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Bringing First-in-Class Oral Enzyme Therapeutics to Patients with Rare and Severe Metabolic and Kidney Disorders

March 2019

Allena Pharmaceuticals, Inc.

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Highlights – Pioneering Oral Enzyme Therapeutic Platform

Significant Unmet Need in Oxalate and Urate Disorders

- Focused on rare and severe metabolic disorders that can cause kidney stones, damage the kidney, and potentially lead to CKD and ESRD
- No approved oxalate therapies; potential untapped multi-billion dollar market

Late-Stage Development Candidate: Reloxaliase

- First-in-class, oral therapeutic candidate for severe hyperoxaluria
- Achieved FDA alignment on pivotal URIROX Phase 3 program in and strategy for accelerated approval pathway
- Enrolling two Phase 3 trials in enteric hyperoxaluria; URIROX-1 topline data expected 2H19
- Enrolling Phase 2 basket study (Study 206) in orphan populations

Pioneering Expertise in Oral Enzyme Therapeutics

- Proprietary technological approach designed to enable treatment of metabolic diseases with oral, non-absorbed enzyme therapeutics
- GI MOA reduces subsequent metabolic burden on the kidney

Second Product Candidate: ALLN-346

- First-in-class, oral therapeutic candidate designed for gout patients with moderate-to-severe CKD; designed to degrade urate in the GI tract, reducing urate burden on kidney
- Gout patients with renal impairment are not optimally managed with existing therapies
- IND submission targeted in 2H19

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Allena Recently Achieved FDA Alignment on Strategy for Accelerated Approval Pathway for Reloxaliase and Design of URIROX-2

URIROX Phase 3 program – a landmark study for patients suffering from enteric hyperoxaluria:

- ✓ Urinary oxalate (UOx) biomarker as surrogate endpoint
- ✓ URIROX-2 has the same primary efficacy endpoint as URIROX-1 with topline data expected in 2H19
- ✓ Kidney stone disease progression as long-term endpoint for clinical benefit
- ✓ Adaptive design elements to streamline clinical benefit phase of URIROX-2

uriROX™ → uriROX-2 → Post-Approval Clinical Benefit Phase

1° efficacy endpoint: Percent change from baseline in 24h UOx excretion during Weeks 1-4
2° efficacy endpoint: Proportion of patients with ≥ 20% reduction in 24h UOx excretion during Weeks 1-4 and percent change from baseline in 24h UOx excretion during Weeks 16-24 (URIROX-2)

Long-term efficacy endpoints to confirm clinical benefit:

Primary: Proportion of subjects with kidney stone disease progression
Secondary: Change in eGFR from baseline and ER visits/hospitalizations/ procedures for management of kidney stones

*Expect to **submit an accelerated approval BLA filing to the FDA** after ~400 patients have been randomized and followed for six months.*

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Allena's Pipeline: First-in-Class Therapeutic Strategy for Oxalate and Urate Disorders

Product	Indication	Discovery	Pre-Clinical	Phase 1	Phase 2	Phase 3	Next Milestone	Commercial Rights
Reloxaliase	Enteric hyperoxaluria						2H19: Topline data URIROX-1	Worldwide
	Systemic oxalosis*						1H19: Interim data	Worldwide
	Primary hyperoxaluria* (Orphan Designation)						1H19: Interim data	Worldwide
	Pediatric hyperoxaluria* (Orphan Designation)						1H19: Interim data	Worldwide
ALLN-346	Hyperuricemia and CKD						2H19: IND filing	Worldwide

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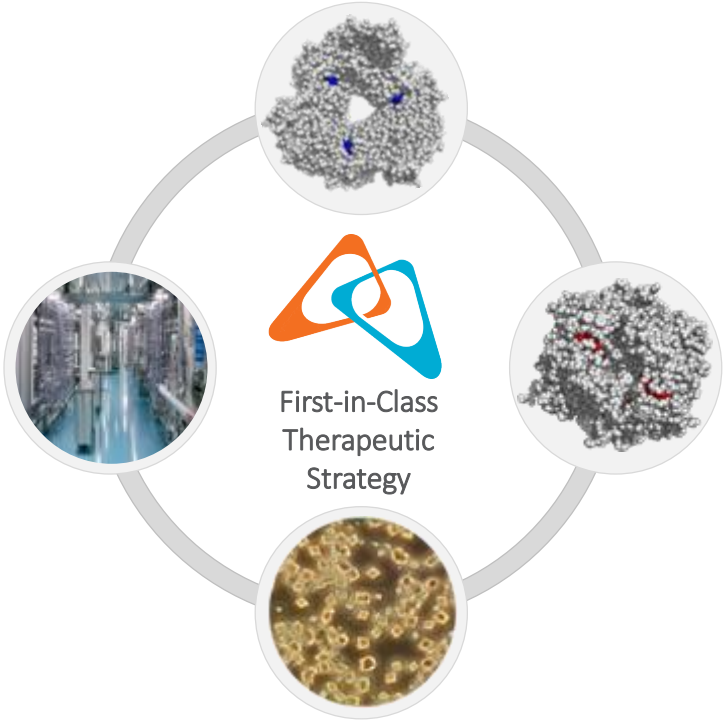
* Being evaluated in a single Phase 2 clinical trial with a basket design (Study 206) that is enrolling subsets of patients suffering from complications of severe hyperoxaluria, including adolescents and adults with primary or enteric hyperoxaluria with advanced CKD, both of which can lead to systemic oxalosis.

