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URIROX-1 and Study 206 Topline Results

November 7, 2019

Allena Pharmaceuticals, Inc.

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This presentation also contains estimates and other statistical data made by independent parties and us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

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Positive Topline Results from URIROX-1 and Study 206

uriROX

Achieved Primary Endpoint:

- ✓ **Highly statistically significant treatment difference (p=0.004), and a 23% reduction in 24-hour UOx from baseline on reloxaliase**
- ✓ **High UOx and kidney stone burden**
- ✓ **Consistent with Phase 2 studies**
- ✓ **Sustained over four weeks of treatment**
- ✓ **Safe and well-tolerated**

uriROX-2

URIROX-2 Positioned for Success

- Same UOx primary endpoint
- URIROX-2 sized for long-term confirmatory endpoint (overpowered for UOx)
- Adaptive design

Study 206

Opportunity to Explore Additional Registrational Path in EH Patients with Advanced CKD:

- ✓ 2 patients with CKD Stage 3: **reduction in UOx of 29% and 42%, and POx of 42% and 16%**
- ✓ 6 patients with CKD Stage 5: **reduction in POx ranged from 19% to 68%**

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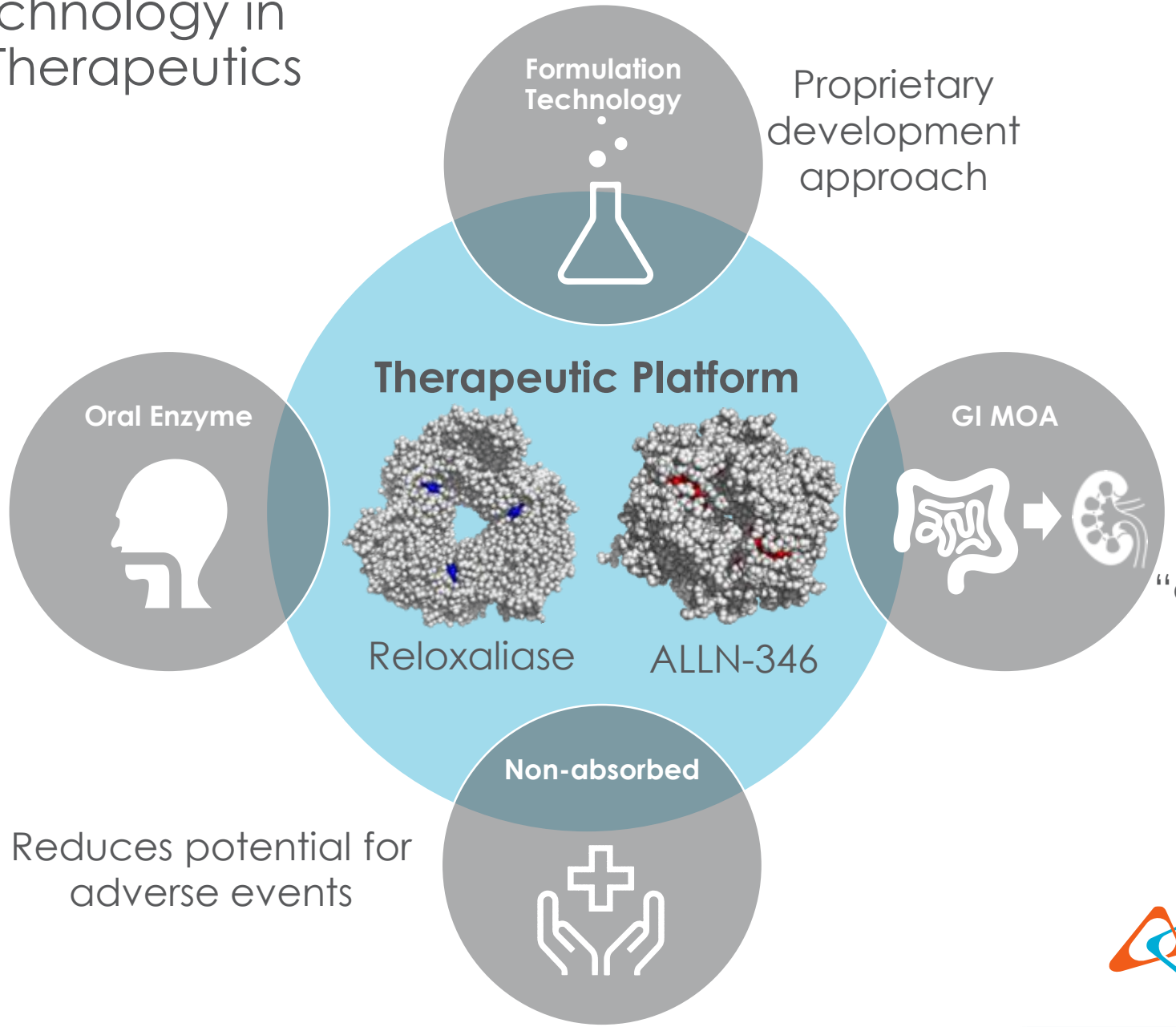
Pioneering Technology in Oral Enzyme Therapeutics



