Omvoh™ is the **FIRST IL-23p19i**

for patients with moderately to severely active UC that offers

FIRST IL-23p19i WITH 4Y REMISSION DATA IN UC[1,2]

LONG-TERM REMISSION FOR UP TO 4 YEARS[1,2]

Meet Max†

†Hypothetical patient

- Max has **moderately to severely active UC**
- He continues to experience **bowel urgency** and other symptoms, like **rectal bleeding** or **frequent stools**, despite current treatment
- **Bowel urgency is his most bothersome symptom,** causing worry that he may not make it to the toilet on time every time[3,4]
- Max is hoping for a treatment that can **address his symptoms while working to gain long-term control**
- He requires a **new treatment** to manage his disease

Patients with UC experience relapsing and remitting periods of disease activity with physical and psychological symptoms that result in reductions in QoL.[3] Treatment effectiveness is not always maintained over time; around 40% of initial responders may subsequently lose response, potentially requiring surgical intervention. Thus, sustaining long-term UC remission is crucial for reducing disability and improving QoL.[2]

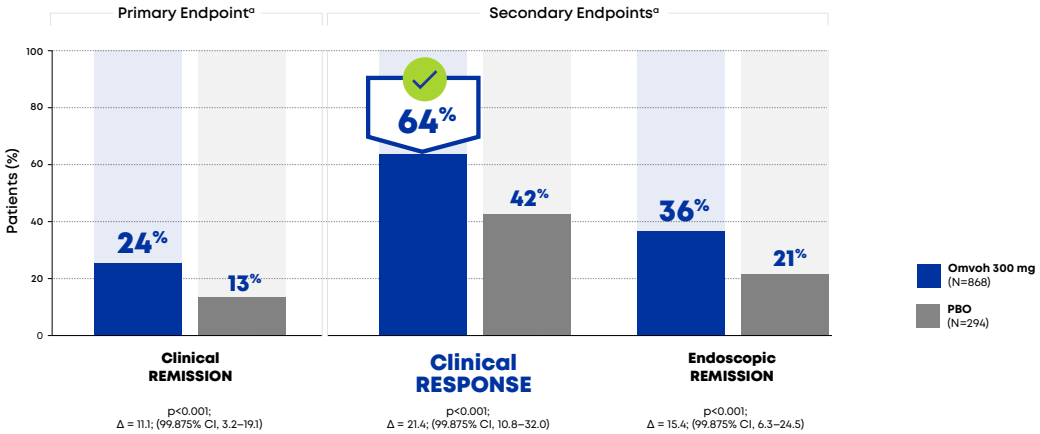
Omvoh offered **RELIEF FROM UC SYMPTOMS** at Week 12[5,6]

A clinical response was achieved by 64% of patients at Week 12 with Omvoh.[5,6] Significantly more Omvoh-treated than placebo-treated patients achieved clinical remission‡ (primary endpoint; p<0.001), clinical response,‡ and endoscopic remission‡ (secondary endpoints; p<0.001) at Week 12 in LUCENT-1.[6]

~1 in 2 patients experienced **remission of symptoms** at **Week 12 with Omvoh[6]**

The LUCENT-1 trial showed that Omvoh offered clinical response at Week 12, regardless of previous treatment history.[5,6]

LUCENT-1 clinical remission, clinical response, and endoscopic remission at Week 12[5,6]

