



Dimerix DMX-200 Phase 2a Data

3rd November 2017

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1. Using proprietary “Receptor HIT” drug discovery platform to identify multiple development programs
2. Lead program is DMX-200 in Phase 2 human trials for Chronic Kidney Disease (CKD)
 - Uses compounds that are already known
 - Orphan Drug in house development path, targeting Focal Segmental Glomerulosclerosis (FSGS)
3. **Positive Phase 2a results – diverse group of patients across multiple sub-groups**
4. **Compelling Diabetic Nephropathy Data – a licensable opportunity**
5. DMX-200 Phase 2b study to provide data for 3 CKD sub-group indications, including FSGS as lead orphan indication and out licence, diabetic nephropathy for out licencing, IgA nephropathy as potential follow on orphan indication with out license opportunity.

Corporate overview

Corporate Snapshot

ASX Code	DXB#
Share Price (25 Oct 17)	\$0.185
Market cap	\$17m
Cash (30 Sep 2017)	\$1.6m
(R&D tax incentive, \$545,771 received 17 th October 2017)	
Shares on issue*	91.9m

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

#Consolidation completed 31st October 2017

Share price history



Experienced board and management

Dr James Williams – Chairman



- Co-founder of Dimerix and iCeutica (acquired in 2011 and now with 3 FDA drug approvals)
- Co-founder and Investment Director of Yuuwa Capital (\$40M venture fund)

Hugh Alsop – Director



- Accomplished and commercially-focused pharmaceutical and biotechnology executive
- Responsible for successful global commercialisation programs and NDA registrations

Kathy Harrison – Chief Executive Officer



- 20 years operational and strategic experience in drug development including at AMRAD, Cytopia Research Pty Ltd, Phosphagenics Ltd
- Registered Patent Attorney

David Franklyn – Director



- Experienced Director of ASX-listed companies in a variety of sectors
- Extensive experience in financial analysis, corporate advice, business management and IR

Dr Robert Shepherd – Head of Drug Development



- Drug developer with experience in a wide range of projects / therapeutic areas
- PhD in biomedical research, and background in finance and project management

Dr Sonia Poli – Director



- Former Senior Management at Hoffman la Roche and Executive at Addex Therapeutics
- 20 years international experience in small molecule drug development

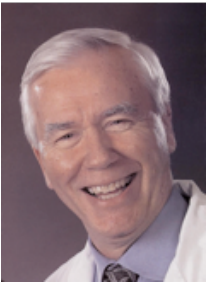
Medical advisory board

David Packham – Chair



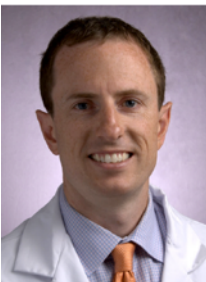
- Director of the Melbourne Renal Research Group.
- More than 30-years experience participating in over 40 international clinical trials in a variety of chronic kidney conditions, and serves on advisory boards for Astra Zeneca, Otsuka and Vifor.

Daniel Cattran



- Professor of Medicine at the University of Toronto and Senior Scientist at the Toronto General Research Institute.
- Chair of the Toronto Glomerulonephritis Registry, which currently includes over 12,000 cases of biopsy proven GN.

Jonathan Hogan



- Assistant Professor of Medicine and Clinical Director of the Glomerular Disease Centre at the University of Pennsylvania.
- Dr Hogan is a nationally-recognized expert in glomerular diseases and onconeurology, and has published more than 25 papers in peer reviewed medical journals

David Power



- Director of Nephrology at Austin Health and Professorial Associate at the University of Melbourne.
- Recipient of multiple competitive research grants from the MRC (UK) and the NH&MRC (Australia) and author of over 150 peer-reviewed scientific publications

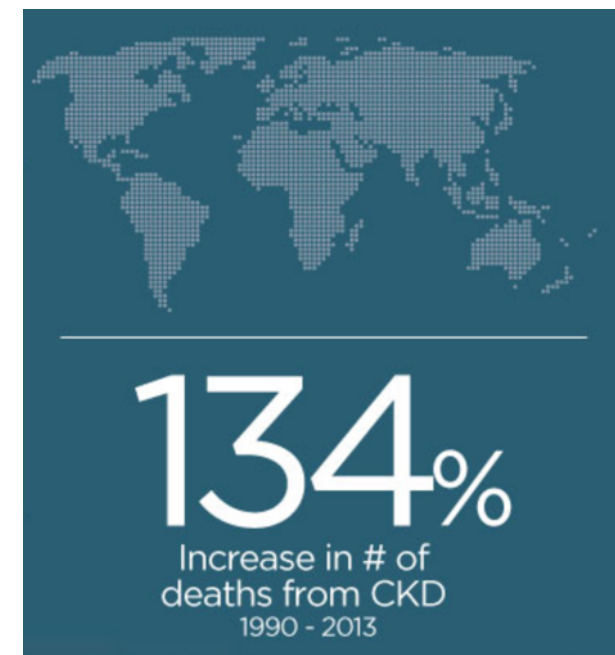
Alessia Fornoni



- Chief of Nephrology and Hypertension at the University of Miami Miller School of Medicine and Chair of the Peggy and Harold Katz Drug Discovery Centre.
- Vice President & Chief Scientific Officer of L&F Health LLC, a small start-up company focused on finding a cure for patients with kidney disease.

Chronic kidney disease (CKD) - market opportunity

- CKD is a global health problem affecting over 10% of the population with 26 million patients in the US alone
- CKD can be caused by a number of different types of disease, or be of unknown cause
- CKD gets progressively worse, with patients whose kidneys fail requiring dialysis or kidney transplant
- Hemodialysis treatment costs an average of **US\$89,000 per patient** annually in the United States, and caring for people with end stage renal disease costs the US healthcare system **US\$33billion per annum**



Source: Global Burden of Disease Study 2013

Sources: U.S. Renal Data System, *USRDS 2013 Annual Data Report: Atlas of End-Stage Renal Disease in the United States*, NIH, NIDDK: National Kidney Foundation website www.kidney.org accessed 27 October 2017

Focal segmental glomerulosclerosis (FSGS)

- **FSGS** is characterized by proteinuria, nephrotic syndrome and rapid progression to end-stage renal disease
- DMX-200 has US Orphan Designation for FSGS
- A number of studies have found that FSGS patients with reductions in proteinuria have improved kidney survival.