Expertise and Proprietary Technological Approach in Enzyme Therapeutics Enables First-in-Class Therapeutic Strategy for Oxalate and Urate Disorders



✓ **Pioneering Expertise in Oral Enzyme Therapeutics**

- Design, formulation, and delivery of non-absorbed and stable enzymes orally for activity in GI tract

✓ **First-in-Class Enzyme Therapeutic Candidates**

- Oral enzymes designed to rapidly degrade a specific metabolite within the gut, reducing absorption in blood and urine, and in turn, diminishing disease burden on kidney

✓ **Proprietary and Scalable Manufacturing Capabilities**

- Proven ability to produce large quantities of oral enzymes
- COGS anticipated to be comparable to small molecule therapeutics

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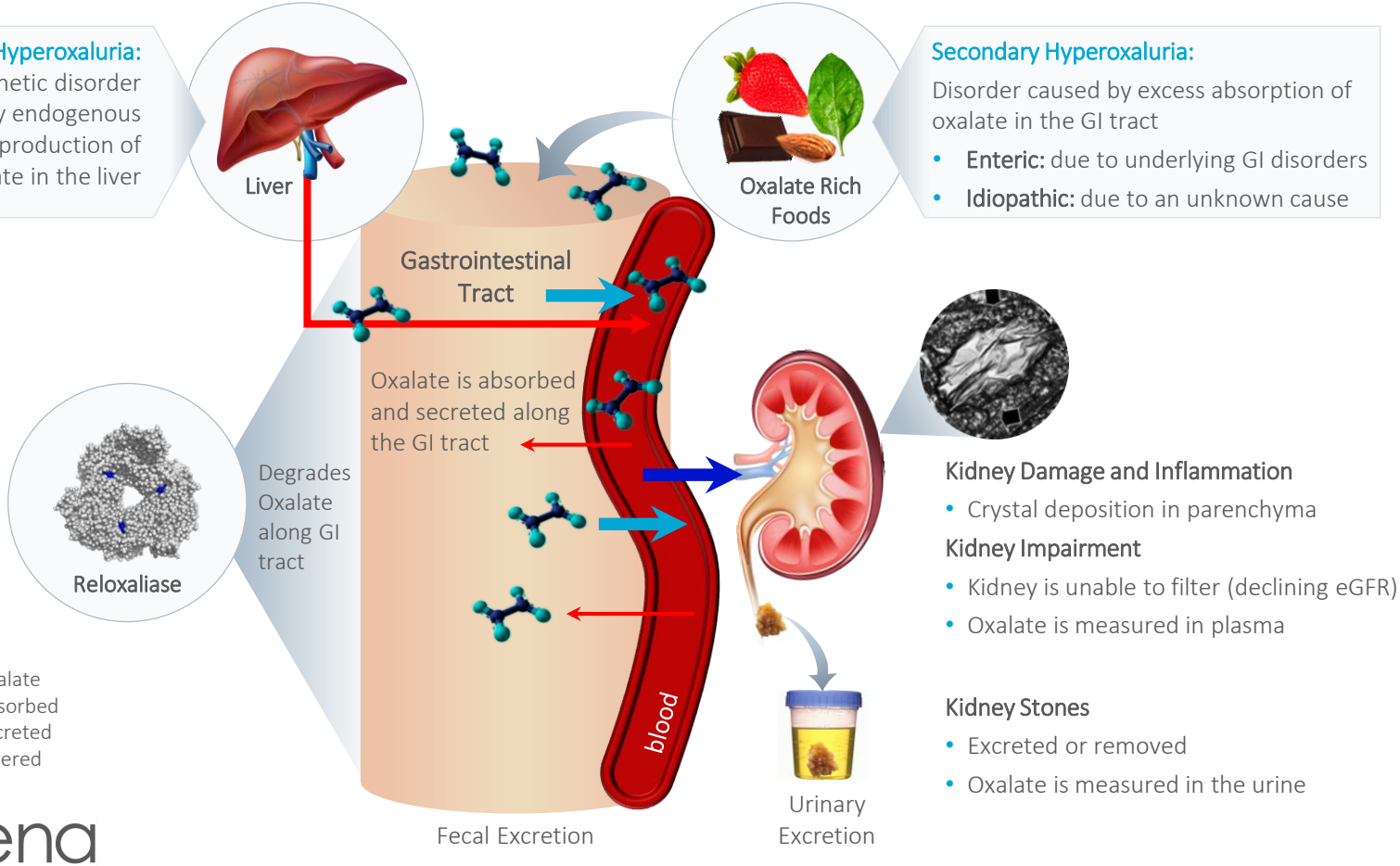
Hyperoxaluria is Characterized by Markedly Elevated Urinary Oxalate Levels

Primary Hyperoxaluria:
Orphan genetic disorder caused by endogenous excess production of oxalate in the liver

Secondary Hyperoxaluria:
Disorder caused by excess absorption of oxalate in the GI tract

- **Enteric:** due to underlying GI disorders
- **Idiopathic:** due to an unknown cause



