Allena PHARMACEUTICALS

Company Presentation

September 2019

Allena Pharmaceuticals, Inc.

These slides, and any accompanying presentation, contain forward-looking statements and information. The use of words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify forward-looking statements. All forward-looking statements are based on estimates and assumptions by our management that, although we believe them to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that we expected, including those risks and uncertainties that are described under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, as well as discussions of potential risks, uncertainties and other important factors in our subsequent filings with the Securities and Exchange Commission. Any forward-looking statement speaks only as of the date on which it was made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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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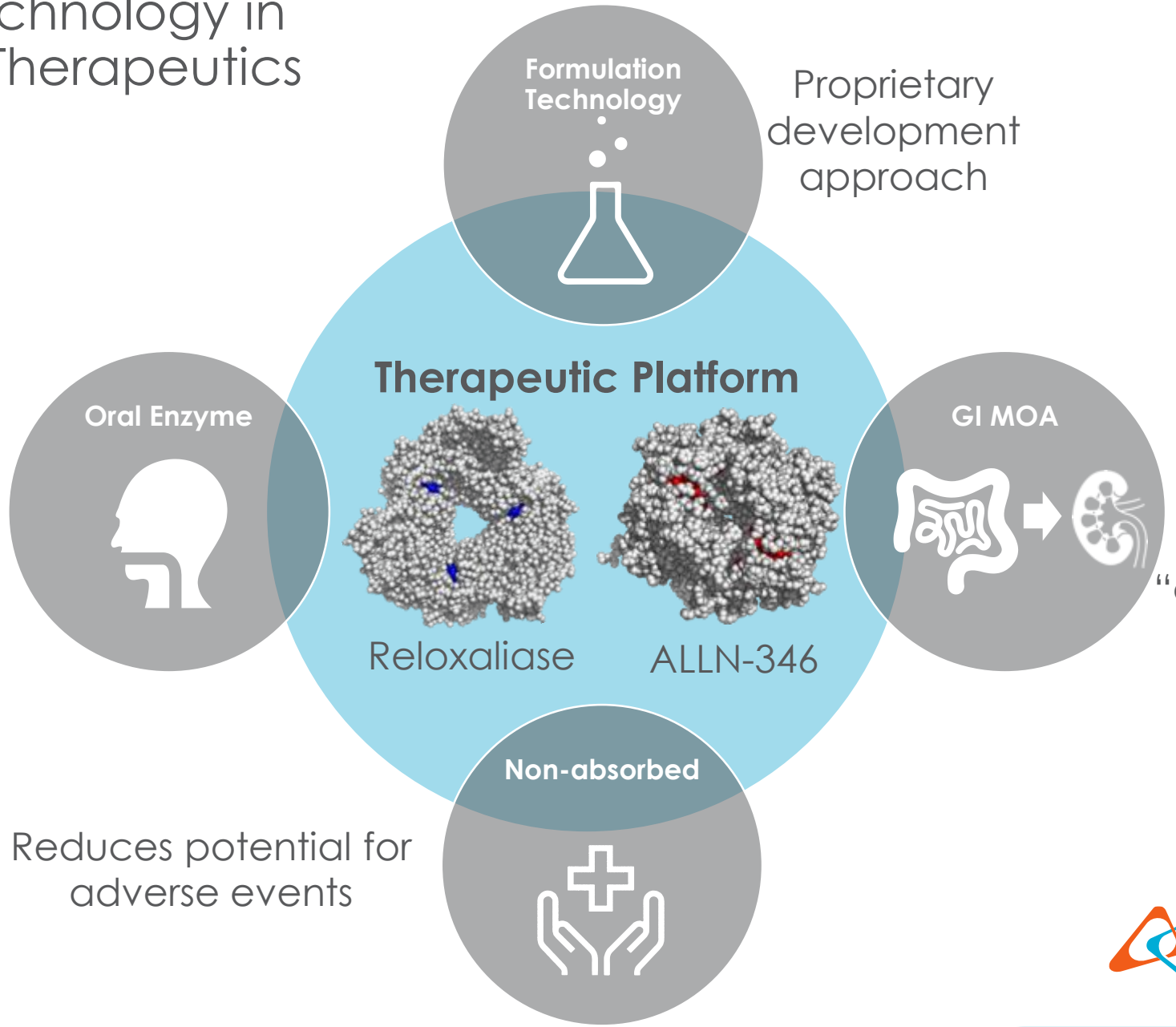
Pioneering Technology in Oral Enzyme Therapeutics



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Reloxaliase: Therapeutic Candidate with Blockbuster Potential

- High Unmet Need in Enteric Hyperoxaluria (EH)
- Novel Non-absorbed Oral Biologic
- Consistent Results across Phase 2 Studies
- Pivotal Phase 3 Studies Ongoing
- FDA Alignment on Accelerated Approval Strategy
- Potential First FDA-Approved Treatment in EH
- Worldwide Marketing Rights

Upcoming Milestone:
Phase 3 URIROX-1 Topline Data in 2H19

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Our Leadership

Louis Brenner, MD
President and
Chief Executive Officer

Annamaria Kausz, MD, MS
Chief Medical Officer

Geoffrey Swire
Vice President of Program
and Alliance Management

Edward Wholihan
Chief Financial Officer

Hugh Wight
Senior Vice President of
Technical Operations

Stephen Yu
Vice President of
Quality Assurance

Broad leadership experience

SANOFI GENZYME
MERCK INVENTING FOR LIFE
accenture
MSD
genzyme
Radius
KERYX
immunogen
amag PHARMACEUTICALS
idera PHARMACEUTICALS
EMD SERONO
McKinsey & Company
Alkermes

