**Efficacy and Safety of Mirikizumab (LY3074828) After 12 Weeks Induction Treatment in a Phase 2 Study of Patients with Crohn’s Disease**

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**BACKGROUND**

The interleukin (IL)-23/Th17 pathway has a significant role in the pathogenesis of Crohn’s disease (CD) with various anti-IL-23 antibodies having shown efficacy in CD.

Mirikizumab (miri) is a humanized immunoglobulin G4 (IgG4)–variant monomeric antibody that binds to the p19 subunit of IL-23.

Phase 2 studies of mirikizumab have shown efficacy in treating ulcerative colitis (UC), psoriasis, and Crohn’s disease leading to further development in ongoing Phase 3 studies.

We assessed safety and efficacy of miri after a 12-Week induction treatment in a Phase 2, multi-centered, randomized, parallel-arm, double-blind, placebo-controlled trial (NCT02891226) in patients with moderate-to-severely active Crohn’s disease.

**REFERENCES**


Koshi, K., Inai, N. C., & Mirikizumab (LY3074828) in the Treatment of Moderate-severe Inflammatory Bowel Disease: Results from a Randomized Phase IIa Study. Gastroenterology 2019; 156 (Supplement 1): 1193-1194


**STUDY DESIGN**

AMAG Study Design and Objectives at Week 12

**Methods**

- **Endoscopy**
  - Endoscopy score determined with central reading

- **Statistics**
  - Treatment comparisons of categorical efficacy variables conducted using a 2-sided alpha level of 0.10 and logistic regression analysis: treatment, geographic region, and prior biologic therapy use included in the model.
  - All p values based on statistical testing without multiple comparisons.
  - Non-responder imputation (NRI): All patients who discontinued from study prior to Week 12 for any reason or failed to have an adequate Week 12 efficacy assessment considered non-responders at Week 12

- **Enrollment Criteria**
  - Inclusion: Crohn’s disease ≥3 months active
  - Sotol fluid ≥4 and abdominal pain ≥2 at baseline
  - SES-CD ≥17 (centrally read) for subjects with left-colonic or ≤2 for subjects with isolated ileal disease
  - Prior treatment for Crohn’s disease: failure/intolerance to conventional treatment and treatment with ≥1 biologic agents

- **Exclusion**
  - Structures, stenoses, any other manifestation which might require surgery
  - Bowel resection, diversion, or placement of a stoma within 6 months; other intra-abdominal surgery within 3 months
  - Previous exposure to any biologic therapy targeting IL-12/23
  - After an amendment, a single prior induction dose of ustekinumab (UST) was allowed

**Key Results**

- **Statistics**
  - **Treatment comparisons of categorical efficacy variables conducted using a 2-sided alpha level of 0.10 and logistic regression analysis: treatment, geographic region, and prior biologic therapy use included in the model.**
  - All p values based on statistical testing without multiple comparisons.
  - **Non-responder imputation (NRI):** All patients who discontinued from study prior to Week 12 for any reason or failed to have an adequate Week 12 efficacy assessment considered non-responders at Week 12

**Conclusions**

- Significant improvement in patient report outcomes (PRO) and CDAI
- Demonstrates few SAEs or discontinuations due to AEs with induction treatment up to 10mg
- Safety profile overall consistent with that of prior treatment of ulcerative colitis
- Mirikizumab induces meaningful improvements in clinical and endoscopic outcomes at Week 12 in patients with moderately to severely active Crohn’s disease.

- **Disclosures**
  - All authors received travel support from: Eli Lilly and Company, Sanofi, Pfizer, Abivax, Janssen, and Takeda
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