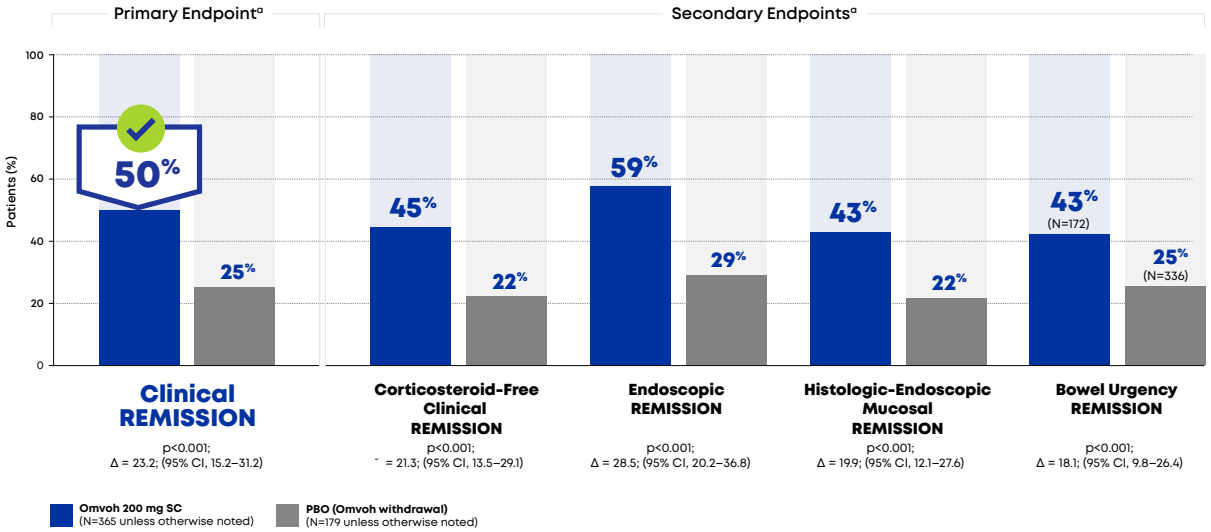


[a]All binary efficacy endpoints were analyzed using the Cochran–Mantel–Haenszel test adjusted for stratification factors. Patients who discontinued treatment, experienced loss of response requiring rescue therapy, or had sporadically missing data were classified as non-responders, with sensitivity analyses performed using multiple imputation.[6]

Omvoh offered SUSTAINED SYMPTOM IMPROVEMENT OVER 52 WEEKS[5,6]

Following 52 weeks of continuous treatment in the **LUCENT-2 trial**, significantly more Omvoh-treated than placebo-treated patients **achieved clinical remission** (50%),‡ **corticosteroid-free remission,‡ endoscopic remission,‡ HEMR,‡ and bowel urgency remission‡** (p<0.001 for all endpoints vs placebo), indicating sustained control of their UC over the long term.[6]

Omvoh offered sustained control of UC following 52 weeks of continuous treatment vs placebo[5,6]



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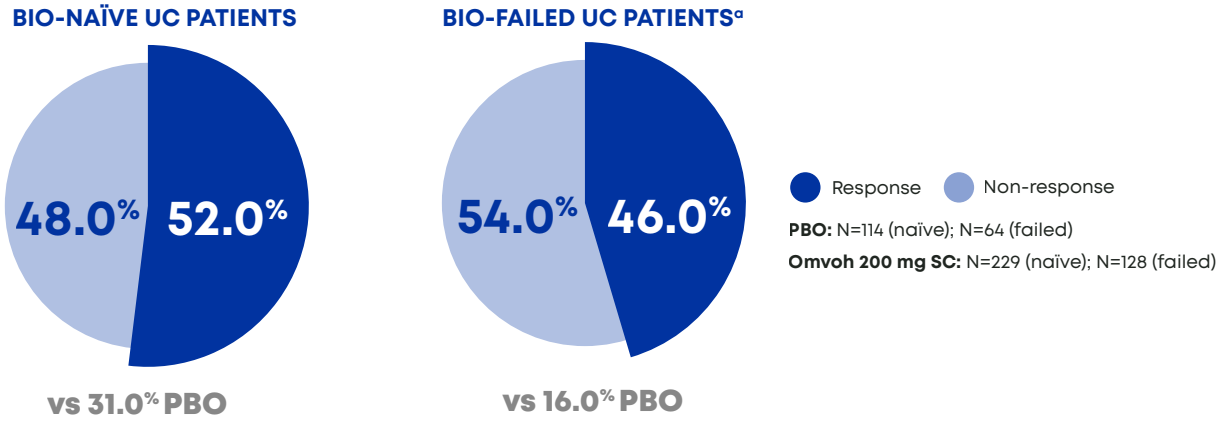
Clinical remission in bio-naïve and bio-failed UC patients at Week 52[6]



