DURABLE CLINICAL REMISSION[1,2]

64% of patients maintained clinical remission through 1 year of continuous treatment with Omvoh[1,2]

Omvoh™ mirikizumab infusion/injection

Dear Doctor,

The efficacy and safety of Omvoh was evaluated in patients with moderately to severely active ulcerative colitis (UC) in the LUCENT-1 and LUCENT-2 trials[1–3]:

- Phase 3, multicenter, randomized, double-blind, placebo controlled clinical trials[1,2]
- At baseline, all patients had inadequate response, loss of response, or intolerance to at least one corticosteroid, immunomodulator, biologic treatment, or tofacitinib for UC[1,2]
- Patients **required a new treatment** to manage their disease

WEEK 0-12

INDUCTION

LUCENT-1

INDUCTION STUDY[3]

- **Omvoh (300 mg)** IV Q4W (Weeks 0, 4 and 8)
- **Placebo** IV Q4W (Weeks 0, 4, and 8)

WEEK 12

Nearly 2 in 3 patients taking Omvoh achieved a clinical response at Week 12[3]

64% of patients taking Omvoh achieved a clinical response after 12 weeks of induction dosing, and **nearly 1 in 4 achieved clinical remission**[3]

CLINICAL RESPONSE[3,*]
(Secondary endpoint)

64%
Omvoh 300 mg IV Q4W (N=868) vs 42% in the placebo group (N=294) (p<0.001)

AND

CLINICAL REMISSION[3,†]
(Primary endpoint)

24%
Omvoh 300 mg IV Q4W (N=868) vs 13% in the placebo group (N=294) (p<0.001)

*Clinical response at Week 12 was defined as ≥2-point and ≥30% decrease in the MMS from baseline; RB=0 or 1, or a ≥1-point decrease from baseline. †Clinical remission at Week 12 was defined as SF=0, or SF=1 with a ≥1-point decrease from baseline; RB=0; ES=0 or 1 (excluding friability)[1]

RE-RANDOMIZED 2:1

WEEK 12

Responders from LUCENT-1 re-randomized 2:1[2]

Clinical responders to induction Omvoh therapy at Week 12 of LUCENT-1 were re-randomized to receive maintenance Omvoh therapy or placebo for 40 weeks in LUCENT-2[2]

WEEK 12-52

MAINTENANCE

LUCENT-2

MAINTENANCE STUDY[2]