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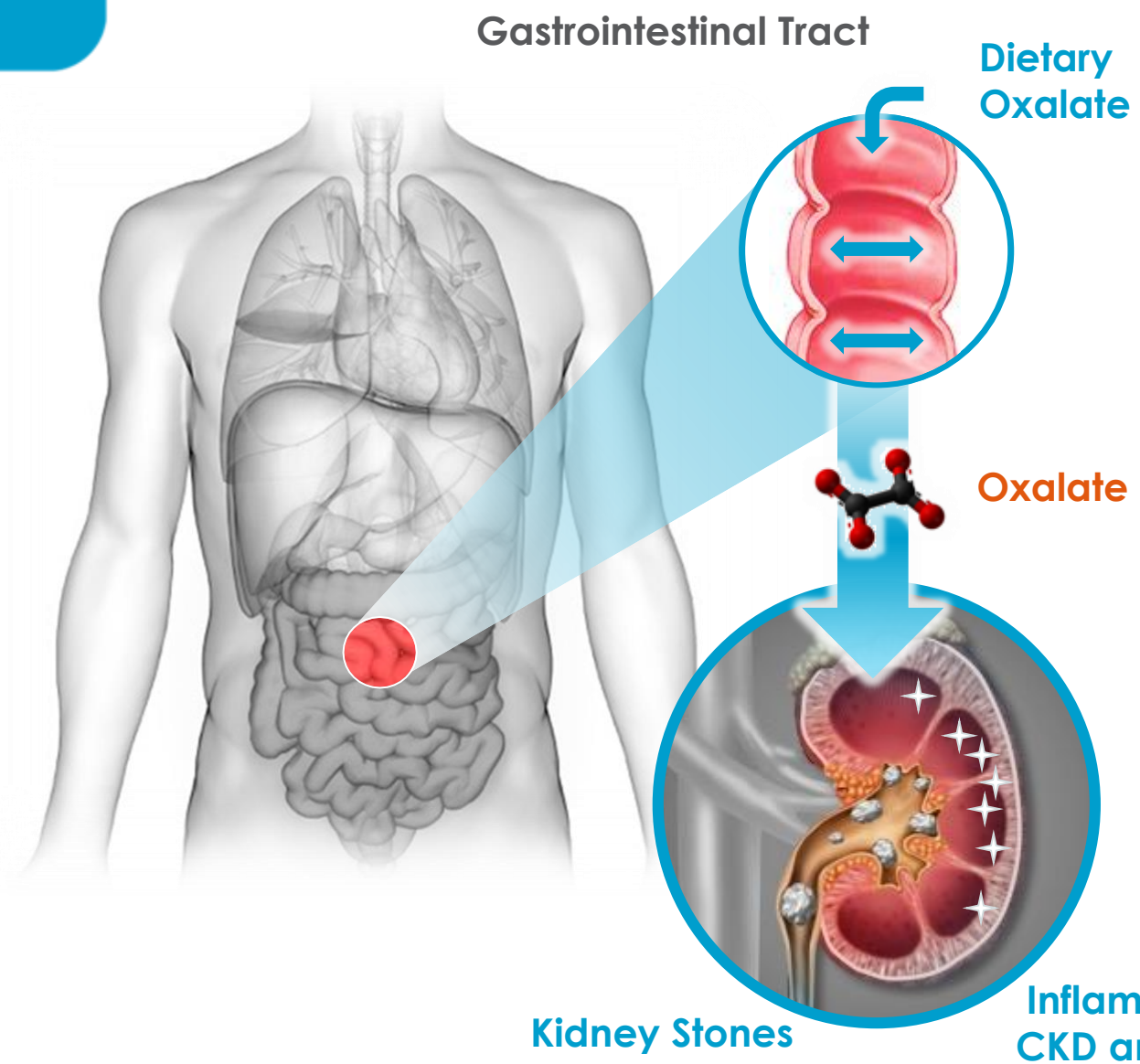
Enteric Hyperoxaluria – Disease Overview



Enteric Hyperoxaluria (EH)

Enteric: Pertaining to the intestinal tract

Hyper: High or excess

Oxal: Oxalate

Uria: In the urine

Definition: Excess absorption of oxalate in the GI tract due to gastric bypass surgery, inflammatory bowel disease, short bowel syndrome, celiac disease and chronic pancreatitis

Consequence: Kidney stones and calcium oxalate crystal deposits in the kidneys which can lead to inflammation, CKD and ESRD

There are no FDA-approved pharmacological therapies to treat any form of hyperoxaluria

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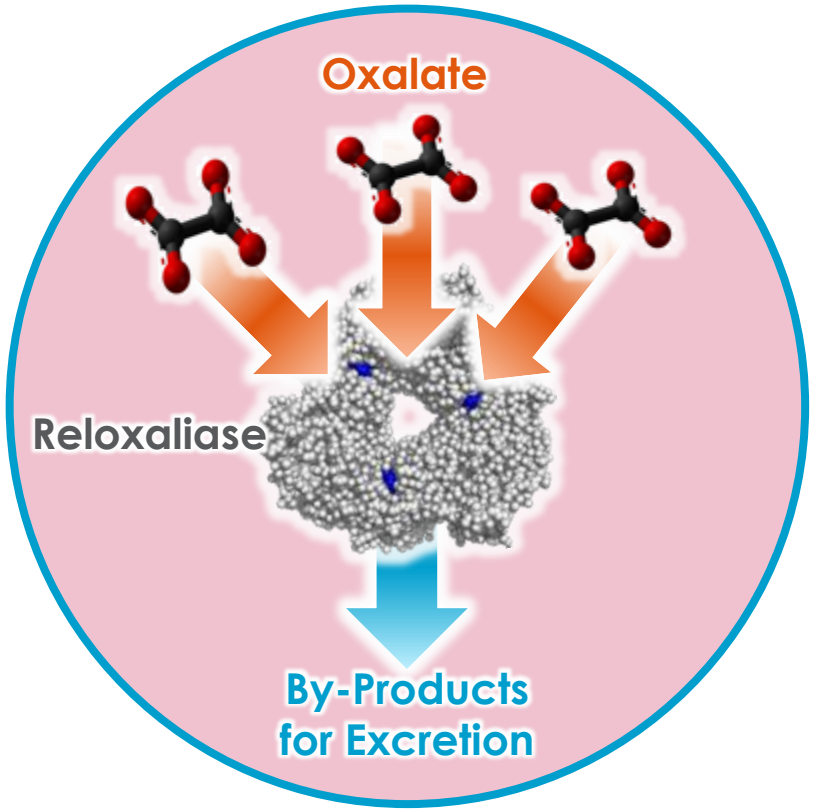
Reloxaliase: First-in-class Therapeutic Candidate for EH

Mechanism of Action

Oxalate Degradation in the Gastrointestinal Tract



Target Product Characteristics

- Crystalline Oxalate-Specific Enzyme
- Oral Capsule Formulation
- Taken with Food
- Non-Absorbed/Non-Systemic
- Room Temperature Stability

