

Abstract: INFO34

Evaluate the Safety and Efficacy of ALLN-177 in Patients with Enteric Hyperoxaluria (UriRox-1)

Session Information

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Description

Hyperoxaluria (HOx) is a serious metabolic disorder and one of the major risk factors for progression of kidney stone disease; it can also lead to chronic kidney disease and end-stage kidney disease. Patients with gastrointestinal (GI) conditions associated with malabsorption (e.g., bariatric surgery, short bowel syndrome, inflammatory bowel disease) can develop HOx due to over-absorption of dietary oxalate, and this is termed enteric HOx. There are no approved therapies for HOx. Current management consists of reducing dietary oxalate and increasing calcium and fluid intake, calcium and citrate supplements, and thiazides – but these are of limited utility.

ALLN-177 is a first-in-class oral enzyme therapy (oxalate decarboxylase) that achieves its therapeutic effect by degrading oxalate within the GI tract, resulting in less oxalate absorbed and thereby lower UOx excretion. A phase 2 RCT in patients with secondary HOx showed that ALLN-177 was well tolerated and led to a meaningful reduction in 24-hr UOx excretion, particularly in patients with enteric HOx.

The current trial is a phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of ALLN-177 in patients with enteric HOx. Eligible subjects will be randomized to ALLN-177 (7,500 units) or placebo orally three to five times daily with meals /snacks for 4 weeks. The study is recruiting subjects ≥ 18 years of age with a history of enteric HOx and baseline 24-hr UOx ≥ 50 mg/d. Key exclusion criteria include inability to reliably obtain adequate 24-hour urine collections, estimated glomerular filtration rate < 30 mL/min/1.73m², active malignancy or autoimmune disorder, and primary hyperoxaluria. The primary endpoint is percent change from baseline in 24-hour UOx excretion during Weeks 1-4 and a key secondary endpoints is proportion of subjects with a $\geq 20\%$ reduction from Baseline in 24-hour UOx excretion during Weeks 1-4.

This trial, registered on ClinicalTrials.gov (NCT03456830) and funded by Allena Pharmaceuticals, is currently enrolling subjects. Information on clinical trial sites can be obtained from Medpace at Phone: 513-579-9911, ext. 12410 or t.veira@medpace.com

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- Allena Pharmaceuticals