Kidney Damage and Inflammation

- Crystal deposition in parenchyma

Kidney Impairment

- Kidney is unable to filter (declining eGFR)
- Oxalate is measured in plasma

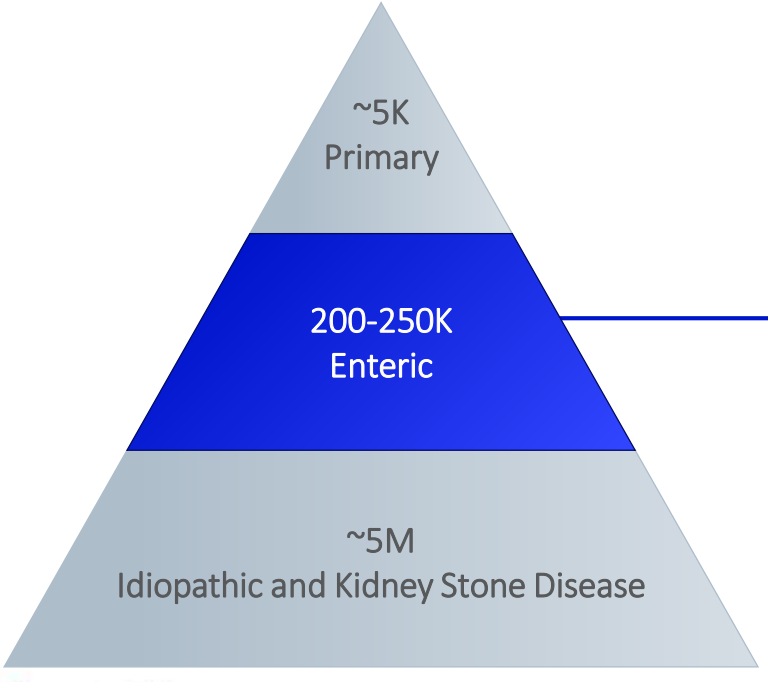
Kidney Stones

- Excreted or removed
- Oxalate is measured in the urine

Source: Illustration adapted from Coe, Fred. "Control of Urine Oxalate Excretion." Kidneystones.uchicago.edu. University of Chicago, kidneystones.uchicago.edu/control-of-urine-oxalate-excretion . March 2017.

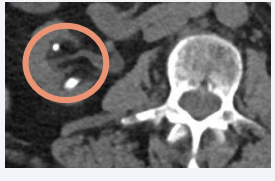
Enteric Hyperoxaluria Patients Are a High Risk Population Who Are Identifiable by Physicians and in Need of Treatment

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

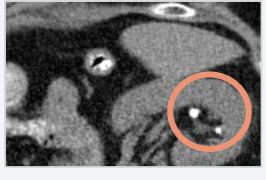


- Enteric GI malabsorptive conditions include: gastric bypass surgery, Crohn's disease, ulcerative colitis, pancreatic insufficiency, celiac disease, and liver disease
- High unmet need: frequent and more complex stones, fail standard of care (i.e., hydration, dietary modifications)
- Stones and CKD burden: $66K average annual direct expenditures four years post GI malabsorptive procedure or disease diagnosis
- EH patients in Allena's Phase 2 clinical program, presented at ASN Kidney Week 2018:
  - Very high baseline UOx
  - 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
- Study 713 Patient Examples:

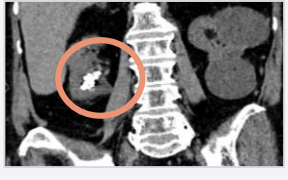
Celiac disease: 3 stones in last 2 years (4 stones visible by CT)



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)



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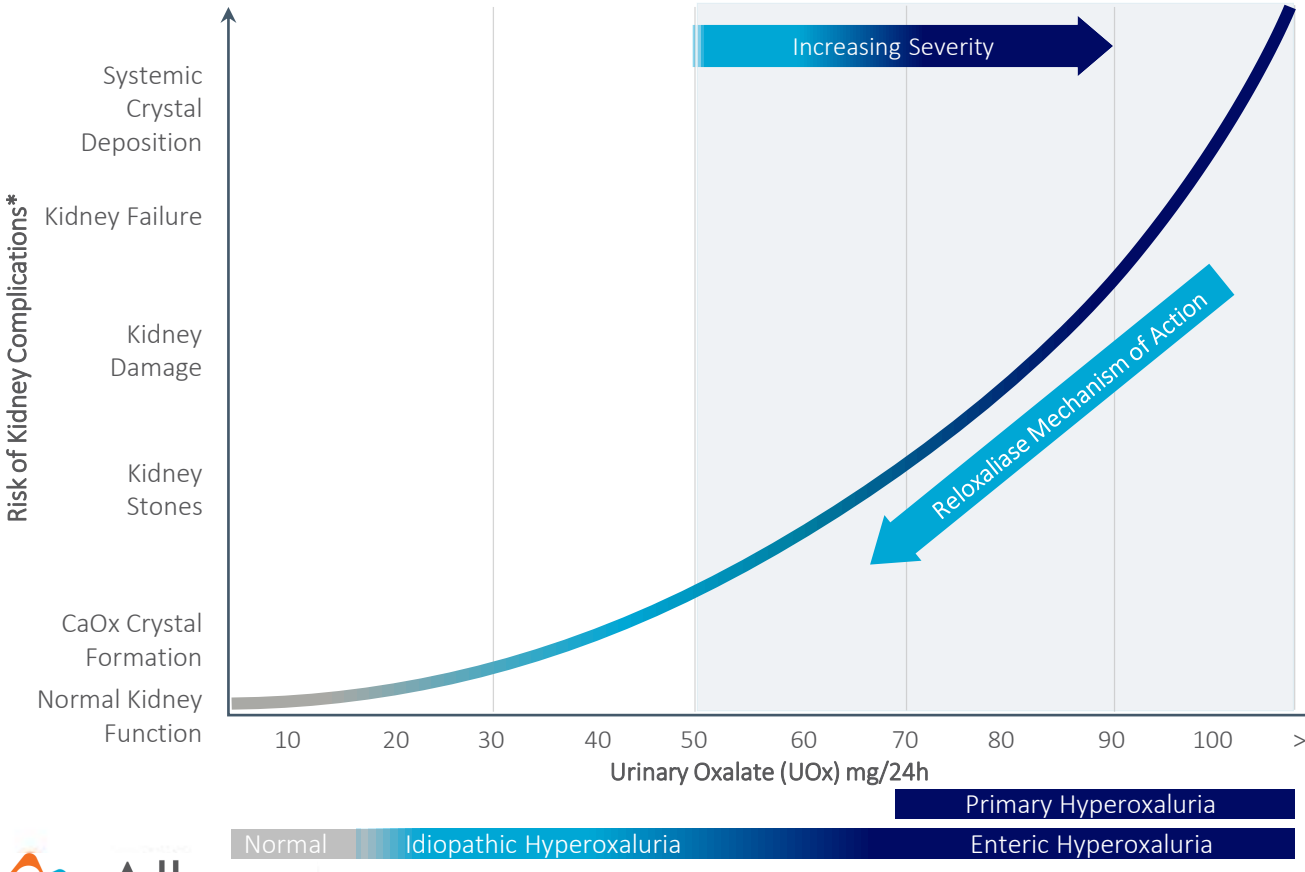
Risk of Renal Complications Rises with Higher Urinary Oxalate Levels: Reduction of UOx Improves Renal Outcomes



