Conclusion Treatment with lubiprostone resulted in increased SBM frequencies and improvement in related symptoms in patients with chronic idiopathic constipation regardless of age, gender, or race.

Disclosure of Interest None Declared.

Abstract PTH-197 Table 1 Change from Baseline for Constipation Severity

<table>
<thead>
<tr>
<th>Age</th>
<th>Baseline Mean</th>
<th>Week 1 Mean</th>
<th>Week 2 Mean</th>
<th>Week 4 Mean</th>
<th>Week 6 Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 65</td>
<td>2.91</td>
<td>-1.21</td>
<td>-1.18</td>
<td>-1.21</td>
<td>-1.19</td>
</tr>
<tr>
<td>≥65</td>
<td>2.76</td>
<td>-1.11</td>
<td>-0.97</td>
<td>-1.00</td>
<td>-1.15</td>
</tr>
</tbody>
</table>

Conclusion Lubiprostone demonstrated long-term efficacy through an overall improvement in constipation severity for up to 12 months regardless of age, gender, or race. Similarly, improvements were noted in abdominal bloating and abdominal discomfort for both race and gender subpopulations along with some significant and positive trend for improvement in the age group analyses.

Disclosure of Interest None Declared.

Conclusion Lubiprostone, a novel ClC-2 activator, has been shown to be efficacious and well-tolerated by patients with chronic constipation in short- and long-term clinical trials. To better characterize the most frequent adverse events (AEs) associated with the use of lubiprostone 24 mcg BID, we examined pooled results of patients enrolled in Phase 2 and 3 trials of 3 to 48 weeks' duration.

Methods Data for all safety-evaluable patients were pooled and compared between treatment groups (placebo vs lubiprostone 24 mcg BID). Nausea, headache, and diarrhoea AEs were analysed in terms of severity, duration, frequency, action taken (eg, drug withdrawn, dose reduced), and outcome. In addition, nausea-related variables were explored in subpopulations of elderly (≥65 years of age) and male patients.

Results The pooled population included 1113 lubiprostone and 316 placebo patients. Approximately 16% were elderly and 13% were male. At least 1 AE occurred in 79.1% of lubiprostone patients, which included 31.1% with nausea, 13.2% with headache, and 13.2% with diarrhoea. At least 1 AE occurred in 39.6% of placebo patients, which included 5.1% with nausea, 6.6% with headache, and 0.9% with diarrhoea. Of those lubiprostone patients who experienced nausea, 88.7% reported nausea to be mild or moderate in severity. Overall, 74.5% of nausea events reported by lubiprostone patients were intermittent, and the median durations of nausea events were 12 and 7.5 days for lubiprostone and placebo patients, respectively. Notably, mean incidences of nausea per patient were 1.3 and 0.5 for lubiprostone and placebo patients, respectively. With regard to action taken, 64.1% of nausea events required no change in treatment regimen, and 9.6% of events resulted in dose reduction. Nausea was less prevalent in subpopulations, occurring in only 18.8% and 8.2% of lubiprostone elderly and male patients, respectively, compared with 34.5% of female patients. Similarly, the majority of lubiprostone patients experiencing headache and diarrhoea had mild-to-moderate symptom severity (59.8% and 82.3%, respectively). Furthermore, headache and diarrhoea events in lubiprostone patients were mostly intermittent (64.2% and 74.0%, respectively), and the median duration of these events were 9 and 4 days, respectively. Discontinuation rates due to nausea, headache, and diarrhoea were 6.7%, 3.7%, and 2.2%, respectively.

Conclusion Nausea, headache, and diarrhoea associated with lubiprostone use are generally mild to moderate in severity, intermittent, and limited in duration.

Disclosure of Interest None Declared.

Conclusion Pooling analysis of the most frequent adverse events associated with the use of lubiprostone

Disclosure of Interest None Declared.

Introduction A positive diagnosis of irritable bowel syndrome (IBS), without the need for recourse to investigation, is encouraged. Patients meeting symptom-based diagnostic criteria for IBS are often given reassurance that there is no serious underlying pathology, and treated symptomatically. However, some studies have suggested that an organic diagnosis, such as coeliac disease or pancreatic...