Sustained Symptom Control With Mirikizumab in Patients With Moderately to Severely Active Ulcerative Colitis in the LUCENT-2 Maintenance Trial

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BACKGROUND
• Ulcerative colitis is a chronic inflammatory bowel disease associated with a relapsing-remitting disease course and symptoms of diarrhea, rectal bleeding, abdominal pain, and bowel urgency
• Mirikizumab is a humanized IgG4-variant monomeric antibody that specifically binds to the p19 subunit of interleukin (IL)-22
• In patients with moderately to severely active ulcerative colitis, treatment with mirikizumab was effective in induction of clinical remission at Week 12 (LUCENT-1; NCT03518068) and in maintenance of clinical remission at Week 40, corresponding to 52 weeks of continuous treatment (LUCENT-2; NCT03524067)

OBJECTIVE
To assess sustained symptom control with mirikizumab during 40 weeks of maintenance treatment (52 weeks of continuous therapy; LUCENT-2) among patients who had a clinical response to mirikizumab during the induction study (LUCENT-1)

METHODS
Study Design
LUCENT-1 (NCT03518068) - Induction Therapy
LUCENT-2 (NCT03524067) - Maintenance Therapy

Key Eligibility Criteria: LUCENT-1
• Age ≥18 years
• Moderate to severe UC (a Mayo score ≥6 and moderate to severe endoscopic activity as determined by a validated ileocolonoscopy
• Response to previous biologic therapy

Key Eligibility Criteria: LUCENT-2
• Moderately to severely active ulcerative colitis
• Modified Mayo Score of 4-9, with an endoscopic subscore of 2-3
• Inadequate response, loss of response, or intolerance to the previous biologic therapy

Assessments
Bowel urgency severity: median (Q1, Q3)
Abdominal pain: VAS score
Rectal bleeding severity: endoscopic Mayo subscore
Stool frequency severity: Mayo subscore
Symptomatic remission

RESULTS
Significantly Greater Rates of Stool Frequency Remission, Rectal Bleeding Remission, and Symptomatic Remission Were Observed With MIRI vs. PBO at 40 Weeks of Continuous Treatment

Statistical Analysis
Analyses were conducted using the modified intent-to-treat population (patients receiving ≥2 dose of mirikizumab or placebo)
- Excludes patients impacted by a chronic inflammatory outcome assessment transition error in Poland and Turkey
- Changes from baseline were compared between treatment arms using mixed-effects model of repeated measures, including treatment, baseline value, visit, interaction of baseline value-by-visit, interaction of visit-by-year, prior biologic or biologic failure, corticosteroid use at baseline (LUCENT-1), global region, and clinical remission status at Week 12 (LUCENT-1)
- Proportions between treatment arms were compared using Cochran-Mantel-Haenszel test adjusted for prior biologic or biologic failure, corticosteroid use at baseline (LUCENT-1), global region, and clinical remission status at Week 12 (LUCENT-1)
- Common risk difference was the difference in proportions adjusted for stratification factors, with confidence intervals calculated using the Mantel-Haenszel-Odds method
- Missing data were handled using non-responder imputation

REFERENCES

DISCLOSURES
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