omvoh™
mirikizumab
infusion/injection

EXTENDED INDUCTION WITH OMVOH®

INCREASED CLINICAL RESPONSE TO 80.3% AT WEEK 24[1]

Benefit for difficult-to-treat patients with moderately to severely active UC[1]

Objective

To assess response over time among patients not responding to initial induction, who **received extended induction with Omvoh (mirikizumab) for an additional 12 weeks**[2]

Difficult-to-treat patients

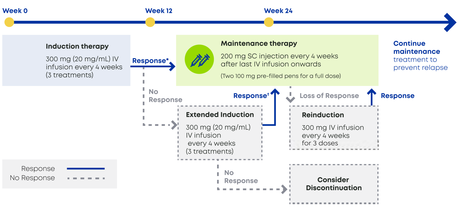
A prolonged course of induction may be required for patients who have[1]**:**

- **More severe disease at baseline**[3]
- **Prior exposure to biologics, which can influence response to subsequent therapies**[4]

Trial design

OMVOH OFFERS FLEXIBLE DOSING OPTIONS

which were assessed in the LUCENT trials[1,5,6]



In **LUCENT-1**, patients (N=1281) were randomly assigned 3:1 to receive Omvoh 300 mg or placebo IV at Week 0, Week 4, and Week 8.[5,1]

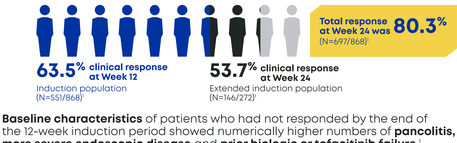
In **LUCENT-2**, patients not achieving clinical response with Omvoh 300 mg IV at Week 12 of LUCENT-1 (N=272) received extended induction treatment with open-label Omvoh 300 mg IV at Week 12, Week 16, and Week 20.[1,6]

*Omvoh responders in LUCENT-1=551/868 (63.5%); 544 entered LUCENT-2.[5,6]
†Omvoh extended induction responders who achieved clinical response at Week 24 in LUCENT-2=146;[1] 144 continued with SC maintenance.[1,6]

Results

OMVOH'S IN-LABEL EXTENDED INDUCTION BENEFITTED DIFFICULT-TO-TREAT PATIENTS[2,5]

WITH OMVOH, CLINICAL RESPONDERS INCREASED TO 80%
following 3 **IV infusion** for Week 12 non-responders[1]



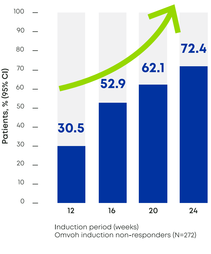
63.5% clinical response at Week 12
Induction population (N=551/868)[1]

53.7% clinical response at Week 24
Extended induction population (N=146/272)[1]

Baseline characteristics of patients who had not responded by the end of the 12-week induction period showed numerically higher numbers of **pancolitis, more severe endoscopic disease** and **prior biologic or tofacitinib failure**.[1]

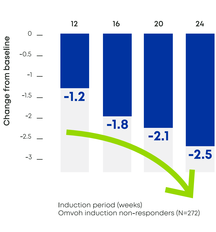
WITH OMVOH, CONTINUED SYMPTOMATIC IMPROVEMENT WAS SEEN
in extended induction responders who continued with maintenance therapy[2]

Symptomatic response[2]



≥30% decrease from induction baseline in the composite clinical endpoint of the sum of stool frequency and rectal bleeding subscore[2]

Bowel urgency
Change from baseline[2]



Change from induction baseline in urgency NRS score (0–10)
A lower score indicates less severe bowel urgency[2]

Safety

OMVOH HAS A CONSISTENT SAFETY PROFILE[5-7]

- The incidences of adverse events during the trials were similar in the Omvoh and placebo groups during both the induction trial and the placebo-controlled maintenance trials[5]
- No new safety signals were identified in the long-term extension trial[7]

Clinical Response: ≥2-point and ≥30% decrease in MMS from baseline; RB=0 or 1 or RB ≥1-point decrease from baseline.

INDICATION
Omvoh is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment.[3]

IMPORTANT SAFETY INFORMATION
The safety of Omvoh was evaluated in three Phase 3 trials.[5,7] The common reported adverse reactions were upper respiratory tract infections, arthralgia, headache, rash and injection site reactions.[3]

ABBREVIATIONS
CI, confidence interval; **IV**, intravenous; **MMS**, Modified Mayo Score; **NRS**, numeric rating scale; **RB**, rectal bleeding; **SC**, subcutaneous; **UC**, ulcerative colitis.

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