INTRODUCTION

• Patients with Crohn’s disease (CD) commonly report abdominal pain, which has significant consequences for patient quality of life.
• In a study of patients with CD, 70% reported pain, and 30% had pain that persisted despite appropriate management of anti-inflammatory or immunosuppressant medications.
• Abdominal pain is not currently an approved indication for treatment in many countries.
• Current treatment options for abdominal pain in patients with CD include nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, and antispasmodics, and, although these strategies have demonstrated limited efficacy and/or undesirable adverse event (AE) profiles.
• The cannabinoid type 2 receptor (CB2) plays a modulatory role in the endocannabinoid system and has been shown to be upregulated in the gastrointestinal tract during intestinal inflammation and wound healing.

METHODS

• Statistical comparisons of AAPS were performed only between Baseline and Week 4 and Baseline and Week 10 over 1 week.
• AAPS ≥ 3.5 were considered active treatment.
• Proportion of subjects who were clinical responders
• Change in AAPS from BL to Week 8

RESULTS

Figure 5. Primary Study Design

Table 2. Summary of Adverse Events

<table>
<thead>
<tr>
<th>Event</th>
<th>BL N = 6</th>
<th>25 mg N = 5</th>
<th>100 mg N = 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>4 (67)</td>
<td>6 (75)</td>
<td>10 (71)</td>
</tr>
<tr>
<td>Headache</td>
<td>0</td>
<td>1 (20)</td>
<td>1 (17)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>0</td>
<td>1 (20)</td>
<td>1 (17)</td>
</tr>
<tr>
<td>Somnolence</td>
<td>0</td>
<td>1 (20)</td>
<td>1 (17)</td>
</tr>
<tr>
<td>Acute interstitial pneumonitis</td>
<td>0</td>
<td>1 (20)</td>
<td>1 (17)</td>
</tr>
<tr>
<td>Acute angle-closure glaucoma</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Acute pancreatitis</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Acute skin rash</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Acute UGI bleeding</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>AEs</td>
<td>4 (67)</td>
<td>6 (75)</td>
<td>10 (71)</td>
</tr>
</tbody>
</table>

Figure 2. Subject Disposition

Figure 3. Baseline abdominal pain score

Figure 4. Weekly Averages of Peak Olorinab Plasma Concentration (predose) and AAPS Clinical Responders (%)

Figure 6. Mean Change in Pain-Free Days Per Week from Baseline (all subjects)

Figure 7. Illustration of Final Study Design

Figure 8. Final Study Design

Figure 9. Final Study Design

Figure 10. Final Study Design

REFERENCES

7. Adams JA et al. Presented at the American Pancreatic Association Scientific Meeting, April 6, 2019; Atlanta, GA.
8. Adams JA et al. Presented at the American Pancreatic Association Scientific Meeting, March 4 & 5, 2019; Atlanta, Georgia.

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DISCLOSURES

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