Independent analysts estimate Focal Segmental Glomerulosclerosis (FSGS) sub-group drug sales to be worth USD \$1 billion per annum in the US alone

Diabetic nephropathy (DN)

- **Diabetic nephropathy 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)

Source: Diabetes 2025 – U.S., state and metropolitan trends, Institute for Alternative Futures; Boyle et al. Projection of the year 2050 burden of diabetes in the U.S. adult population: dynamic modeling of incidence, mortality, and prediabetes prevalence, Population Health Metrics, 2010, 8:29; Boer et al. Temporal trends in the prevalence of diabetic kidney disease in the U.S, JAMA. 2011; 305 (24): 2532-2539; www.cdc.gov/diabetes/statistics/prev/national/figpersons.htm

The North American and global markets are estimated at USD 931m and USD 2,093m in 2014 and are expected to reach USD 1,302.0m USD 2,929m in 2020 (respectively)

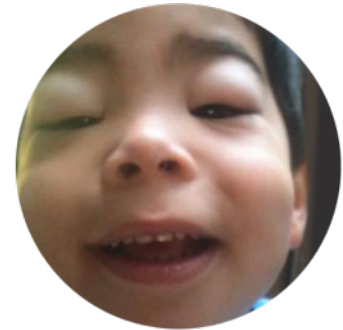
Source: Persistence Market Research, Diabetic Nephropathy Market Report, 2015

Current treatments for CKD

- Damaged kidneys “leak” proteins into the urine. This is called proteinuria and is the most common symptom of kidney disease – relevant measure of treatment efficacy (a prognostic indicator of future kidney damage).
- First line therapy is reducing blood pressure using angiotensin receptor blockers (such as irbesartan) or ACE inhibitors.
- In some types of kidney disease, including the FSGS sub-group, patients are given a cocktail of drugs including immunosuppressants and steroids such as Prednisone, which have **serious and unpleasant side effects**
- **There is a huge unmet medical need for a safe treatment of CKD across the sub-group indications which can significantly reduce proteinuria and prolong the life of the kidney**



Will in remission



Relapse from
nephrotic syndrome



NEPHCURE[®]
Kidney International

Saving Kidneys • Saving Lives



- **NASDAQ: CCXI**
- **Market Cap: ~US\$329 million**
- Completed Phase 2 for CCX140 in **diabetic nephropathy** (a CKD sub-group indication)—
a **CCR2 antagonist**
- Measured urine albumin creatinine ratio (ACR) change from baseline by **16% over placebo (-2% for placebo and -18% for CCX-140 at best dose)** (geometric mean reduction at 12 weeks of 24%)
- Vifor licensed CCX-140 from Chemocentryx with Phase 2 data for use **outside the US** for \$50m upfront, undisclosed milestone payment and double digit royalties



- **NASDAQ: RTRX**
- **Market cap : ~US\$ 917 million**
- Phase 2 asset, sparsentan, **for treating FSGS** (a CKD sub-group indication) – a **dual angiotensin endothelin receptor blocker**
- Patients removed from Standard of Care treatment 2 weeks prior to dosing
- Top line positive data showing improved proteinuria *compared with* standard of care (irbesartan) at 8 weeks
- Standard of Care (Irbesartan) reduced total protein urine excretion per day by 19% and sparsentan by 47.4% (net 28.4%)

DMX-200 – Dimerix lead program for CKD

- DMX-200 is a tablet which is taken in conjunction with existing medications.
- Patients continue taking their standard of care medication (irbesartan) and add a second drug to this (propagermanium), a CCR2 antagonist.
 - This has been confirmed by the US FDA as being an adjunct (not combination) therapy
- Both drugs have been in use for many years, and their safety profile is well understood.
- Patients on the completed Phase 2a Study had the diagnosis across a number of key sub-groups diabetic nephropathy (10), IgA nephropathy (6), other proteinuric diseases (11)

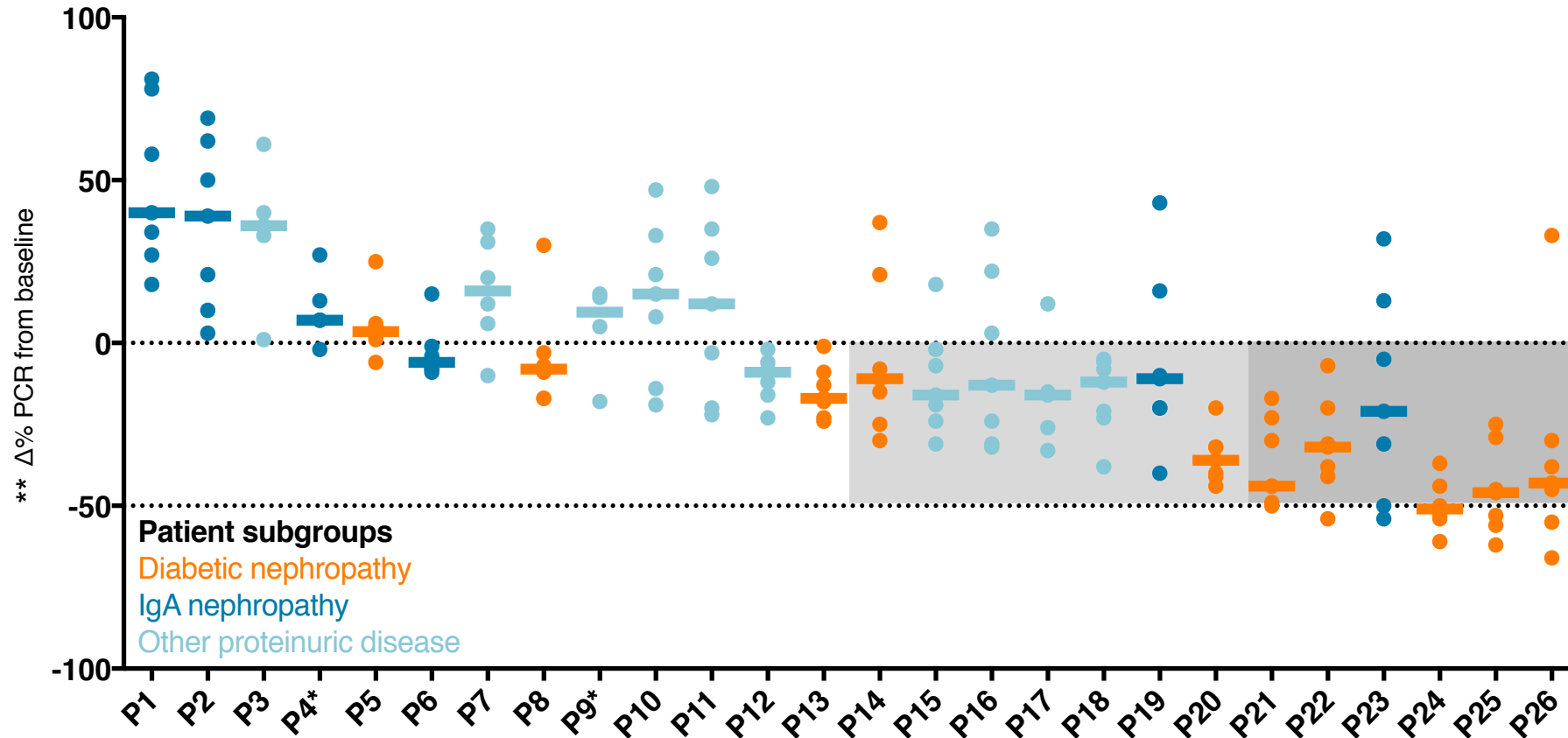


Trial design

- 27 patients in open label dose escalation study across 4 sites in Australia
- Patients were on stable irbesartan prior to and throughout the study.
- Patients additionally received an oral dose of propagermanium
- Propagermanium dose escalated at four week intervals, unless proteinuria was within normal limits.