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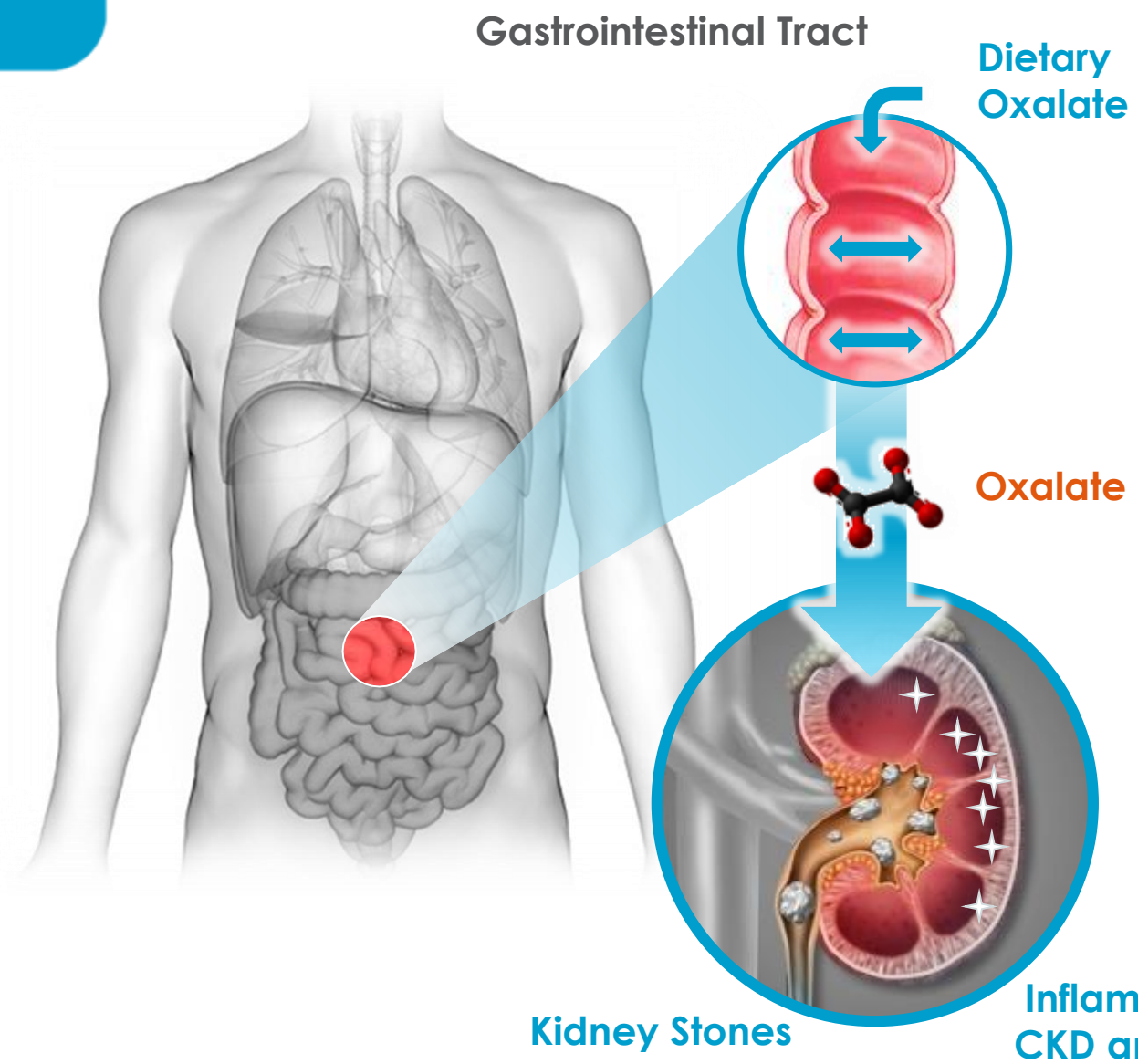
First-in-Class Oral Enzyme Therapeutic Pipeline

Product	Indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Next Milestone	Commercial Rights
Reloxaliase	Enteric Hyperoxaluria						2H19: Topline data URIROX-1 2H21: Topline data URIROX-2	Worldwide
	Enteric Hyperoxaluria with Advanced CKD						2H19: Topline data Study 206	Worldwide
ALLN-346	Hyperuricemia with CKD						2H19: IND filing	Worldwide

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

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

[1]Borghi N Eng J Med. 2002; Taylor and Curhan, J Am Soc Nephrol. 2007

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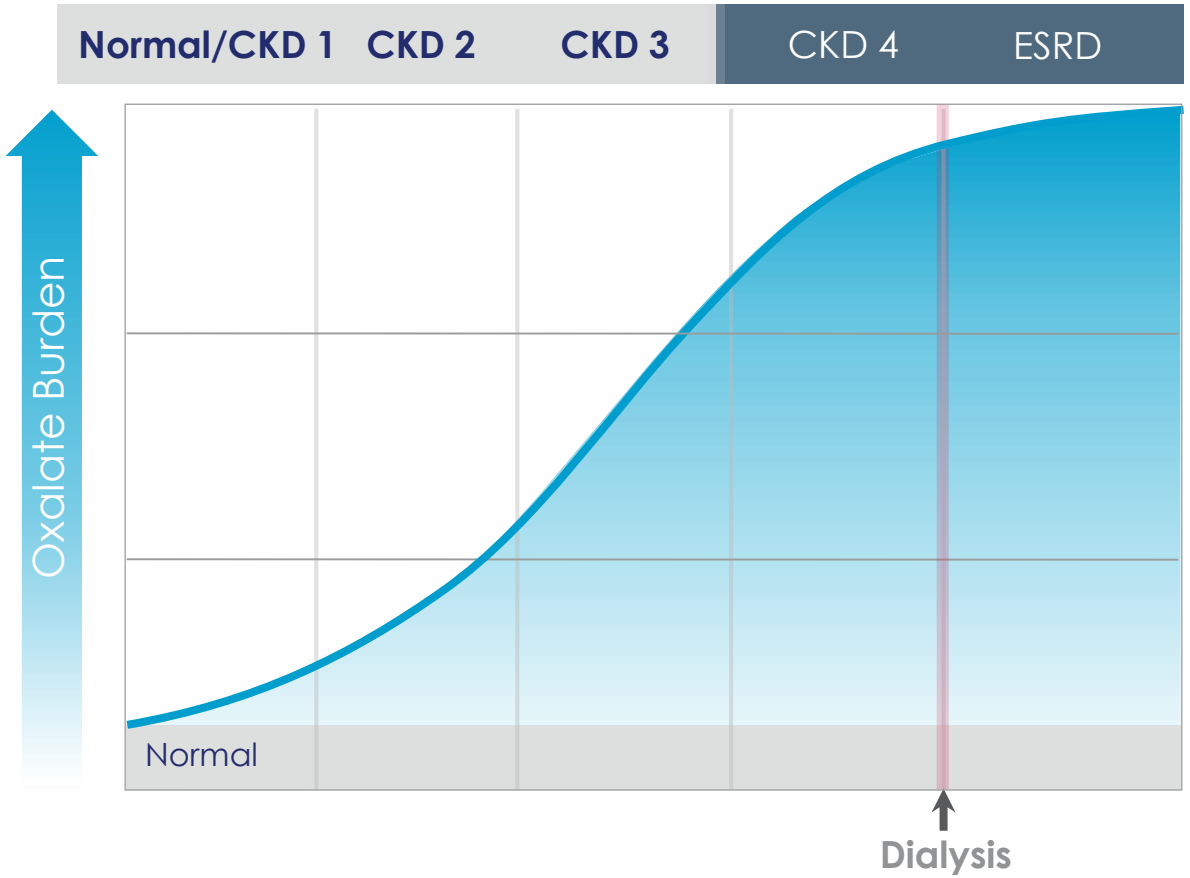
Unmet Need: Reduce Risk of Oxalate Damage to the Kidney

