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 shou.ld be >4 weeks.

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Disclosure of Interest W. Chey Consultant for: Ironwood Pharmaceuticals, Forest Research Institute, B. Lavins Shareholder of: Ironwood Pharmaceuticals, Employee of: Ironwood Pharmaceuticals, S. Shiff Shareholder of: Forest Research Institute, Employee of: Forest Research Institute, J. MacDougall Shareholder of: Ironwood Pharmaceuticals, Employee of: Ironwood Pharmaceuticals, C. Kurtz Shareholder of: Ironwood Pharmaceuticals, Employee of: Ironwood Pharmaceuticals, M. Currie Shareholder of: Ironwood Pharmaceuticals, Employee of: Ironwood Pharmaceuticals, J. Johnston Shareholder of: Ironwood Pharmaceuticals, Employee of: Ironwood Pharmaceuticals.

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

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Introduction Linaclotide 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 linaclotide 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 linaclotide- 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, linaclotide 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 Linaclotide 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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PWE-168 IS THERE A RELATIONSHIP BETWEEN IRRITABLE BOWEL SYNDROME SYMPTOMS AND SMALL BOWEL BACTERIAL OVERGROWTH?

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Abstract PWE-167 Table 1 IBS-QOL sexual subscale results

	Placebo (ITT)	Linaclotide (ITT)	Change from baseline Δ	*P*-value (ITT)	Placebo (IS)	Linaclotide (IS)	Change from baseline Δ	*P*-value (IS)
Overall (n)	795	803	5.2	<0.0001*	249	273	7.2	0.0007*
Baseline	68.9 (31.9)	66.9 (30.9)			27.2 (17.8)	29.5 (17.7)		
Week 12	79.7 (25.9)	83.1 (23.6)			57.8 (29.9)	67.9 (28.1)		
Females (n)	706	733	5.2	<0.0001*	228	256	6.7	0.0016*
Baseline	68.0 (32.3)	66.1 (31.1)			26.6 (17.8)	29.5 (17.8)		
Week 12	79.8 (25.8)	83.2 (23.4)			58.5 (30.2)	68.6 (27.7)		
Males (n)	89	70	4.2	0.3129*	21	17	10.2	0.2389*
Baseline	76.3 (28.1)	74.5 (28.7)			32.7 (16.5)	30.1 (17.7)		
Week 12	78.9 (26.7)	81.5 (26.0)			50.0 (25.7)	57.8 (33.2)		

Data are mean (SD)
**P*-values based on change-from-baseline treatment difference for linaclotide vs placebo (ANCOVA)