Omvoh® (mirikizumab): an **IL-23p19 INHIBITOR** achieving both

EARLY AND LONG-TERM EFFICACY

in patients with Crohn's disease[1]

Consider Omvoh for your patients with moderately to severely active Crohn's disease when you have decided it's time for a different treatment.[2]

NOW APPROVED FOR CD[2]

Crohn's disease continues to take control of Morgan's everyday life

Meet Morgan†:

- Experiences abdominal pain, diarrhoea, and bowel urgency[3]
- Hopes for symptomatic relief and long-term control[2,3]
- Continues to have an impacted QoL despite being on treatment[4]

Considering the chronic nature of the disease, additional therapeutic options that can improve the management and outcomes for patients with Crohn's disease are needed.[5]

†Hypothetical patient

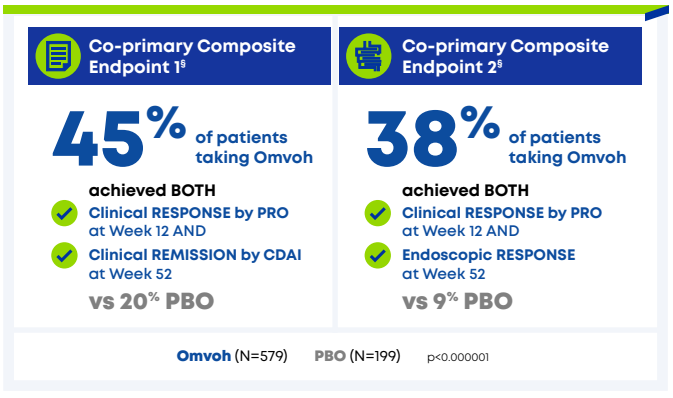
The VIVID-1 trial

The efficacy and safety of Omvoh — an IL-23p19 inhibitor — vs either placebo or ustekinumab was assessed in patients with moderately to severely active Crohn's disease in the VIVID-1 trial — a global Phase 3, randomised, double-blind, double-dummy, placebo-controlled, and active controlled clinical trial with a **treat-through design.**[1,‡] The treat-through design of the trial helped capture both early response and response over time.[1]

Omvoh demonstrates early and sustained efficacy in patients like Morgan with moderately to severely active Crohn's disease

Patients achieved both early clinical response by PRO‡ at Week 12 and key outcomes at Week 52[1]

In the VIVID-1 trial, Omvoh-treated patients achieved both co-primary composite endpoints compared to placebo-treated patients. A large proportion of patients who achieved early clinical response by PRO at Week 12 went on to achieve sustained outcomes as measured by clinical remission by CDAI‡ and endoscopic response‡ at Week 52.[1]



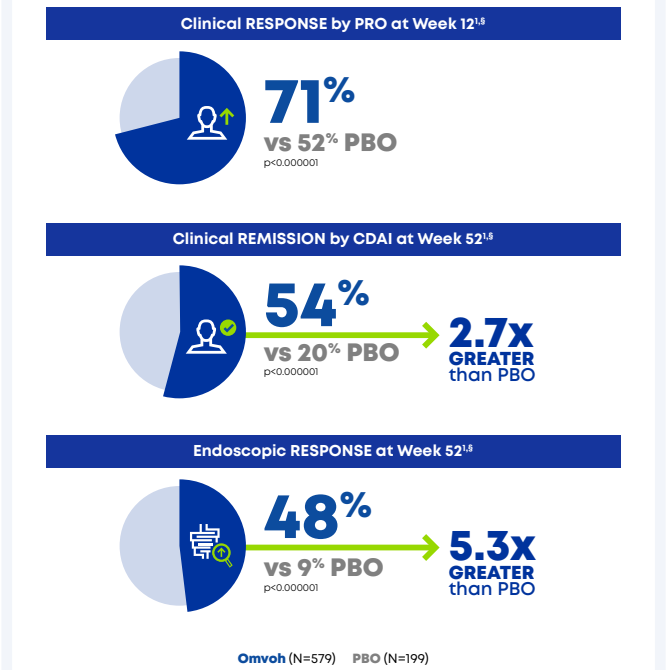
Omvoh is a promising addition to the armamentarium for treating patients with Crohn's disease, that has shown strong efficacy vs placebo in both co-primary composite endpoints as well as key secondary endpoints.