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; 3:1363-1372

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Initially Targeting EH Patients with Underlying Malabsorptive GI Diseases, Kidney Stones and CKD

4.4M

Estimated Patients with GI Malabsorptive Conditions with No Prior Kidney Stones or CKD

Patients potentially at risk for enteric hyperoxaluria[1]

200-250K

Estimated Patients with Enteric Hyperoxaluria and Kidney Stones

~5% of patients developed kidney stone disease

80-100K

Estimated Patients with Kidney Stones and Chronic Kidney Disease (CKD)

~2% of patients with kidney stone disease developed CKD

~16K

In Late Stage (IV-V) or Transplant in Year 4

~16K In CKD Stages IV-V or transplant in year 4

uriROX Program

Study 206

4-year progression of disease

- Analysis tracked patients for whom an enteric disease diagnosis or procedure code was entered between 7/1/10 - 6/30/12 who did not have a claim with an KSD, CKD/ESRD/ Dialysis diagnosis or procedure code from 1/1/10 - 6/30/10. Analysis showed that approximately 5% of patients subsequently developed one or more kidney stones ("Kidney Stone Disease"), of which 40% also developed CKD over the subsequent four years to determine prevalence in 2012. 2017 figures apply 3.6% CAGR to 2012 population figures.
- Approximately 9% of patients develop CKD without kidney stone disease within 4 years
- [1]Truven Health Analytics, part of the IBM Watson Health business longitudinal Claims Analysis, August 2017

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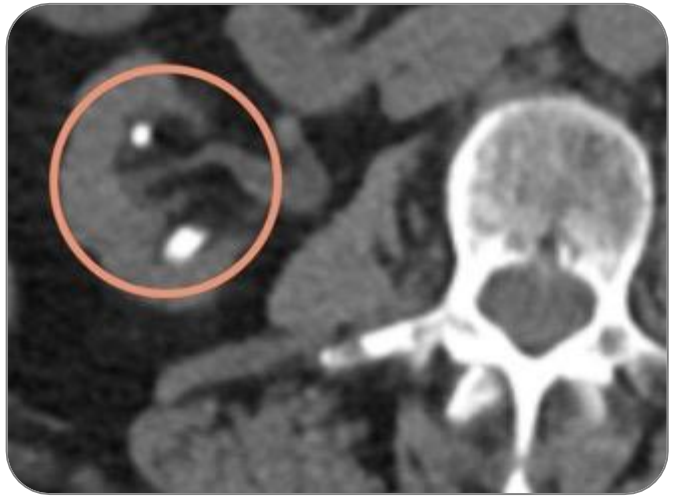
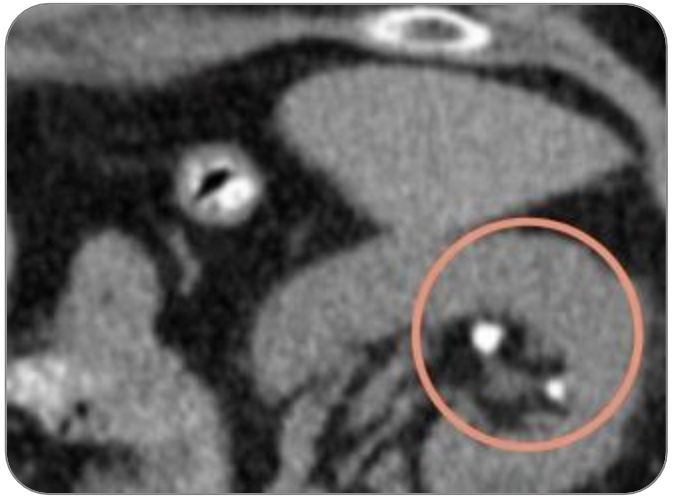
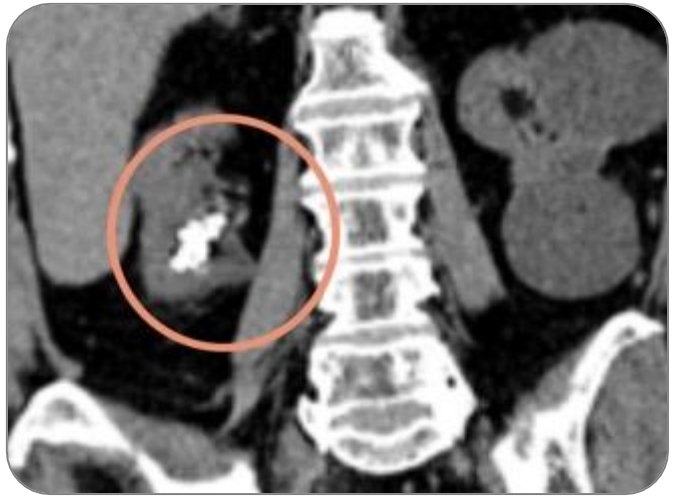
Patient Examples