Key Peer Review Studies:

- Higher baseline UOx predicts future stone events in enteric hyperoxaluria patients (Lieske ASN 2017)
- 50% reduction in risk of kidney stone recurrence associated with ≥20% decrease in UOx (Borghi 2002)
- 25-50% reduction in kidney stone recurrence rate associated with ≥20% decrease in UOx (Curhan and Taylor 2008)
- Preservation of renal function associated with ~10% reduction in UOx (Milliner 1994)

Literature and KOL Input:

~20% reduction in UOx would be clinically meaningful

* The complications noted in the figure represent a general progression of kidney harm and disease associated with increasing urinary oxalate excretion levels. Not all patients experience this progression and there is considerable variability among individuals between urinary oxalate excretion levels and kidney function and disease.

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Illustrative Diagram

Sources: Robertson and Hughes, Scanning Microsc. 1993; Keddis Curr Opin Nephrol Hypertens. 2013; Robertson and Peacock, Nephron. 1980; Milliner, Kidney Int. 2006; Curhan and Taylor, Kidney Int. 2008; Milliner, Clin J Am Soc Nephrol. 2015. Key Studies: Borghi N Eng J Med. 2002; Taylor and Curhan, J Am Soc Nephrol. 2007; Milliner, N Eng J Med 1994 and Lieske JASN Abstract Supplement 2017

Allena Initially Targeting Enteric Hyperoxaluria Patients with Underlying Malabsorptive GI Diseases and Kidney Stones

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

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

~0.2% 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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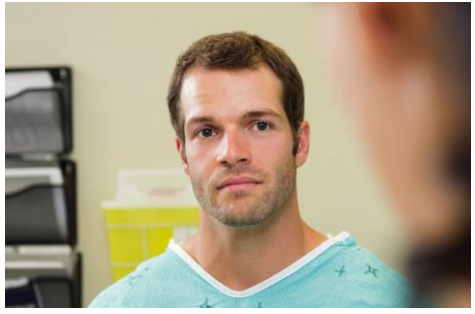
The Patient Journey for Severe Hyperoxaluria Patients Can Include Complex Specialty Care with Progressive Disease



Recurrent Kidney Stones
Stone Clinic
Kidney Stone Disease Management
Nephrologist/Urologist

Metabolic Management
Complex Specialty Care
Monitoring Kidney Function
Nephrologist

Renal Damage and ESRD
Dialysis Center
Routine
Dialysis

URIROX Program

Study 206

Strong Patient Advocacy: The Kidney Health Initiative project brings together patients, clinicians, industry and the FDA to evaluate potential endpoints for future clinical trials in enteric and primary hyperoxaluria

Oxalosis & Hyperoxaluria Foundation
STEPPING STONES TO A CURE

KHI
KIDNEY HEALTH INITIATIVE

FDA

ASN

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Waever & Holihan Patient Market Research January 2017, https://www.asn-online.org/khi/mission.aspx.

