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Company Presentation

March 2020

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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Our Purpose

Making a Difference for Patients with Rare Metabolic and Kidney Disorders

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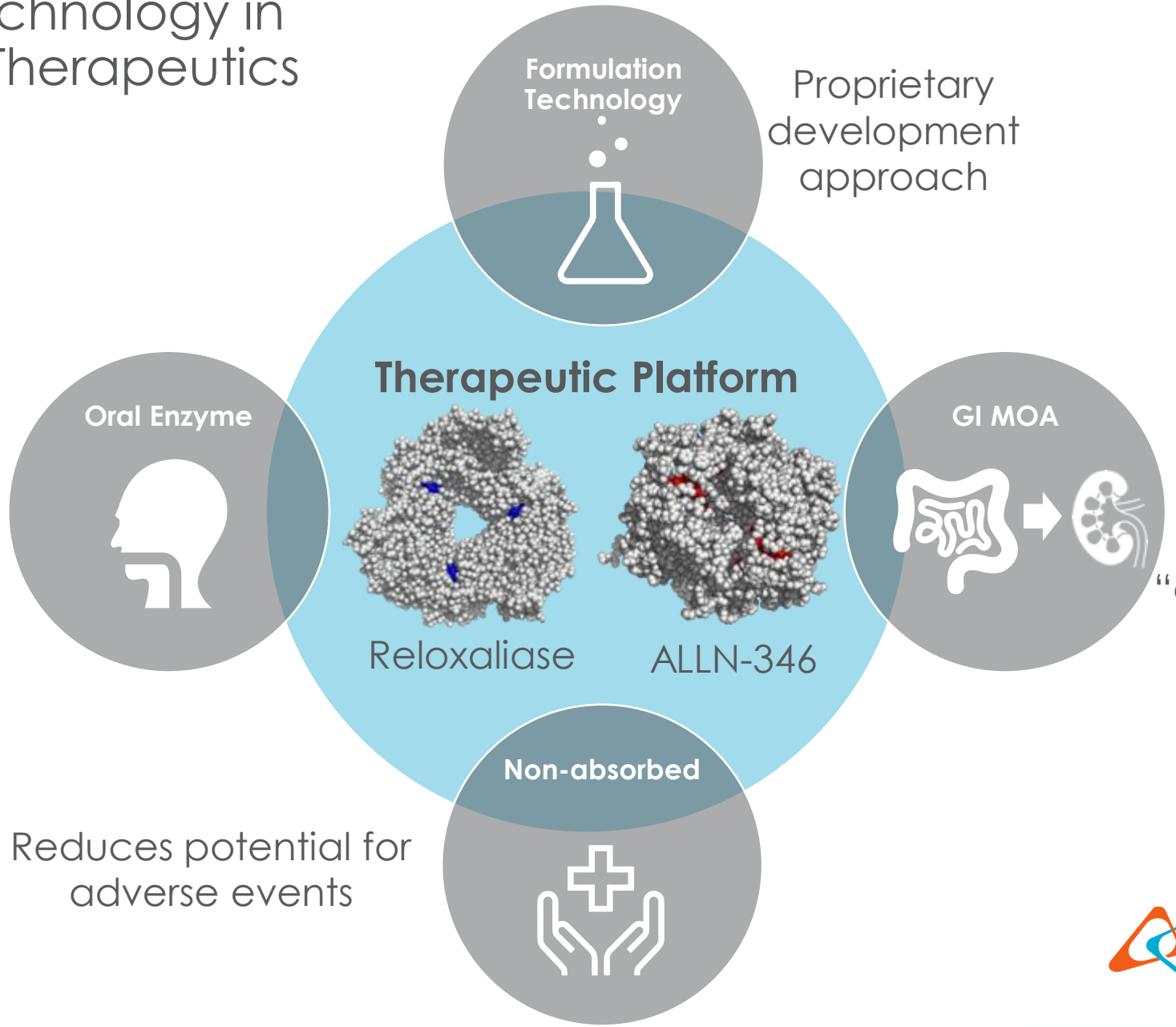
Pioneering Technology in Oral Enzyme Therapeutics



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Allena Recent Highlights

Streamlined URIROX-2 design following recent FDA engagement

Full URIROX-1 results increase confidence in URIROX-2

Positive Study 206 results support exploration of expedited pathways to approval in EH patients with advanced CKD

ALLN-346 IND submission positions program for first-in-human clinical study

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FDA Agreement in Principle on Streamlining URIROX-2

Streamlined URIROX-2 design following recent FDA engagement

- ✓ Reduced sample size from N=400 to N=200 based on higher kidney stone event rate observed in URIROX-1
- ✓ Accelerated first sample size reassessment for kidney stone events from N=240 to N=130
- ✓ Added interim analysis for UOx data at N=130

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Reloxaliase: Therapeutic Candidate with Blockbuster Potential

- High unmet need in enteric hyperoxaluria (EH) with no approved therapies
- Novel oral non-absorbed MOA limits oxalate burden on the kidney
- Positive results in first Phase 3 study, URIROX-1
  - Statistically significant reduction in UOx
  - Well tolerated safety profile
  - Well received by KOLs and treating clinicians
- Second pivotal Phase 3 study, URIROX-2, ongoing with FDA alignment on accelerated approval strategy
- Worldwide marketing rights

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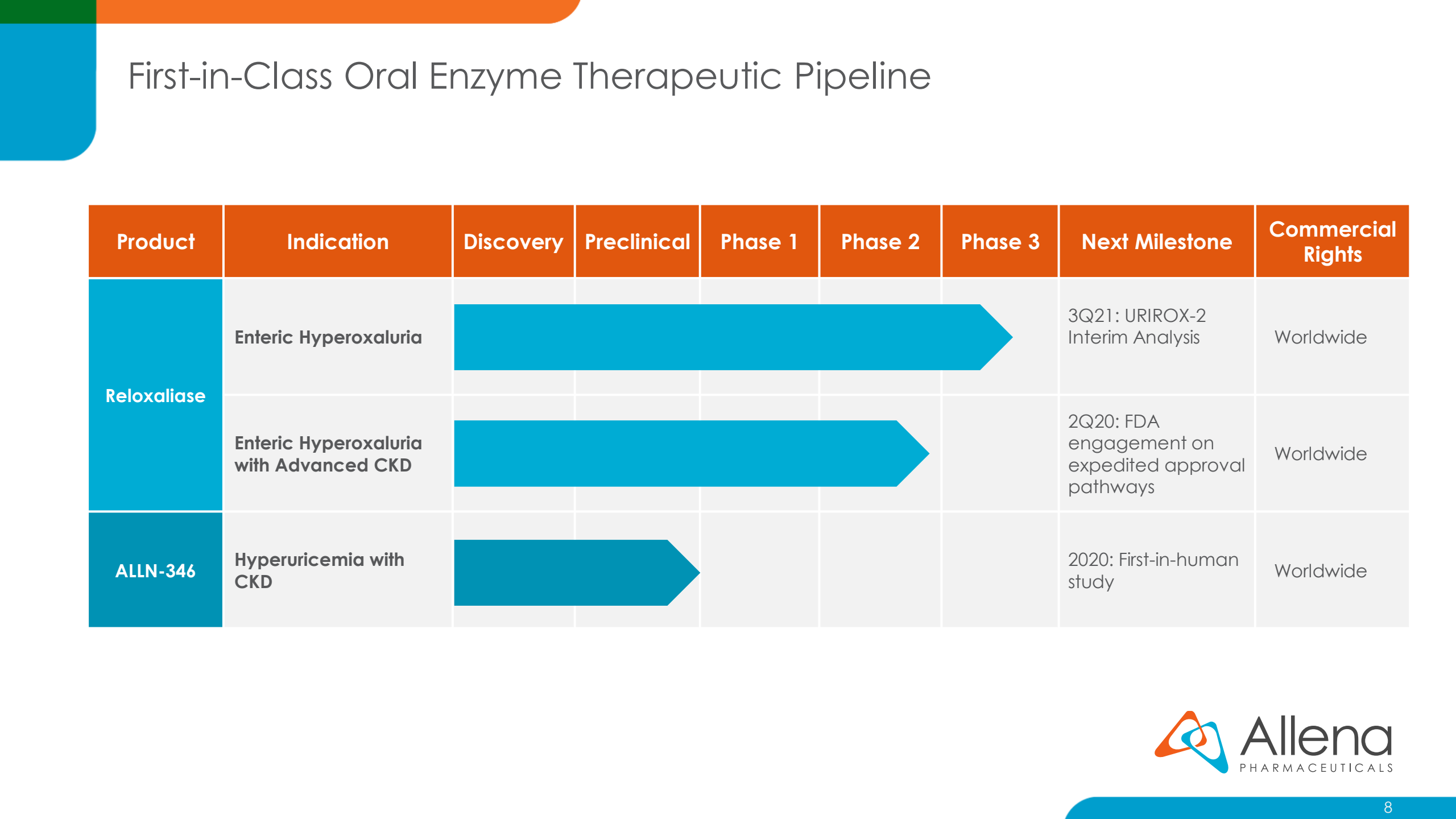
First-in-Class Oral Enzyme Therapeutic Pipeline

Product	Indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Next Milestone	Commercial Rights
Reloxaliase	Enteric Hyperoxaluria						3Q21: URIROX-2 Interim Analysis	Worldwide
	Enteric Hyperoxaluria with Advanced CKD						2Q20: FDA engagement on expedited approval pathways	Worldwide
ALLN-346	Hyperuricemia with CKD						2020: First-in-human study	Worldwide



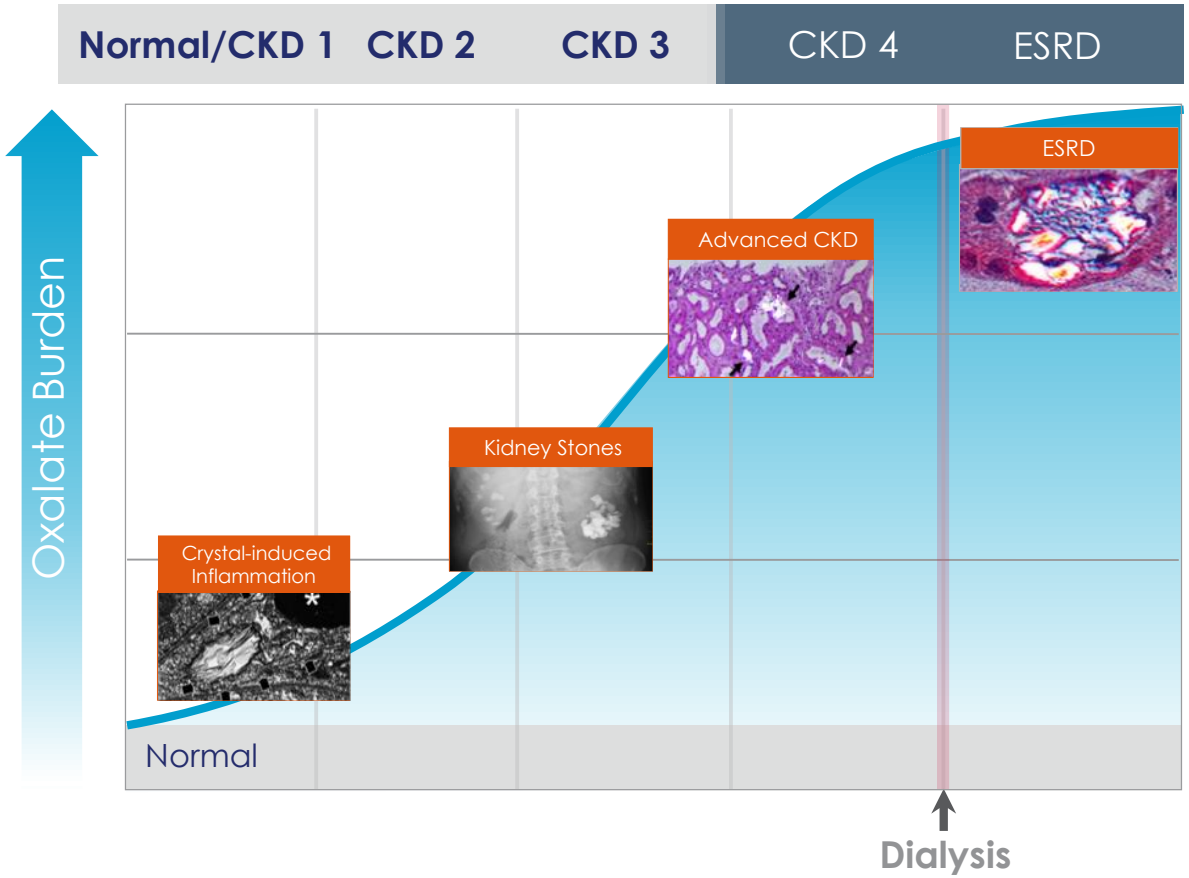
Unmet Need: Reduce Risk of Oxalate Damage to the Kidney