Celiac disease
3 stones in last 2 years
(4 stones visible by CT)



Gastric Bypass
8 stones in the last 5 years
(3 stones visible by CT)



Whipple
(Pancreatic Insufficiency)
14 stones in last 5 years
(16 stones visible by CT)

- Very high baseline UOx mean ~100 mg/24h
- On average, EH subjects had experienced 6 stones prior to enrollment, with an average of 3 kidney stones visible by routine CT scan at time of enrollment

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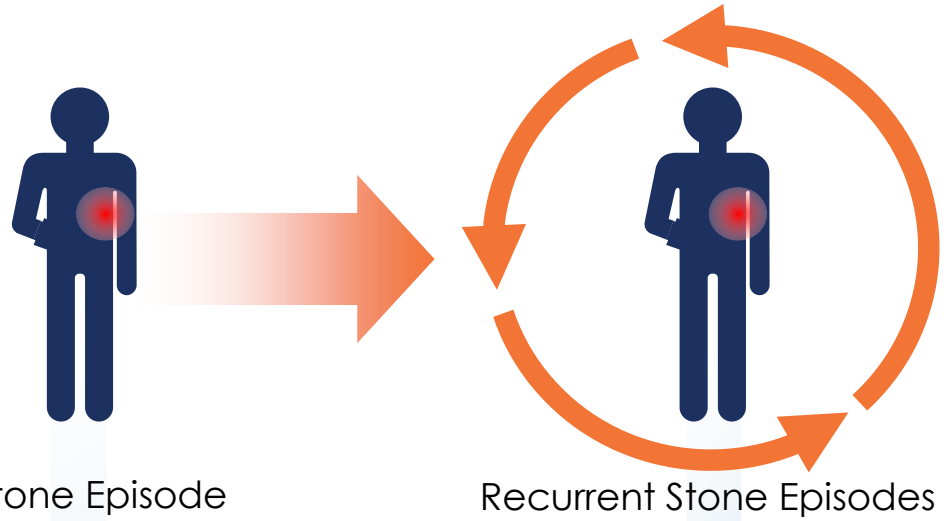
Enteric Hyperoxaluria Patient Journey

Kidney stones, often the first clinical manifestation of hyperoxaluria, facilitate patient identification



First Stone Episode

Recurrent Stone Episodes

Urologist

- Manages patient during stone episode and clears obstructing stone
- May defer to nephrologist for management, close management of urine chemistry is less likely

*Very severe patients or patients with **CKD** may be referred to nephrologist upon first stone*

Nearly all recurrent stone formers are eventually referred to a nephrologist

Recurrent Stone Episodes

Chronic Kidney Disease

Stones and CKD burden: $66K average annual direct expenditures four years post GI malabsorptive procedure or disease diagnosis

Nephrologist

- Monitors risk factors for stone formation and prescribes therapy as needed to manage urine chemistry

ESRD/Dialysis

Kidney Transplant

- Monitors CKD progression, manages ESRD, dialysis and transplantation

Source: Health Advances Analysis, 2019

Current Treatment Approach is Suboptimal

Diet & Non-specific Supplements

- High Fluid Intake to Increase Urine Output
- Restrictions to Reduce Oxalate Intake
  (Oxalate rich foods are part of a healthy diet)
- Potassium Citrate
- Calcium Supplementation

Surgery

- Kidney Stone Removal
- Kidney Transplantation

Other

- Thiazide Diuretics
- Dialysis

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

Jan's Journey with EH

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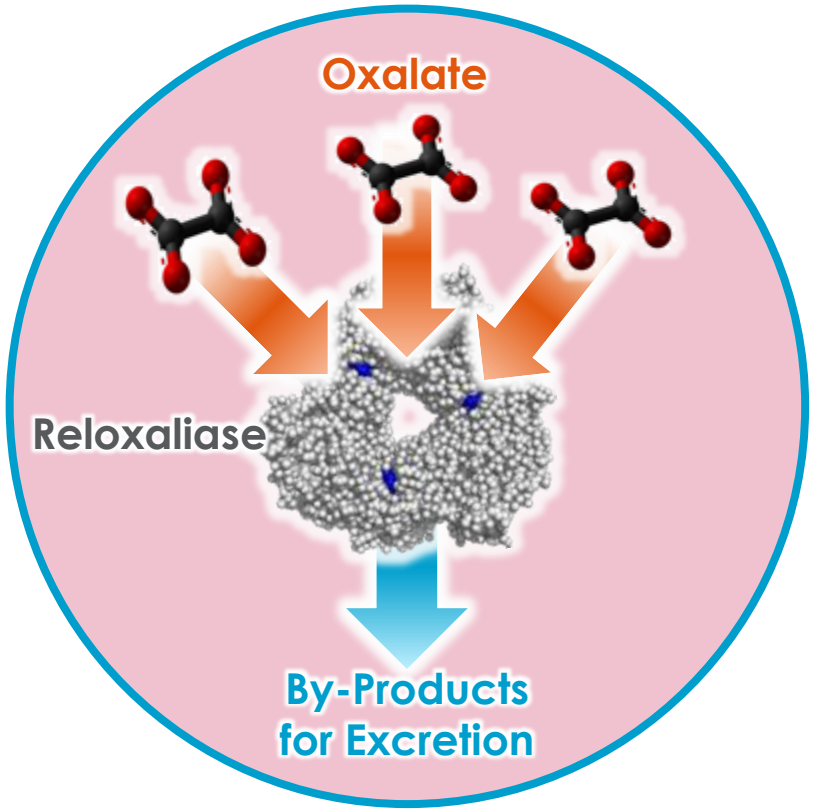
Reloxaliase: First-in-class Therapeutic Candidate for EH