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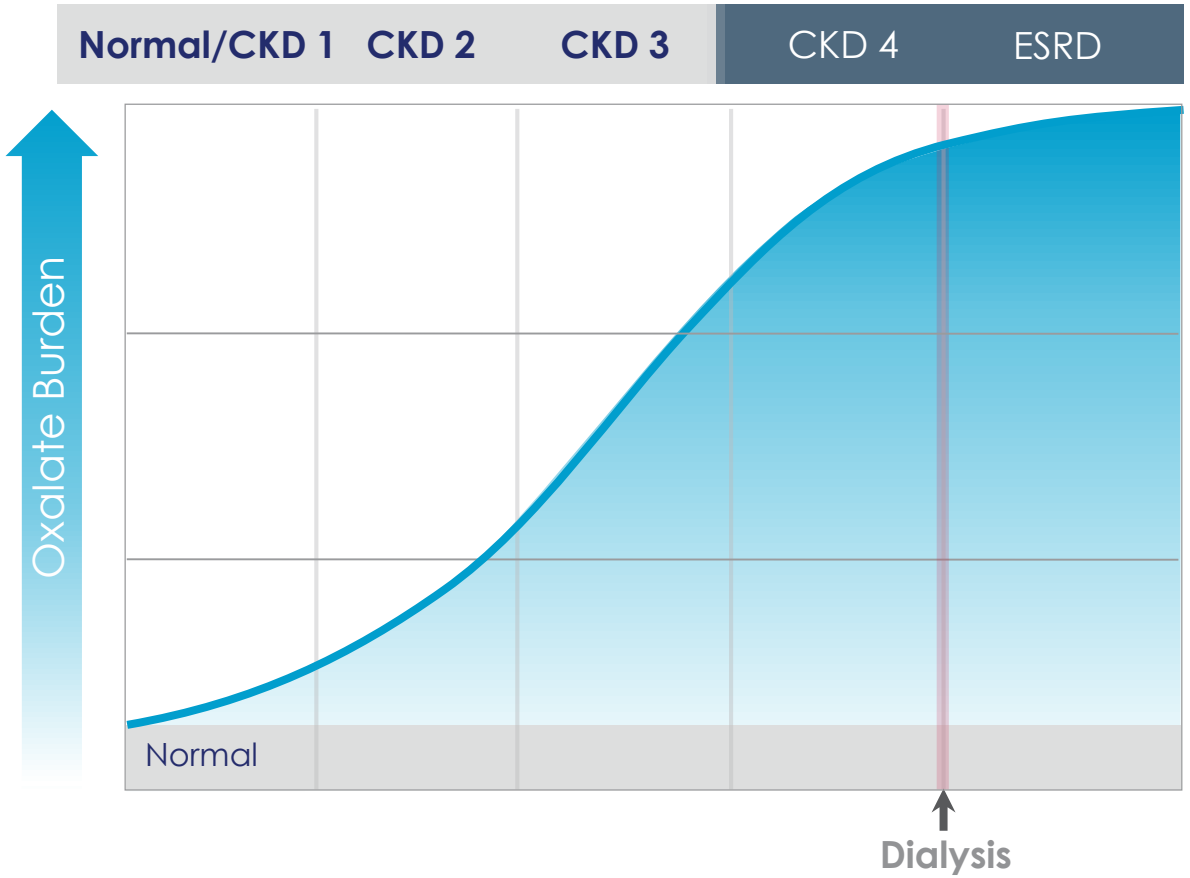
Reloxaliase Development Program Addresses the Full Spectrum of Disease

uriROX

Study Population:
Enteric Hyperoxaluria

Study 206

Enteric Hyperoxaluria with CKD and Hyperoxalemia



- The clinical literature suggests that a ≥ 20% reduction in urine oxalate (UOx) could result in a 25-50% lower incidence of kidney stone recurrence, and may increase renal survival[1]
- By reducing oxalate levels, potential to slow CKD progression, enable kidney transplant and protect new kidney post-transplant

[1]1Borghi N et al. Eng J Med. 2002; Taylor and Curhan, Kidney Int. 2008; Curhan GC et al., J Am Soc Nephrol., 2017; Zhao et al. Clin J Am Soc Nephrol. 2016

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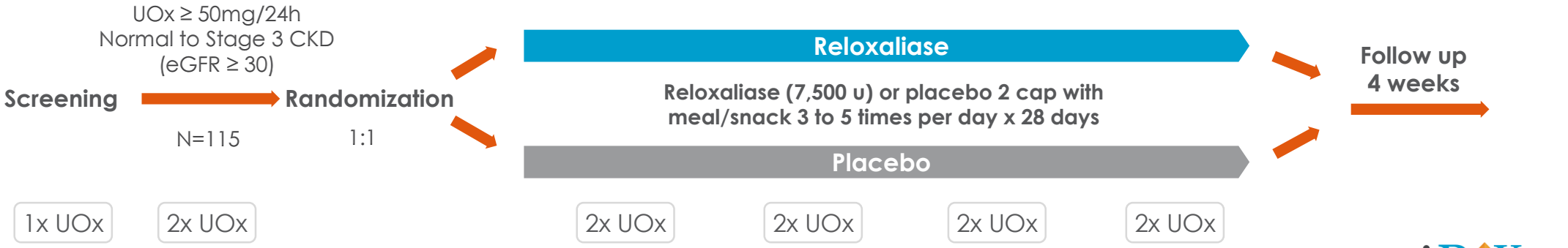
URIROX-1: Evaluate the Safety and Efficacy of Reloxaliase in Patients with Enteric Hyperoxaluria



Primary Endpoint:

- Percent change from baseline in 24h UOx excretion during Weeks 1 to 4

Key Secondary Endpoint:

- Proportion of subjects with a ≥ 20% reduction from baseline in 24h UOx excretion during Weeks 1 to 4

Pre-specified, Stratified Analysis

- Subset analysis of the primary and lead secondary endpoint in subjects with a history of bariatric surgery