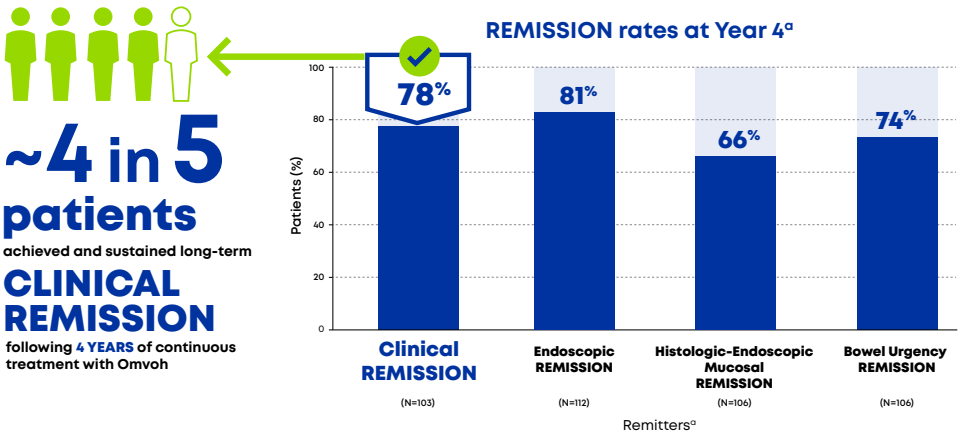
[a]Bio-failed: Patients with a prior inadequate response, loss of response, or intolerance to biologic therapy or Janus kinase inhibitors (tofacitinib) as of LUCENT-1 induction baseline.[6]

At 4 years (Week 212), patients taking Omvoh achieved long-term results, including mucosal healing[1]

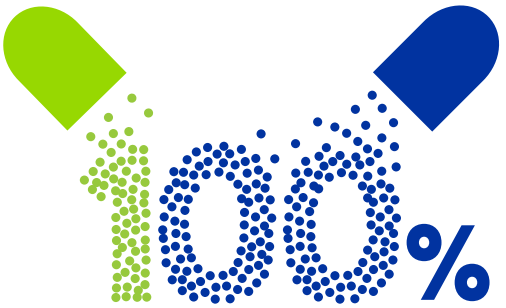
The LUCENT-3 trial is one of the first long-term extension studies in UC to provide data for endpoints such as clinical remission, endoscopic remission, histologic-endoscopic mucosal remission, and bowel urgency remission.[1,6,7] Results from LUCENT-3 suggest that Omvoh provides long-term (212 weeks) sustained and durable efficacy across all studied endpoints.[1]

Findings were consistent across the endpoints of clinical, endoscopic, and bowel urgency remission, as well as HEMR, over 4 years of treatment, regardless of prior treatment experience.[1]

Omvoh offered sustained control of UC following 212 weeks of continuous treatment in Week 52 remitters[1,§]



[a]Maintenance remitters as observed: Induction responders who were clinical remitters at Week 40 in LUCENT-2 following 52 weeks of continuous treatment with Omvoh. Patients who discontinue treatment or are otherwise missing data are excluded from analyses.[1]



OF OMVOH-TREATED
patients who maintained
CLINICAL REMISSION
at Week 212[a]
WERE FREE OF CORTICOSTEROIDS
for at least 12 weeks prior to Week 160[1]

Although effective for induction of clinical remission, corticosteroids are not as effective as maintenance agents and are associated with systemic toxicities.[8] Long-term use of corticosteroids is associated with additional side effects and increased risks of diabetes, cardiovascular disease, and mortality.[8]

Therefore, avoidance of corticosteroids is an important patient- and physician-preferred treatment goal for managing UC in clinical practice.[8]

[a]Maintenance remitters as observed: Induction responders who were clinical remitters at Week 40 in LUCENT-2 following 52 weeks of continuous treatment with Omvoh. Patients who discontinue treatment or are otherwise missing data are excluded from analyses.[1]

How does Omvoh help in resolving mucosal inflammation?

