Effect of Linacotide on IBS-QOL Sexual Subscale Scores in Patients with Irritable Bowel Syndrome with Constipation: Results from 2 Phase 3 Trials

Introduction Linacotide is a minimally absorbed guanylate cyclase-C agonist approved for treatment of IBS with constipation (IBS-C). IBS often results in diminished quality of life (QOL), including decreased sexual desire and activity. This post hoc analysis aimed to determine if linacotide treatment improved IBS-QOL sexual subscale scores in IBS-C patients, compared to placebo.

Methods Data from 2 randomised, double-blind Phase 3 linacotide trials in IBS-C were pooled. The IBS-QOL was administered at baseline and Week 12. The sexual subscale includes items on difficulty with sexual activity and reduced sexual desire, both rated on a 5-point scale (1 = not at all, 2 = slightly, 3 = moderately, 4 = quite a bit, 5 = extremely/a great deal); the sum of both items is scaled from 0 (worst) to 100 (best). Changes in the scores from baseline to Week 12 were compared for linacotide- vs placebo-treated patients in the intent-to-treat (ITT) population and the Impaired Sexuality (IS) subgroup (baseline sexual subscale scores ≤ 50).

Results Of 1598 ITT patients with baseline sexual subscale scores, 522 (33%) had a score ≤50 indicating significant impact of IBS on sexual desire and activity (females: 484/1439 [34%]; males: 38/159 [24%]). At Week 12, linacotide significantly improved change-from-baseline sexual subscale scores vs placebo in the ITT population and IS subgroup (Table, p < 0.001 for both). Although baseline scores for males were higher (better) than for females, improvement vs placebo for males was similar to females in the ITT population and greater for the IS subgroup. However, the male sample size was too small to establish statistical significance.

Conclusion Linacotide treatment significantly improves IBS-QOL sexual subscale scores in IBS-C patients compared with placebo, in both the total population and in patients with impaired sexuality at baseline.

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