

Allena Pharmaceuticals						
Name of study	Objective	Major Inclusion criteria	Major exclusion criteria	Major endpoints and time points	Centers participating in Europe	More information available at
Establishing the Safety and Efficacy of Reloxaliase in Patients with Enteric Hyperoxaluria	<ol style="list-style-type: none"> 1. Determine long-term safety and efficacy of reloxaliase for decreasing 24-hour urine oxalate (UOx) 2. Evaluate effect of reloxaliase on kidney stone disease progression and kidney function 3. Assess impact of reloxaliase on healthcare resource utilization and quality of life 	<ol style="list-style-type: none"> 1. Enteric disorder associated with fat malabsorption and known or suspected hyperoxaluria (e.g., history of kidney stone or oxalate nephropathy) 2. UOx \geq50 mg/24h 3. At least 1 kidney stone within past 2 years 4. Stable regimen of medications for management of kidney stone risk factors 	<ol style="list-style-type: none"> 1. Unable to obtain reliable 24-hour urine collections 2. eGFR $<$30 mL/min/1.73 m² 3. Cannot establish Baseline kidney stone burden via imaging 4. Known genetic, congenital, or other cause of kidney stone 	<p>Primary Change in 24-hour UOx from Baseline (Weeks 1-4)</p> <p>Secondary</p> <ol style="list-style-type: none"> 1. Change in 24-hour UOx from Baseline (Weeks 16-24) 2. Proportion of subjects with \geq 20% reduction in 24-hour UOx (Weeks 1-4) <p>Long-Term Endpoints (2-4 years)</p> <p>Primary: Kidney stone disease progression</p> <p>Secondary:</p> <ol style="list-style-type: none"> 1. Hospitalizations or emergency room visits or procedures for kidney stones 2. Change in eGFR from Baseline 	<p><u>France</u> Vandoeuvre-les-Nancy CHRU de Nancy – Hospitaux de Brabois</p> <p>Marseille AP-HM Hopital de la Conception</p> <p><u>Switzerland</u> Lausanne Centre Hospitalier Universitaire Vaudois</p> <p><u>Future centers planned in:</u> Austria Belgium Croatia Germany Italy Portugal Romania Russia Spain United Kingdom</p> <p>Center locations will be updated at: https://clinicaltrials.gov/ct2/show/NCT03847090</p>	<p>If interested in participating, please email: clinical302@allenapharma.com</p> <p>For additional trial information: https://clinicaltrials.gov/ct2/show/NCT03847090</p> <p>OR</p> <p>https://www.allenapharma.com/sites/default/files/NEW_AS_N20_InfoPoster.pdf</p> <p>OR</p> 