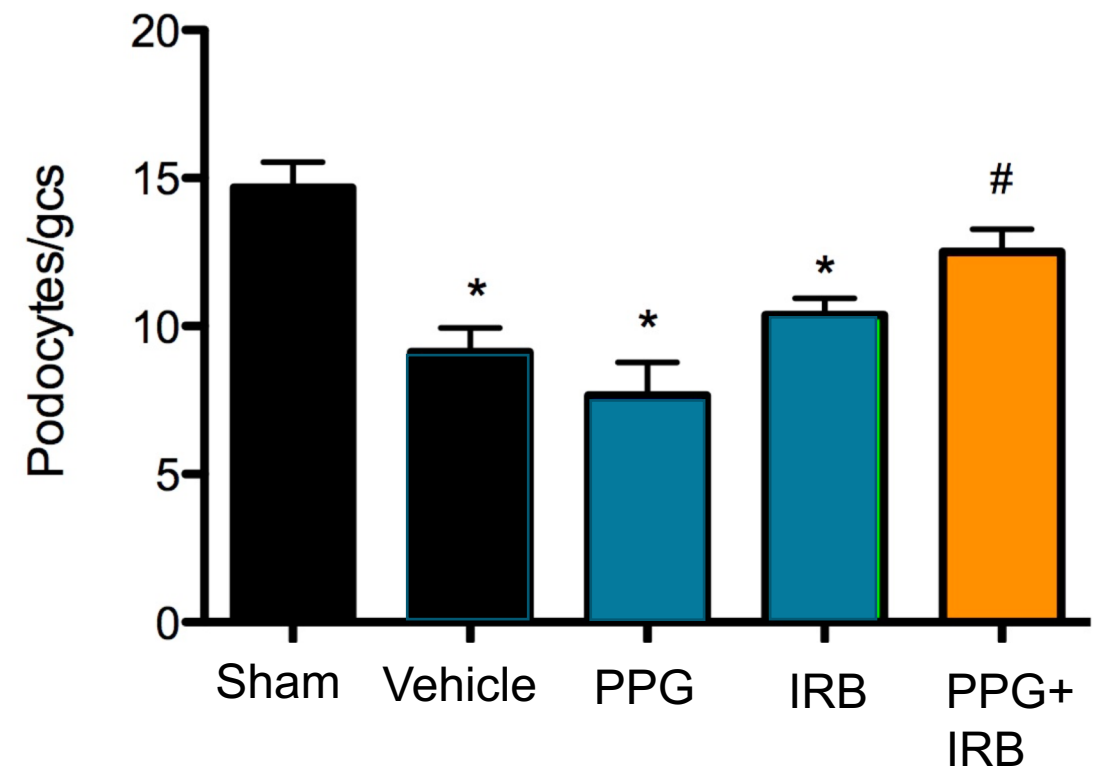
Reduced proteinuria



Decreased macrophage infiltration



Preservation of podocyte numbers



- Broad, class based claims granted in US and Australia (any CCR2 antagonist with any angiotensin receptor blocker)
- Current clinical studies defining broader composition protection



US009314450B2

(12) United States Patent Pfleger et al.	(10) Patent No.: US 9,314,450 B2 (45) Date of Patent: Apr. 19, 2016
(54) COMBINATION THERAPY	(56) References Cited
(75) Inventors: Kevin D. G. Pfeleger , Nedlands (AU); Elizabeth McCall , Dalkeith (AU); James Williams , Kensington (AU)	U.S. PATENT DOCUMENTS 4,391,904 A 7/1983 Litman et al. 4,671,958 A 6/1987 Rodwell et al. 4,751,180 A 6/1988 Connors et al. 4,925,673 A 5/1990 Steiner et al. 4,935,233 A 6/1990 Bell et al. 5,013,556 A 5/1991 Woodruff et al. 5,492,904 A 2/1996 Wong 5,663,188 A 9/1997 Fossa et al. (Continued)
(73) Assignee: DIMERIX BIOSCIENCE PTY LTD. , Victoria (AU)	FOREIGN PATENT DOCUMENTS EP 1 422 228 5/2004 JP 2005-528721 9/2002 (Continued)
(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 407 days.	OTHER PUBLICATIONS Del et al. <i>J. Cardiovascular Pharmacology</i> , 2001, 38, 395-405.* Yanahita et al. <i>Arterioscler. Thromb. Vasc. Biol.</i> , 2002, 22, 969-974.* Gupta, Achla. "Targeting Opioid Receptor Heterodimers: Strategies for Screening and Drug Development". <i>The AAPS Journal</i> 2006, 8 (1) Article E6, pp. 153-159. Gurskaya, Nadya G. "GFP-like chromoproteins as a source of far-red fluorescent proteins". <i>FEBS Letters</i> 507 (2001) 16-20. Hamdan, Tadi F. "High-Throughput Screening of G-Protein-Coupled Receptor Antagonists Using a Bioluminescence Resonance Energy
(21) Appl. No.: 13979,127	
(22) PCT Filed: Jan. 11, 2012	
(86) PCT No.: PCT/AU2012/000014 § 371 (c)(1), (2), (4) Date: Jul. 10, 2013	
(87) PCT Pub. No.: WO2012/094703 PCT Pub. Date: Jul. 19, 2012	
(65) Prior Publication Data US 2013/0289084 A1 Oct. 31, 2013	