- **Omvoh (200 mg)** SC Q4W
- **Placebo** SC Q4W

WEEK 52

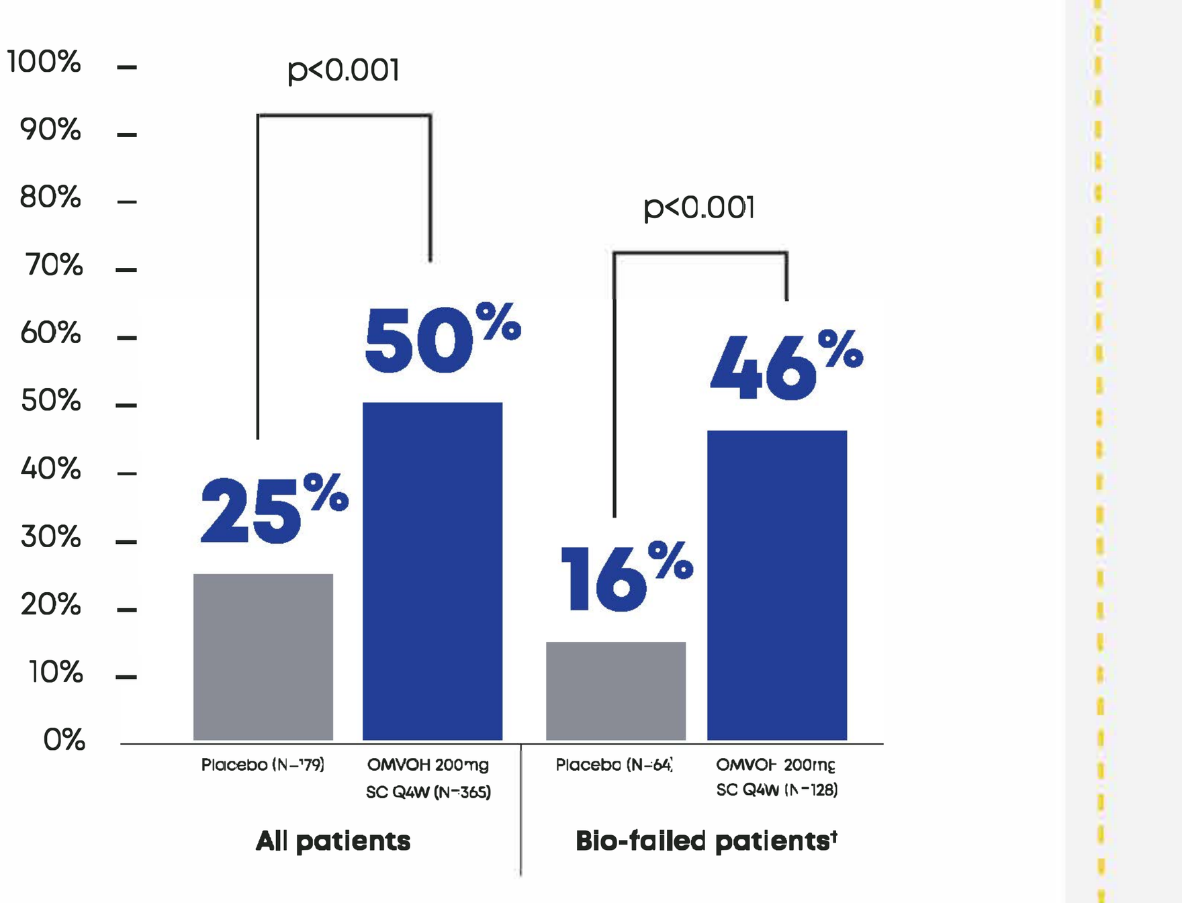
Omvoh provided sustained clinical remission at Week 52[1,2,4]

Among patients who achieved a clinical response in LUCENT-1, 50% of all patients and 46% of bio-failed patients achieved clinical remission at Week 52[1,2,4]

98% OF PATIENTS WHO ACHIEVED CLINICAL REMISSION AFTER 1 YEAR OF TREATMENT WITH OMVOH WERE **STEROID-FREE** FOR AT LEAST THE PREVIOUS 12 WEEKS (n=178/182).[2,*]

*The data presented are from a post hoc analysis and were not type I error controlled. Therefore treatment differences between Omvoh and placebo cannot be regarded as statistically significant.[1]

PATIENTS ACHIEVING CLINICAL REMISSION* AT WEEK 52[1,2,4]



*Clinical remission was defined as SF=0, or SF=1 with a ≥1-point decrease from baseline; RB=0; ES=0 or 1 (excluding friability).
†Bio-failed includes biologic-failed and tofacitinib-failed patients. An additional 1 patient on placebo and 8 patients on Omvoh were previously exposed to but did not fail a biologic or JAKi. These patients were excluded from the bio-naive/bio-failed subgroup analysis.[1]

DURABLE

64% OF PATIENTS WHO ACHIEVED CLINICAL REMISSION ON OMVOH AT WEEK 12 MAINTAINED CLINICAL REMISSION THROUGH 1 YEAR[1,2]

Omvoh demonstrated durable clinical remission at Week 52[1,2]

BIO-FAILED PATIENTS[1,*]
Maintained clinical remission from Week 12 through Week 52[1,4]

67% OMVOH 200 MG SC Q4W (N=36)

VS

11% PLACEBO (N=18)