Omvoh demonstrated long-term HEMR at 4 years (Week 212)[1]

66%

of patients achieved HEMR at 4 years (Week 212), as observed[1,a]

Omvoh 200 mg SC Q4W (N=106)

Achieving HEMR following 4 years of Omvoh indicated resolution of visible inflammation and an absence of neutrophils.[1,9] Among Omvoh-treated patients who were remitters at Week 52, 66.0% (N=106) had achieved HEMR at Week 212.[1]

These data suggest that Omvoh treatment is effective in improving patient symptoms as well as endoscopic and histologic mucosal healing, which is important in achieving favourable long-term patient outcomes.[1]

[a]Maintenance remitters as observed: Induction responders who were clinical remitters at Week 40 in LUCENT-2 following 52 weeks of continuous treatment with Omvoh. Patients who discontinue treatment or are otherwise missing data are excluded from analyses.[1]

Omvoh delivered long-term bowel urgency remission at 4 years (Week 212)[1]

BU is the most bothersome UC symptom, occurring during both disease activity and remission.[10] BU has a profound impact on patients' QoL, often leading to withdrawal from education, work, and social activities.[10] Over 80% of patients with UC experience BU, irrespective of their treatment status.[10] Because BU can vary in severity, it is crucial to assess both its recurrence and intensity for effective management.[11] Omvoh offered sustained efficacy over 4 years by reducing both the recurrence and severity of BU.[1] In the induction trial, patients reported reductions in BU with Omvoh therapy.[6]

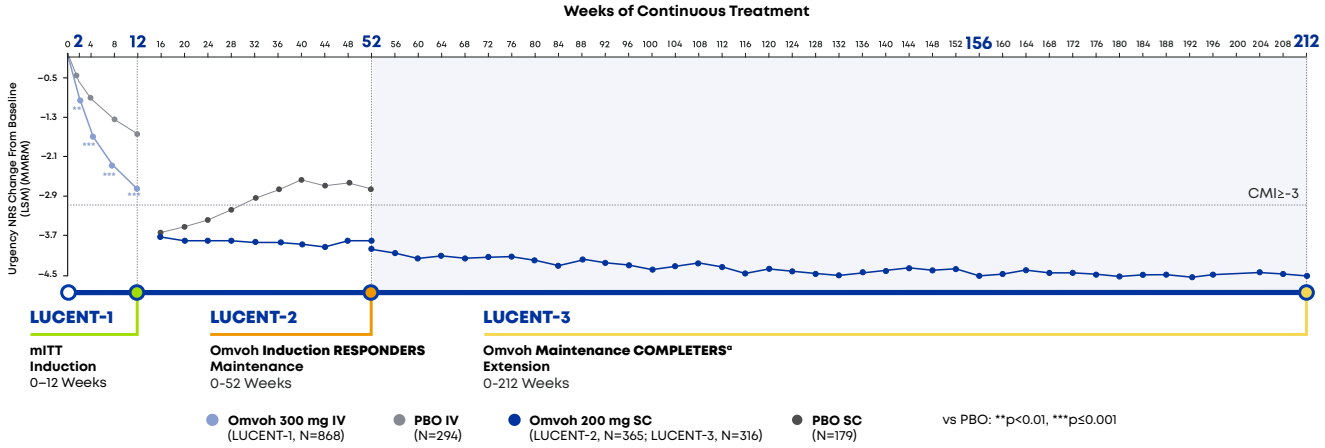
Among patients who were remitters[§] at Week 52,

74%

of patients achieved bowel urgency remission at 4 years (Week 212), as observed

Omvoh 200 mg SC Q4W (N=106)

Omvoh significantly improved bowel urgency as early as Week 2 and continued through 4 years[1,12,§]



[a]Maintenance completers who were induction responders and who moved into LUCENT-3.[1]
MMRM was used for treatment comparison, adjusting for baseline stratification factors. LSM were reported for each treatment group except for W0 of maintenance (W12 continuous treatment); no treatment comparisons in LUCENT-3.[1]

Safety

NO ADDITIONAL SAFETY SIGNALS
were identified after 4 years of Omvoh treatment.[1]

VIEW SAFETY PROFILE

Real-life experience: From LUCENT trials to real-life impact

*...even days after the first infusion, **she started feeling better**, and within one month, **she went into symptomatic remission**.*

— Prof. Sebastian Zeissig
Bern University Hospital, Bern, Switzerland.