URIROX-1: Patient Demographics and Baseline Characteristics

Category / Statistic	Reloxaliase (N=58)	Placebo (N=57)
Age (years) – Mean (SD)	58.7 (10.09)	58.6 (10.18)
Gender, n (%) Female	28 (48.3)	27 (47.4)
Enteric condition, n (%) Bariatric surgery [Roux-en-Y gastric bypass] Inflammatory bowel disease Short bowel syndrome Pancreatic insufficiency Other	 40 (69.0) [27 (46.6)] 10 (17.2) 3 (5.2) 3 5.2) 2 (3.4)	 38 (66.7) [27 (47.4)] 10 (17.5) 8 (14.0) 0 1 (1.8)
Baseline UOx (mg/24h) – Mean (SD)	87.3 (28.87)	91.1 (41.64)
Baseline UOx ≥ 90 mg/24h, n (%)	22 (37.9)	23 (40.4)
Number of kidney stone episodes in past 5 years- Mean (SD)	8.8 (27.49)	14.2 (43.23)
eGFR (mL/min/1.73m^2) - Mean (SD)	76.4 (22.71)	80.5 (24.60)
CKD Stage 3, n (%)	16 (27.6)	14 (24.6)

High Burden of Disease

- Baseline UOx of 89.2 mg/day
- Average 11 stone events in last 5 years
- 16.5% reported KS events during study[1]
- 26% CKD Stage 3

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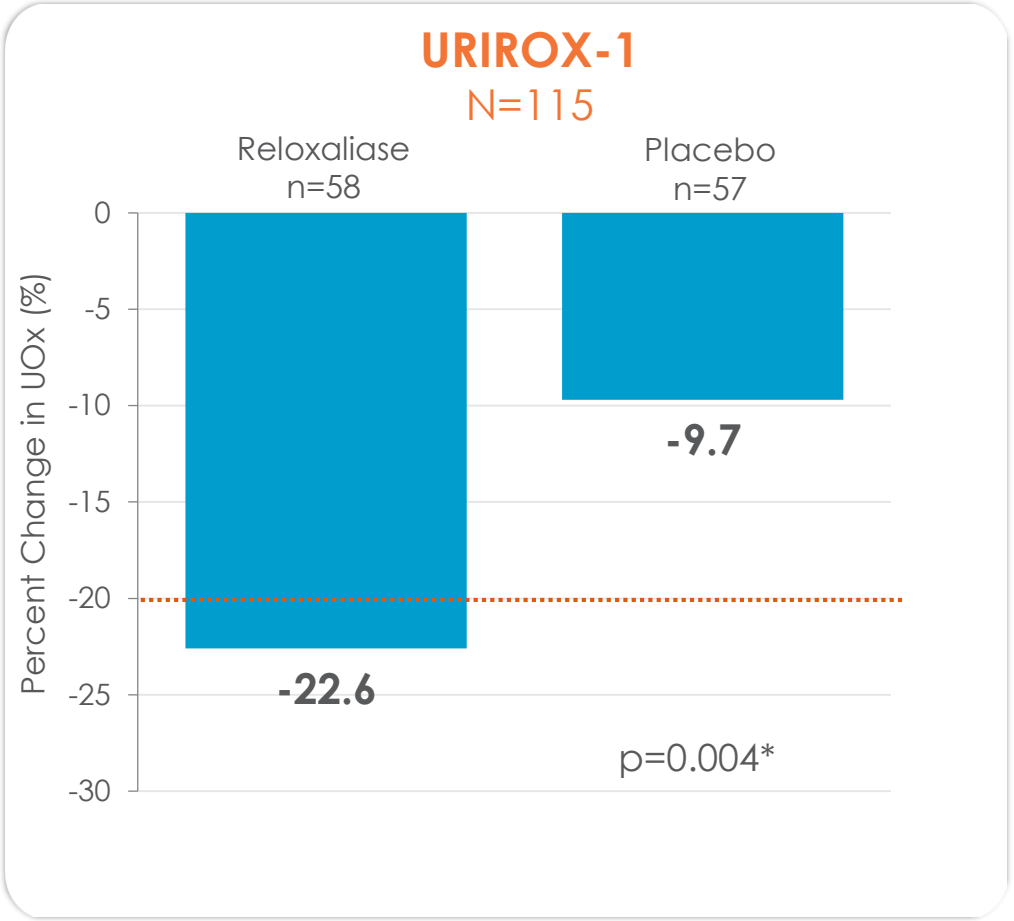
1. Kidney stone events during the study period were approximately equally distributed between treatment and placebo groups

URIROX-1 Primary Endpoint: Statistically Significant Reduction of UOx



- Achieved primary endpoint
- Highly statistically significant response verses placebo (P=0.004)
- 22.6% reduction in UOx from baseline (LS mean)
- -14.3% LS mean treatment difference

*Percent change from Baseline in 24-hour UOx excretion during Weeks 1 to 4

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URIROX-1: Summary of Efficacy

	Overall Population		Pre-Specified Sub-Population Analysis	
	Reloxaliase (N=58)	Placebo (N=57)	Bariatric Reloxaliase (N=40)	Bariatric Placebo (N=38)
PRIMARY ENDPOINT: Percent change in 24h UOx from Baseline during Weeks 1-4				
Comparison in percent change from baseline[a]				
LS mean relative ratio (95% CI)[b]	-14.329 (-22.81, -4.92)		-16.190 (-26.68, -4.20)	
P-value	**0.004**		**0.010**	
SECONDARY ENDPOINT: Proportion with ≥20% Reduction in 24h UOx from Baseline during Weeks 1-4				
n/N (%)	28/58 (48.3)	18/57 (31.6)	20/40 (50.0)	11/38 (28.9)
Comparison between treatments[c]				
Odds ratio (95% CI)	2.141 (0.97, 4.74)		2.891 (1.07, 7.82)	
P-value	**0.061**		**0.036**	

CI, confidence interval; LS, least squares; MMRM, mixed model repeated measures; N, number of subjects dosed; SE, standard error
[a]Baseline is defined as the average of the UOx values derived from the two baseline 24-hour urine collections prior to randomization.
[b]LS means, CIs, and p-values are based on an MMRM model.
[c]Odd ratio, confidence interval, and p-value are from a stratified logistic regression model.