Study Summary

The graph shows individual patient PCR** values as % change from baseline value during treatment ranked by PCR reduction level.



* Patients withdrawn from study before completion

** Protein Creatinine Ratio (PCR), a measure of levels of proteinuria and indicator of CKD. An alternate measure is the Albumin Creatinine Ratio (ACR).

Primary Endpoint Met: DMX-200 was safe and well tolerated

- Adverse events consistent with underlying patient population
- No changes in the rate or severity of adverse events with propagermanium.
- No clinically significant trends in safety signals from baseline; including blood pressure, eGFR, and serum potassium.

Secondary Endpoints: Efficacy demonstrated with particular effect in some patients

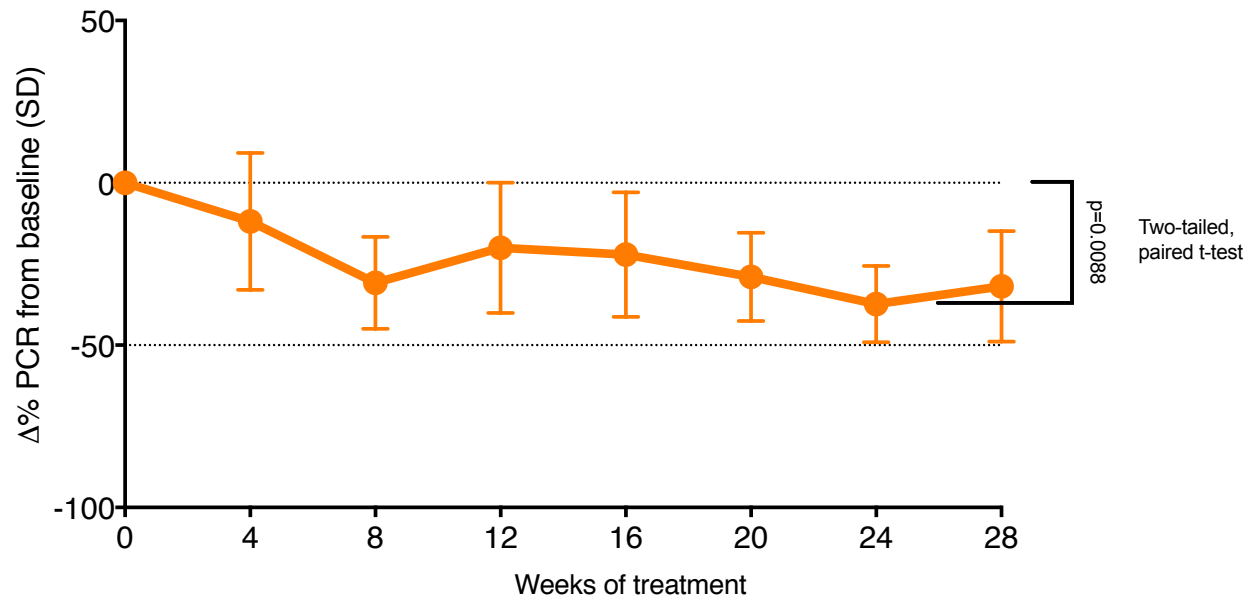
- 25% (6/24) patients achieved were responders: “participants achieving normalization of proteinuria or a 50% reduction in proteinuria”, and is additional to any effect of irbesartan (standard of care) (a 50% reduction is a high criteria level)
- **Responders at the sub-group level:**
 - 83% (5/6) had a primary diagnosis of diabetic nephropathy, and
 - 17% (1/6) had a primary diagnosis of IgA nephropathy
- **54% (13/24) achieved at least a 30% reduction in PCR at any dose level of propagermanium.**

Post hoc analysis – average Protein Creatinine Ratio (PCR) and Albumin Creatinine Ratio (ACR) in Diabetic Nephropathy Group

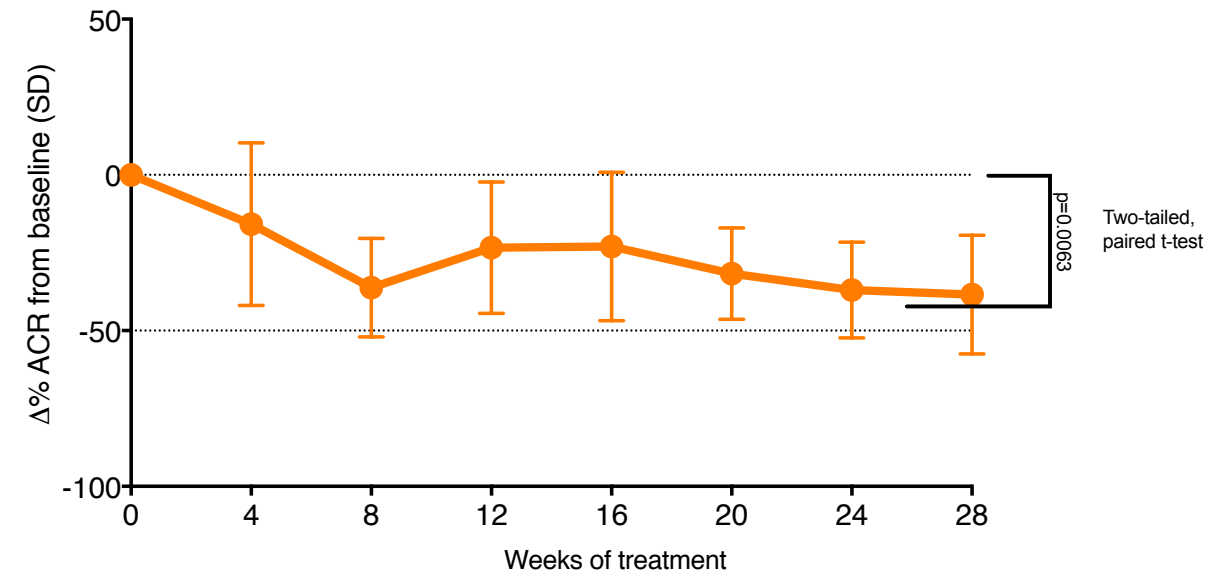


- **50% (5/10) of diabetic nephropathy** patients showed a **greater than 50% reduction** from baseline in PCR during treatment.
- **These compelling data** justified additional analysis, based on **average responses across the diabetic nephropathy group** using both (PCR) as well as the measure used by some competitors (ACR)

Reduction in PCR (24-hr) of diabetic nephropathy patient cohort (n=10) during combined treatment with irbesartan and propagermanium.