How Omvoh helped a patient with UC return to normalcy

Hear from your peers about their real-life experience with Omvoh

Bio-experienced Patient Case WATCH NOW

Bio-naïve Patient Case WATCH NOW

Omvoh has a CONSISTENT SAFETY PROFILE[1,2,5-7]

Across the LUCENT-1 and -2 trials, the incidences of adverse events were similar in the Omvoh and placebo groups.[5,6] No new safety signals were identified in the long-term extension trial across all patient populations including elderly, bio-naïve, or bio-experienced.[1,2,7]

AEs in the LUCENT trials[1,6,13,14]

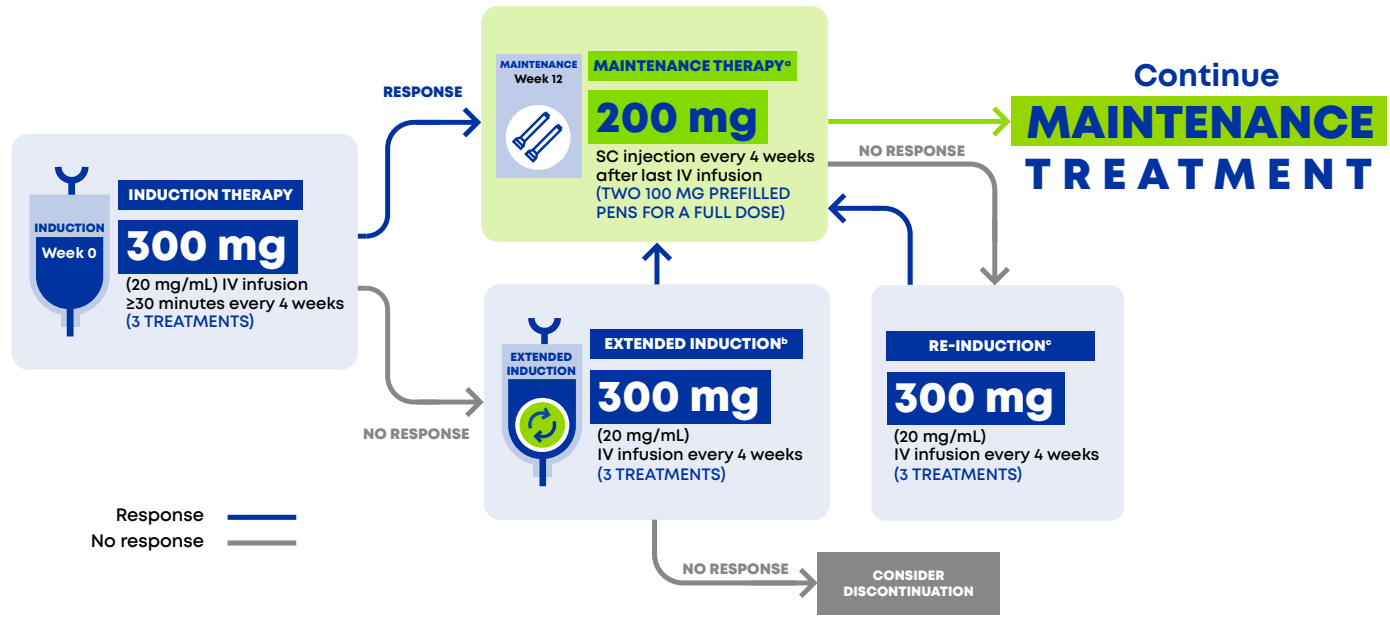
AEs	LUCENT-1 Induction Week 12		LUCENT-2 Maintenance Week 52		LUCENT-3 OLE Week 212
Common AEs[a]					
n (%)	PBO (N=321)	Omvoh 300 mg IV Q4W[b] (N=958)[c]	PBO (N=192)	Omvoh 200 mg SC Q4W[d] (N=389)[c]	Omvoh 200 mg SC Q4W (N=339)[c] [EAIR][e]
Nasopharyngitis	10 (3.1)	39 (4.1)	11 (5.7)	28 (7.2)	40 (11.8) [4.8]
Arthralgia	4 (1.2)	20 (2.1)	8 (4.2)	26 (6.7)	22 (6.5) [2.6]
Injection-site pain	-	-	6 (3.1)	17 (4.4)	12 (3.5) [1.4]
Headache	9 (2.8)	32 (3.3)	2 (1.0)	16 (4.1)	28 (8.3) [3.3]
Rash	2 (0.6)	5 (0.5)	0	14 (3.6)	4 (1.2) [0.4]
Pyrexia	3 (0.9)	14 (1.5)	5 (2.6)	13 (3.3)	24 (7.1) [2.8]
Anemia	19 (5.9)	32 (3.3)	9 (4.7)	8 (2.1)	-
Serious AEs					
Infections: Serious	2 (0.6)	7 (0.7)	3 (1.6)	3 (0.8)	10 (2.9) [1.1]
Infections: Opportunistic	1 (0.3)	5 (0.5)	0 (0)	5 (1.3)	7 (2.1) [0.8]
Hepatic events	5 (1.6)	15 (1.6)	4 (2.1)	12 (3.1)	16 (4.7) [1.8]
Malignancies	0 (0)	2 (0.2)	1 (0.5)	1 (0.3)	5 (1.5) [0.6]
Non-Melanoma Skin Cancer (NMSC)	0 (0)	0 (0)	1 (0.5)	0 (0)	0 (0) [0.0]
Malignancies excluding NMSC	0 (0)	2 (0.2)	0 (0)	1 (0.3)	5 (1.5) [0.6]
Adjudicated cerebro-cardiovascular events[f]	2 (0.6)	1 (0.1)	1 (0.5)	0 (0)	5 (1.5) [0.6]
Immediate hypersensitivity reactions[g]	1 (0.3)	10 (1.0)	2 (1.0)	7 (1.8)	8 (2.4) [0.9]