uriROX

Study Population:
Enteric Hyperoxaluria

Study 206

Enteric Hyperoxaluria with CKD and Hyperoxalemia



Enteric Hyperoxaluria

- Most recognized manifestation is kidney stone disease
- May progress to CKD and nephropathy due to high plasma and/or urine oxalate
- Renal replacement therapy required in > 50% of EH patients with oxalate nephropathy; most remained dialysis dependent with ~30% mortality rate
- By reducing oxalate levels, potential to slow CKD progression, enable kidney transplant and protect new kidney post-transplant

Source: 1. Lumlertgul et al, *Kidney Int Rep* 2018

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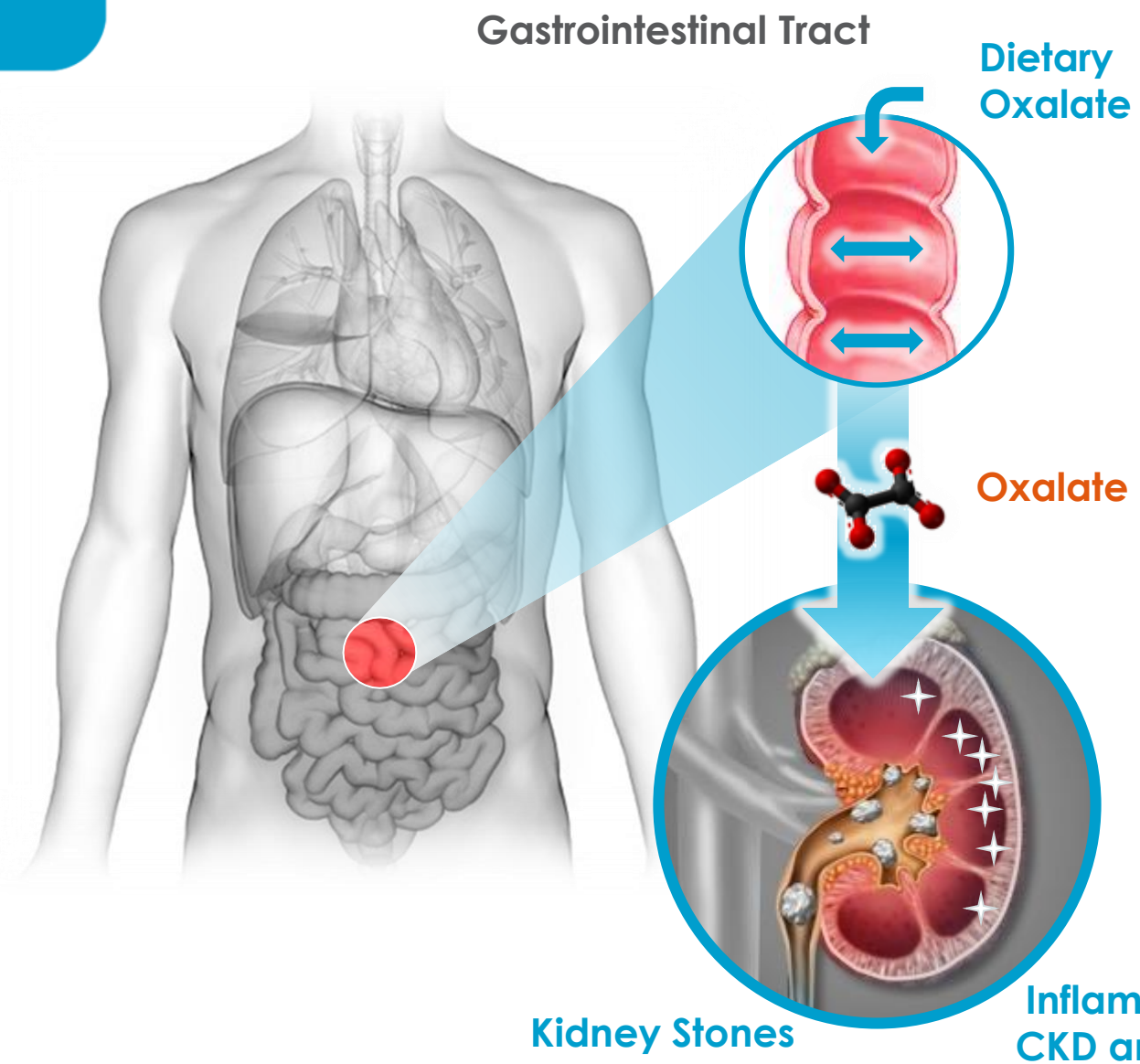
Enteric Hyperoxaluria: Disease Overview



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 and other malabsorptive conditions

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

Therapeutic Strategy: ≥ 20% reduction in urine oxalate (UOx) could result in a 25-50% lower incidence of kidney stone recurrence, and may increase renal survival[1]

[1]1Borghi N Eng J Med. 2002; Taylor and Curhan, Kidney Int. 2008; Curhan GC et al., J Am Soc Nephrol., 28 2017; Clin J Am Soc Nephrol. 2016 Jan 7; 11(1): 119–126.

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Current Treatment Approach is Suboptimal

Diet & Behavioral Modification

- High Fluid Intake to Increase Urine Output
- Restrictions to Reduce Oxalate Intake
  (Oxalate rich foods are part of a healthy diet)
- Decrease Sodium Intake

Targeted Therapeutics

- Thiazide Diuretics (for Hypercalciuria)
- Potassium Citrate (for Hypocitraturia)

ESRD

- Kidney Transplantation
- Dialysis

Surgery

- Kidney Stone Removal
  - Ureteroscopy
  - Shockwave lithotripsy
  - Percutaneous nephrolithotomy

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

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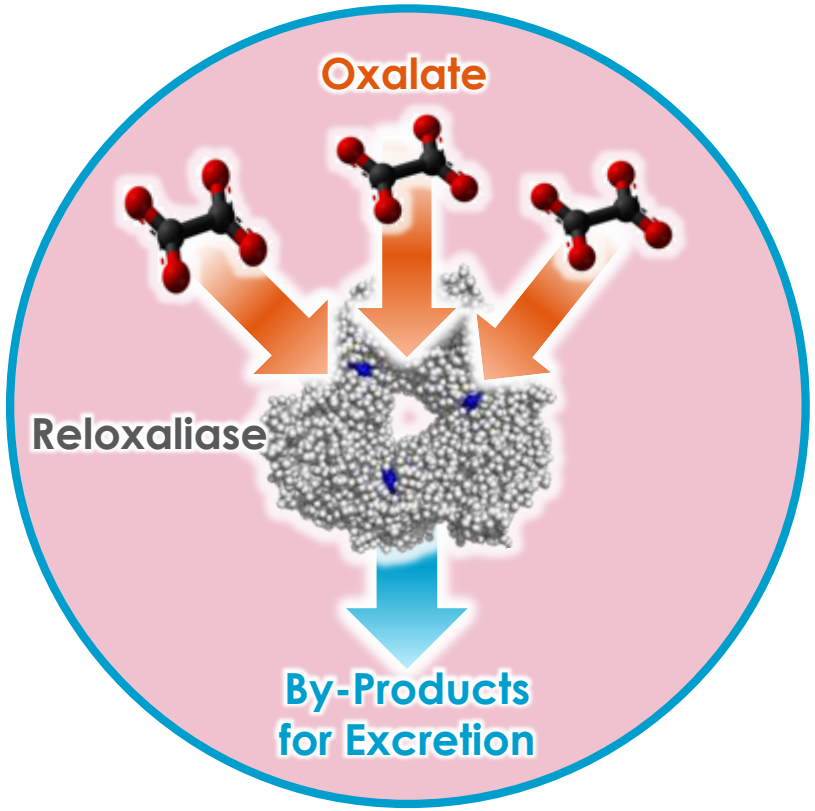
Reloxaliase: First-In-Class Therapeutic Candidate for EH

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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Evolution of Reloxaliase Program in Enteric Hyperoxaluria

Preclinical	Ph 1 Healthy Volunteers	Ph 2 Open Label	Ph 2 Randomized Controlled	Ph 3 Randomized Controlled
✓	✓	✓	✓	UR-1:✓, UR-2: initiated 1Q 2019
Progressive Increase in Enzyme Activity Porcine Rhubarb Model Presented at AUA 2016 Porcine Western Diet Model Presented at ASN 2016	n=30 A Double Blind, Placebo Controlled, Randomized Cross-Over Study with ALLN-177, an Orally Administered Oxalate Degrading Enzyme Langman et al, *Am. J Nephrol* 2016; 44:150-158 Presented at ASN 2014	n=16 [396] Multicenter, Open Label, Single Arm Outpatient Study in Enteric and Idiopathic Hyperoxaluria Presented at ASN 2015 Lingeman et al, *Inter Urol Nephrol* 2019 n=18 [206] Multicenter, Global, Open-label Phase 2 Basket Study in Primary Hyperoxaluria, or Enteric Hyperoxaluria with Advanced CKD and Elevated Plasma Oxalate Presented at ASN 2019 (interim data)	n=67 713: Multi-Center, Randomized, Double-Blind, Placebo-Controlled in Enteric and Idiopathic Hyperoxaluria Presented at ASN 2017	uriROX N=115 URIROX-1: Multi-Center, Global, Randomized, Double-Blind, Placebo-Controlled Study in Enteric Hyperoxaluria Presented at ASN 2019 uriROX-2 n≈200 URIROX-2: Multi-Center, Global, Randomized, Double-Blind, Placebo-Controlled Study in Enteric Hyperoxaluria (Ongoing)