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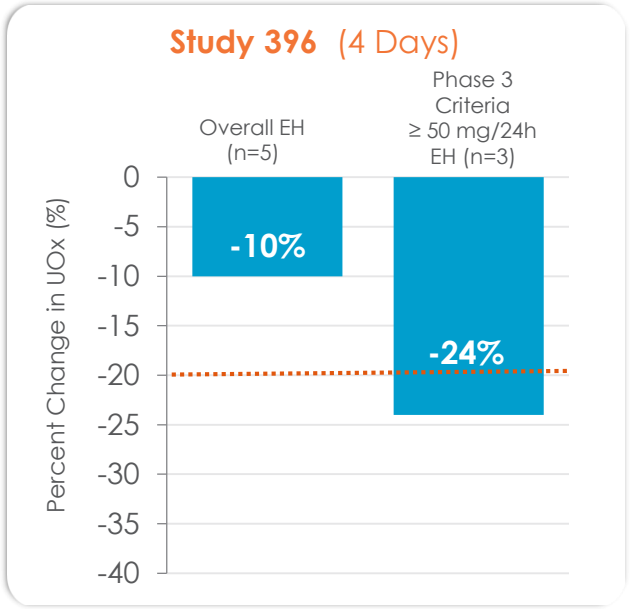
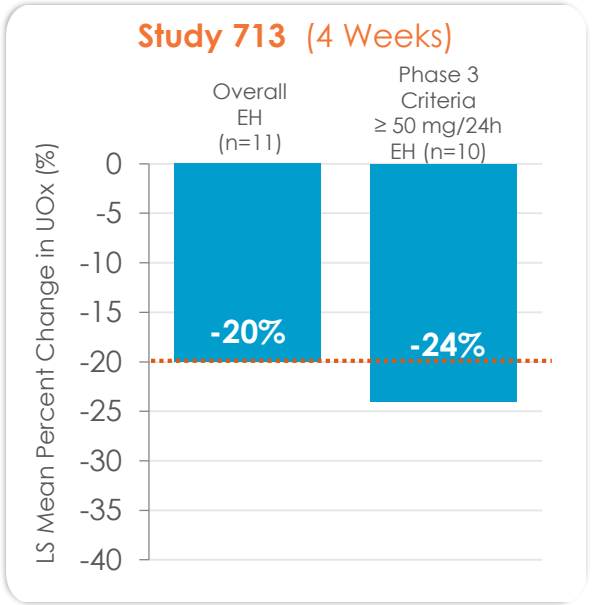
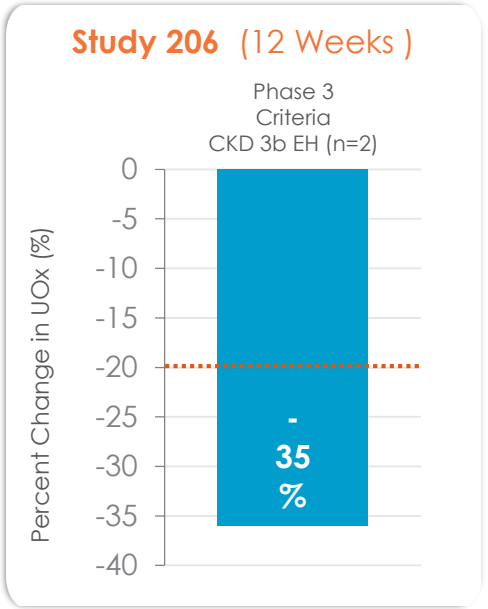
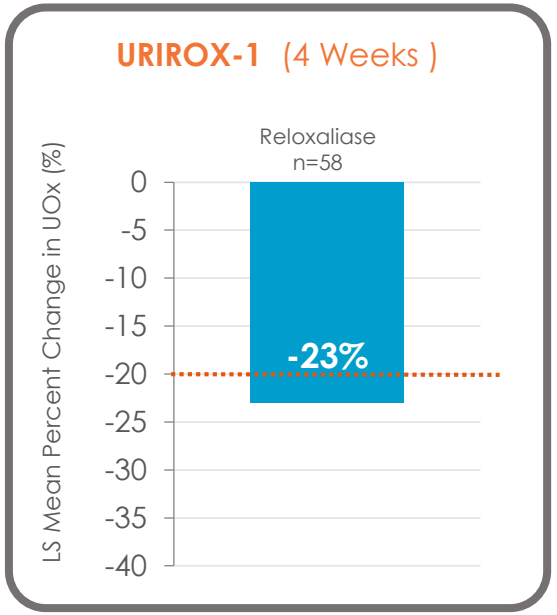
Consistent Reloxaliase Treatment Effect Across Phase 2 and Phase 3 Studies

- Consistent reduction in UOx of ≥ 20% from baseline in reloxaliase treated patients
- Highly significant response in pivotal trial compared to placebo (P=0.004)
- Well tolerated