[a]Common adverse events were defined as those that occurred in at least 3% of the patients in any trial group during the induction or maintenance trial.[6] [b]Omvoh 300 mg as an intravenous infusion at Weeks 0, 4, and 8.[6] [c]The safety population was used for adverse event assessments and includes participants from Poland and Turkey affected by the electronic clinical outcome assessment error in LUCENT-1 and LUCENT-2, as well as patients on blinded Omvoh at the end of LUCENT-2 who were not in remission or response and who were not included in the efficacy analysis.[2,6] [d]Omvoh 200 mg as a subcutaneous injection at Week 12 and every 4 weeks thereafter for up to an additional 40 weeks.[6] [e]EAIR per 100 PY is the number of events per 100 cumulative years of exposure; for example, in 100 patients treated for an entire year.[13] [f]No instances by MACE during LUCENT-1; 1 instance of MACE (ischaemic stroke) in the placebo group during LUCENT-2. In LUCENT-3, 1 instance of MACE was reported (determined by the investigator to not be related to Omvoh).[2,6,14] [g]Within 24 hours of drug administration or on the day of drug administration when time is missing.[6]

Omvoh offers flexible dosing options to help meet your patients' needs[5]

Current treatments for UC are often limited by primary non-response, secondary loss of response, or incomplete response.[15,¶] Up to 40% of patients experience primary non-response in clinical trials of biologics for the treatment of IBD, meaning that patients miss an opportunity to find relief from the symptoms of UC.[15,16] Patients with difficult-to-treat UC may require a prolonged course of induction if they have severe disease at baseline or prior exposure to biologics, which can influence response to subsequent therapies.[15,17]

Easy and flexible start with Omvoh[5]



[a]Omvoh responders in LUCENT-1=551/868 (63.5%); 544 entered LUCENT-2.[5]
[b]For patients who do not achieve adequate therapeutic benefit at Week 12 of induction, Omvoh 300 mg by IV may be continued at Weeks 12, 16, and 20 (extended induction therapy). If therapeutic benefit is achieved with the additional IV therapy, patients may initiate Omvoh SC dosing (200 mg) every 4 weeks, starting at Week 24. Omvoh should be discontinued in patients who do not show evidence of therapeutic benefit to extended induction therapy by Week 24.[5]
[c]Patients with loss of therapeutic response during maintenance treatment may receive 300 mg Omvoh by IV infusion every 4 weeks for a total of 3 doses (re-induction). If clinical benefit is achieved from this additional IV therapy, patients may resume Omvoh SC dosing every 4 weeks. The efficacy and safety of repeated re-induction therapy have not been evaluated.[5]