CLINICAL REMISSION AT WEEK 52 IN ALL PATIENTS WHO ACHIEVED CLINICAL REMISSION AT WEEK 12 IN LUCENT-1[1,2,†]

64% Omvoh 200 mg SC Q4W (N=143)

VS

37% Placebo (N=65) (p<0. 001)

CLINICAL REMISSION MAINTAINED THROUGH 1 YEAR OF CONTINUOUS TREATMENT WITH OMVOH[1,2]

*Prespecified subgroup analysis is not controlled for multiplicity. Bio-failed includes tofacitinib-failed patients. An additional 1 patient on placebo and 8 patients on Omvoh were previously exposed to but did not fail a biologic or JAKi. These patients were excluded from the bio-naive/bio-failed subgroup analysis.[1]

†Clinical remission at Week 52 was defined as SF=0, or SF=1 with a ≥1-point decrease from baseline; RB=0; ES=0 or 1 (excluding friability). The placebo arm is Omvoh induction responders randomized to placebo.[2]

ES, endoscopic subscore; **IL-23p19**, interleukin 23, subunit p19; **IV**, intravenous; **MMS**, Modified Mayo Score; **Q4W**, every 4 weeks; **RB**, rectal bleeding; **SC**, subcutaneous; **SF**, stool frequency; **UC**, ulcerative colitis

REFERENCES

1. Omvoh™ USPI October 2023.
2. D'Hoens G, Dubinsky M, Kobayashi T, et al. Mirikizumab os induction and moincenance therapy for ulcerative colitis: Results from the phase 3 LUCENT program, 2022.
3. Morris N, Liz. Zhao M, et ol. Phase 3, multicenter, randomized, double-blind. parallel, placebo-controlled induction study of mirikizumab in conventional-foiled and biologic-failed patients with moderately to severely active ulcerative colitis (LUCENT-1). 2021
4. D'Haens G, et al. N Engl J Med. 2023;388(26):2444-2455_Supplementary.

Omvoh INDICATION

Omvoh™ (mirikizumab) is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.[1]

The safety of Omvoh was evaluated in two randomized, double-blind, placebo-controlled Phase 3 trials.[2,3] In LUCENT-1 (induction), adverse drug reactions in more than 1% of Omvoh-treoted patients and higher than placebo included: upper respiratory tract infections (7.9%), headache (3.3%) and rash (U%), In LUCENT-2 (maintenance), adverse drug reactions in more than 1% of Omvoh-treated patients and higher than placebo included: upper respiratory tract infections (11.8%}, injection site reactions (8.7%), headache (4.1%) and rash (3.6%). Serious adverse events occurred in 2.8% of LUCENT-1 Omvoh-treated patients vs 5.3% of placebo-treated patients. Discontinuations due to adverse events occurred in 1.6% of Omvoh-treoted patients vs 7.2% of placebo-treated patients, In LUCENT-2, serious adverse events occurred in 3,3% of Omvoh-treated patients vs 7.8% of placebo-treated patients. Discontinuations due to adverse events occurred in 1.5% of Omvoh-treoted patients vs 8.3% of placebo-treated patients. In LUCENT-1, adverse events of special interest included serious infection (0,7% vs placebo 0.6%). opportunistic infection (narrow. excluding oral candidiasis and oral fungal infection) (0,5% vs placebo 0.3%), hepatic events (1.6% vs placebo 1.6%), malignancy (0.2% vs placebo 0%), major adverse cardiac event (0% vs placebo 0%). In LUCENT-2. adverse events of special interest included serious infection (0.8% vs placebo 1.6%), opportunistic infection (narrow, excluding oral candidiasis ond oral fungal infection) (1.3% vs placebo 0%), hepatic events (3.1% vs placebo 2J%), malignancy (0,3% vs placebo 0.5%), major adverse cardiac event (0% vs placebo 0.5%)[1-3]. In the maintenance study (LUCENT-2), injection-site reactions were reported by 8.7% of patients toking Omvoh compared to 4,2% of patients taking placebo.[1]

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