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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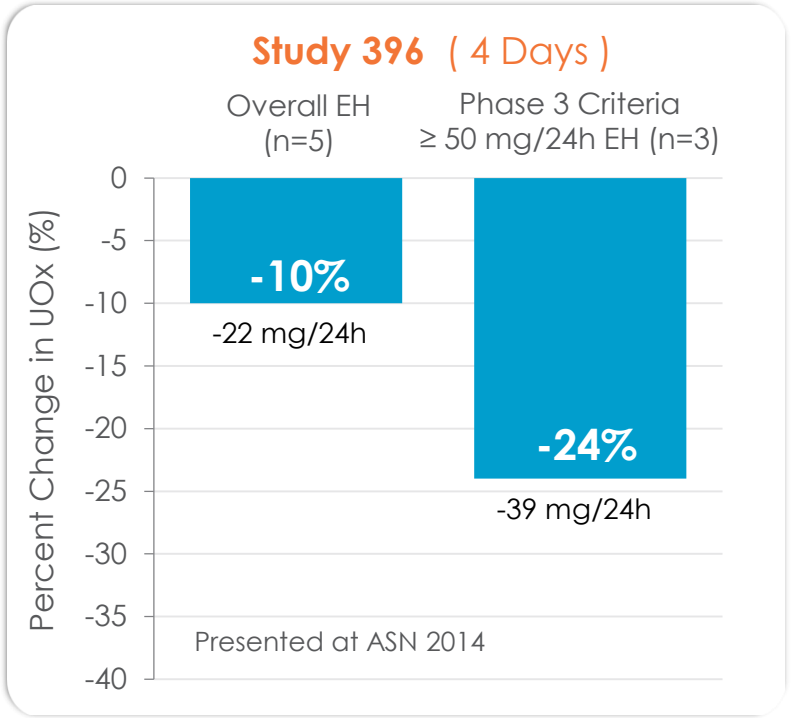
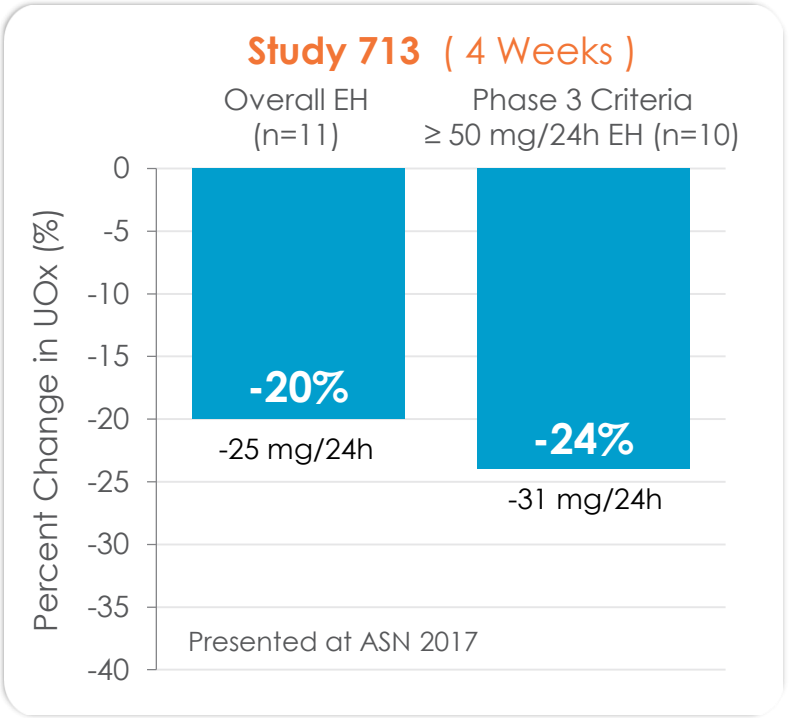
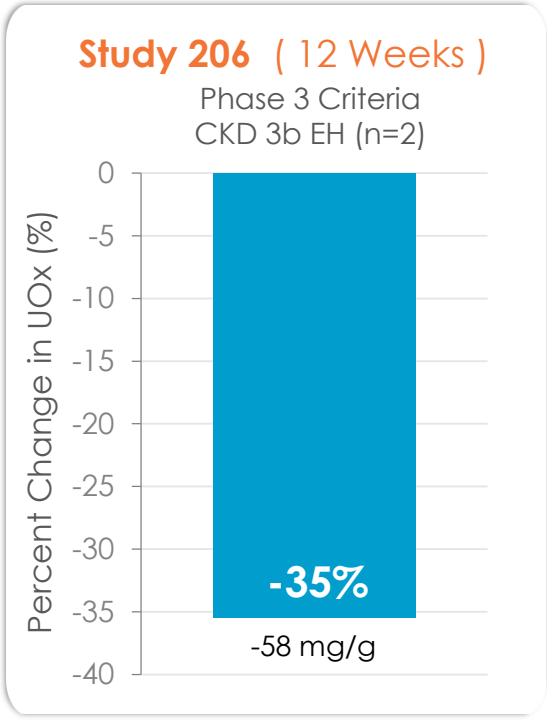
Consistent Phase 2 Clinical Results in EH De-risk Phase 3 Program

- Consistent response in patients with EH
- ≥ 50mg/24h UOx baseline entry criteria for URIROX-1
- Well tolerated