Prof. Marc Ferrante

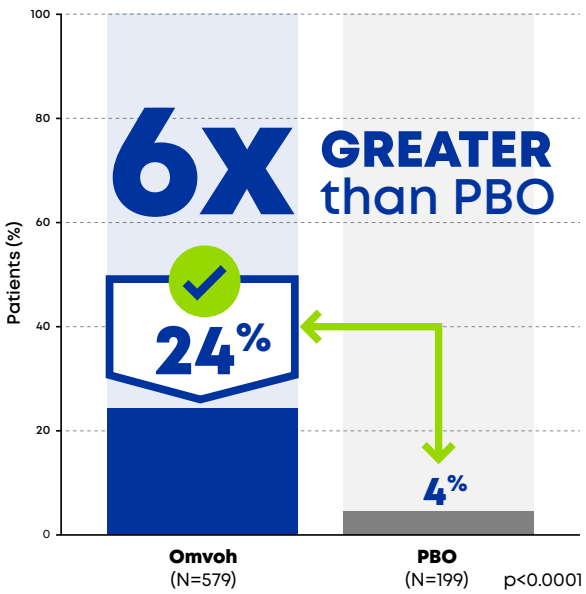
WATCH NOW

Omvoh showed early and long-term efficacy in patients with moderately to severely active Crohn's disease[1]

Patients treated with Omvoh also met all the major secondary endpoints compared to patients treated with placebo, including clinical response by PRO at Week 12, as well as clinical remission by CDAI and both endoscopic response and remission‡ at Week 52.[1]



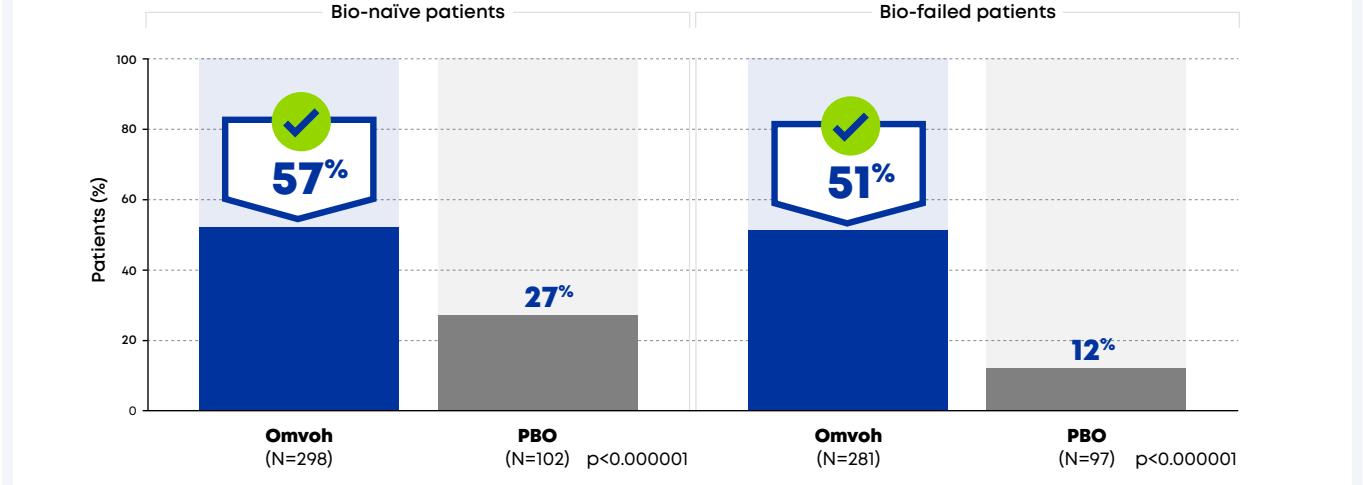
ENDOSCOPIC REMISSION at Week 52[1,§]