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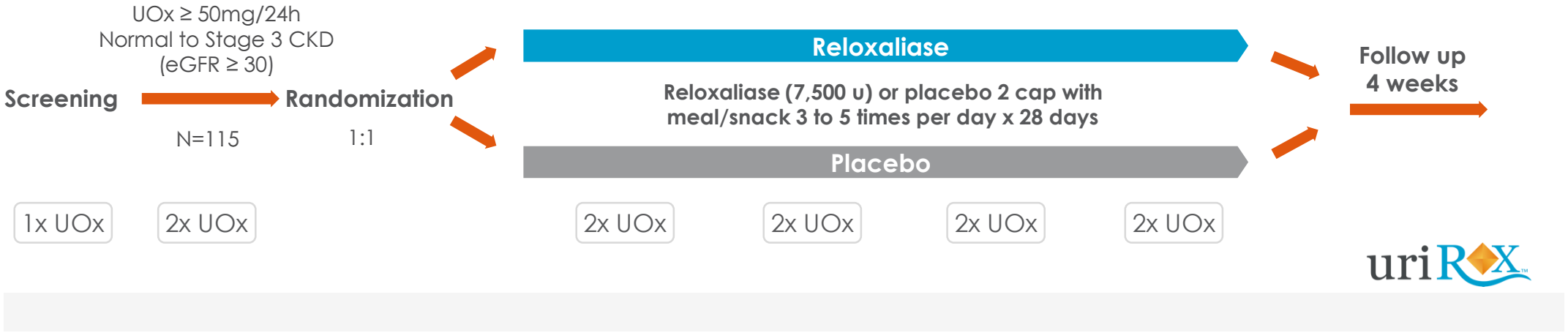
URIROX-1: Evaluate the Safety and Efficacy of Reloxaliase in Patients with Enteric Hyperoxaluria



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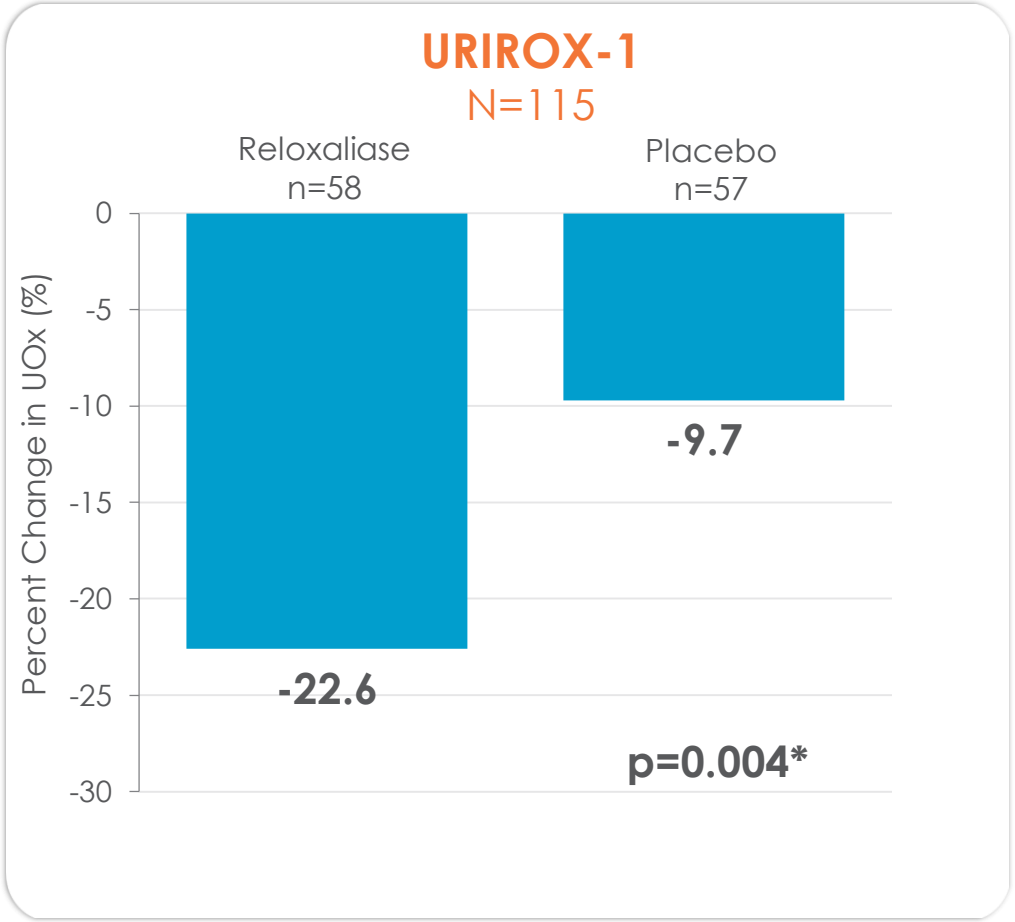
1. Kidney stone events during the study period were approximately equally distributed between treatment and placebo groups

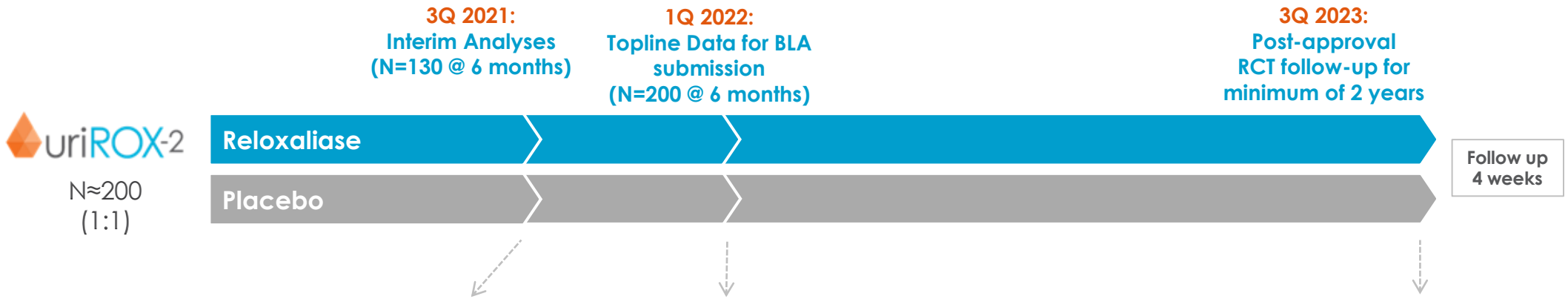
URIROX-1 Primary Endpoint: Statistically Significant Reduction of UOx



- Achieved primary endpoint
- Highly statistically significant response vs. 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

Streamlined URIROX-2 Clinical Trial Design and Expected Milestones



INTERIM ANALYSES

Conditional probability for confirming UOx reduction (primary and secondary endpoint)

- *SSR1: sample size increase if necessary*

Assessment of whether interim KS event rate is consistent with estimate upon which the sample size was based

- *SSR1: sample size increase if necessary*

FILING REQUIREMENTS

Conditional probability for confirming clinical benefit (KSD)

- *SSR2: sample size increase if necessary*

Primary Endpoint: Percent change from baseline in 24h UOx excretion during weeks 1 to 4

Secondary Endpoint: Percent change from baseline in 24h UOx excretion during Weeks 16 to 24

Model of relationship between UOx and KS events, informed by data from the study

LONG-TERM EFFICACY ENDPOINTS TO CONFIRM CLINICAL BENEFIT

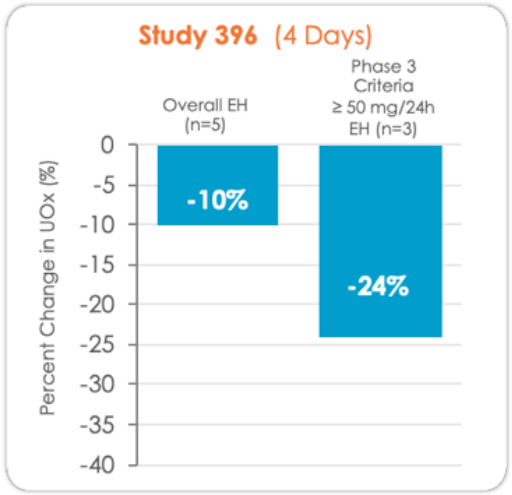
Primary Endpoint: KSD progression

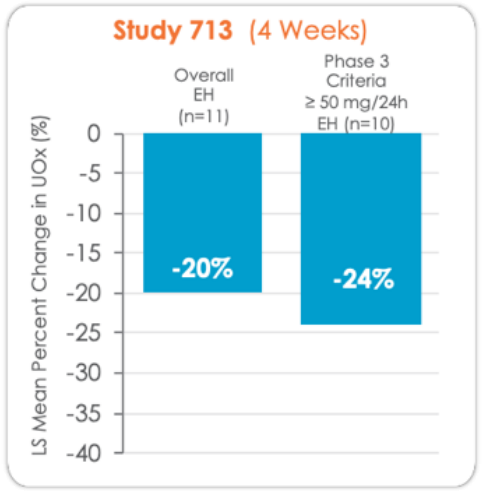
Secondary Endpoints:

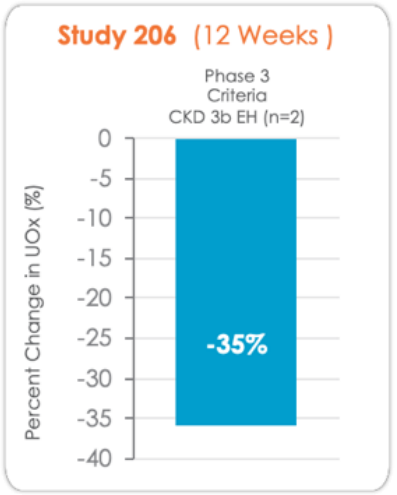
- *Hospitalizations, ER visits, procedures*
- *Change in eGFR*

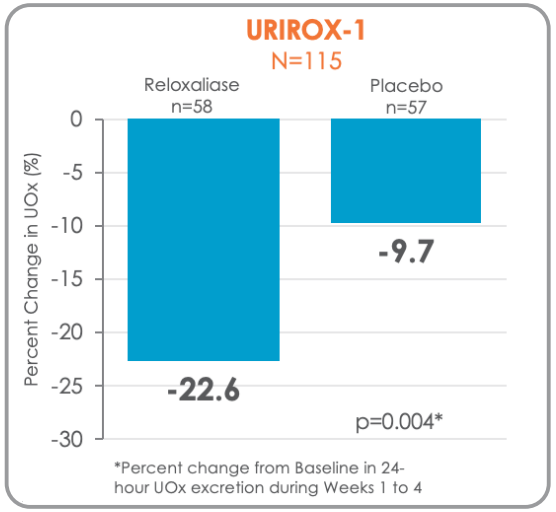
Primary Endpoint: Reloxaliase has Demonstrated a ≥20% Treatment Effect in Four Independent Clinical Studies

- URIROX-2 shares common enrollment criteria and primary endpoint with URIROX-1
- URIROX-2 sample size N=200 vs. N=115 in URIROX-1
- In URIROX-1:
  - Reloxaliase demonstrated a highly statistically significant treatment difference vs. placebo (P=0.004)
  - Reloxaliase 22.6% LS mean reduction in UOx consistent with Phase 2 studies