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Reloxaliase for the Treatment of Hyperoxaluria

Clinical and Regulatory Progression of Reloxaliase (ALLN-177)

2° Hyperoxaluria

Preclinical	Ph 1 Healthy Volunteers	Ph 2 Open Label	Ph 2 Randomized Controlled	Ph 3 Randomized Controlled
✓	✓	✓	✓	Initiated 1Q 2018 and 4Q 2018
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 Multicenter, Open Label, Single Arm Outpatient Study in Enteric and Idiopathic Hyperoxaluria Presented at ASN 2015	n=30 649: Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Crossover in Enteric and Idiopathic Hyperoxaluria n=67 713: Multi-Center, Randomized, Double-Blind, Placebo-Controlled in Enteric and Idiopathic Hyperoxaluria Presented at ASN 2017	URIROX-1 n≈124 URIROX-1: Multi-Center, Global, Randomized, Double-Blind, Placebo-Controlled Study in Enteric Hyperoxaluria URIROX-2 n≈400 URIROX-2: Multi-Center, Global, Randomized, Double-Blind, Placebo-Controlled Study in Enteric Hyperoxaluria

1° Hyperoxaluria

Preclinical	Orphan Designation	Ph 2 Open Label	
✓	✓	Enrolling	
AGTKO Mouse Model Grujic et al, *Am. J Nephrol* 2009; 29: 86-93 Porcine Dietary Hydroxyproline and Porcine Sodium ox-IV injection model	FDA grants Orphan Disease Designation for ALLN-177 in both PH and Pediatric Hyperoxaluria (Primary and Secondary) EC grants Orphan Disease Designation for ALLN-177 in PH	Study 206: Clinical Trial in Patients with Primary or Enteric Hyperoxaluria and Hyperoxalemia CT.GOV: NCT03391804	uriROX CT.GOV: NCT03456830 uriROX-2 CT.GOV: NCT03847090

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Study 713: Substantially Greater Reloxaliase Treatment Response in Enteric Population

	Overall (n=67)		Enteric (n=18)	
Key Endpoints: Reloxaliase vs. placebo	**Δ**	**p-value**	**Δ**	**p-value**
Change in UOx (mg/24h) from baseline to week 4	-6.35 mg/24h	0.160	-16.45 mg/24h	0.184
Change in UOx (mg/24h) from baseline to TWA across 4 weeks[1]	-8.13mg/24h	0.016	-25.69 mg/24h	0.018
Percent change in UOx from baseline to TWA across 4 weeks[1]	-14.23%	0.015	-39.15%	0.010

Responder Analysis: Proportion of Patients with Reduction in TWA UOx Excretion

Threshold Reduction in TWA UOx	-10%	-20%	-30%	-40%	-50%
Enteric Reloxaliase (%)	73	64	36	18	9
Enteric Placebo (%)	29	14	0	0	0

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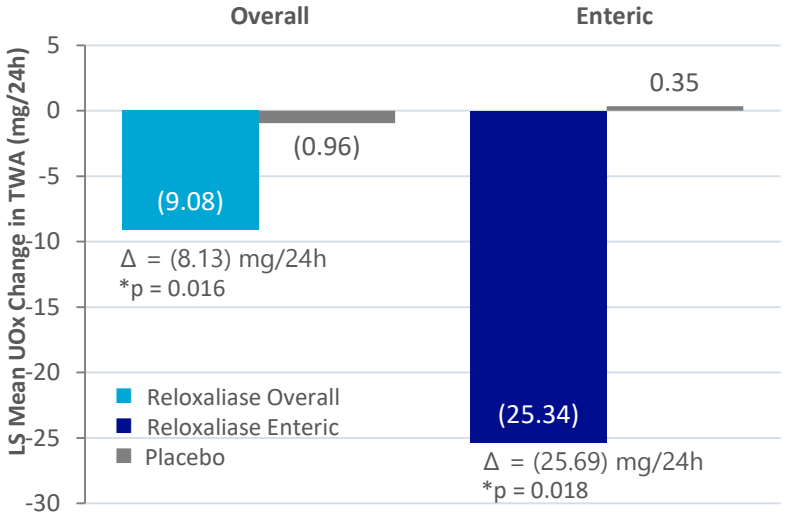
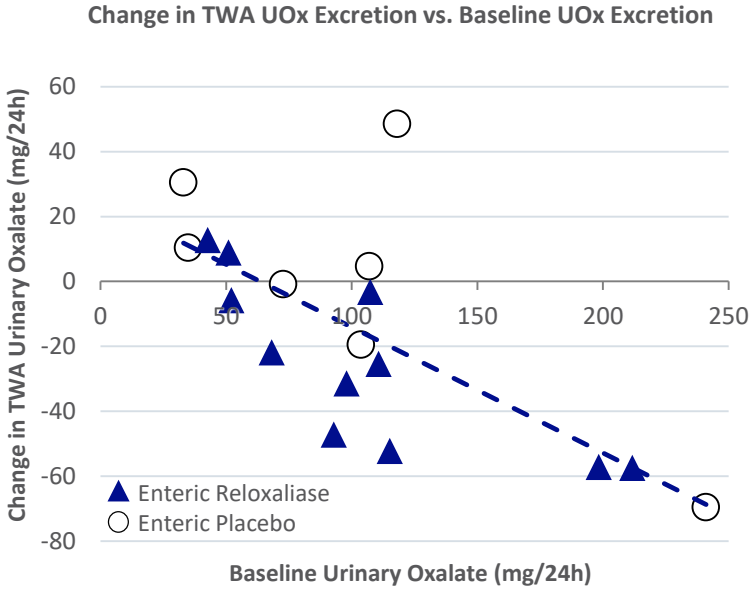
1. Beyond the primary endpoint analysis, all p-values are descriptive.