Omvoh demonstrated efficacy consistently across both bio-naïve and bio-failed patients at Week 52[6]

In the bio-naïve and bio-failed subset of patient population, a higher percentage of Omvoh-treated patients achieved clinical remission by CDAI at Week 52 when compared to placebo-treated patients.[6]

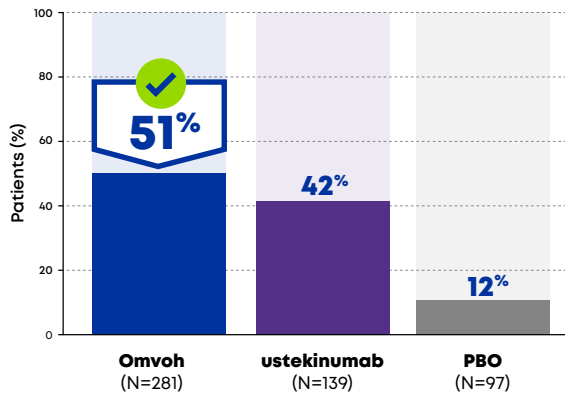
CLINICAL REMISSION by CDAI in bio-naïve and bio-failed patients at Week 52[6,¶]



Numerically more bio-failed patients achieved clinical remission by CDAI with Omvoh vs ustekinumab[6]

Omvoh achieved the goal of showing non-inferiority to ustekinumab on clinical remission by CDAI, with notably higher percentage of bio-failed patients achieving clinical remission by CDAI at Week 52.[6]

CLINICAL REMISSION by CDAI in bio-failed patients[6,¶]



Prespecified subgroup analysis not controlled for multiplicity.

In biologic-failed patients, Omvoh demonstrated a numerical trend towards greater response rates compared with ustekinumab for CDAI clinical remission.

Prof. Marc Ferrante

VIEW THE INFOGRAPHIC TO LEARN MORE ABOUT OMVOH EFFICACY IN CROHN'S DISEASE

VIEW INFOGRAPHIC

Omvoh offers continuous bowel urgency improvement through Week 52

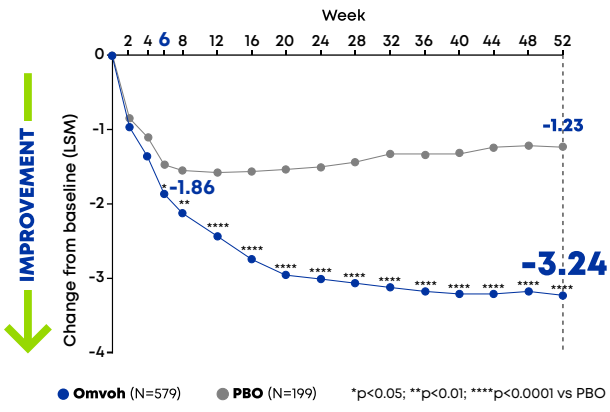
Over 50% of Crohn's disease patients report bowel urgency to be in their top 3 disruptive symptoms and HCPs might underestimate its burden.[4] Omvoh achieved bowel urgency improvement indicated by a decrease in Urgency NRS score from baseline as early as Week 6, with continued improvement through Week 52.[7]

When I have a patient with urgency and Crohn's disease, which is more common than we have previously thought, I would definitely think of Omvoh as a treatment choice for that patient.