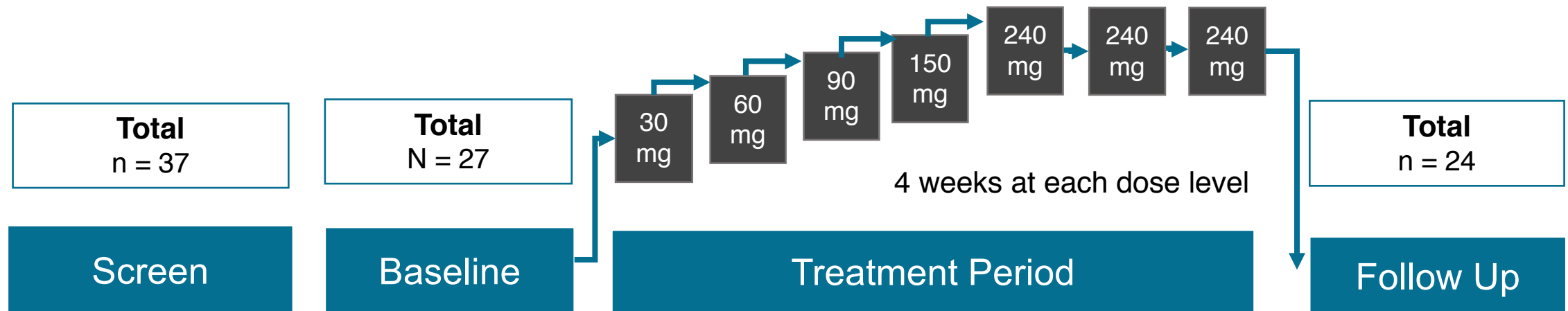
DMX-200 Study design Phase 2a

Primary Endpoints

- Incidence and severity of Adverse Events
- Clinically significant changes in the safety profile of participants (biochemistry, hematology, urinalysis, physical examinations)