■ UOx

Presented at ASN 2014

Presented at ASN 2017

Presented at OHF 2019

Presented at ASN 2019

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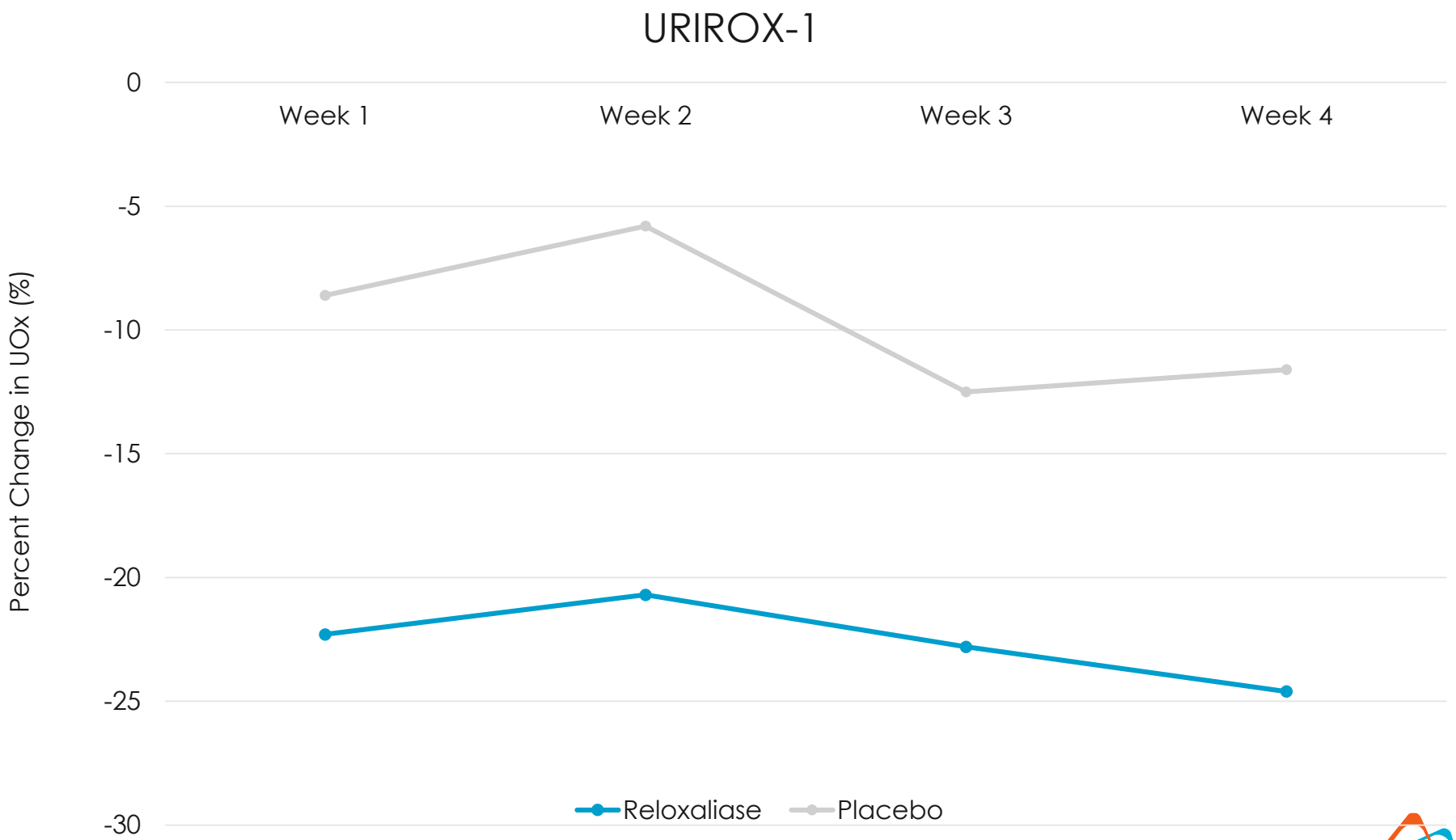
Study 206 UOx adjusted to creatinine (Cr) to correct for renal dysfunction. Data shown with Phase 3 entry criteria is based on a post hoc analysis

Reloxaliase Demonstrates Sustained Reductions in UOx Across Weeks 1-4



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Reloxaliase Generally Well-Tolerated in Clinical Trials to Date

	Study 396	Study 649		Study 713		UROX-1	
	All (n=16)	Reloxaliase (n=30)	Placebo (n=24)	Reloxaliase (n=32)	Placebo (n=35)	Reloxaliase (n=58)	Placebo (n=57)
	n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
TEAE[1]	9 (56.3%)	13 (43.3%)	6 (25.0%)	16 (50%)	22 (62.9%)	40 (69.0%)	30 (52.6%)
Severe TEAE	0	0	0	0	0	1 (1.7)[4]	0
Related TEAE	2 (12.5%)	5 (16.7%)	2 (8.3%)	3 (9.4%)	8 (22.9%)	17 (29.3%)	11 (19.3%)
Serious AE (SAE)	0	1 (3.3%)[2]	0	0	0	1 (1.7%)[4]	0
Related SAEs	0	0	0	0	0	0	0
AEs Leading to Study Drug Withdrawal	0	1 (3.3%)[2]	0	0	2 (5.7%)[3]	0	1 (1.8%)
AEs Leading to Death	0	0	0	0	0	0	0

1. TEAE = Treatment emergent adverse events are defined as AEs with onset at the time of or following the first dose of treatment with study drug through 7 days after their last dose of study medication, or AEs starting before the start of treatment but increasing in severity or relationship at the time of or following the start of treatment through 7 days after their last dose of study medication.
2. One subject reported congestive heart failure of moderate severity, considered not related to study drug, but secondary to a recent cardioversion for atrial fibrillation. This resulted in hospitalization and withdrawal from the study; same subject in both rows.
3. Two placebo treated subjects withdrew from study drug, one after nearly 4 weeks of treatment due to nausea, considered not related, and another due to hives/dermatitis with onset 3 days after starting placebo, considered possibly related.
4. Unrelated to reloxaliase

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Phase 3 Program Design for Accelerated Approval Strategy

