2023. LUCENT

RCT/Mirikizumab/UC/ Induct&Maintain

Mirikizumab as Induction and Maintenance in Ulcerative Colitis

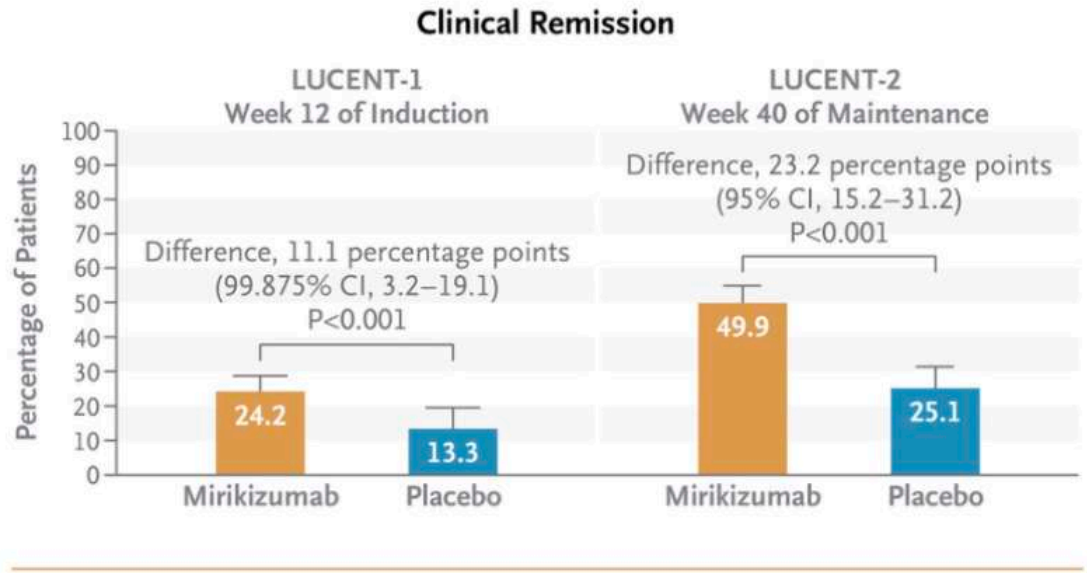
Two phase 3 randomized, double-blind, placebo controlled trials. Patients with moderate to severe ulcerative colitis were randomized to mirikizumab 300mg IV (3 doses q4w) vs. Placebo at induction. Patients with response to mirikizumab induction were randomized to mirikizumab 200mg vs placebo up to week 52.

Primary endpoints: Clinical remission at week 12 induction and at week 52 (week 40 of maintenance).

Results: N=1281

- Clinical remission at week 12: 24.2% MIRI vs 13.3% pbo, p<0.001
- Clinical remission at week 52: 49.9% MIRI vs 25.1% pbo, p<0.001
- Adverse events: nasopharyngitis and arthralgia more frequent in MIRI arm than in placebo.
- There were 8 cases of cancer in the mirikizumab arm: 3 colon cancer, 1 rectal cancer, 1 kaposi sarcoma, 1 gastric cancer and 2 squamous cell carcinomas.

Conclusion:
Mirikizumab is more effective than placebo in inducing and maintaining clinical remission in patients with ulcerative colitis



D'Haens G et al. N Engl J Med. 2023; 388: 2444-2455