Study 713: Substantially Greater Reloxaliase Treatment Response in Enteric Population





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

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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Phase 3 Program Incorporates Key Learnings from Phase 2

Phase 2 Program		Phase 3 Program
Identified Phase 3 Patient Population	✓	• Enteric hyperoxaluria is a rare disease without available treatment
Identified Pivotal Endpoint	✓	• Percent change from baseline in 24h UOx excretion during Weeks 1-4, comparing reduction in the average UOx excretion across Weeks 1-4 with reloxaliase to placebo
Identified Key Secondary Endpoints	✓	• Proportion of subjects with a ≥ 20% reduction from baseline in 24h UOx during Weeks 1-4 • Percent change from baseline in 24h UOx excretion during Weeks 16 to 24
Identified Phase 3 Trial Design	✓	• Multicenter, global, parallel, RCT vs placebo with adaptive design strategy • Dosing up to 5x per day per meal or snack • UOx screening and baseline both ≥ 50mg/24h • Six month safety and UOx biomarker phase with minimum of 2 year long-term follow-up phase post approval
Identified Endpoint to Confirm Clinical Benefit Post Approval	✓	• Kidney Stone Disease (KSD) progression • Change in estimated glomerular filtration rate (eGFR) • Emergency room visits, hospitalizations or procedures for the management of KSD

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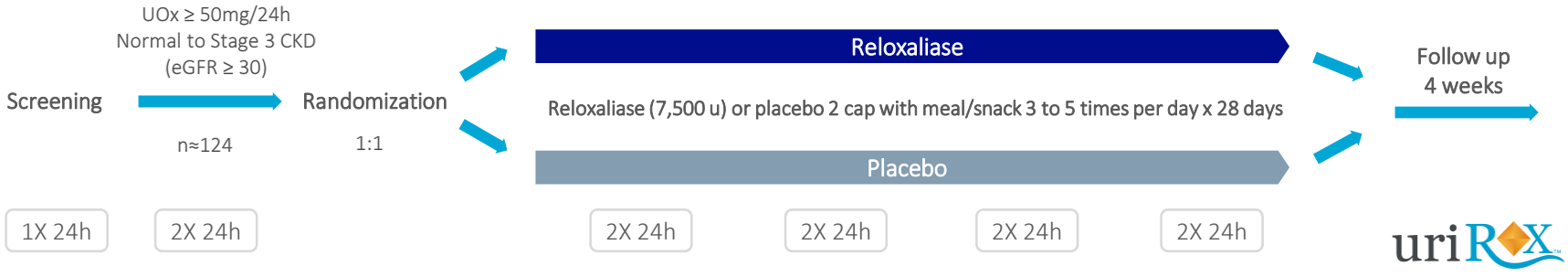
URIROX-1: Evaluate the Safety and Efficacy of Reloxaliase in Patients with Enteric Hyperoxaluria



Key Design Elements Based on Phase 2 Experience:

- Reducing UOx variability
  - Benchmark adequacy of collections to baseline 24h urine creatinine
  - Both screening and average baseline UOx ≥ 50mg/24h
  - Enhanced site and subject training for consistent collections
- Increasing dose frequency to better match eating patterns of EH patients
  - EH patients average 28% of total daily oxalate intake from snacks (up to 40-50% in some subjects)

Study Update:

- > 50% enrolled
- Pretreatment data on initial patient cohort demonstrates decreased variability from screening to baseline in 24h UOx
- No safety concerns identified in blinded data
- On target to deliver topline data in 2H 2019

Primary Endpoint:

- Percent change from baseline in 24h UOx excretion during Weeks 1-4, comparing reduction in the average UOx excretion across Weeks 1-4 with reloxaliase to placebo

Lead Secondary Endpoint:

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

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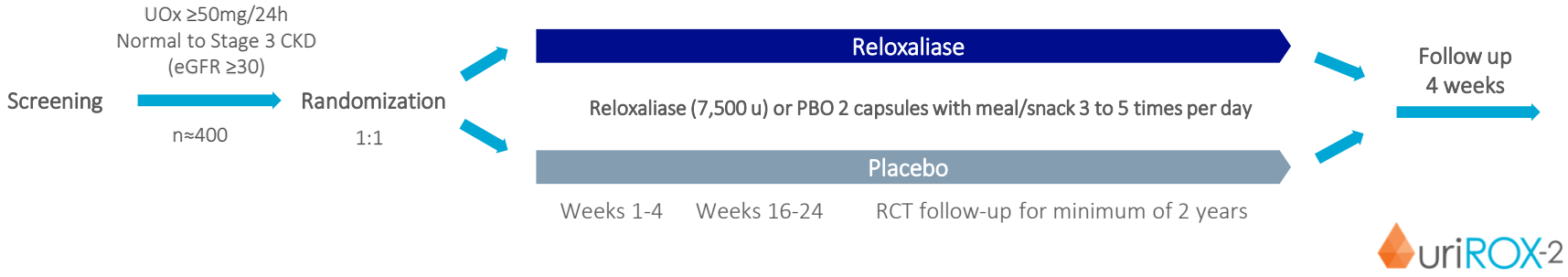
URIROX-2: Evaluate the Efficacy and Safety of Reloxaliase in Patients with Enteric Hyperoxaluria



Patient Population:

- Patients with enteric hyperoxaluria UOx ≥50 mg/d, history of kidney stones and eGFR ≥30 prior to screening
- Randomization stratified by: bariatric surgery vs. other enteric condition

Endpoints for UOx Biomarker:

- **Primary**: Percent change from baseline in 24h UOx excretion during Weeks 1-4, comparing reduction in the average UOx excretion across Weeks 1-4 with reloxaliase to placebo
- **Secondary**: proportion of subjects with a ≥20% reduction from baseline in 24h UOx excretion during Weeks 1-4 and percent change from Baseline in 24h UOx excretion during Weeks 16 to 24

