**Background**

- Interleukin (IL)-23 is a key cytokine in the pathogenesis of inflammatory bowel disease.

- Mirikizumab, a p18-directed IL-23 antibody, demonstrated efficacy and was well tolerated during 12 weeks of induction followed by an additional 40 weeks of maintenance treatment in a Phase 2, randomized clinical trial (NCT02589665) in patients with moderately to severely active ulcerative colitis (UC).

- Bowel movement urgency is one of the most bothersome and important symptoms experienced by patients with UC and is an often-overlooked aspect of their quality of life (QoL).

**Objective**

To evaluate the effect of mirikizumab on patient-reported bowel movement urgency.

**Methods**

Study Design, AMAC

- Patients used a paper diary to report daily symptoms, including presence or absence of bowel movement urgency each day.
- All mirikizumab-treated patients with bowel movement urgency at baseline had improvements in bowel movement urgency at Week 12. Improvements were significant versus placebo for the mirikizumab 200-mg and 600-mg groups.
- Numerical differences in treatment effect were observed as early as Week 4.
- Difference versus placebo was statistically significant at Week 8 in the mirikizumab 200-mg group.

**Key Results**

**Absence of Bowel Movement Urgency Induction Period**

- All mirikizumab-treated patients with bowel movement urgency at baseline had improvements in bowel movement urgency at Week 12. Improvements were significant versus placebo for the mirikizumab 200-mg and 600-mg groups.
- Numerical differences in treatment effect were observed as early as Week 4.
- Difference versus placebo was statistically significant at Week 8 in the mirikizumab 200-mg group.

**Baseline Demographics and Characteristics Induction Period Population**

- Data were collected throughout maintenance treatment with minimal variation in response in the Maintenance Period.

**RESULTS**

**Baseline**

**Baseline**

**Demographics**

- Age, years
- Female, %
- Weight, kg
- Disease duration, years
- Concomitant therapies at baseline, %

**Charateristics**

- SUSA use
- Corticosteroids
- Thiopurines
- Number of unique prior biologic therapies, n (%)
- Absence of urgency defined as 3 consecutive days prior to baseline, irrespective of urgency status at Week 12

**Supporting Information**

- Table S1: Absence of urgency defined as 3 consecutive days prior to baseline, irrespective of urgency status at Week 12

**Conclusions**

- In patients who reported bowel movement urgency at baseline, mirikizumab treatment resulted in significantly higher proportions of patients with absence of bowel movement urgency compared to placebo at Week 12.
- Numerical improvements in bowel movement urgency were observed as early as Week 4 and statistically significant improvements were observed by Week 8.

- The improvement in bowel movement urgency was sustained through Week 52.

- To the authors' knowledge, this is the first study to assess the effects of IL-23 on bowel movement urgency.

- Reduction in bowel movement urgency is consistent with improvements in the signs and symptoms of UC and QoL, following treatment with mirikizumab in the Phase 2 AMAC clinical trial.

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Eli Lilly and Company.

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2. Sandborn WJ, et al. Bowel movement urgency is one of the most bothersome and important symptoms experienced by patients with UC and is an often-overlooked aspect of their quality of life (QoL).

3. Interleukin (IL)-23 is a key cytokine in the pathogenesis of inflammatory bowel disease.

4. Baseline demographics and characteristics induction period population.

5. Bowel movement urgency is one of the most bothersome and important symptoms experienced by patients with UC and is an often-overlooked aspect of their quality of life (QoL).

6. Absence of urgency defined as 3 consecutive days prior to baseline, irrespective of urgency status at Week 12.

7. Absolute improvement in bowel movement urgency.