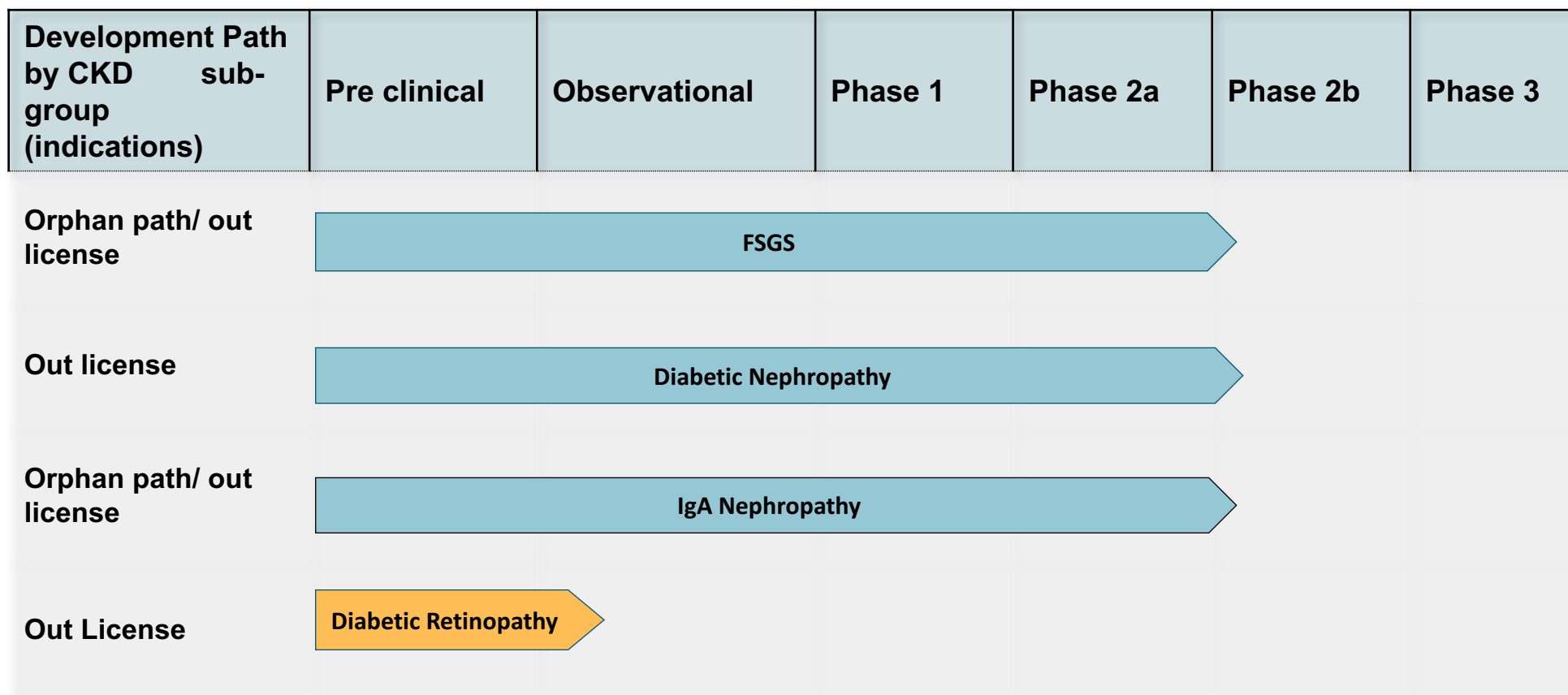


Reduction in ACR (24-hr) of diabetic nephropathy patient cohort (n=10) during combined treatment with irbesartan and propagermanium.



- Diabetic nephropathy patients had a **statistically significant mean** reduction in **PCR of 31.9%** between baseline and the last two periods of treatment (**p=0.0088**)
- Diabetic nephropathy patients had a **statistically significant mean** reduction in **ACR of 35.6%** between baseline and the last two periods of treatment (**p=0.0063**)

