Gastroenterología y Hepatología 47 (2024):S127

Gastroenterología y Hepatología

https://www.elsevier.es/gastroenterologia

P-95 - HEALTH-RELATED QUALITY OF LIFE FROM THE INFLAMMATORY BOWEL DISEASE QUESTIONNAIRE IN PATIENTS WITH ULCERATIVE COLITIS TREATED WITH ETRASIMOD IN THE PHASE 3 ELEVATE UC 52 AND ELEVATE UC 12 TRIALS

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Resumen

Introduction: Etrasimod is an investigational, once-daily, oral, selective sphingosine 1-phosphate receptor 1,4,5 modulator (S1P1,4,5) in development for the treatment of moderately to severely active ulcerative colitis (UC). ELEVATE UC 52 and ELEVATE UC 12 were two phase 3 studies that demonstrated efficacy and safety of etrasimod in patients with UC in which several patient-reported outcomes were collected. Here we report a post hoc analysis assessing health-related quality of life (HRQoL) in the ELEVATE programme with the validated Inflammatory Bowel Disease Questionnaire (IBDQ). (Chen XL *et al.* Health Qual Life Outcomes. 2017;15:1-13).

Methods: In ELEVATE UC 52 (NCT03945188) and ELEVATE UC 12 (NCT03996369), patients (16-80 years) with moderately to severely active UC were randomised 2:1 to once-daily etrasimod 2 mg or placebo (PBO). Patients in the full analysis set with modified Mayo Scores 5-9 with a completed 32- item IBDQ questionnaire at baseline, week 12 (both trials) and week 52 (ELEVATE UC 52 only) were included in this analysis. Least squares mean (LSM) change from baseline for IBDQ total score and IBDQ domain scores were compared between etrasimod and PBO arms in both trials at each time point (data as observed), along with the proportion of patients who achieved IBDQ remission (IBDQ total score ≥ 170; nonresponder imputation).

Results: At baseline, a total of 237 and 191 etrasimod-treated patients and 112 and 96 PBO treated patients completed the IBDQ for ELEVATE UC 52 and ELEVATE UC 12, respectively. LSM change from baseline in IBDQ total scores for etrasimod vs. PBO were 42.8 vs. 27.4 (difference [95% CI] 15.4 [6.5, 24.4]; p 0.001) and 55.8 vs. 38.1 (difference [95%CI] 17.7 [6.6, 28.6]; p = 0.002) at week 12 and week 52, respectively, in ELEVATE UC 52, and 47.5 vs. 30.2 1 (difference [95%CI] 17.3 [8.5, 26.2]; p 0.001) at week 12 in ELEVATE UC 12. A greater proportion of etrasimod-treated patients achieved IBDQ remission at week 12 in both trials and week 52 in ELEVATE UC 52. Etrasimod-treated patients demonstrated significant

improvements from baseline vs. PBO in all 4 IBDQ domains in both trials. Across all IBDQ domains, improvements were seen at 12 weeks and the LSM change from baseline was greatest among etrasimod-treated patients at all time points.

Conclusions: Patients treated with etrasimod demonstrated greater improvement from baseline in total and all 4 domain scores of the IBDQ at the end of the 12-week induction phase and 52- week maintenance phase in comparison with PBO. These findings demonstrate the benefits of etrasimod on disease specific HRQoL and support the clinical findings from the ELEVATE programme.