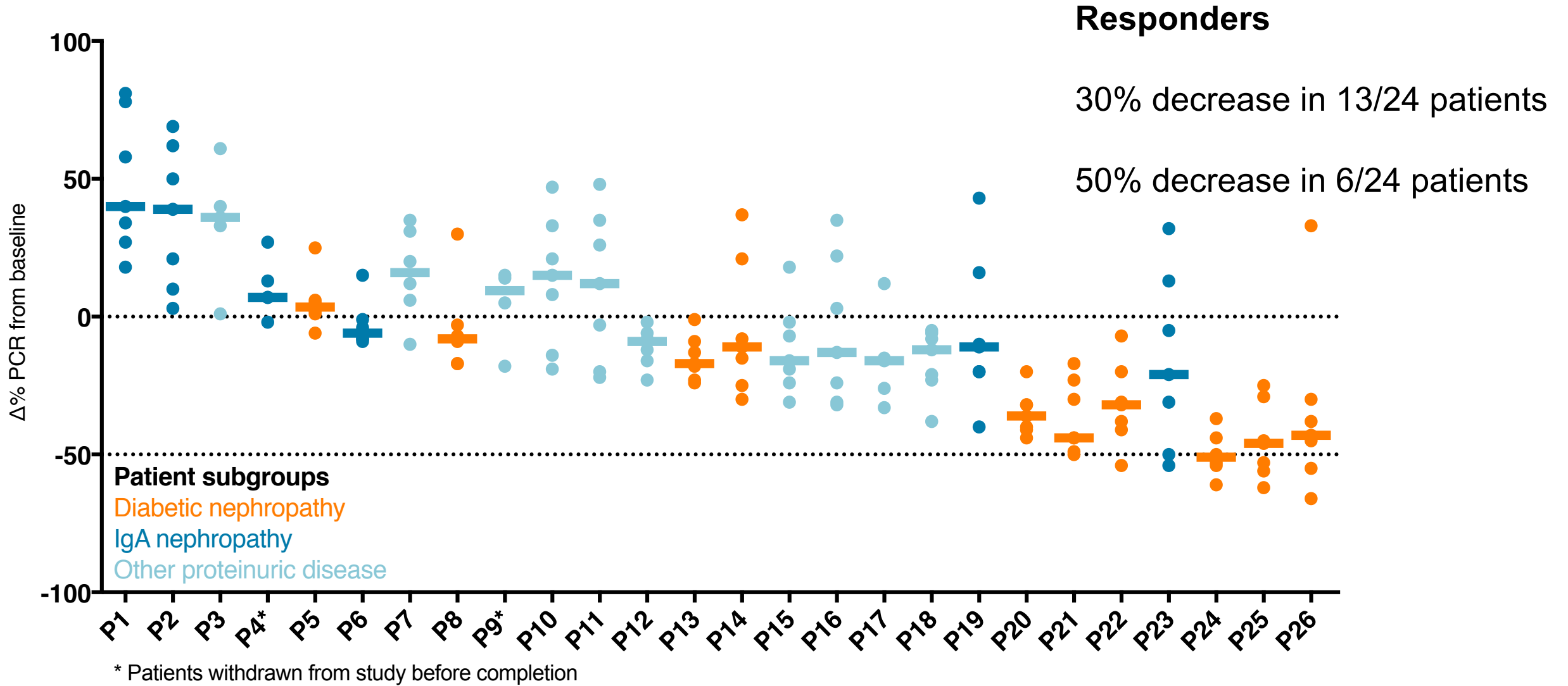
Secondary Endpoints

- The proportion of responders, defined as those participants achieving normalization of proteinuria or a 50% reduction in proteinuria

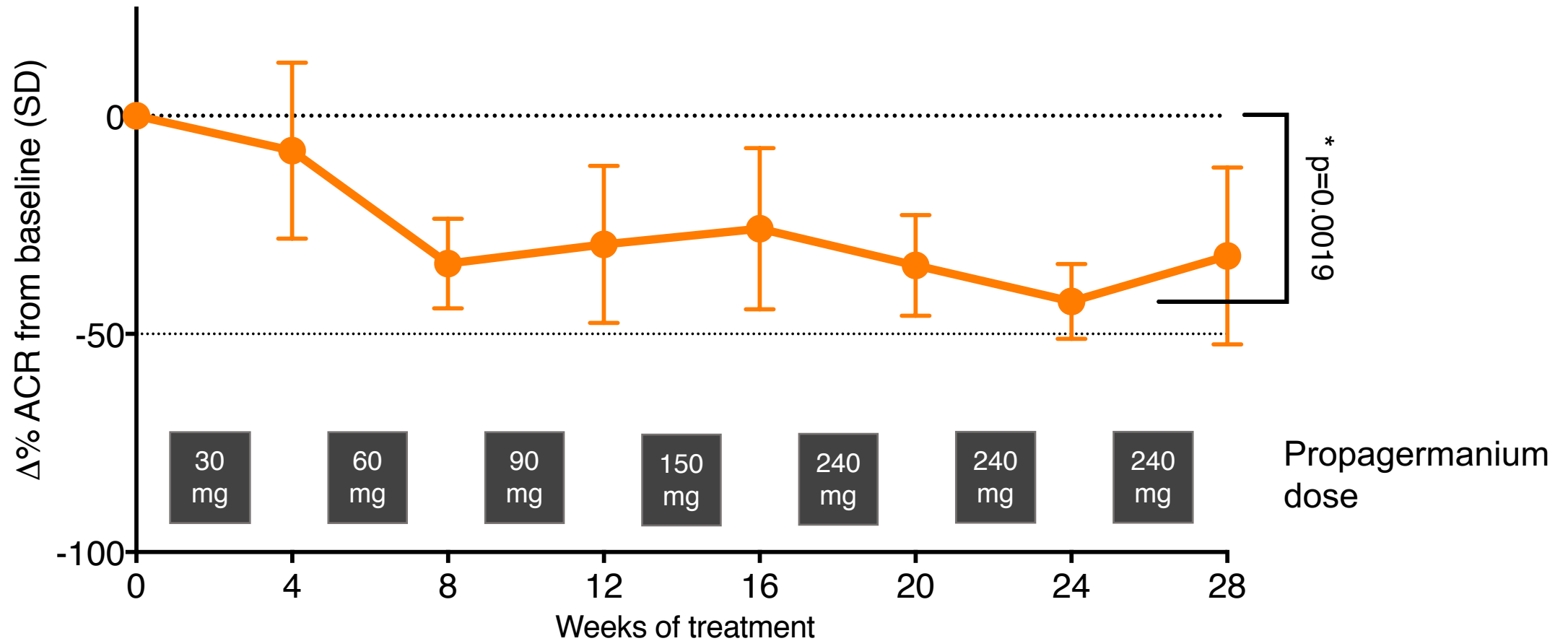


Patients on stable irbesartan at least 3 months prior to and during treatment period