DMX-200 – a pipeline in a program

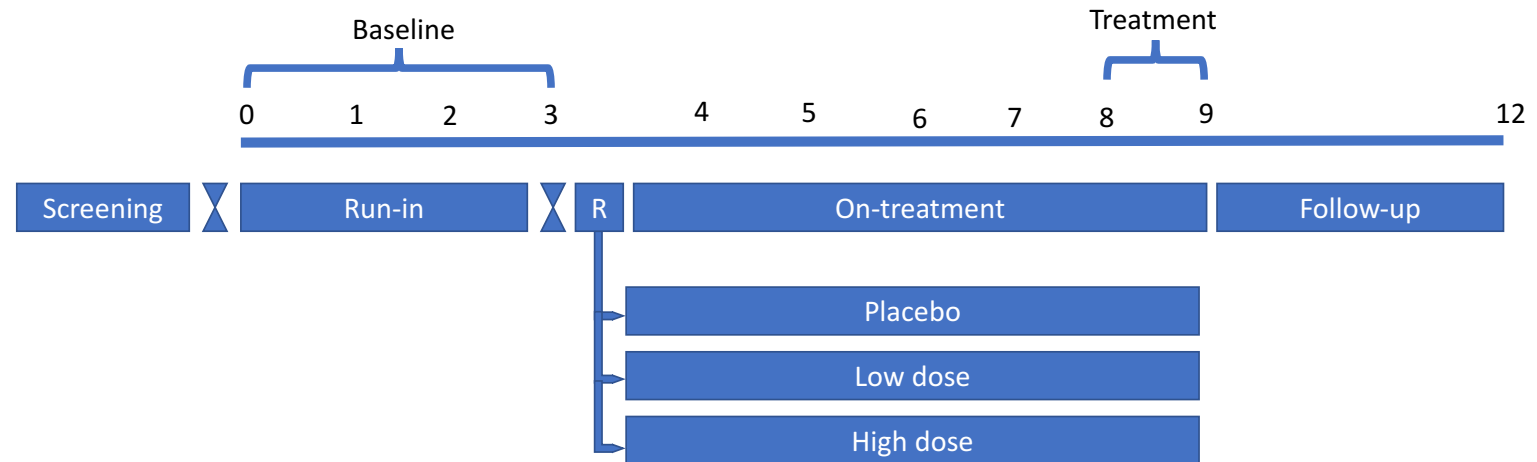


- Glomerular diseases with an inflammatory component
- **FSGS** an Orphan indication, faster path to market and compelling license opportunity
- **Diabetic Nephropathy** an enormous market potential and compelling data from Phase 2a (greatly exceeded expectations)
 - Phase 2a data supports statistical powering for the diabetic nephropathy group
- **IgA nephropathy** is one of the most aggressive types of chronic kidney diseases with limited treatment options
 - 1/6 of the patients in our study was a 50% responder – this is unheard of in this condition
 - Limited treatment options, ***the most common off-label treatment*** of this disease ***recently had a trial terminated due to safety concerns*** (Jicheng et al. Effect of Oral Methylprednisolone on Clinical Outcomes in Patients With IgA Nephropathy The TESTING Randomized Clinical Trial, *JAMA*. 2017;318(5):432-442. doi:10.1001/jama.2017.9362)

DMX-200 Phase 2b Study Design

- Double blind, placebo controlled
- Three patient groups: DN(n=60), FSGS plus IgAN (n=30), for total N=90
- 3-month run-in to ensure stable disease prior to randomisation
- Patients randomised to 6-month of continuous treatment with low dose of propagermanium, high dose of propagermanium, or placebo.
- All patients followed-up for 3-months to determine rebound following treatment
- Optional protocols for diabetic retinopathy screening, and collection of patient data during an optional special access program

Indicative cohort schedule



DMX-200 Phase 2b Study Endpoints



Primary Endpoint	Secondary Endpoints	Exploratory Endpoints
• Change in 24-hour ACR from baseline (mean of run-in) to the end of treatment (month 5 & 6) for DN cohort	• Incidence and severity of AEs throughout study • Clinically significant changes in the safety profile of participants • Change in 24-hour ACR from baseline (mean of run-in) to the end of treatment (month 5 & 6) for FSGS and IgAN cohort	• Steady-state plasma PK • Change in PCR, eGFR and total protein excretion • Effect of removing propagermanium on ACR, eGFR, PCR, total protein excretion • Effects on plasma and urine biomarkers of inflammation. • Effect on biomarkers of kidney disease progression. • * Evaluation of safety, tolerability and efficacy in patients that continue to receive propagermanium under compassionate access. • * Change in retinopathy of diabetic patients.

NB: These are subject to final amendments in conjunction with MAB and investigators

* Evaluated under optional protocols

DMX-200 Intellectual Property

- Dimerix has **granted patents** in the USA, Australia and Japan covering the lead program DMX-200 (US patent no 9,314,450); and pending applications in Europe and other major jurisdictions including
- The '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
- Additional applications have been filed for the extended release formulation and dosage regimes
- The therapy patent expires in **2032**



- ✓ Human pharmacokinetics (PK) study to optimise dose of DMX-200 for extended release formulation on track to complete 2H CY2017 (3 tablets daily reduced down to 2 tablets daily)
- ✓ Presentation of Phase 2a data by CEO Kathy Harrison at BioEurope on 7th November 2017, a major industry partnering and investment forum
- ✓ Commencement of Phase 2b trial (recruiting Q1 calendar 2018)
- ✓ Phase 2a data analysis and Phase 2b study design discussions with big pharma and medical advisory board (ongoing)
- ✓ Filing Orphan Drug designation in Europe, 2018 (US already attained)
- ✓ Meetings with European Regulatory Advisors (2018).



Contact

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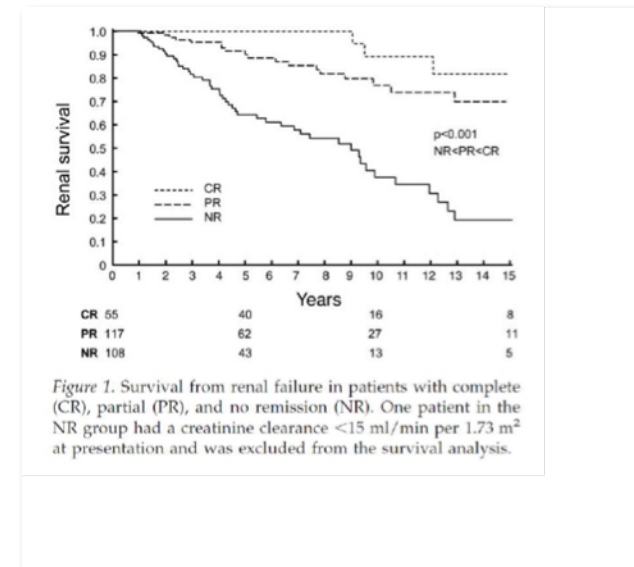
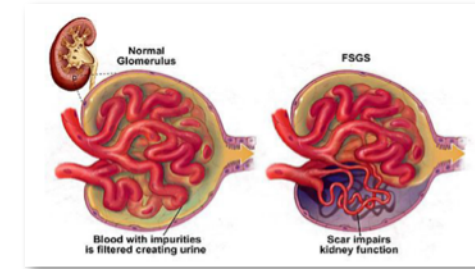
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Additional Details

FSGS: An orphan disease with limited treatment options

- Focal segmental glomerulosclerosis (FSGS) is a group of clinical-pathological syndromes sharing a common glomerular scarring lesion and characterized by proteinuria, nephrotic syndrome and rapid progression to end-stage renal disease
- The disease is manifested by marked proteinuria (2-10g/day), dyslipidemia, hypoalbuminemia and severe edema
- A number of studies have found that FSGS patients with reductions in proteinuria have improved kidney survival.
- Troyanov et.al. (2005) found a strong association between reduction of proteinuria (either complete or partial response) and the survival from renal failure in a study of 281 FSGS patients in Canada.*
- Limited treatment options: RAS inhibitors => Steroids => Transplant (30-40% recurrence)

