patients: 72 vs. 47% for Degree of Relief of IBS Symptoms, 70 vs. 47% for Degree of Relief of Abdominal Pain, and 59% vs. 33% for SBM frequency (all comparisons: p < 0.0001). For all parameters, most linaclotide-treated patients (≥70%) who had response at Week 4 were improved at Week 12. For linaclotide-treated patients whose symptoms were unchanged at Week 4 for Degree of Relief of IBS Symptoms and Degree of Relief of Abdominal Pain, 36 and 39% were improved at Week 12, vs. 19 and 21% of the placebo group, respectively (p < 0.05). For SBM frequency, 30% of linaclotide-treated patients vs. 17% of placebo-treated patients without response at Week 4 were improved (SBMs ≥2) at Week 12 (p < 0.05).

Conclusion Patients whose IBS symptoms improved after 4 weeks with linaclotide were likely to maintain improvement. At least 30% of linaclotide patients who were unchanged at Week 4 experienced symptom improvement by Week 12. The significant differences between linaclotide and placebo in the percentage of patients improved at Week 12 who were unchanged at Week 4 indicates that in some patients ≥1 month of linaclotide therapy may be required for improvement. Hence, an initial course of linaclotide therapy in patients with IBS-C should be >4 weeks.

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PWE-167 EFFECT OF LINACLODITE ON IBS-QOL SEXUAL SUBSCALE SCORES IN PATIENTS WITH IRITABLE BOWEL SYNDROME WITH CONSTIPATION: RESULTS FROM 2 PHASE 3 TRIALS

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Introduction Linaclootide 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 posthoc analysis aimed to determine if linaclootide treatment improved IBS-QOL sexual subscale scores in IBS-C patients, compared to placebo.

Methods Data from 2 randomised, double-blind Phase 3 linaclotide 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 to 0 (worst) to 100 (best). Changes in the scores from baseline to Week 12 were compared for linaclootide- 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, linaclootide 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 Linaclootide 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.

Study funded by Forest Laboratories, Inc., and Ironwood Pharmaceuticals, Inc.


PWE-168 IS THERE A RELATIONSHIP BETWEEN IRITABLE BOWEL SYNDROME SYMPTOMS AND SMALL BOWEL BACTERIAL OVERGROWTH?

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Introduction Bacterial overgrowth is associated with IBS-C. The aim of this study was to evaluate the relationship between bacterial overgrowth as measured by breath hydrogen test and small bowel bacterial overgrowth (SBBO) tests (endo) and the symptoms of IBS.

Methods Study participants were asked to complete an IBS symptomatology questionnaire and a breath hydrogen test over a 4-hour period. The breath hydrogen test was conducted to determine the presence of SBBO with or without assay of endotoxin. Endotoxin was measured using an ELISA kit.

Results A total of 100 participants were included in the study. The mean age was 39 years (range: 20-70 years), and 60% were female. A total of 60 participants had SBBO and 40 did not. The average breath hydrogen level for participants with SBBO was 215 parts per million (ppm), while for those without SBBO it was 125 ppm. The endotoxin level was significantly higher in participants with SBBO (p<0.05).

Conclusion There is a significant relationship between the presence of SBBO and IBS symptoms, as well as an association between endotoxin levels and IBS symptoms.