■ Urinary Oxalate

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

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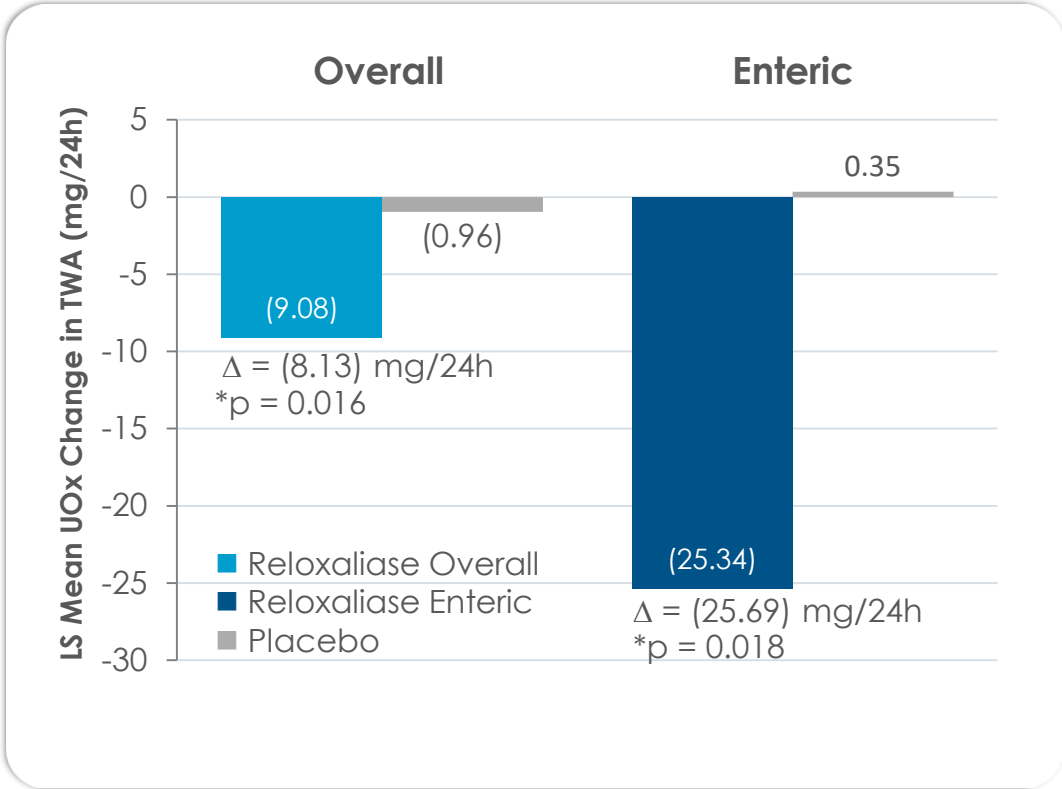
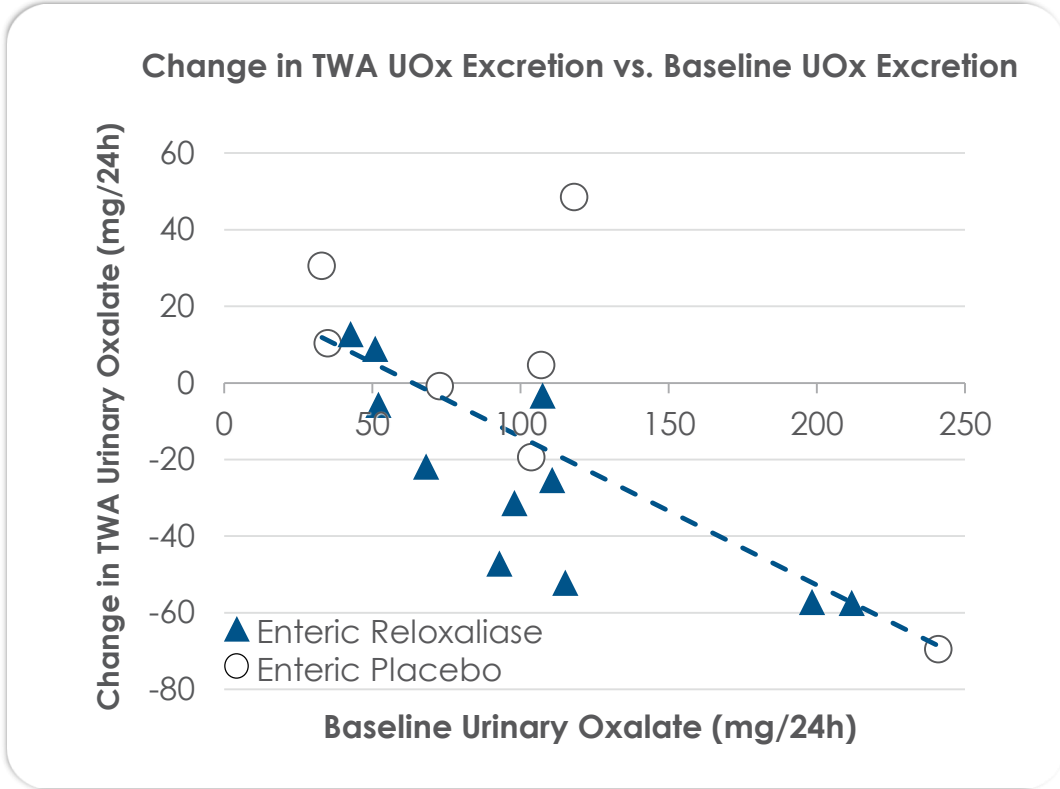
Study 713: Substantially Greater Reloxaliase Treatment Response in Enteric Population





*Beyond the primary endpoint analysis, all p-values are descriptive.

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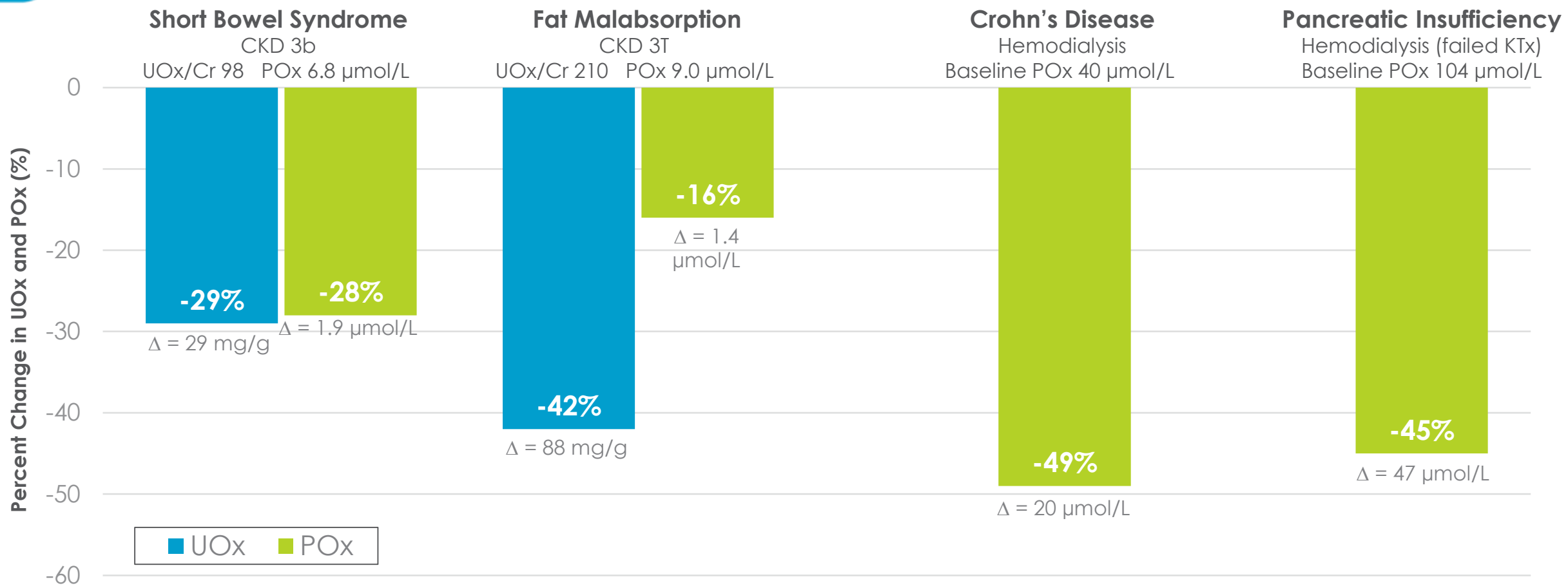
Study 206: Reloxaliase Demonstrated a Robust Reduction in UOx and POx in Four EH Patients with Advanced CKD