Dr. Alissa Walsh

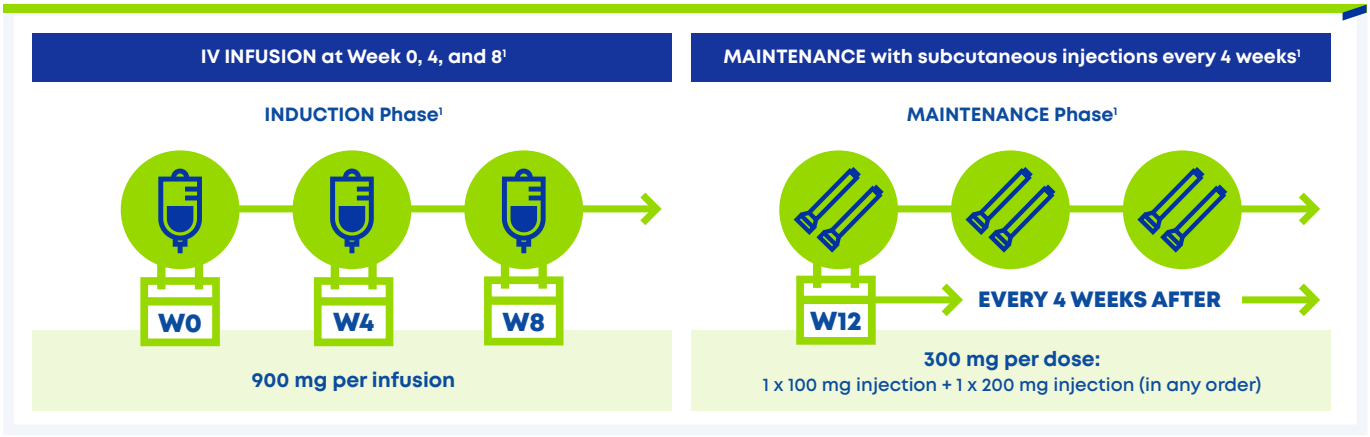
WATCH NOW

Urgency NRS Score[7,#]



Dosing that meets the unique needs of patients with Crohn's disease

Omvoh dosing begins with intravenous infusion induction and transitions to patient self-injection for maintenance.[1]



Favourable safety profile

The safety of Omvoh was evaluated in the VIVID-1 Phase 3 clinical trial.[1] The most common treatment-emergent adverse events (occuring in ≥5% of patients) through 1 year of treatment with Omvoh were mild to moderate.[1] In total, 10.3% of patients receiving Omvoh reported a serious adverse event, and 5.1% discontinued treatment due to an adverse event.[1]

VIEW FULL SAFETY TABLE

Mirikizumab clearly has a very good efficacy and safety profile that many patients but also HCPs will like.

So, there is clearly a role for putting this in our treatment armamentarium.

Prof. Marc Ferrante

Omvoh SAFETY PROFILE

Adverse events[a]	Weeks 0 to 52[1] Omvoh N=630	ustekinumab N=309	PBO N=211
COVID-19	16.5%	15.2%	13.7%
Anaemia	6.7%	4.9%	6.6%
Arthralgia	6.5%	2.6%	5.2%
Headache	6.5%	4.9%	4.3%
URTI	6.0%	7.1%	4.3%
Nasopharyngitis	5.7%	6.1%	4.3%
Diarrhoea	5.6%	NA%	4.7%
Pyrexia	4.0%	NA%	3.8%

Serious adverse events, discontinuation, and death	Weeks 0 to 52[1] Omvoh N=630	ustekinumab N=309	PBO N=211
SAE	10.3%	10.7%	17.1%
Treatment discontinuations due to AE	5.1%	2.6%	9.5%

Adverse events of special interest	Weeks 0 to 52[1] Omvoh N=630	ustekinumab N=309	PBO N=211
Serious infection	2.2%	2.9%	2.8%
Opportunistic infection (narrow)	1.1%	0.3%	0%
Major adverse cardiac event	0%	0.6%	0.9%
Malignancy			
Non-Melanoma Skin Cancer (NMSC)	0.2%	0.0%	0.5%
Malignancies excluding NMSC	0.2%	0.0%	0%
Infusion site reaction	0.2%	1.3%	0%
Injection site reaction	10.8%	5.8%	6.5%
Suicide/self-injury (narrow)[b]	0.3%	0%	0%
Hepatic event (narrow)[c]	6.2%	2.6%	4.3%

