CONCLUSIONS

- Mirikizumab therapy was associated with improved FACIT-fatigue scores compared to PBO during induction (Weeks 0-12). This change was sustained until week 52.
- During the maintenance period (Weeks 52-52), a high proportion of patients in all miri groups achieved the minimum clinically important difference on the FACIT–Fatigue scale (miri 200mg: 77.4%; miri 600mg: 56.3%; miri 1000mg: 64.1%; PBO: 37.5%).
- These results show that miri improves fatigue in patients with moderately to severely active CD.

BACKGROUND

- Mirikizumab (mi) is a humanized monoclonal antibody directed against the p19 subunit of IL-23, and has previously demonstrated efficacy in treating ulcerative colitis (UC) and moderate to severely active CD.
- Crohn’s disease (CD) is an inflammatory bowel disease (IBD), characterized by inflammation of the digestive tract.
- IL-23 has been shown to play a key role in driving immune responses in patients with Crohn’s disease.
- Fatigue is a common symptom experienced by patients with CD which can adversely affect patient quality of life (QoL).

OBJECTIVE

- Evaluate the impact of miri treatment on fatigue in patients with moderately to severely active CD.

METHODS

Study Design

- This study was a Phase 2, randomized, double-blind, placebo-controlled trial (NCT02891226).
- Baseline patients with CD were randomized to a 2:1:2 allocation across 4 treatment arms (placebo (PBO) and 200mg, 600mg, and 1000mg miri).
- Patients who received miri and achieved ≥1 point improvement by Week (W) 12 in Simple Endoscopic Score for Crohn’s Disease (SES-CD) were randomized in a 1:1 ratio and stratified based on previous exposure to biologic therapy (R1).
- In the IV/IV treatment group, patients who received miri during induction and were non-improvers at W12 were subsequently randomized to the IV/IV or IV/SC groups.

Statistical analysis

- Change in FACIT-fatigue from baseline to Week 12 was compared between treatment groups using a mixed model for repeated measures (MMRM).
- The model included treatment, geographic region, prior CD biologic therapy, visit, and visit by treatment interactions. An unstructured covariance structure was used.
- The change from baseline to week 52 in the FACIT–fatigue are presented descriptively.

RESULTS

- At W12 higher rates of patients achieved MCID FACIT-Fatigue (mi 200mg: 77.4%; mi 600mg: 56.3% miri 1000mg: 64.1%; PBO: 37.5%). These improvements were sustained through Week 52 in patients who received miri during induction, with 68.3% and 69.6% of patients in the IV/IV and IV/SC groups and 53.3% of NI/1000mg group, respectively, having MCID change from baseline on the FACIT–Fatigue scale.

Table 1. Baseline demographic characteristics of each trial arm

<table>
<thead>
<tr>
<th>Trial Group</th>
<th>Mean Age</th>
<th>% Males</th>
<th>% White</th>
<th>% Asian</th>
<th>% Black</th>
<th>% Hispanic</th>
<th>% Female</th>
<th>% Education</th>
<th>% Employed</th>
<th>% Income $50,000 or more</th>
</tr>
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<tbody>
<tr>
<td>PBO</td>
<td>46.3</td>
<td>56.7</td>
<td>94.3</td>
<td>3.1</td>
<td>2.6</td>
<td>0.4</td>
<td>47.3</td>
<td>16.3</td>
<td>15.3</td>
<td>40%</td>
</tr>
<tr>
<td>miri 200mg</td>
<td>46.3</td>
<td>56.7</td>
<td>94.3</td>
<td>3.1</td>
<td>2.6</td>
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<td>47.3</td>
<td>16.3</td>
<td>15.3</td>
<td>40%</td>
</tr>
<tr>
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<td>46.3</td>
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</tr>
<tr>
<td>miri 1000mg</td>
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<td>0.4</td>
<td>47.3</td>
<td>16.3</td>
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<td>40%</td>
</tr>
</tbody>
</table>

DISCLOSURES

- Study was sponsored by Eli Lilly and Company.
- Moderated by the Digestive Disease Week 2022 Conference Chair.
- This study was previously presented at Digestive Disease Week 2022.

Figure 1. Change from baseline in Induction period (Weeks 0-12)

Figure 2. Change from baseline in Maintenance period (Weeks 12-52)

Figure 4. Percentage of patients achieving MCID on the FACIT–Fatigue scale for Weeks 0-12 (A) and Weeks 12-52 (B).

Figure 5. Observed changes from baseline on the FACIT–Fatigue scale were maintained from Weeks 12-52 for those in the miri treatment arms.