Urinary Oxalate (UOx mg/d) was normalized to creatinine g/day; UOx reduction was calculated as a mean change from baseline using UOx measurements over 12 weeks; UOx was not measured in subjects on dialysis

Plasma oxalate (POx umol/L) reduction was calculated as a mean change from baseline using POx measurements over 12 weeks

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Reloxaliase Generally Well-Tolerated in Clinical Trials to Date

	Study 396	Study 649		Study 713	
	All (n=16)	Reloxaliase (n=30)	Placebo (n=24)	Reloxaliase (n=32)	Placebo (n=35)
	n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**
TEAE[2]	9 (56.3%)	13 (43.3%)	6 (25.0%)	16 (50%)	22 (62.9%)
Severe TEAE	0	0	0	0	0
Related TEAE	2 (12.5%)	5 (16.7%)	2 (8.3%)	3 (9.4%)	8 (22.9%)
Serious AE (SAE)	0	1 (3.3%)[2]	0	0	0
Related SAEs	0	0	0	0	0
AEs Leading to Study Drug Withdrawal	0	1 (3.3%)[2]	0	0	2 (5.7%)[3]
AEs Leading to Death	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.

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Reloxaliase Phase 3 Program Enhancements

- Dosing up to 5x per day per meal or snack
- UOx screening and baseline both ≥ 50mg/24h to reduce UOx variability
- Primary endpoint: average 24-hour UOx excretion across Weeks 1-4
- Accelerated approval strategy

Phase 3 Program Design for Accelerated Approval Strategy

uriROX

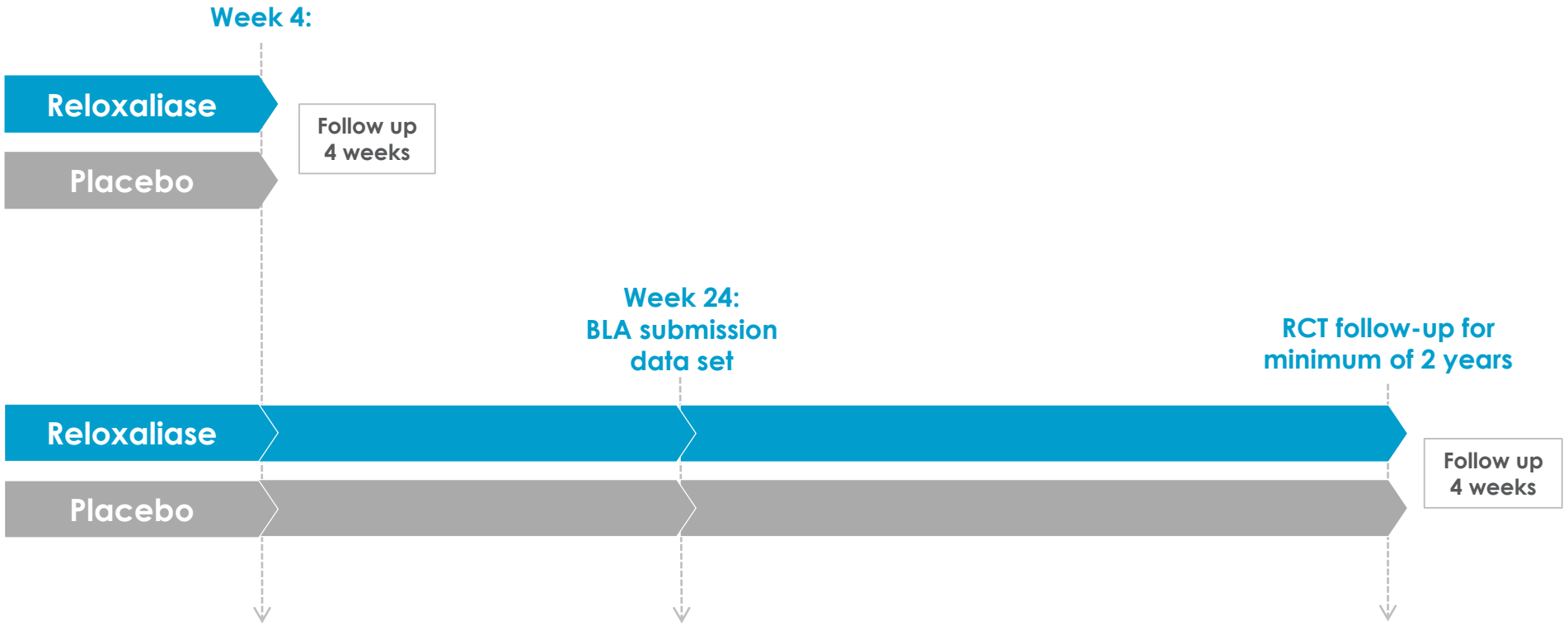
n≈124 (1:1)