■ UOx

Presented at ASN 2014

Presented at ASN 2017

Presented at OHF 2019

Presented at ASN 2019

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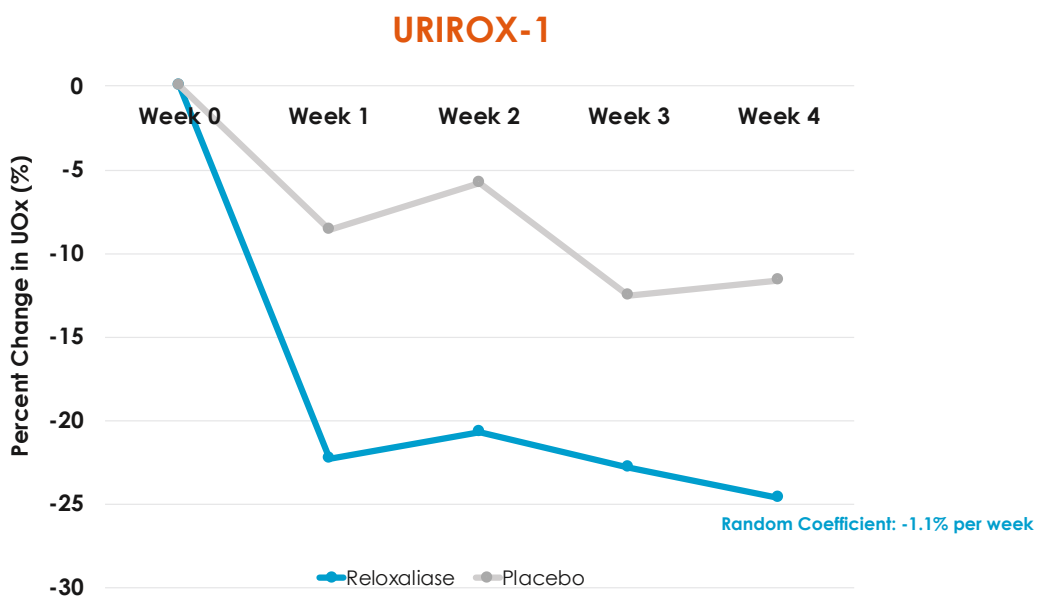
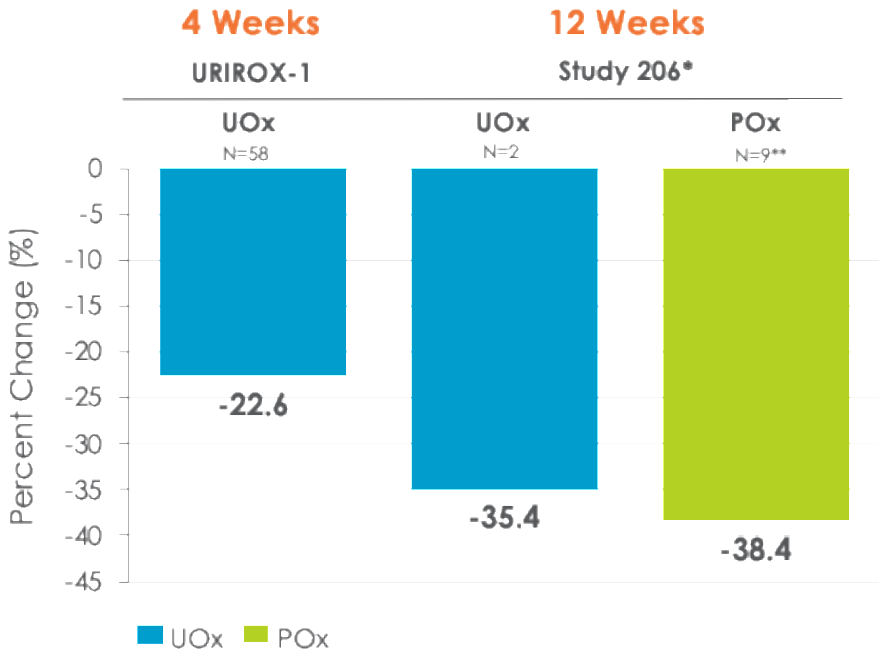
Secondary Endpoint: Confidence in Sustained Reloxaliase Reductions During Weeks 16-24

Reloxaliase Demonstrates Sustained Reductions in UOx Across Weeks 1-4



Reloxaliase MOA Supports Potential For Cumulative Treatment Effect Over Time



** Data presented at ASN (Nov 2019)*
*** Mean was calculated if at least 2 of 3 values were available*

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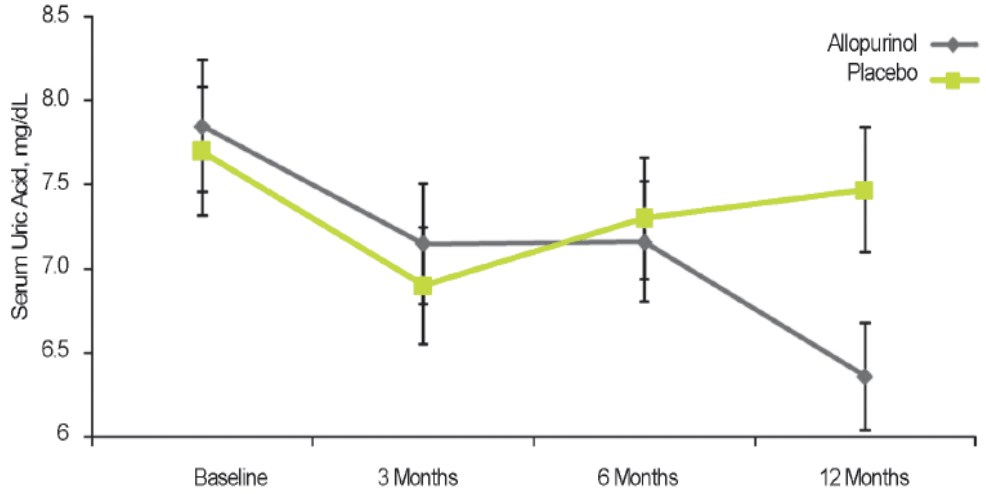
Renal and Metabolic Disease Studies Show Waning of Placebo Effect Over Time

Reference	Active Drug	Patient Population	Surrogate Marker	Time of Max PBO Effect	Final Timepoint	PBO Change from Baseline at Time of Max PBO Effect	PBO Change from Baseline at Final Timepoint
Golmohammadi 2017	Allopurinol	Hyperuricemia	Serum Uric Acid (mg/dl)	3 months	12 months	**-10.4%**	**-3.0%**
Ala-Opas 1987	Hydrochlorothiazide	Hypercalcuria	Urine Oxalate (umol)	1 month	6 months	**-14.5%**	**1.8%**
Scholz 1982	Hydrochlorothiazide	Hypercalcuria	Urine Calcium (ug/min)	3 months	12 months	**-19.7%**	**-0.7%**
Sprague 2009	Lanthanum	Hyperphosphatemia	Serum Phosphate (mg/dL)	2 weeks	8 weeks	**-9.3%**	**-4.2%**
Block 2012	Calcium acetate, Lanthanum, Sevelamar	Hyperphosphatemia	Serum Phosphate (mg/dL)	3 months	9 months	**-4.2%**	**-0.6%**
Bailey 2012	Dapagliflozin	Diabetes	HbA1c %	4 weeks	24 weeks	**-2.6%**	**0.5%**
Bode 2015	Canagliflozin	Diabetes	HbA1c %	6 weeks	104 weeks	**-2.6%**	**2.2%**



Example: Golmohammadi 2017

Active drug effect on serum uric acid increases over study as placebo effect resolves to baseline

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Source: Boston Strategic Partners, 2020

Reloxaliase Generally Well-Tolerated in Clinical Trials to Date

	Study 396	Study 649		Study 713		URIROX-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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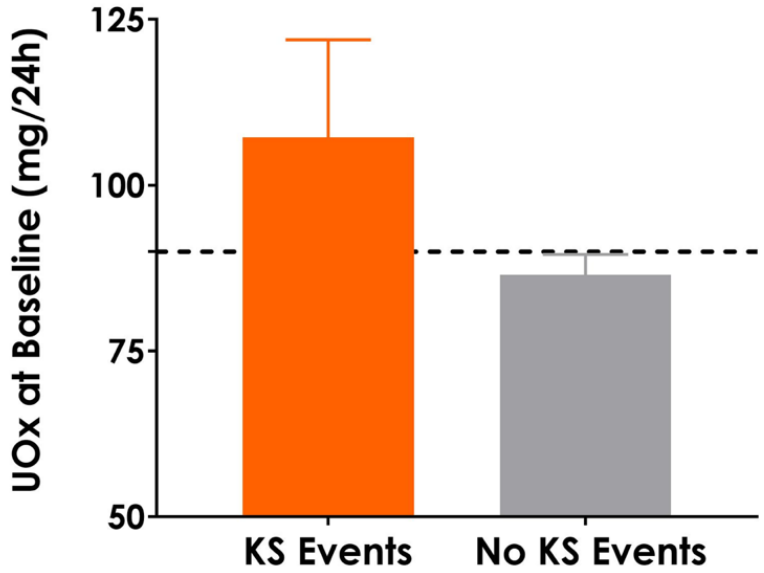
URIROX-1 Confirms Increased KS Risk Associated With High UOx

Historic KS Burden URIROX-1 Population

UOx at Baseline (mg/24h)	<90	>90
n	66	43
KS mean (SE)	8.6 (3.4)	14.7 (6.9)

Available kidney stone history data within 5 years prior to enrollment

Baseline UOx for Patients With or Without a KS Event During URIROX-1



Patients	15*	100
Baseline UOx, mean (SE)	107.2 (14.7)	86.5 (3.1)