Phase 2a efficacy summary (N=27)

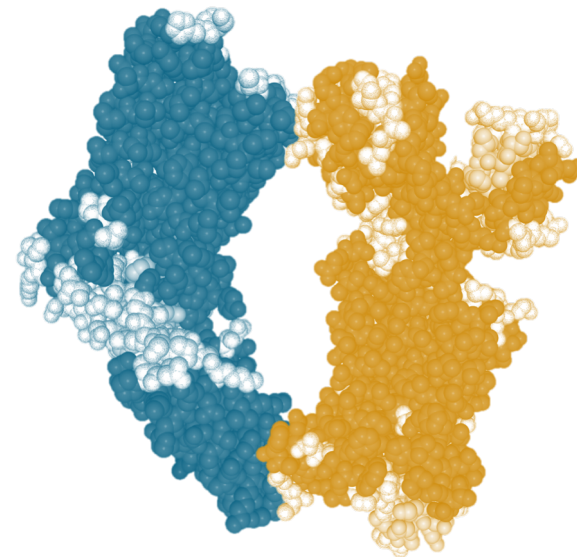


ACR mean reduction 35.6% n=10



Angiotensin II Type 1 Receptor (**AT1R**) & Chemokine Receptor 2 (**CCR2**) Targets for **Inflammatory Nephrosis**

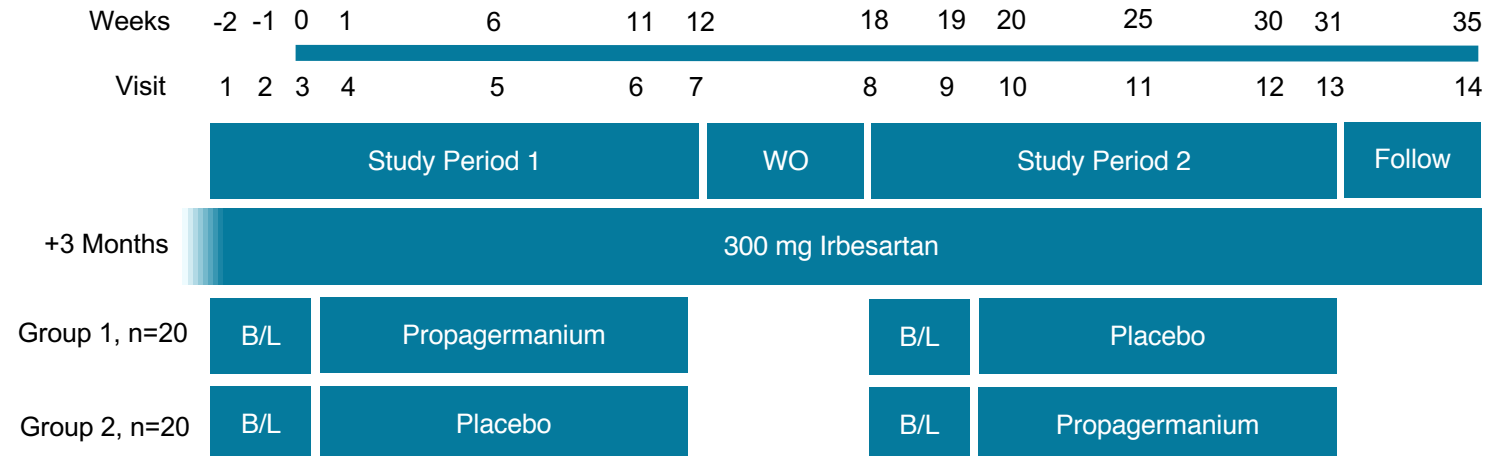
ACTION for DKD



Design of DMX-200 ACTION for DKD

2-way crossover design allows:

- Improved statistical power as each patient is their own control
- All patients to receive therapy
- Powered to detect a 30% reduction in proteinuria



Ethics approval announced 18 July 2018