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
Comparison of the percent change from baseline in the average 24-hour UOx excretion across Weeks 1-4 with reloxaliase vs placebo

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

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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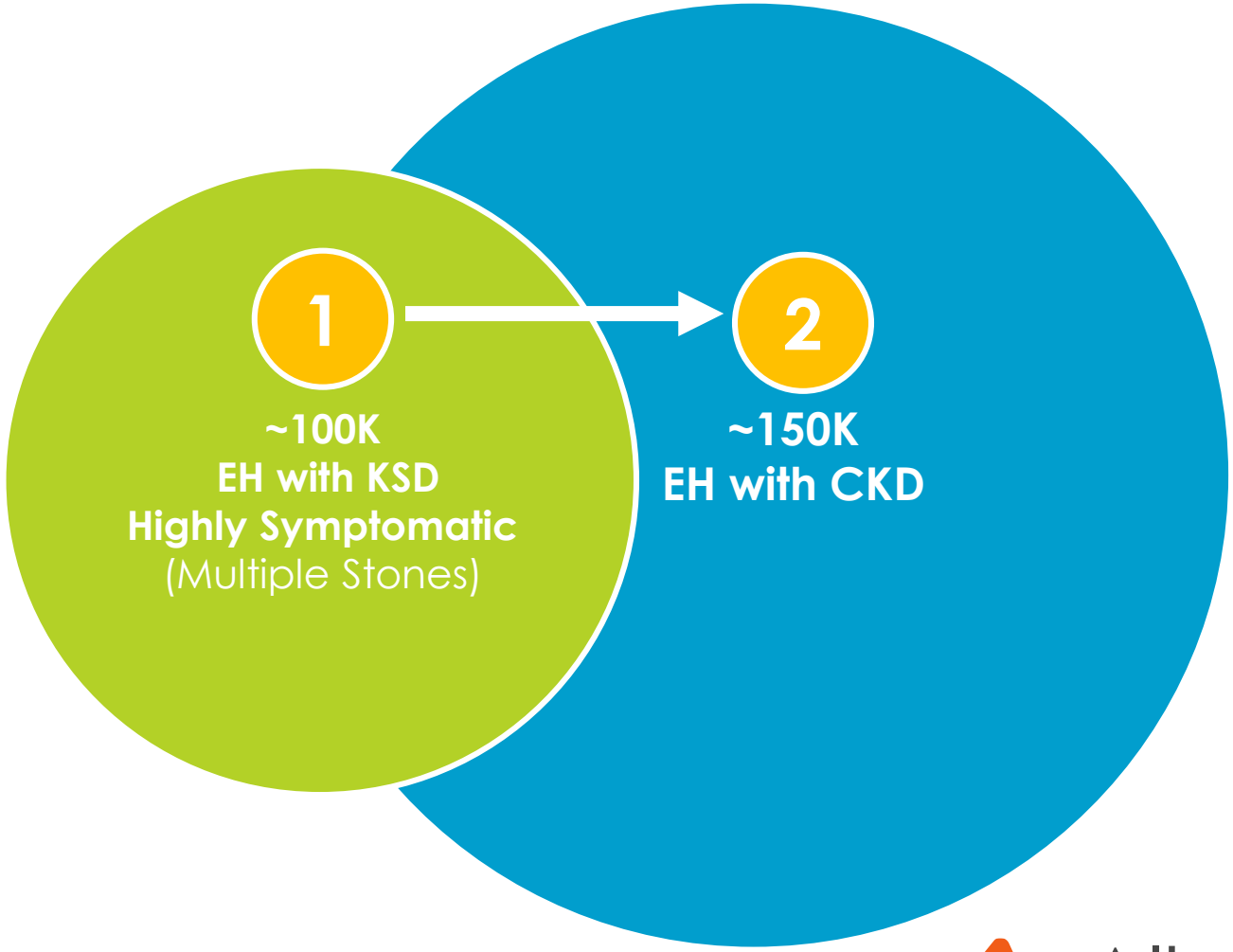
Unlocking Blockbuster Potential in Enteric Hyperoxaluria

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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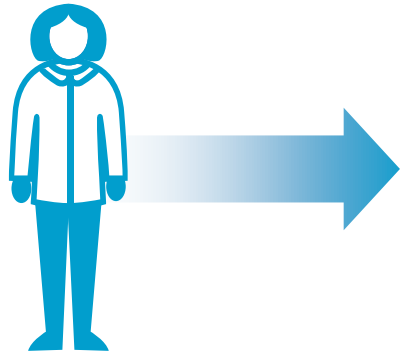
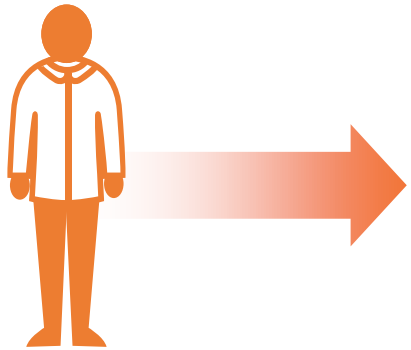
US Commercialization Strategy

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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Reloxaliase: Therapeutic Candidate with Blockbuster Potential

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Upcoming Milestone:
Phase 3 URIROX-1 Topline Data in 2H19

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Upcoming Milestones

TARGET	MILESTONE	STATUS
2Q19	**Study 206 Initial Data**	✓
2H19	**URIROX-1 Topline Data**	On Track
2H19	**Study 206 Topline Data**	On Track
2H19	**ALLN-346 IND Filing**	On Track
2H20	**ALLN-346 Initial Data**	On Track
2H21	**URIROX-2 Topline Data**	On Track

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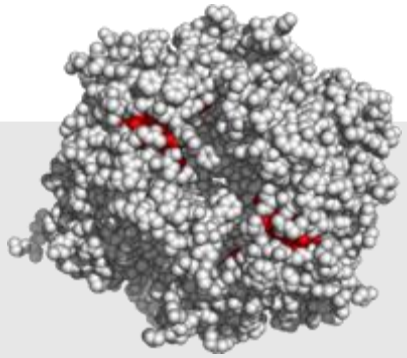
Appendix

ALLN-346: 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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