** Actual annual KS event rate in URIROX-1 (0.78) is 3.5x the rate initially used to power URIROX-2*

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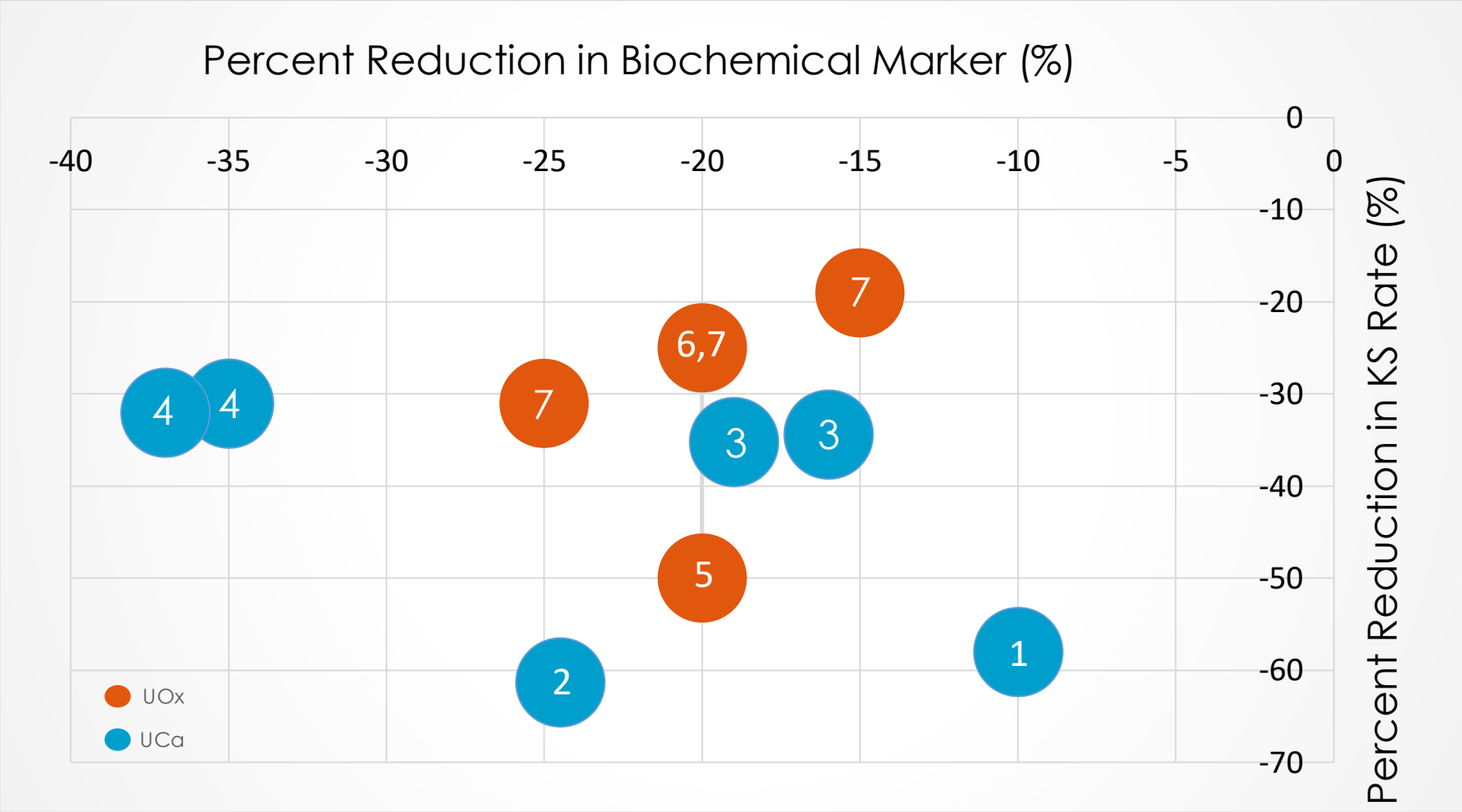
Long-term Clinical Endpoint: Interventional and Observational Studies and Modeling Demonstrate Biomarker Reduction Leads to Substantial Reduction in KS



References:
1. Ohkawa et al; Br J Urol. 1992
2. Ashlstrand et al ; Br J Urol. 1984
3. Ettinger et al, J Urol. 1988
4. Borghi et al, J Cardiovasc Pharmacol. 1993
5. Borghi, et al, N Engl J Med. 2002
6. Curhan et al; Kidney Int. 2008
7. Mayo Model Dataset

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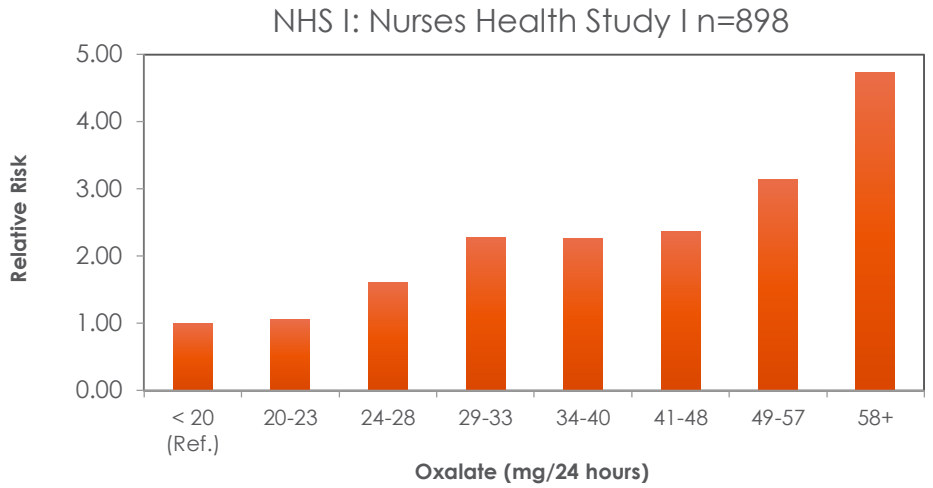
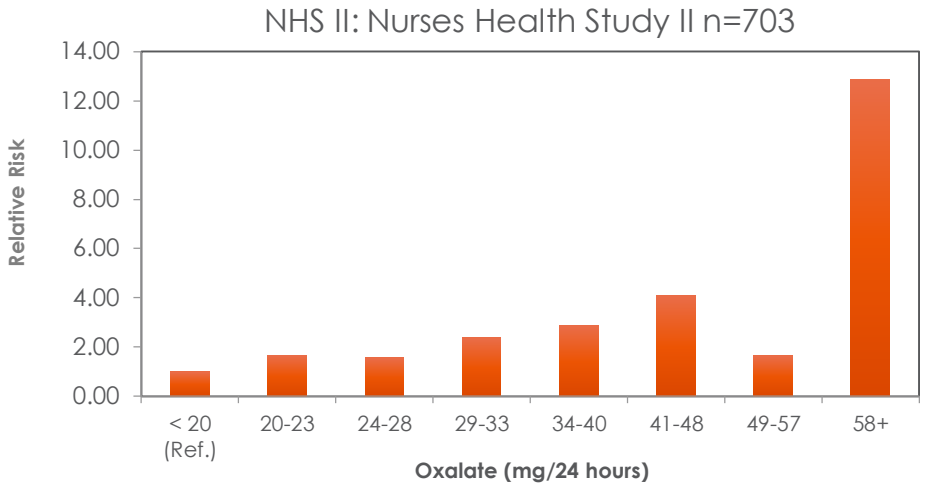
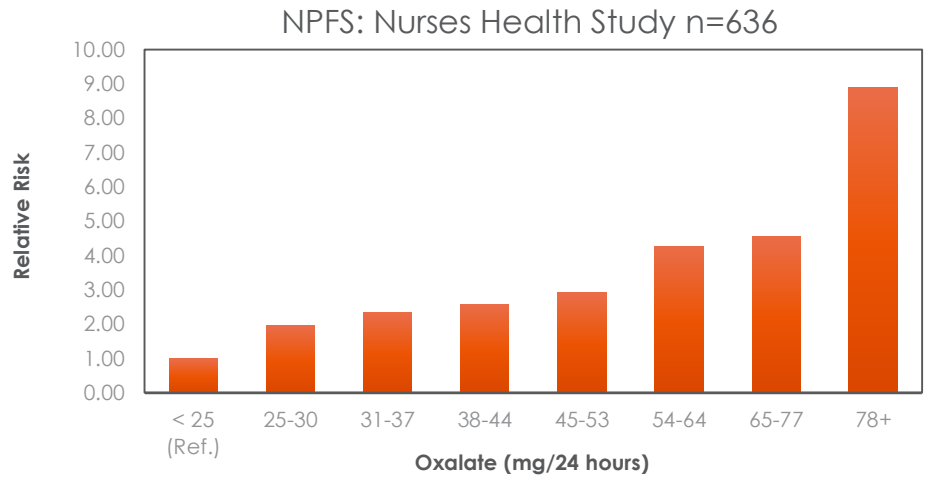
Risk of Kidney Stones Increases Progressively with UOx Levels







- Assuming a non-linear relation, the multivariate RR* per 20% higher oxalate (avg of two collections):
  - NHS1: 1.37 (1.23, 1.53); p <0.001
  - NHS2: 1.22 (1.11, 1.33); p <0.001
  - HPFS: 1.17 (1.07, 1.29); p =0.001
  - **Pooled: 1.25 (1.14, 1.36); p<0.001**
- Similar to the multivariate RR* per 10 mg higher oxalate is:
  - NHS1: 1.37 (1.18-1.60; p <0.0001)
  - NHS2: 1.53 (1.30-1.80; p <0.0001)
  - HPFS: 1.24 (1.10-1.39; p =0.0004)

*adjusted for age and other 24-hr urinary risk factors

HPFS = Health Professional Follow-up Study; NHS = Nurses Health Study

GC Curhan and EN Taylor. 24-h uric acid excretion and the risk of kidney stones. Kidney Int 2008; 73:489; GC Curhan, et al. Absolute Compared with Percentage Differences in 24-Hour Urine Oxalate and Likelihood of Being a Kidney Stone Former Session Information . ASN kidney week, 2017

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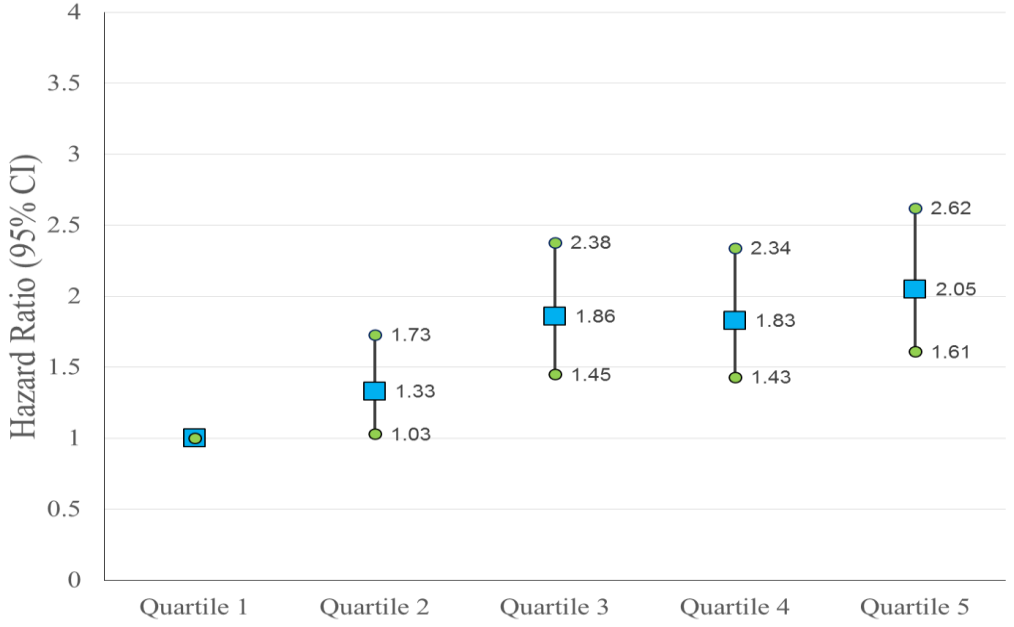
Higher 24h Urinary Oxalate Excretion Is a Risk Factor for CKD Progression and ESRD

UOx mg/24h	Quartile 1 < 11.4 mg	Quartile 2 11.5 – 16.1 mg	Quartile 3 16.2 – 21.0 mg	Quartile 4 21.1 mg – 27.7 mg	Quartile 5 27.8 – 102.1 mg
No.	625	625	624	626	623
ESRD Events	99	128	171	168	186
ESRD Events/1000py	2.38	3.18	4.44	4.37	4.90

24h Urinary Oxalate Excretion

- 3,123 participants of the Chronic Renal Insufficiency Cohort study (CRIC)
- Participants were followed longitudinally for incident ESRD and/or halving of eGFR

Risk of ESRD



Source: Waikar et al; 2019

Long-Term Clinical Benefit Endpoint: KSD Progression

Achieving Long-Term Clinical Benefit

- MOA supports potential for cumulative treatment effect
- Comparable studies show waning of placebo effect
- URIROX-1 confirms increased KS risk associated with high UOx
- Sample size reassessments support long-term endpoint POS
- ~20% reduction in UOx could result in 25-50% reduction in KS recurrence and may increase renal survival[1]
- eGFR endpoint can also support long-term clinical benefit

Mitigating Long-Term Risk

- Of 185 products first approved via the FDA accelerated approval pathway since 1996, only 3 have been removed from the market (Latham & Watkins analysis)
- Opportunity for real world evidence enhance data package and adoption
- Favorable risk-benefit profile expected to persist with >2-year safety dataset
- Alnylam and Dicerna UOx likely approval precedents
- Emerging patient advocacy environment (OHF, Alnylam, Dicerna, etc.)