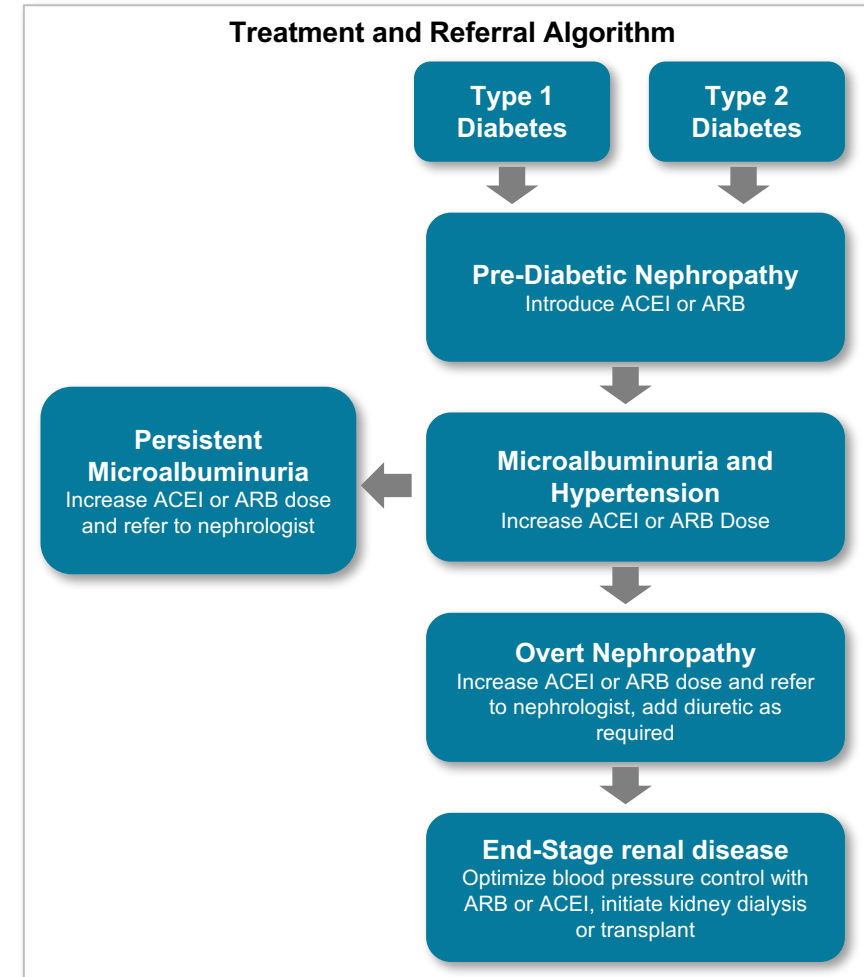


Troyanov S, Wall CA, Miller JA, Scholey JW, Cattran DC; "Focal and segmental glomerulosclerosis: definition and relevance of a partial remission," *J Am Soc Nephrol*. 2005 Apr;16(4):1061-8.

Diabetic Nephropathy

- Diabetic nephropathy is the single most common cause of chronic kidney disease worldwide and is associated with significant increase in cardiovascular morbidity and mortality
 - US prevalence is estimated as 3.0% (9M patients)
- The disease is a microvascular complication of longstanding type 1 and type 2 diabetes characterized by albuminuria (abnormal excretion of albumin in the urine), overt nephropathy (proteinuria > .5g/24h and decline in glomerular filtration rate) and hypertension
- Diabetic nephropathy may result in end-stage renal disease (ESRD), requiring dialysis or kidney transplantation
- The goal of treatment is to prevent the progression from microalbuminuria to overt nephropathy, reduce the rate of renal function decline and occurrence of cardiovascular events
 - Current treatment: RAS inhibitors; Diuretics

Source: Medscape accessed December 2013; Treatment of diabetic nephropathy, UpToDate accessed December 2013; Fried et al. Combined angiotensin Inhibition for the treatment of diabetic nephropathy, The New England Journal of Medicine, 2013; Cooper Mark, Pathogenesis prevention and treatment of diabetic nephropathy, The Lancet 352:9123 213-219, 1998



Study Design Phase 2a

Primary Objectives

- To determine the safety and tolerability of propagermanium when added to standard irbesartan treatment in participants with proteinuria

Primary Endpoints

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

Key Inclusion Criteria

- Adults > 18 years
- PCR ≥ 50 mg/mmol (442 mg/g) over 24-hours
- eGFR 20-60 ml/min/1.73m²
- Serum creatinine men: 115-291 mmol/L (1300-3291 mg/dL), women: 132-309 mmol/L (1492-3494 mg/dL)
- Stable irbesartan for 3-months

Secondary Objectives

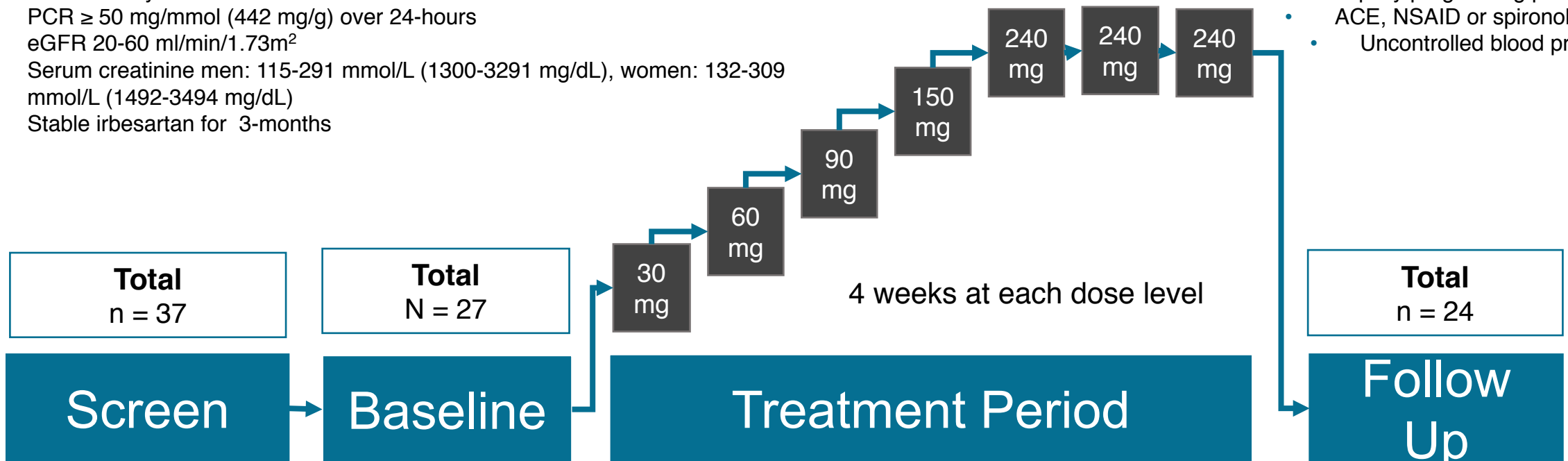
- To evaluate the effects of propagermanium on various biomarkers when added to standard irbesartan in participants with proteinuria

Secondary Endpoints

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

Key Exclusion Criteria

- Rapidly progressing proteinuria
- ACE, NSAID or spironolactone
- Uncontrolled blood pressure



Phase 2a Primary end point - safety

- Combined therapy with propagermanium and irbesartan was well tolerated.
- Adverse events were consistent with underlying patient and population co-morbidities.
- There was no change in the rate of AEs or severity of AEs with dose of propagermanium.
- There were no clinically significant trends in biochemistry, hematology, urinalysis hematology or vital signs from baseline during treatment including blood pressure, eGFR, and serum potassium.

