PTH-195 LUBIPROSTONE TREATMENT IMPROVES CONSTIPATION AND RELATED SYMPTOMS IN PATIENTS REFRACTORY TO OTHER CONSTIPATION THERAPIES

doi:10.1136/gutjnl-2013-304907.682

[1]R M Panas, [2,*]T Joswick, [3]P Lichtlen, [1]D Panigrahi, [4]R Ueno. *[1]Medical Affairs; [2]R&D, Sucampo Pharmaceuticals, Bethesda, United States; [3]R&D; [4]Sucampo Pharmaceuticals, Zug, Switzerland*

Introduction Constipation affects millions globally; however, many patients are dissatisfied with currently-available laxative treatments, with most interested in access to other treatment options[1]. Lubiprostone (24 mcg BID) has been shown to be effective and well-tolerated in patients with refractory constipation.

Methods Post-hoc analysis was conducted to evaluate whether lubiprostone provides relief in patients who are refractory or lacking adequate relief from other common constipation therapies. Pooled patient and medication data from two pivotal trials were assessed. Patients with a history of constipation despite the use of constipation medication during the 90 days prior to initiation of study medication were included. Response rates and symptomatic improvements in this subpopulation of refractory patients were analysed based on treatment assignment in the clinical trial: lubiprostone (24 mcg BID) or placebo. Analysis was performed on the whole and by the class of prior medication usage. Patients were considered full responders if they achieved ≥4 spontaneous bowel movements (SBMs)/week. Patients achieving ≥3 but < 4 SBMs/week were moderate responders; those with < 3 SBMs/week were non-responders. Symptomatic improvements were also assessed.

Results Full response to treatment ranged from 52.8 to 67.2% across the 4 weeks of treatment, as compared to 32.3% to 47.4% for placebo patients. For patients who were moderate responders, response rates increased to 64.8–80.0% among the lubiprostone treatment group compared to only 46.6–57.9% of placebo patients. Lubiprostone produced a significant and full response over placebo, respectively, among the refractory patients who previously took contact laxatives 50.9–64.9% vs. 21.3–42.6%; PEG solutions 57.5–75.0% vs. 32.5–52.5%; or enemas 50.0–71.4% vs. 23.3–50.0%. For symptoms of constipation such as stool consistency and straining, lubiprostone treatment resulted in statistically significant improvements compared to placebo at each study week (p≤0.001). In particular, lubiprostone statistically significantly improved overall stool consistency among patients who previously used contact laxatives (p≤0.001), enemas (p≤0.007) or PEG solutions (p≤0.003) at all treatment weeks. Statistically significant improvements in straining were seen at all treatment weeks in patients who previously used PEG solutions (p≤0.018).

Conclusion Given the statistically significant response to lubiprostone in patients refractory to other constipation therapies, lubiprostone may be a helpful addition to the armamentarium for patients suffering from chronic idiopathic constipation.

Disclosure of Interest None Declared.

REFERENCE

1. Müller-Lissner *et al.* Aliment Pharmacol Ther 2013; 37(1):137–145.

PTH-196 LUBIPROSTONE DEMONSTRATES EFFICACY IN ADULT PATIENTS WITH CONSTIPATION REGARDLESS OF AGE, GENDER OR RACE

doi:10.1136/gutjnl-2013-304907.683

[1]R M Panas, [2,*]T Joswick, [2]G Dolecek, [3]P Lichtlen, [1]D Panigrahi, [4]R Ueno. *[1]Medical Affairs; [2]R&D, Sucampo Pharmaceuticals, Bethesda, United States; [3]R&D; [4]Sucampo Pharmaceuticals, Zug, Switzerland*

Introduction Constipation is a common condition affecting millions globally. Lubiprostone has demonstrated safety and efficacy in treating adults with chronic idiopathic constipation. Through an analysis of the subgroups of two Phase 3 studies, the efficacy of lubiprostone based on factors such as age, gender, and race was reviewed.

Aims and Methods Combined data from two Phase 3 well-controlled studies were used to analyse the following subpopulations: non-elderly (< 65 years) and elderly (≥65 years); male and female; and white and non-white. The efficacy endpoints for spontaneous bowel movement (SBM) frequency, stool consistency, and straining were compared between placebo and lubiprostone (24 mcg BID) groups within each subpopulation.

Results Among non-elderly patients, lubiprostone produced a greater increase (p≤0.001) in SBM frequency each week over placebo. Statistically significant increases were observed in the elderly (p = 0.0188 to p = 0.0268) at each week except Week 2 (p = 0.0806). Statistically significant improvements were noted in females (p≤0.001) at all weeks and in males at all weeks (p = 0.0115 to p = 0.0500) except Week 3 (p = 0.0758). For non-whites (p = 0.0003 to p = 0.0021) and whites (p≤0.001), statistically significant increases in SBM frequencies were reported at all weeks. Table 1 shows the weekly change in SBM frequency for each group. Stool consistency was improved with lubiprostone in the non-elderly (p = 0.0172 to p = 0.0441) and the elderly (p≤0.001) at all weeks. Straining was also improved with lubiprostone treatment at all weeks in non-elderly patients (p≤0.001), with similar improvement trends observed in the elderly. Stool consistency and straining were statistically significantly improved with lubiprostone at all weeks (p≤0.001) in females. A similar trend was observed for males but did not achieve statistical significance at all weeks. Lubiprostone improved stool consistency at all weeks in whites (p≤0.001) and non-whites (p≤0.0001 to p = 0.0006). Straining was improved at all weeks for whites (p≤0.001) and non-whites (p≤0.0001 to p = 0.0144).

Table 1 Weekly Change in SBM Frequency

			Mean Change From Baseline							
	Baseline		Week 1		Week 2		Week 3		Week 4	
	Plac	Lubi	Plac	Lubi	Plac	Lubi	Plac	Lubi	Plac	Lubi
Non Elderly	1.52	1.40	2.13	4.33	1.80	3.56	1.60	3.95	1.66	3.84
Elderly	1.83	0.98	2.38	5.37	1.85	4.41	1.16	4.80	1.34	5.15
Males	1.28	1.38	2.13	4.77	1.20	4.66	1.91	4.91	1.47	4.31
Females	1.59	1.36	2.17	4.39	1.88	3.51	1.50	3.91	1.64	3.92
Non Whites	1.49	1.23	2.20	5.94	1.82	4.82	1.95	5.31	2.30	5.39
Whites	1.57	1.39	2.15	4.11	1.81	3.40	1.44	3.76	1.45	3.66

Abstract PTH-196 Figure 1