[1]1Borghi N Eng J Med. 2002; Taylor and Curhan, Kidney Int. 2008; Curhan GC et al., J Am Soc Nephrol., 28 2017; Clin J Am Soc Nephrol. 2016 Jan 7; 11(1): 119–126.

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 Treatment of Adult and Pediatric Patients with Primary or Enteric Hyperoxaluria and Advanced CKD ('Basket' Study)

Rationale

- Signal seeking study in hyperoxalemia and orphan populations: EH with CKD, EH on dialysis, EH post kidney transplant, PH1-3
- First time assessing plasma oxalate (POx), to determine subsequent utility as endpoint in RCT
- First exposures in dialysis, PH, and adolescents

Hypothesis

- Declining kidney function leads to oxalate accumulation in plasma (hyperoxalemia) and body (systemic oxalosis)
- By degrading oxalate in GI tract, reloxaliase may be able to reduce oxalate burden as measured by UOx and Pox

Study Design

- Open-label study of subjects ≥ 12yrs in PH or EH w/ hyperoxalemia
- Key Endpoint: Change from baseline in POx and 24h UOx excretion

(CT.GOV: NCT03391804)

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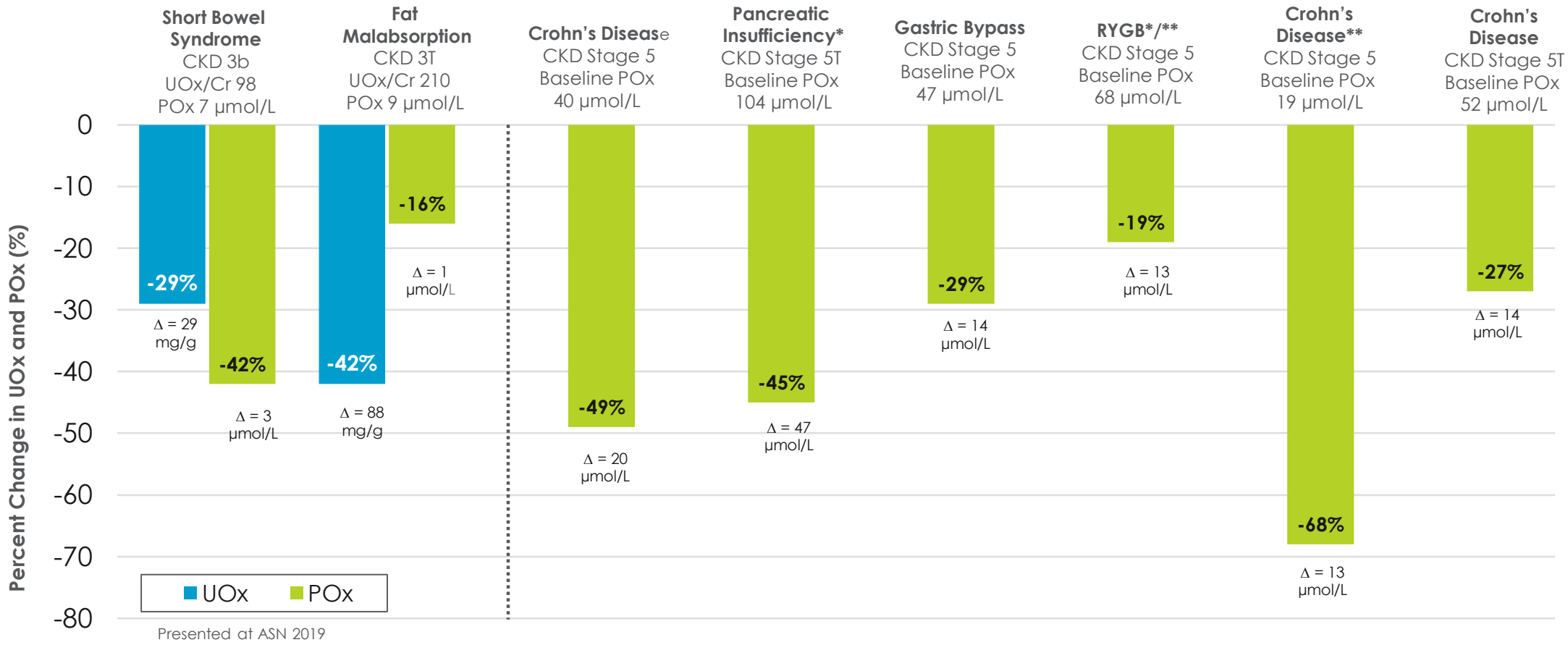
Study 206: Reloxaliase Demonstrates Robust Reduction in Oxalate Burden in Eight EH Patients with Advanced CKD



Presented at ASN 2019

Engagement with FDA in 1Q 2020 to explore expedited approval pathways

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/1.73m²
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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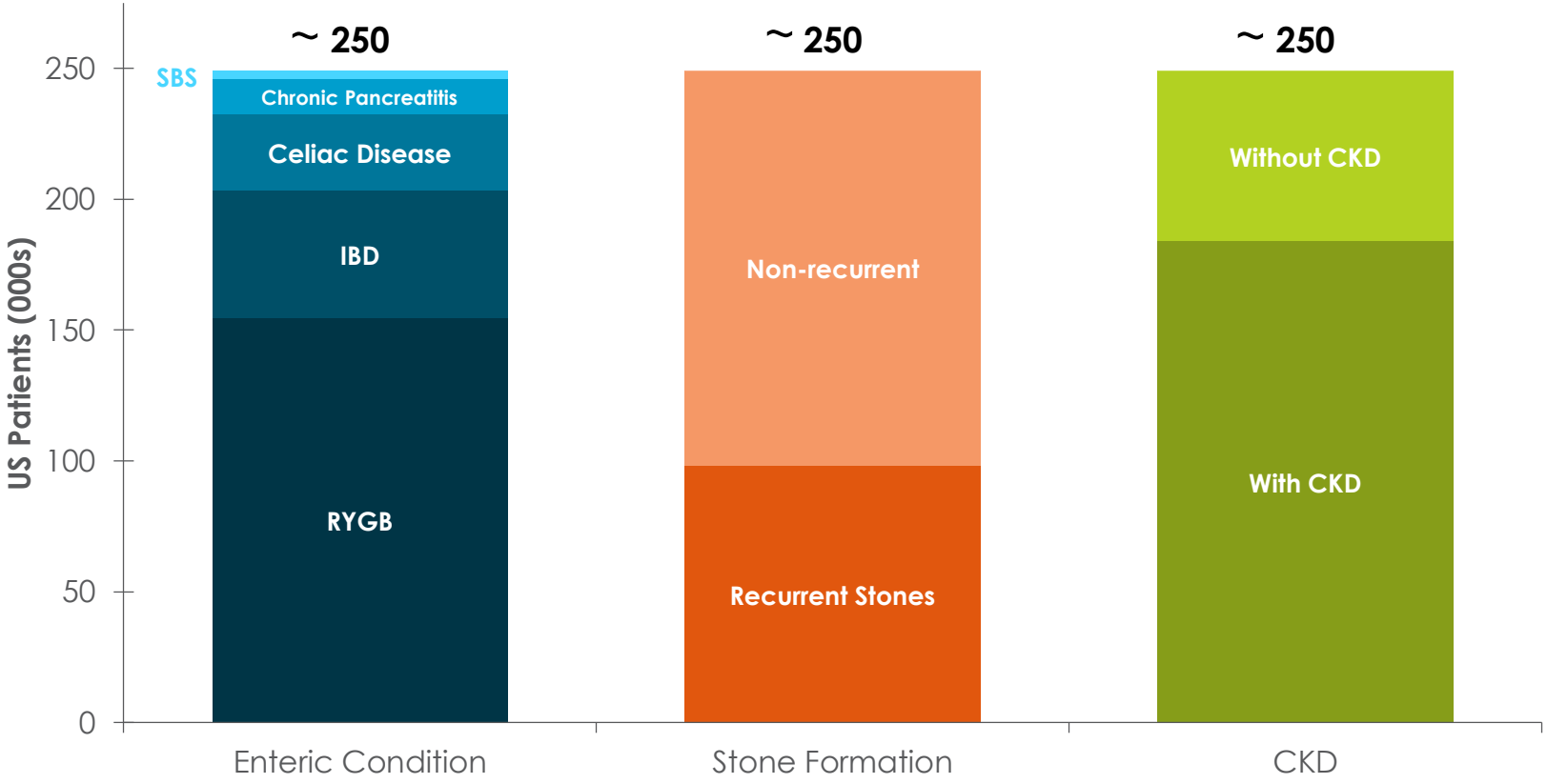
Enteric Hyperoxaluria – Patient Segmentation

There are ~250,000 EH patients in the US: 40% have recurrent stones and 74% have CKD

US Enteric Hyperoxaluria Patients, 2019



Source: Health Advances interviews and analysis, Health Advances EH Patient Markov Model.