	Overall	PPG dose				
		30mg	60mg	90mg	150mg	240mg
All AEs	119 (8.5)	20 (8.8)	16 (7.2)	16 (7.5)	18 (8.1)	49 (9.6)
Mild AEs	60 (4.3)	10 (4.4)	12 (5.4)	9 (4.2)	10 (4.5)	19 (3.7)
Moderate AEs	52 (3.7)	8 (3.5)	4 (1.8)	6 (2.8)	5 (2.2)	29 (5.7)
Severe AEs	7 (0.5)	2 (0.9)	None	1 (0.5)	3 (1.3)	1 (0.2)
IP-related AEs*	22 (1.6)	7 (3.1)	3 (1.4)	6 (2.8)	1 (0.4)	5 (1.0)
Serious AEs (SAE)**	9 (0.6)	3 (1.3)	None	None	2 (0.9)	4 (0.8)

Table: Total number and (annualized rate) of AEs by dose of propagermanium, N=27.

* Events assessed by the investigator to be possibly, probably or definitely related to IP

** n=5 patients had an SAE/s during study consistent with their co-morbidities: low hemoglobin (not related to IP), stroke (remotely related to IP), melena/anemia (not related to IP), cholecystitis/pancreatitis (not related to IP), NSTEMI (remotely related to IP), fluid overload (not related to IP), ESRF (not related to IP), and intermittent depression/suicidal ideation (possibly related to IP).

Phase 2a Secondary Pre Specified Endpoint - Proteinuria



- 24 patients completed dosing and were assessed for efficacy.
- 6 patients achieved the pre-specified criteria of responders: “participants achieving normalization of proteinuria or a 50% reduction in proteinuria”.
- Responders appeared to be concentrated among those with a primary diagnosis of diabetic nephropathy, **83% (5/6) of responders had a primary diagnosis of diabetic nephropathy, and 17% of responders (1/6) had a primary diagnosis of IgA nephropathy**
- Proteinuria responses were all achieved in patients receiving irbesartan for a minimum of 3 months prior to receiving IP, and are considered additional to any effect of irbesartan on proteinuria.
- Of the patients that completed dosing, 54% (n=13) achieved at least a 30% reduction in PCR at any dose level of propagermanium.

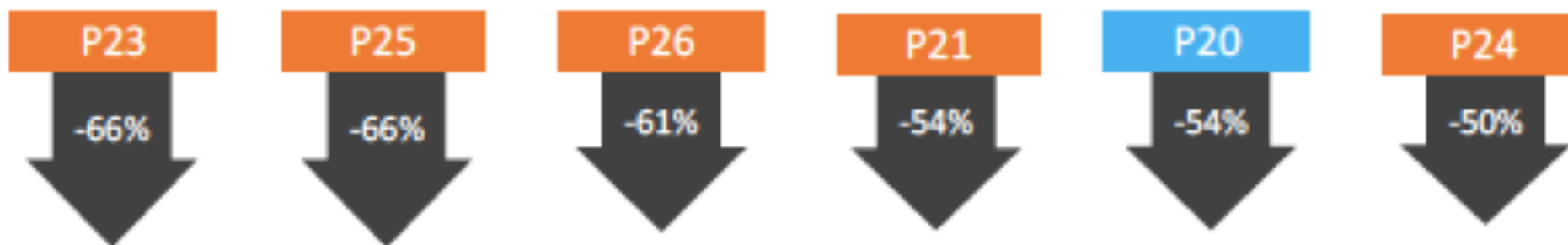
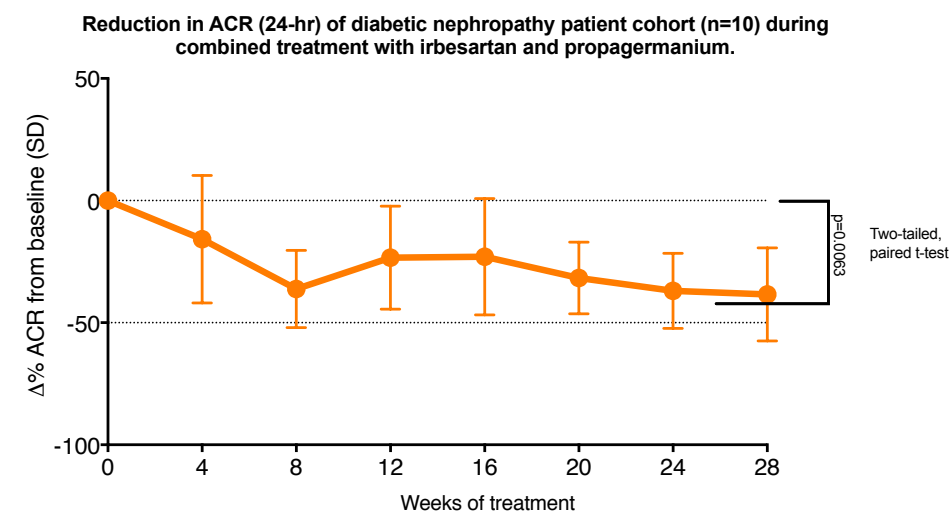
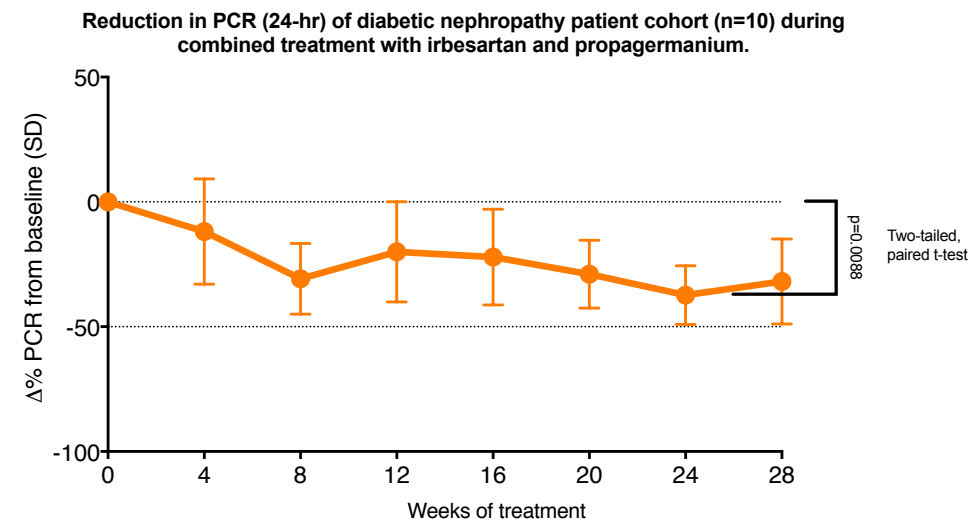


