2022. SERENE-UC

Phase 3/ ADA / UC / Maintain

Higher vs. standard adalimumab maintenance regimens in patients with moderately to severely active UC: Results from the SERENE-UC maintenance study

Phase 3, double blind randomized controlled trial. Induction and maintenance regimens in UC with: ADA 40 mg/eow (SIR) vs ADA 40 mg/ew (HIR)

- 2 regimens: Clinical adjusted based on symptoms and biomarkers and TDM (Therapeutic Drug Monitoring) based on symptoms, biomarkers, ADA levels.

- Induction primary outcome: Response w8;
- Maintenance primary outcome: Clinical remission at w52.

Results:

- Induction w8: 13.3% vs 10.9% of patients receiving the higher induction regimen vs standard induction regimen achieved clinical remission, p=ns
- Clinical remission w52: 39,5% ADA ew vs 29% ADA eow, p=ns.

Conclusions:

No statistical difference between ADA eow vs ADA ew in the different endpoints. ADA ew was safe and well tolerated.

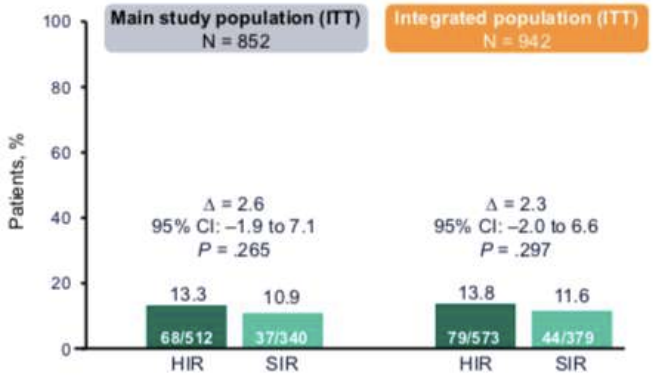

Figure 2. Clinical remission at week 8 (primary efficacy end point–induction study). Clinical remission was defined as FMS ≤2 with no subscore >1 (ITT analysis set). Adjusted difference by stratification factors. Central reviewer scoring of endoscopy results was used for all efficacy assessments. RBS and SFS components of FMS were based on entries into patient diary averaged over 5 days before each study visit. Missing data were handled by nonresponder imputation.

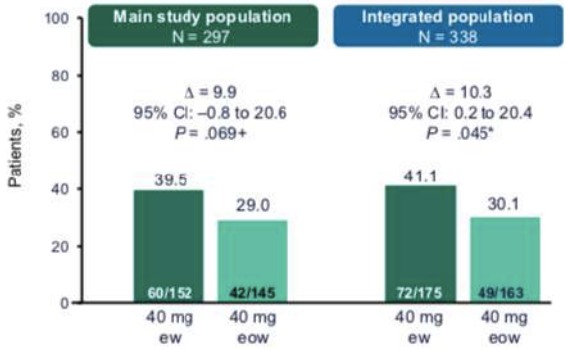

Figure 3. Clinical remission among patients with week-8 response (primary efficacy end point–maintenance study). Clinical response was defined per FMS; FMS decrease from baseline ≥3 and ≥30%, plus RBS decrease from baseline ≥1 or absolute RBS of 0 or 1. *P* values for comparison between 40 mg ew and 40 mg eow calculated using Cochran–Mantel–Haenszel test adjusted for stratification factors. Missing data were handled by nonresponder imputation.

HIR Higher regimen
SIR Standard regimen

Panés J et al.Gastroenterology 2022;162:1891–1910