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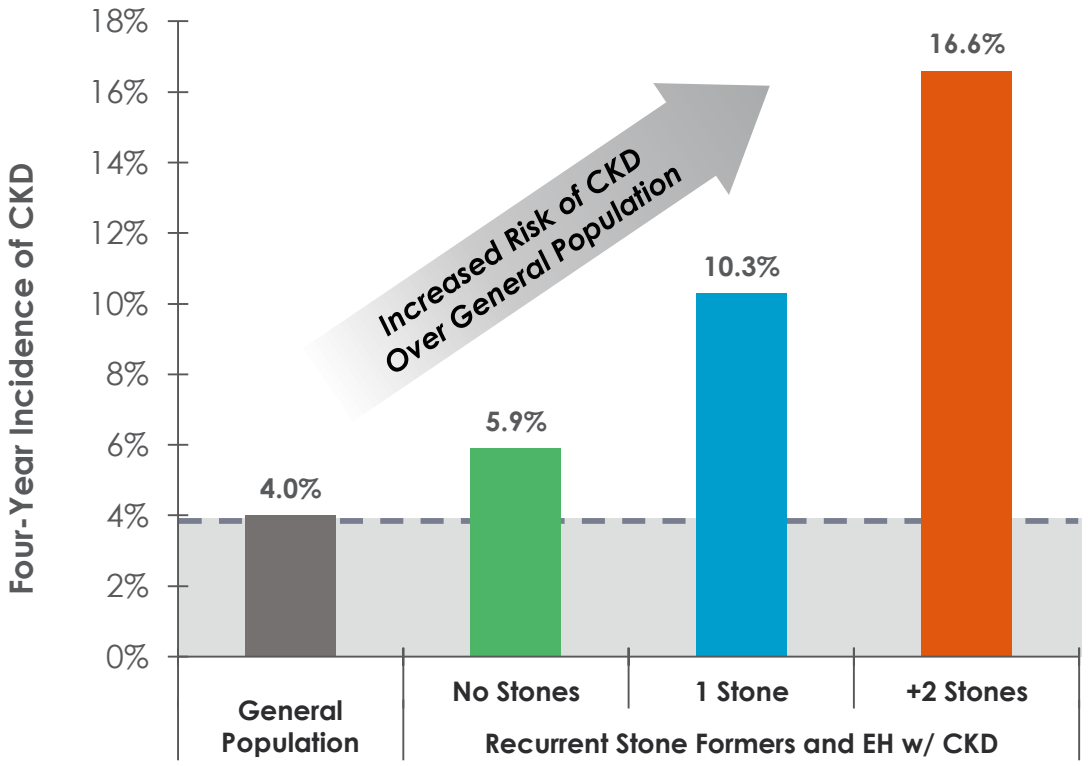
Enteric Hyperoxaluria – Increased Risk of CKD

Patients with enteric disease are far more likely to develop CKD, particularly those with a history of kidney stones

Risk of Developing CKD

Four-Year Incidence of CKD, Truven Analysis



Risk of Developing CKD by Enteric Indication

Four-Year Incidence of CKD, Truven Analysis

Enteric Indication	No Stones	1 Stone	+2 Stones
Crohn's Disease	5.4%	11.3%	15.6%
Ulcerative Colitis	5.4%	11.8%	15.6%
RYGB	5.2%	8.7%	16.2%
Chronic Pancreatitis	10.0%	17.5%	20.5%
Short Bowel*	9.6%	16.6%	21.5%

*Small bowel resection or gastrectomy with Roux-en Y.

Source:Health Advances analysis, Allena Truven analysis, CDC CKD Surveillance Program, UpToDate.

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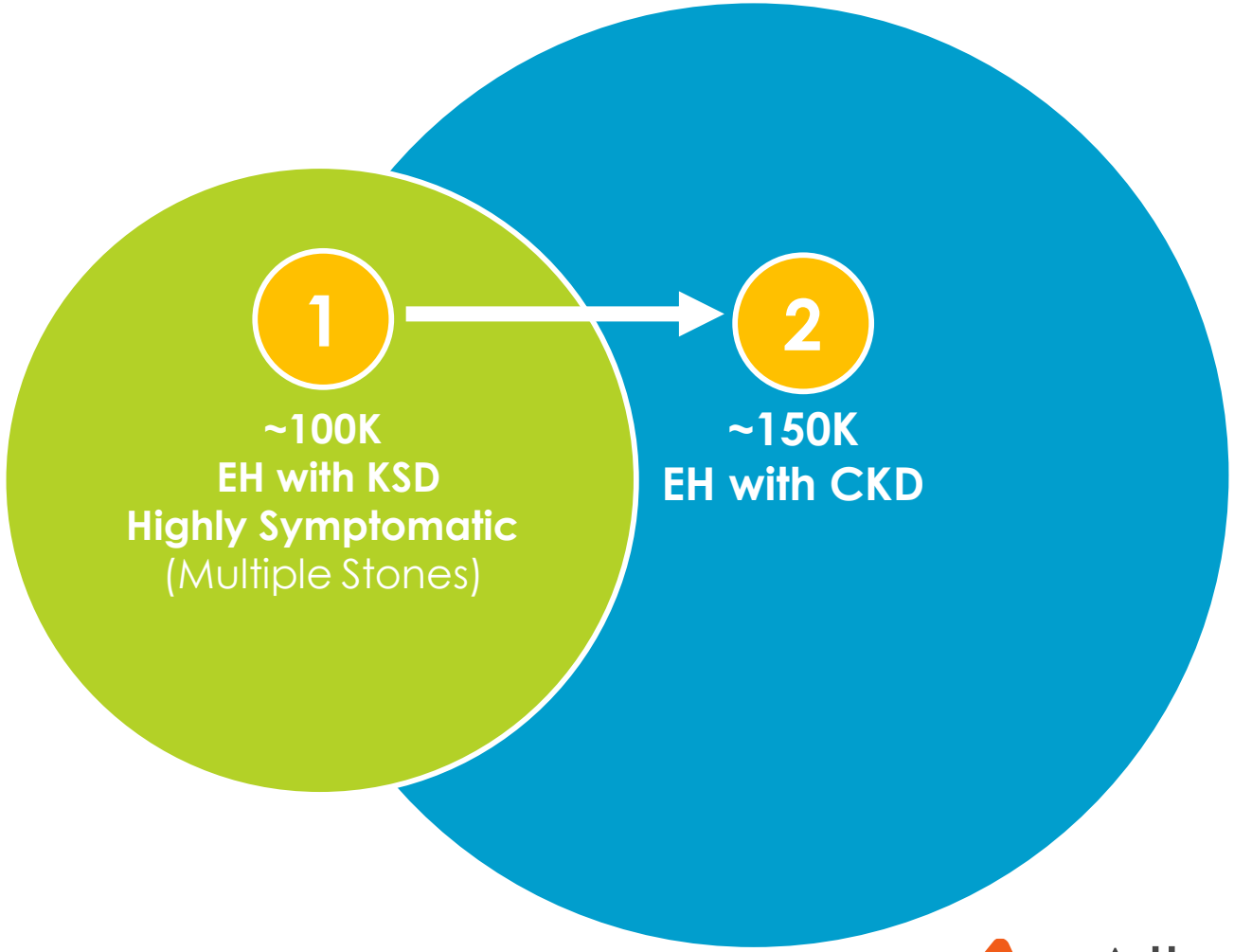
Unlocking Blockbuster Potential in Enteric Hyperoxaluria

US Target Patient Population is ~250,000

1. Launch Focus

2. Clinical Outcomes Data to Drive Penetration



Source: Health Advances Analysis, 2019

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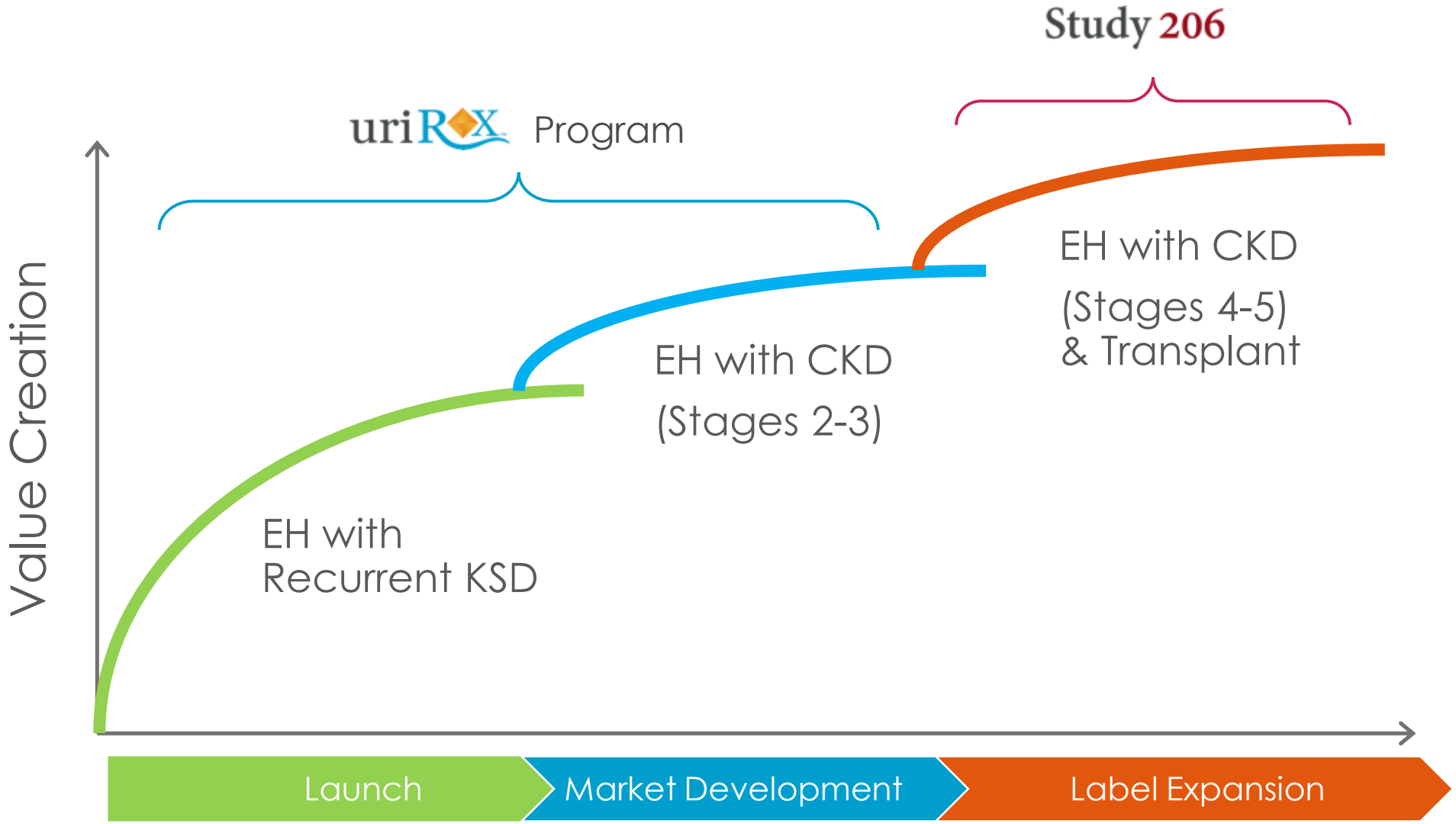
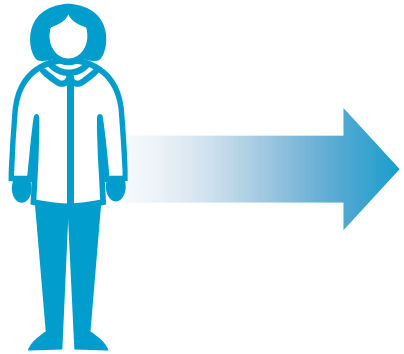
Clinical Program Designed to Facilitate Penetration in EH



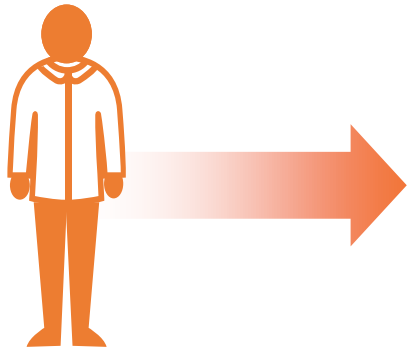
US Commercialization Strategy

Allena Sales Force Target Audience



~5,000

Nephrologist



~7,000

Urologist

Source: Health Advances Analysis, 2019

High-Volume Prescribing Physicians, Treating the Majority of EH Patients with KSD and/or CKD

Settings of Care

Kidney Stone Clinics

Nephrology and Urology Practices

Hospitals

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Market Research Indicates Immediate Adoption Based On UOx Data