Adaptive Design Strategy:

- Expect to submit an accelerated approval BLA filing after n≈400 have been randomized and followed for six months
- Incorporates adaptive design elements that will, if necessary, allow for increases in sample size and duration of treatment to support confirmation of clinical benefit

Endpoints for Post-Approval Confirmatory Study:

- **Primary:** Kidney stone disease progression – composite of either symptomatic kidney stones or finding of new or enlarged kidney stones using imaging
- **Secondary:** Change in estimated glomerular filtration rate (eGFR), and ER visits/hospitalizations/procedures for management of kidney stones

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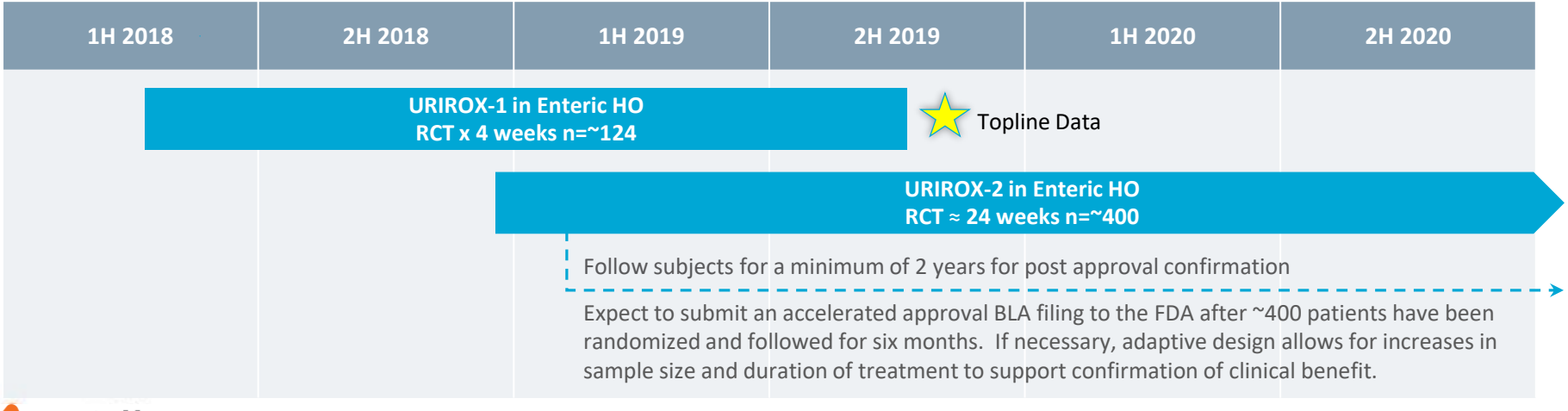
Reloxaliase Pivotal Program in Enteric Hyperoxaluria Incorporates Consistent Biomarker Endpoints in Both Phase 3 Trials

Key Features	URIROX-1	URIROX-2
Biomarker measurement: UOx as surrogate endpoint	✓	✓
Primary efficacy endpoint: percent change from baseline in 24h UOx excretion during Weeks 1-4, comparing reduction in the average UOx excretion across Weeks 1-4 with reloxaliase to placebo	✓	✓
Lead secondary efficacy endpoint: proportion of subjects with a ≥ 20% reduction from baseline in 24h UOx excretion during Weeks 1-4	✓	✓
Dosing: up to 5x a day with meals and snacks	✓	✓



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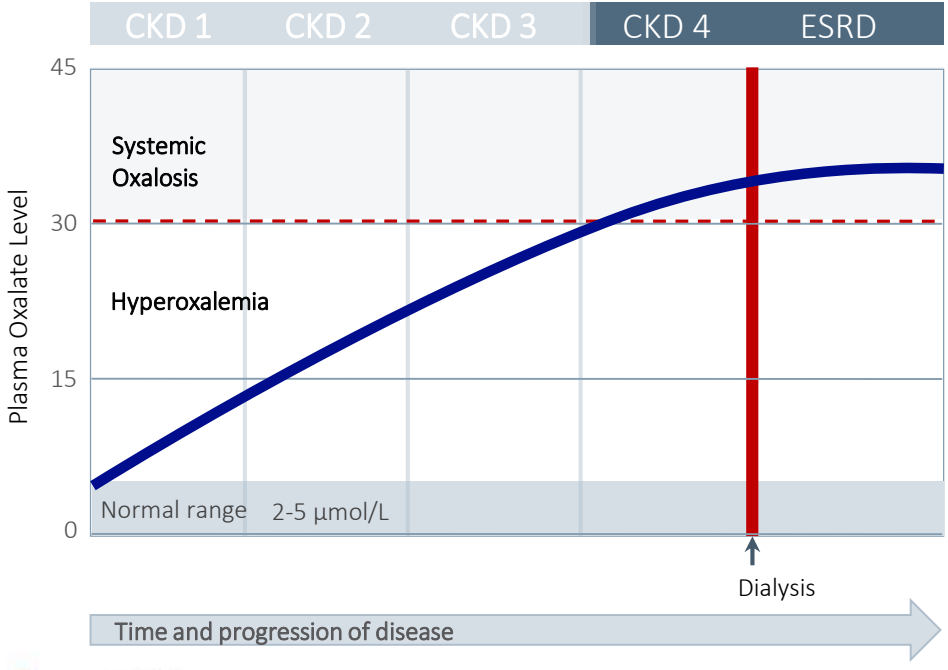
Reloxaliase Additional Indications