uriROX

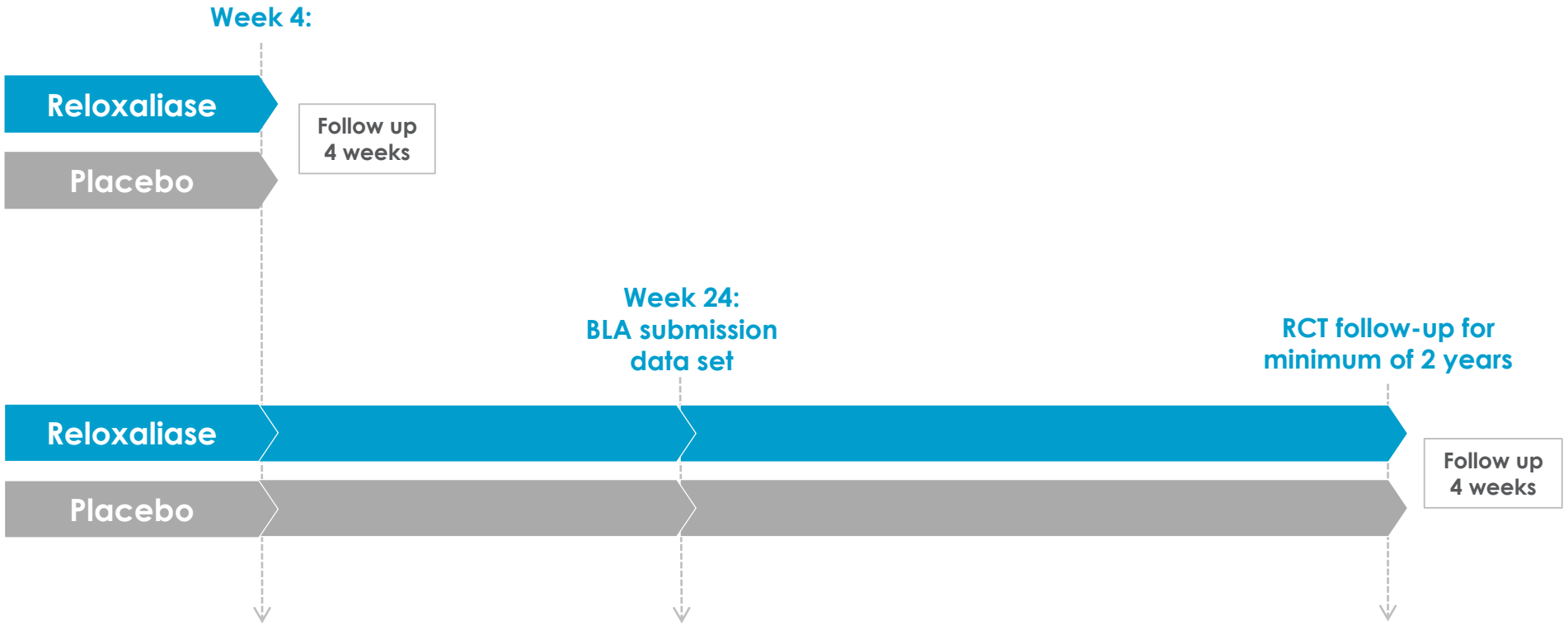
N=115 (1:1)

UOx ≥ 50mg/24h, Normal to Stage 3 CKD (eGFR ≥ 30)

Reloxaliase (7,500 u) or placebo 2 cap with meal/snack 3-5 x per day

uriROX-2

N≈400 (1:1)



PRIMARY ENDPOINT
Percent change from baseline in 24h UOx excretion during Weeks 1 to 4

SECONDARY ENDPOINT
Proportion of subjects with a ≥ 20% reduction from baseline in 24h UOx during Weeks 1-4

SECONDARY ENDPOINT
Percent change from baseline in 24h UOx excretion during Weeks 16 to 24

ADDITIONAL FILING DATA ELEMENTS
- Model of relationship between UOx and KS events, informed by data from the study
- Sufficient conditional power to meet long term primary endpoint

POST-APPROVAL CONFIRMATORY ENDPOINTS
Primary: Kidney stone disease progression
Secondary: Change in eGFR and ER visits / hospitalizations / procedures for management of kidney stones

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Positive URIROX-1 Results Highlight Potential for Accelerated Approval Submission and Provide Insights for URIROX-2 Success

Accelerated Approval Submission

- URIROX-2 shares common UOx primary endpoint and key secondary endpoints with URIROX-1
- Sized for demonstrating long-term clinical benefit, URIROX-2 is overpowered to achieve UOx primary endpoint (n~400)
- Consistent and sustained reloxaliase treatment effect
- Continued attractive tolerability profile

Post-Approval Confirmatory Endpoints

- UOx decrease in placebo group not expected to be sustained in longer URIROX-2 study due to less frequent urine collections and difficulty maintaining dietary changes for 2+ years
- Literature review of metabolic disease studies suggests that treatment response is retained or improved over time despite placebo effect[1] (e.g., phosphate, glucose)
- URIROX-2 kidney stone event rate modeled conservatively based on medical records and claims
  - URIROX-2 will also capture asymptomatic events via imaging
  - URIROX-1 data suggests high rate of stone events
  - Adaptive design with two sample size reassessments (N=240, N=400) to ensure adequacy of the trial to achieve long-term endpoint

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1. Block GA et al. AJKD. 2015;65(5):728-736; Khan A et al. Diabetes Care 2018;41:994–100

Reloxaliase has Potential to Benefit EH Patients With Advanced CKD

EH Patients with CKD can Progress to ESRD

	Opportunity		URIROX-2[†] Population	Study 206 Population[*]
1	Delay CKD Progression	Delay progression to more severe stages of CKD	✓	✓
2	Increase Pre-Transplant Eligibility	Lower oxalate levels in EH patients seeking a transplant, allowing them to qualify for a transplant		✓
3	Improve Post-Transplant Graft Success	Lower oxalate levels in the post-transplant population to decrease the chance of graft failure and/or renal function decline		✓

[†]URIROX-2 Long-Term efficacy endpoints include change in estimated glomerular filtration rate (eGFR) from Baseline

