Background

Reloxaliase (ALLN-177) is a first-in-class oral enzyme therapy that specifically targets oxalate and achieves its therapeutic effect by degrading oxalate within the GI tract, resulting in less systemic oxalate absorption and thereby lowering systemic oxalate concentrations.

Methods

Key Study Objectives

1. To determine the efficacy of reloxaliase in reducing UOx excretion in patients with EH
2. To determine the safety of reloxaliase in patients with EH

Trial Design Features (Figure 1)

- Phase 1: Multi-center, randomized, double-blind, placebo-controlled trial
- Placebo-controlled, crossover design
- Duration: 48 weeks
- Randomization: 1:1 to receive reloxaliase (7,500 units) or placebo 3 to 5 times per day for 4 weeks
- Primary outcome measure: reduction in 24-hour UOx excretion

Results

- The proportion of subjects with a ≥20% reduction in 24-hour UOx excretion during Weeks 1-4 was 48.3% in the reloxaliase group, compared with 22.6% in the placebo group (p=0.0040, 2-sided).
- Overall, the percent change from baseline in 24-hour UOx excretion was -22.6% across Weeks 1-4, representing a 22.6% reduction from baseline.

Bifidobacterium infantis, and 3.4% and 5.3% for nausea.

No deaths and no related serious adverse events were reported. GI events reported by >2 subjects included, in descending order of occurrence, diarrhea 4.4% and 1.8%, flatulence 6.9% and 1.8%, and nausea 3.4% and 5.3%

Conclusions

Reloxaliase was well tolerated. There was a higher proportion of subjects on reloxaliase reporting AEs compared with placebo; these were mainly GI in nature. Compliance with the study drug was very high (97%), with no difference between treatment groups.

References


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