Footnotes
[a]Events that occurred in at least 5% of the patients in any trial group. Events are listed according to decreasing frequency in the Omvoh group.[1]
[b]Both events were suicidal ideation; one participant had prior history of suicide attempt, the other had a history of anxiety.[1]
[c]One participant presented non-concomitant increases in ALT/AST and TB increase. The participant had a diagnosis of Gilbert's Syndrome with fluctuating indirect hyperbilirubinemia through the study period and a one-time ALT increase (3.6-fold ULN) at Week 48 when TB was normal.[1]

Abbreviations
AE, adverse events; **ALT,** alanine aminotransferase; **AST,** aspartate aminotransferase; **NA,** not available; **PBO,** placebo; **SAE,** serious adverse events; **TB,** total bilirubin; **ULN,** upper limit of normal; **URTI,** upper respiratory tract infections.

Indications

Crohn's disease
Omvoh is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment.[2]

Ulcerative colitis
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.[2]

Safety information

Crohn's disease
The safety of Omvoh was evaluated in a Phase 3 clinical trial.[1] The most common adverse events (occurring in ≥5% of patients) were COVID-19, anaemia, arthralgia, headache, upper respiratory tract infection, nasopharyngitis, and diarrhoea.[2]

Ulcerative colitis
The safety of Omvoh was evaluated in three Phase 3 trials.[8,9] The common reported adverse reactions were upper respiratory tract infections, arthralgia, headache, rash, and injection site reactions.[2]

Footnotes

‡**Treat-through design:** Week 52 parameter was assessed regardless of Week 12 PROs. **Clinical response by PRO:** ≥30% decrease in stool frequency and/or abdominal pain, and neither score worse than baseline. **Clinical remission by CDAI:** CDAI score of <150. **Endoscopic response:** Endoscopic response was defined as ≥50% reduction from baseline in SES-CD Total Score. **Endoscopic remission:** SES-CD Total Score ≤4 and at least a 2-point reduction vs baseline and no subscore >1 in any individual variable.[1]
§All categorical endpoints of superiority comparison were analysed with the Cochran–Mantel–Haenszel test adjusted by stratification factors. Non-responder imputation was used for categorical endpoints.[1]
¶Response rates were compared between treatment arms using the Fisher's exact test in subgroups, with missing data imputed as non-response.[6]
#Data are LSM, and comparisons were performed using ANCOVA with mBOCF.[7] For participants in the PBO group who switched to mirikizumab at W12, baseline values were carried forward to derive the change from baseline at W52.[10]

Abbreviations

ANCOVA, analysis of covariance; **CD,** Crohn's disease; **CDAI,** Crohn's Disease Activity Index; **HCP,** healthcare professional; **IL-23p19i,** interleukin-23 subunit p19 inhibitor; **LSM,** least squares mean; **mBOCF,** modified baseline observation carried forward; **NRS,** numeric rating scale; **PBO,** placebo; **PRO,** patient-reported outcome; **QoL,** quality of life; **SES-CD,** Simple Endoscopic Score for Crohn's Disease; **SmPC,** Summary of Product Characteristics; **W,** Week.

References

1. Ferrante M, et al. Lancet. 2024;404(10470):2423–2436. **2.** Omvoh Local Label. **3.** Rubin DT, et al. Inflamm Bowel Dis. 2021;27(12):1942–1953. **4.** Schreiber S, et al. Dig Dis Sci. 2024;69(7):2333–2344. **5.** Gordon JP, et al. Eur J Gastroenterol Hepatol. 2015;27(7):804–812. **6.** Jairath V, et al. Oral presentation at ECCO 2024:OP35. **7.** Data on file, Eli Lilly and Company.**8.** D'Haens G, et al. N Engl J Med. 2023;388(26):2444–2455. **9.** Sands BE, et al. Inflamm Bowel Dis. 2024:izae235. doi: 10.1093/ibd/izae253. **10.** Jairath V, et al. Poster presented at UEGW 2024:P0550.

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