Figure: Peak reduction in PCR (24-hr) from baseline for responders

Phase 2a Post hoc analysis

- **50% (5/10) of diabetic nephropathy patients showed a greater than 50% reduction** from baseline in PCR (24-hr) during treatment.
- **This compelling data in the diabetic nephropathy group justified additional statistical analysis for that group, based on average responses across the entire group**
- Diabetic nephropathy patients had a statistically significant **mean reduction in PCR (24hr) of 31.9%** between baseline and the last two periods of treatment (**$p=0.0088$**)
- **An alternate measure of proteinuria used by some competitors is the albumin creatinine ratio (ACR)**
- Diabetic nephropathy patients had a statistically significant **mean reduction in ACR (24hr) of 35.6%** between baseline and the last two periods of treatment (**$p=0.0063$**)
- To confirm this finding across all time points, a repeat measures mixed model (linear regression) was used to integrate all PCR (24-hr) measurements across the treatment period. A significant decrease in PCR (24-hr) during treatment was shown (**$p=0.0159$**).



DMX-200 Phase 2b Key Inclusion Exclusion Criteria



General Inclusion

- Adults > 18 to 75 years
- BMI 20-40 kg/m²
- Proteinuric disease > 6 months duration
- eGFR 40-90 ml/min/1.73m²
- Taking stable (> 3-month) 300 mg irbesartan

General Exclusion

- Use of an ACE or symptomatic use of immunomodulatory agents including steroids
- Previous renal transplant or known non-diabetic renal disease, except related to hypertension
- BP > 140/90 mmHg or uncontrolled BP
- Significant medical conditions related to cardiac, hepatic, or immune function

FSGS cohort

- Biopsy-proven primary FSGS or documented genetic mutation
- Protein excretion >1 g/day
- < 50% fibrosis on most recent biopsy
- If using immunosuppressant, stable dosing > 3 months

Diabetic nephropathy cohort

- Primary renal diagnosis of diabetic nephropathy
- Haemoglobin A1c (HbA1c) 6.0-10.0%
- Protein excretion 1-3 g/day
- Not using immunosuppressants

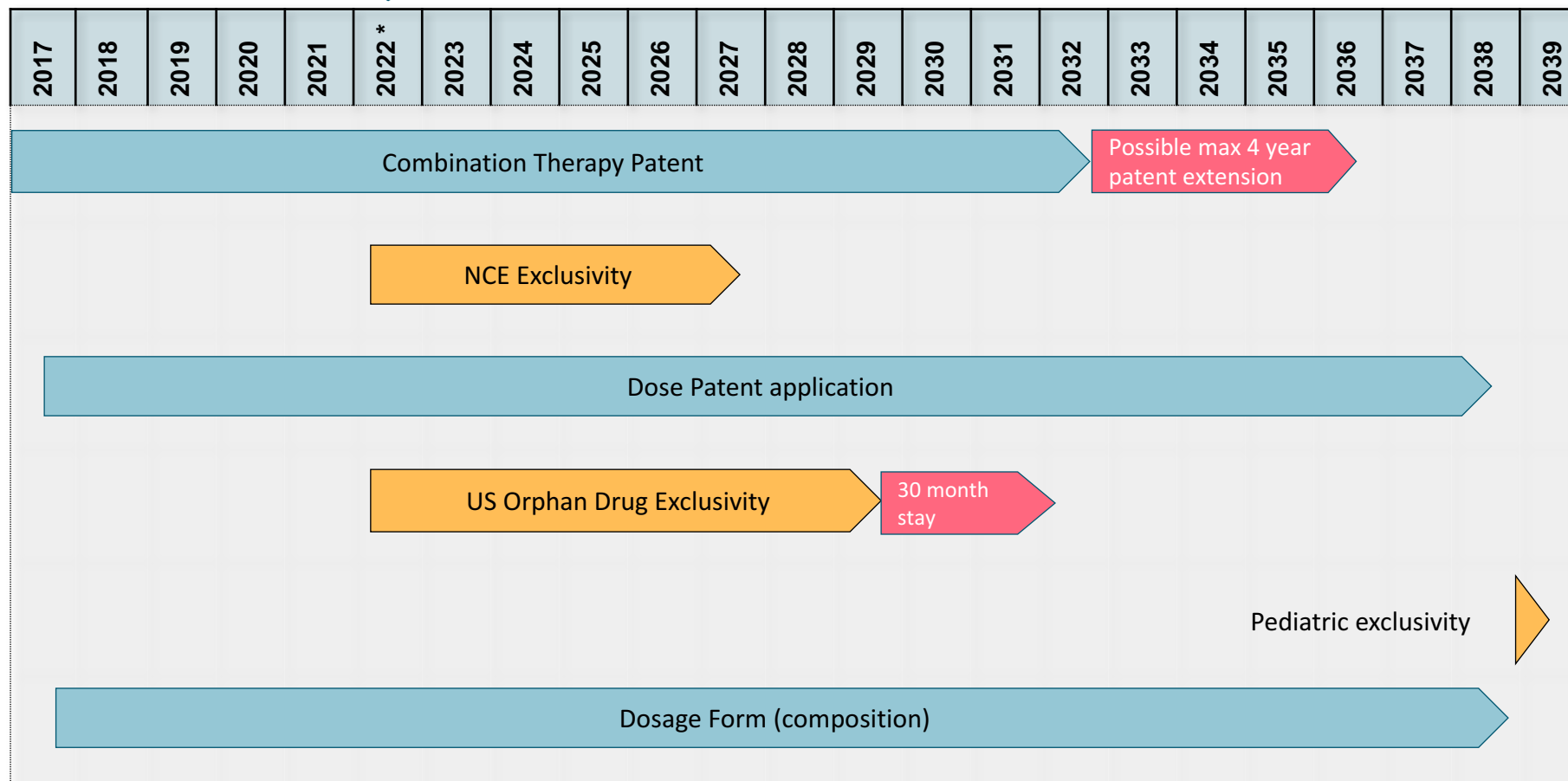
IgA nephropathy cohort

- Biopsy-proven primary IgA nephropathy diagnosis
- Protein excretion 1-3 g/day
- If using immunosuppressant, stable dosing > 3 months

NB: These are subject to final amendments in conjunction with MAB and investigators

DMX-200 US IP and data exclusivity strategy for FSGS

*assumed DMX-200
registration for FSGS



Patent extension to a maximum of 14 years post approval patent life – measured from the effective date of the IND to the date of filing the NDA