- Health Advances tested URIROX-2 target product profile (TPP) showing 20-30% UOx reduction with 27 physicians and payers
  - Physicians believe that elevated UOx levels are associated with KSD and CKD
  - Positive feedback on TPP from both physicians and payers:
    - Physicians: High intention to prescribe (83%) based on biomarker data alone
    - Payers: Majority (67%) coverage of reloxaliase with biomarker data alone
- Physician results reinforced by October 2019 Roth survey (N = 42)
- Recent KOL feedback on URIROX-1 UOx topline data consistent with prior market research
  - *"I was enthusiastic when I saw the data…I'm ready to write a prescription for it" – David S. Goldfarb, MD, NYU*
  - *"Based on these data, reloxaliase is definitely better than anything we have in clinical practice today" - Orson Moe, MD, University of Texas Southwestern Medical Center*
- Subsequent physician and payer testing of URIROX-1 TPP showing net 15% UOx reduction was also very positive
  - *"That's an easy selling point for a lot of nephrologists - oxalate is a risk factor for stones, oxalate is a risk factor for progression of CKD, and we can lower your oxalate by 22.5 percent if you take this drug" – KOL Nephrologist*
  - *"If you've got strong efficacy that shows a long-term decrease in kidney stone disease progression by 20 percent, that to me is strong enough" – KOL Urologist*

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ALLN-346: First-In-Class Oral Enzyme Candidate Entering Clinical Development for Patients with Hyperuricemia and CKD

- Current US market for urate-lowering therapeutics exceeds $1B
- High unmet need for gout patients with moderate to severe CKD
- GI non-absorbed MOA targets uric acid in intestine
- Preclinical proof-of-concept demonstrated in murine and porcine studies
- IND cleared for first-in-human clinical study
- Established regulatory path for serum uric acid as approvable endpoint
- Worldwide marketing rights

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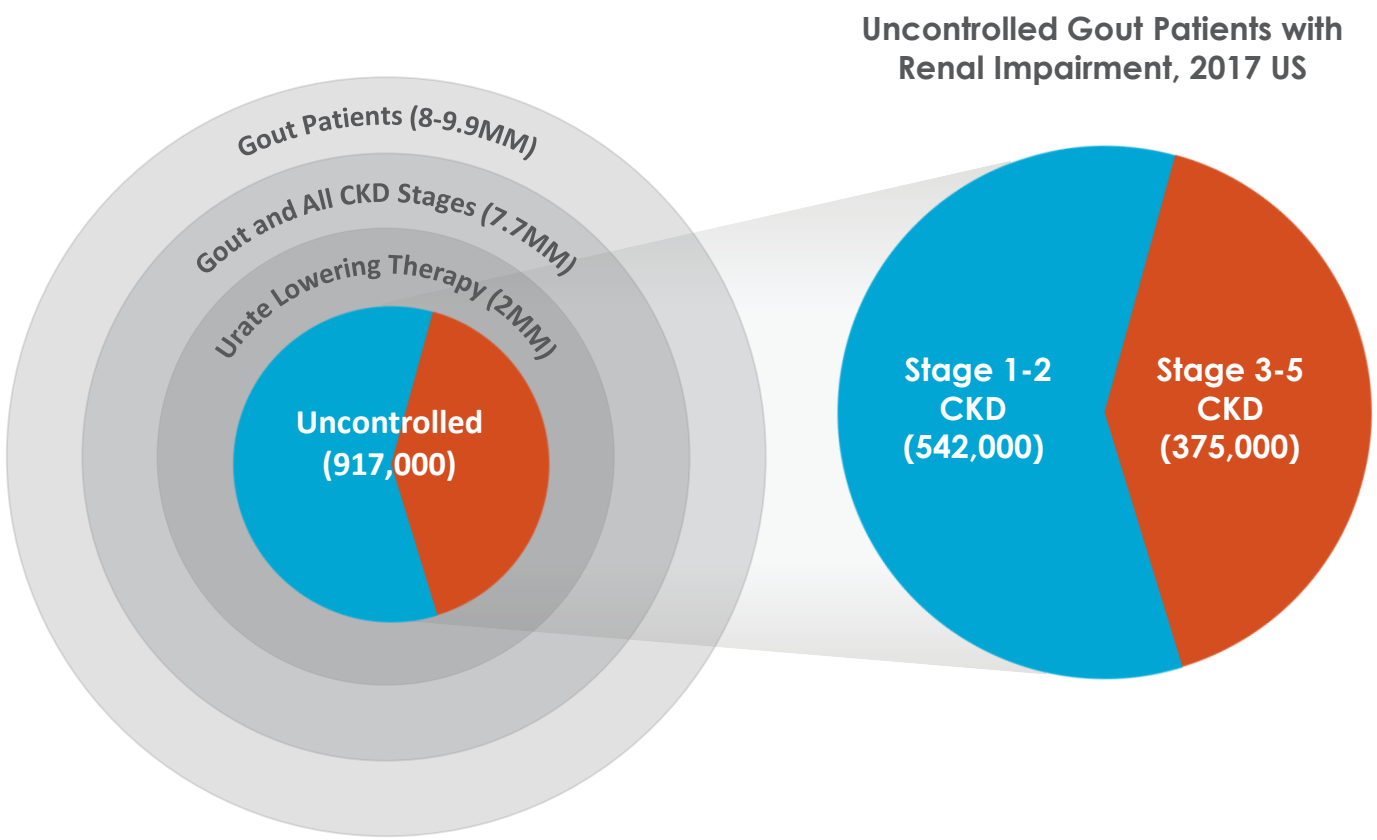
Significant Unmet Need in Gout Patients with Moderate-to-Severe CKD

Gout Market 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 ULTs
  - Contraindications
  - Drug-drug interactions
  - Co-morbidities (e.g. cardiovascular)
- Significant unmet need for safe and effective therapy that can be used in patients with renal impairment



Source: 1. Lim JJ, Fu AC, and Reasner D. Prevalence of CKD and Uncontrolled Gout Among US Adults: Results from NHANES 2007-2012.

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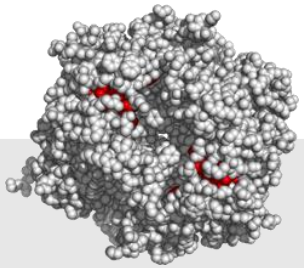
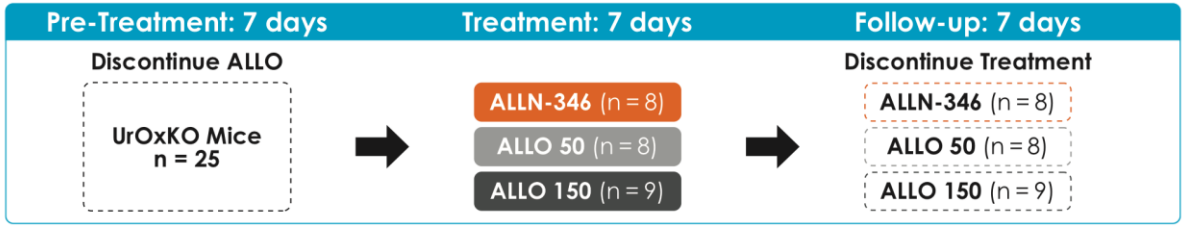
ALLN-346: Novel Urate-Degrading Enzyme Optimized for Stability in GI Tract

ALLN-346



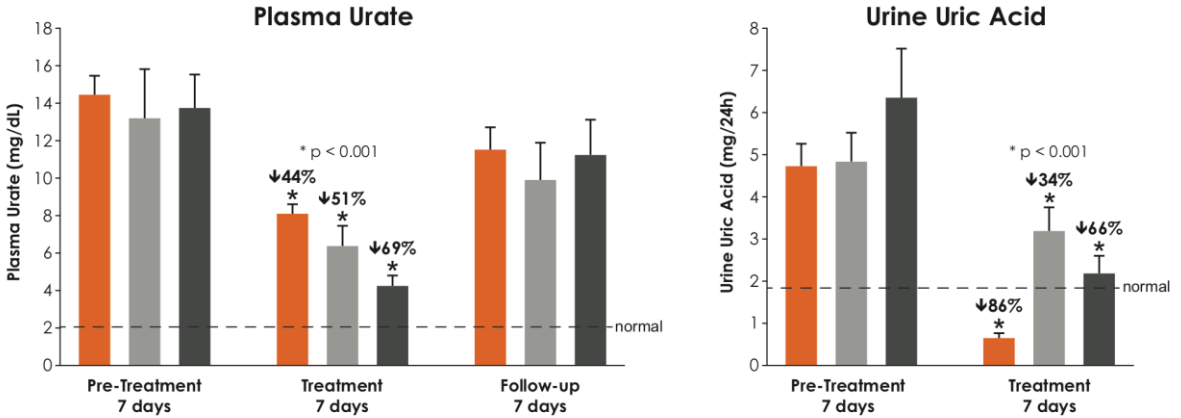
- ✓ Novel orally administered urate degrading enzyme
- ✓ Encapsulated tablet formulation optimized for stability in GI tract, the primary route of uric acid elimination in patients with impaired renal function
- ✓ Demonstrated robust reduction in urine and plasma uric acid in severe animal model of hyperuricemia with advanced CKD (presented at ACR 2018)
- ✓ IND submission cleared January 2020
  - ✓ Ready to initiate clinical studies in 2020

Urate Oxidase Knockout (UrOxKO) Mouse Phenotype



Treatment: ALLN-346 mixed with food (~700 units/day); ALLO (50 mg/L or 150 mg/L) in drinking water

Figure 1: Significant Reduction in Plasma Urate and Urine Uric Acid with ALLN-346 or ALLO Therapy



Shown is mean (standard error), $p < 0.05$ for difference between pre-treatment to treatment, paired t-test

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Upcoming Milestones

TARGET	MILESTONE	
1Q20	ALLN-346 IND Acceptance	✓
2Q20	FDA Engagement on Registrational Path in High-Risk EH Patients with Advanced CKD	
4Q20	ALLN-346 Initial Phase 1 Data	
3Q21	URIROX-2 Interim Analysis	
1Q22	URIROX-2 Topline Data for BLA Submission	

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Appendix

References

Reference	Biomarker Outcome
1 Ohkawa, 1992	A 10% thiazide-mediate reduction in urine calcium was associated with a 58% reduction in stone formation rate per year over 4 years compared to placebo
2 Ahlstrand, 1984	A 24.5% reduction in urine calcium during bendroflumethiazide treatment is associated with a 61.3% reduction in stone formation rate per year over 4 years
3 Ettinger, 1988	A 16-19% reduction in urine calcium during chlorthalidone (25 or 50mg/d) treatment is associated with a 34.4-35.2% reduction in stone formation rate per year compared to placebo
4 Borghi, 1993	A 35-37% reduction in urine calcium during indapamide +/- allopurinol treatment is associated with a 31-32% reduction in stone formation rate compared to PBO over 3 years
5 Borghi, 2002	A 20% decrease in UOx was associated with a 50% reduction in CaOx stone recurrence over 5 years
6 Curhan, 2008	A ~20% decrease in UOx was associated with a ~25% reduction in CaOx stone recurrence
7 Mayo Dataset	A ~15-30% decrease in UOx is associated with a ~20-37% reduction in CaOx stone recurrence over 5 years, prediction model

Publications available upon request

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