Elevated Plasma Oxalate Increases Risk for CaOx Crystal Deposition in the Kidney and Other Organ Systems

uriROX Study 206

Study Population: Enteric Hyperoxaluria | Primary and Enteric Hyperoxaluria with Hyperoxalemia



Unmet Need: Reduce Risk of Oxalate Damage to the Kidney

- Oxalate crystals are associated with renal inflammation, fibrosis and progressive renal failure[1]
- Patients with hyperoxalemia or systemic oxalosis can accumulate oxalate in the blood and other tissues, creating "oxalate stores" in the body[2,3]
- Hyperoxalemia or systemic oxalosis can prohibit patients from getting a transplant[4] or jeopardize the transplanted kidney[2,4,5]
- Growing awareness of association between oxalate crystal deposition and poor long-term graft survival, declining kidney function and return to dialysis[4,5,6,7]

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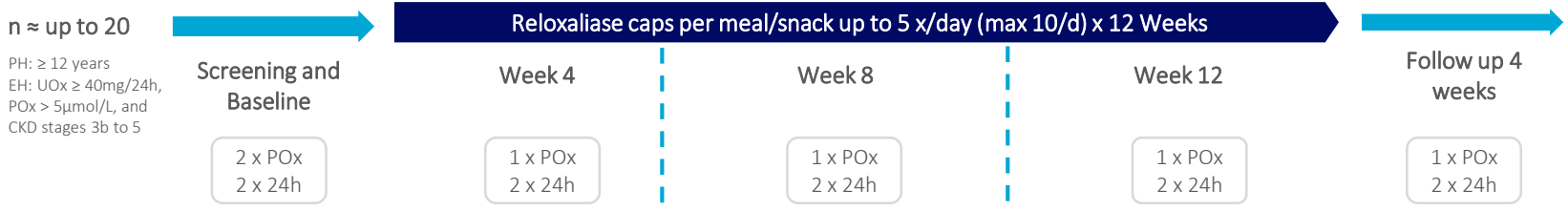
Source: 1. Ermer T 2016 Curr Opin Nephrol Hypertens. 2. Roodnat JI 2017 Transplant Direct 3. Elgstoen KB 2010 Neph Dial Transplant 4.Health Advances interviews and analysis, OPTN 5.Pinheiro HS 2005 Am J Transplant 6. Bagnasco SM 2009 Nephrol Dial Transplant 7. Palsson R J Am Soc Nephrol 28, 2017:356.

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

Study Update:

- 8 enrolled subjects across multiple PH and EH subpopulations
- Pretreatment sequential testing suggests variability in POx
- Safety: 12 weeks exposure, longest to date - no safety concerns/ no signals
- Expect to present initial data at 2Q 2019 scientific conference

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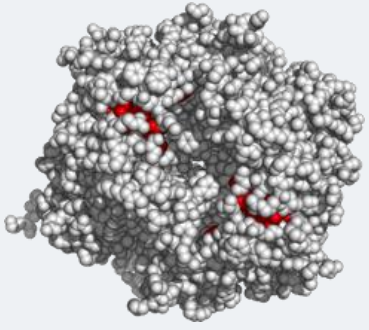
ALLN-346: Significant Opportunity in Gout Patients with Moderate-to-Severe CKD

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*

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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.

Execution of Clinical and Regulatory Milestones

YEAR	TARGET	MILESTONE	STATUS
2018	1Q18	Initiate URIROX-1	✓
	1Q18	Initiate Study 206, Phase 2 Study in PH and EH with Hyperoxalemia	✓
	2H18	Present ALLN-346 Animal Data	New ✓
	2H18	Initiate URIROX-2	✓
	2H18	Study 206 Interim Data	Update ✓
2019	1H19	File IND ALLN-346	2H19
	2Q19	Study 206 Initial Data	On Track
	2H19	URIROX-1 Topline Data	On Track
	2H19	Study 206 Topline Data	On Track

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Highlights – Pioneering Oral Enzyme Therapeutic Platform

Significant Unmet Need in Oxalate and Urate Disorders

- Focused on rare and severe metabolic disorders that can cause kidney stones, damage the kidney, and potentially lead to CKD and ESRD
- No approved oxalate therapies; potential untapped multi-billion dollar market

Late-Stage Development Candidate: Reloxaliase

- First-in-class, oral therapeutic candidate for severe hyperoxaluria
- Achieved FDA alignment on pivotal URIROX Phase 3 program in and strategy for accelerated approval pathway
- Enrolling two Phase 3 trials in enteric hyperoxaluria; URIROX-1 topline data expected 2H19
- Enrolling Phase 2 basket study (Study 206) in orphan populations

Pioneering Expertise in Oral Enzyme Therapeutics

- Proprietary technological approach designed to enable treatment of metabolic diseases with oral, non-absorbed enzyme therapeutics
- GI MOA reduces subsequent metabolic burden on the kidney

Second Product Candidate: ALLN-346

- First-in-class, oral therapeutic candidate designed for gout patients with moderate-to-severe CKD; designed to degrade urate in the GI tract, reducing urate burden on kidney
- Gout patients with renal impairment are not optimally managed with existing therapies
- IND submission targeted in 2H19

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