*Potential clinical outcomes to be assessed in future studies

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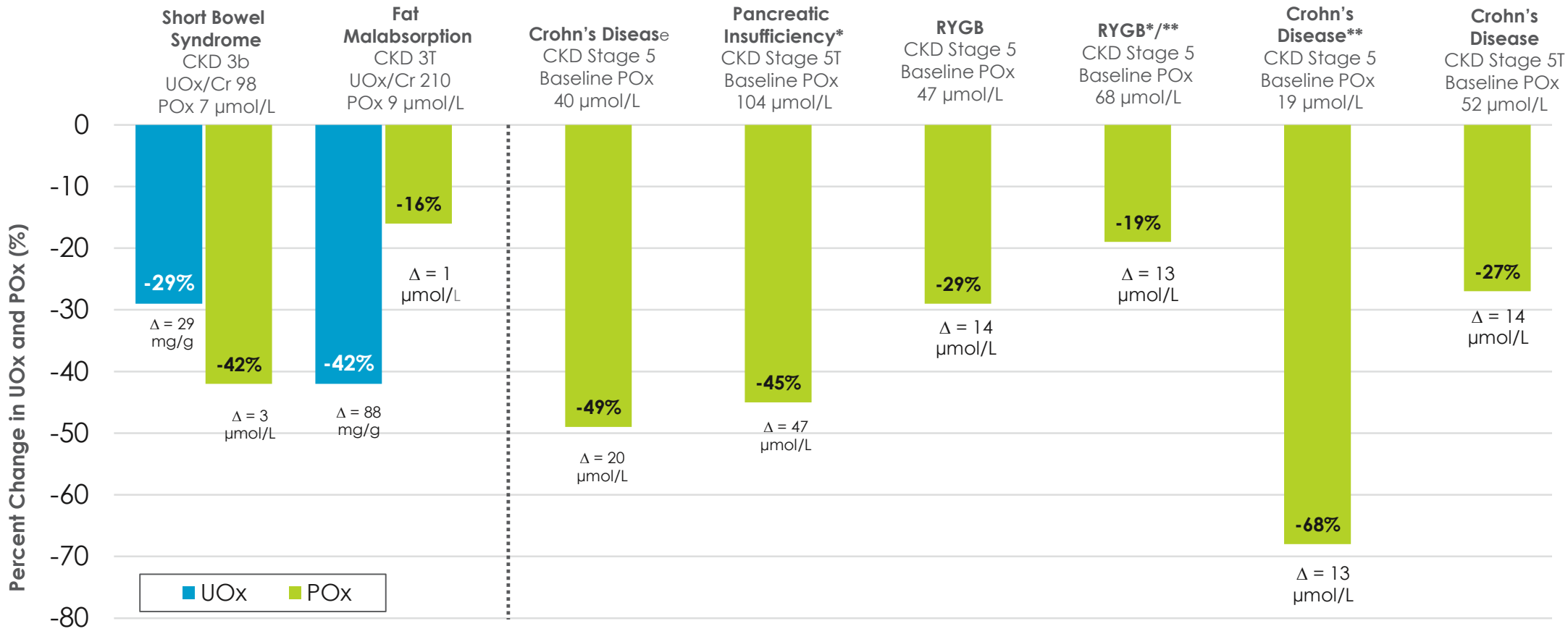
Study 206: Reloxaliase Demonstrates Robust Reduction in Oxalate Burden in Eight EH Patients with Advanced CKD



Urinary Oxalate (UOx mg/d) was normalized to creatinine mg/g; UOx reduction was calculated as a mean change from baseline using UOx measurements over 12 weeks; UOx was not measured in subjects on dialysis or on subjects with eGFR ≤ 15 ml/min/1.73m^2

Plasma oxalate (POx µmol/L) reduction was calculated as a mean change from baseline using POx measurements over 12 weeks.
*Subject had only 1 POx sample during the study

**Subject treatment ongoing

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Reloxaliase: Therapeutic Candidate with Blockbuster Potential

- High Unmet Need in Enteric Hyperoxaluria (EH)
- Novel Non-absorbed Oral Biologic
- URIROX-1 Trial Achieves Primary Endpoint with Highly Significant Reduction in UOx (p=0.004)
- Consistent Results across Phase 2 and 3 Studies
- Favorable Risk Benefit Profile
- FDA Alignment on Accelerated Approval Strategy
- Potential First FDA-Approved Treatment in EH
- Study 206 Data Supporting Further Development in EH with Advanced CKD
- Worldwide Marketing Rights

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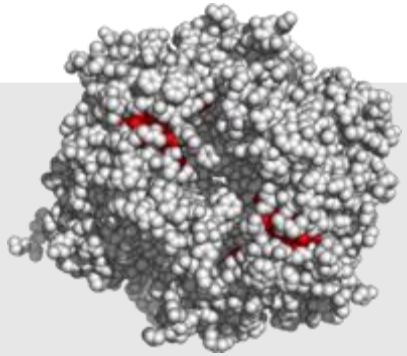
ALLN-346: Platform Extension Addressing Significant Opportunity in Gout Patients with Moderate-to-Severe CKD

Gout Market is Incompletely Served by Existing Therapies

- ~375,000 gout patients with moderate to severe CKD who have uncontrolled gout on urate lowering therapy (ULT)*
- Gout patients with renal impairment are not optimally managed due to limitations of existing therapies
  - Gout patients with kidney and liver problems are contraindicated for allopurinol, Uloric, and Zurampic
  - Current ULT's may interact with other medications
  - Co-morbidities (e.g. cardiovascular) may also limit ULT options
- Significant unmet need for safe and effective therapy that can be used in patients with renal impairment



ALLN-346 Therapeutic Strategy:

- Novel urate degrading enzyme optimized for stability in the GI tract
- MOA: orally administered, gut restricted enzyme therapeutic
- Animal POC: demonstrated a robust reduction in urine and plasma uric acid levels in a severe animal model of hyperuricemia with advanced CKD
  - *Data presented at American College of Rheumatology meeting October 22, 2018*

Sources: . *Lim JJ, Fu AC, and Reasner D. Prevalence of CKD and Uncontrolled Gout Among US Adults: Results from NHANES 2007-2012. Poster presented at: The National Kidney Foundation Spring Clinical Meetings; April 18-22, 2017; Orlando Florida. Fletcher Spaght Analysis July 2016; Image: Retailleau, P., Colloc'h, N., Vivares, D., Bonnete, F., Castro, B., El Hajji, M., Prange, T. (2005) Urate oxidase from Aspergillus flavus: new crystal-packing contacts in relation to the content of the active site. Acta Crystallogr.,Sect.D, 61, 218-229; D. Grujic Urol Res 2008, 193.

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Upcoming Milestones

TARGET	MILESTONE	STATUS
2Q19	**Study 206 Initial Data**	✓
4Q19	**URIROX-1 Topline Data**	✓
4Q19	**Study 206 Topline Data**	✓
4Q19	**ALLN-346 IND Filing**	On Track
2H20	**ALLN-346 Initial Data**	On Track
2H21	**URIROX-2 Topline Data**	On Track

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Q&A

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URIROX-1 and Study 206 Topline Results

November 7, 2019