Omvoh is the **FIRST IL-23p19i** in UC that helps patients like Max† **ACHIEVE AND SUSTAIN THEIR TREATMENT GOALS** for up to 4 years of continuous treatment[1,2,5-7]:

- **LONG-TERM** clinical, endoscopic, corticosteroid-free, and histologic-endoscopic mucosal **REMISSION**[1,‡]
- **EARLY AND SUSTAINED CONTROL** of symptoms, including bowel urgency[1,12]
- Consistent safety profile, with **NO NEW SAFETY SIGNALS** up to 4 years[1,2,5-7]
- In-label **FLEXIBLE DOSING** along with a single, citrate-free maintenance dose[5]

Footnotes

†Hypothetical patient.

‡**Bowel urgency remission**: Urgency NRS score=0 or 1 in patients with a baseline urgency NRS score of ≥3. **Clinical remission**: SF=0 or 1 with ≥1-point decrease in modified Mayo score from baseline; RB=0; and ES=0 or 1 (excluding friability). **Clinical response**: ≥2-point and ≥30% decrease in the modified Mayo score from baseline; RB=0 or 1, or ≥1-point decrease from baseline. **Endoscopic remission**: ES=0 or 1 (excluding friability). **HEMR**: Histologic remission with resolution of mucosal neutrophils, defined using the Geboes scoring system with subscores of 0 for grades: 2B (lamina propria neutrophils); 3 (neutrophils in epithelium); 4 (crypt destruction); 5 (erosion or ulceration); ES=0 or 1 (excluding friability). **Corticosteroid-free clinical remission**: Clinical remission at Week 40, remission of symptoms at Week 28, and no glucocorticoid use for ≥12 weeks before Week 40.[1,6]

§Maintenance remitters as observed: Induction responders who were clinical remitters at Week 40 in LUCENT-2 following 52 weeks of continuous treatment with Omvoh. Patients who discontinue treatment or are otherwise missing data are excluded from analyses.[1]

¶Primary non-response is defined as a lack of clinical benefit during standard induction therapy, and secondary loss of response is defined as loss of response during maintenance treatment.[15]

INDICATIONS

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.[5]

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.[5]

SAFETY INFORMATION

Ulcerativecolitis

The safety of Omvoh was evaluated in three Phase 3 trials. The most common adverse events (occurring in ≥5% of patients) were COVID-19, ulcerative colitis, nasopharyngitis, headache, pyrexia, and arthralgia.[2,6]

Crohn's disease

The safety of Omvoh was evaluated in two Phase 3 clinical trials. The most common adverse events (occurring in ≥5% of patients) were diarrhoea, COVID-19, anaemia, arthralgia, headache, upper respiratory tract infection, and nasopharyngitis.[18,19]

Abbreviations

AE, adverse event; **Bio-failed**, biologic failed; **Bio-naïve**, biologic naïve; **BU**, bowel urgency; **CI**, confidence interval; **CMI**, clinically meaningful improvement; **EAIR**, exposure-adjusted incidence rate; **ES**, endoscopic subscore; **HCP**, healthcare professional; **HEMR**, histologic-endoscopic mucosal remission; **IBD**, inflammatory bowel disease; **IL-23p19i**, interleukin-23 subunit p19 inhibitor; **IV**, intravenous; **LSM**, least squares means; **MACE**, major adverse cardiovascular event; **mITT**, modified intent-to-treat; **MMRM**, mixed-effects model for repeated measures; **NRS**, Numeric Rating Scale; **OLE**, open-label extension; **PBO**, placebo; **PY**, patient-years; **Q4W**, every 4 weeks; **QoL**, quality of life; **RB**, rectal bleeding; **SC**, subcutaneous; **SF**, stool frequency; **UC**, ulcerative colitis; **W**, week; **Y**, year.

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