NOW APPROVED! OMVOH (MIRIKIZUMAB)™[1]

Omvoh helped patients with ulcerative colitis (UC) achieve sustained clinical remission and reduced bowel urgency severity[1,2]

omvoh™ mirikizumab infusion/injection

UC GUIDELINES HIGHLIGHT ADDRESSING BOWEL URGENCY AS AN IMPORTANT TREATMENT GOAL[3]

Bowel urgency is one of the most **bothersome, disruptive, and important symptoms** experienced by patients with UC.[4]

47% of patients (n=72/153) on advanced therapy reported **wearing a diaper, pad, or other protection at least once a week due to worry** or anticipation of a bowel urgency accident[5]

72% of patients said bowel urgency had a high impact on their quality of life.[6]

OMVOH IS ONE OF THE **FIRST UC TREATMENTS TO ASSESS** BOWEL URGENCY AS A **KEY SECONDARY ENDPOINT** IN CLINICAL TRIALS.[1,2,4]

> *"The LUCENT trials were the first to assess the reduction of bowel urgency using a new scale."*
>
> *"The patients treated with Omvoh showed considerable improvements in bowel urgency...compared to those treated with placebo."*
>
> — TL Name

Do you have UC patients that need a different treatment?

Dr. XY talks about the first trial to include a scale to measure bowel urgency, the patient's most bothersome symptom.

WATCH NOW

MEET MIA*

Mia has **moderately to severely active UC** and is still experiencing UC symptoms including bowel urgency

- She **continues to experience** bowel urgency and other symptoms, like rectal bleeding or frequent stools, despite biologic treatment[6]
- Bowel urgency is **her most bothersome symptom,** causing worry that she may not make it to the toilet on time every time[7,8]
- You've determined **Mia is ready** for the next biologic

CONSIDER OMVOH (MIRIKIZUMAB) FOR YOUR PATIENTS WITH UC WHEN YOU'VE DECIDED IT'S TIME FOR A DIFFERENT TREATMENT[1]

Are you ready to make the urgent change with Omvoh?

View infographic for more information on dosage and administration of Omvoh

VIEW INFOGRAPHIC

OMVOH PROVIDED SUSTAINED CLINICAL REMISSION AT WEEK 52[2]

Sustained clinical remission was demonstrated in the LUCENT-2 maintenance study† of patients with moderately to severely active UC.[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.[2,9]

PATIENTS ACHIEVING CLINICAL REMISSION‡ AT WEEK 52 WITH OMVOH[2,§]

50% OF ALL PATIENTS | **46%** OF BIO-FAILED PATIENTS¶

vs **25%** and **16%** in the placebo group, respectively

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

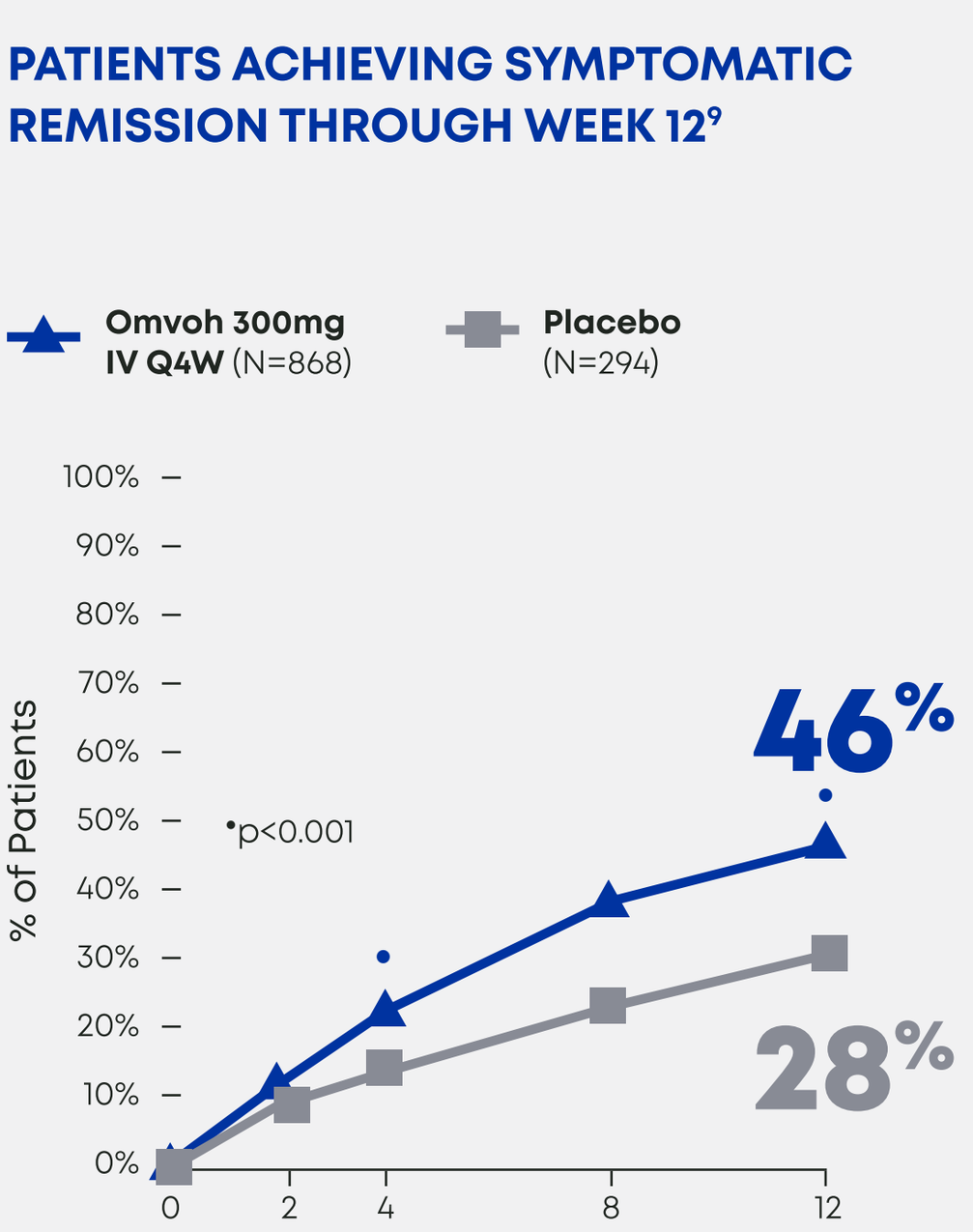
OMVOH PROVIDED IMPROVEMENT OF UC SYMPTOMS THROUGH WEEK 12[1,9]

Among patients in the LUCENT-1 **induction phase**, Omvoh provided **early symptomatic relief.[1,10]**

SYMPTOMATIC REMISSION[9]

Improvement in stool frequency and rectal bleeding

PATIENTS ACHIEVING SYMPTOMATIC REMISSION THROUGH WEEK 12[9]



Symptomatic remission was defined as SF=0, or SF=1 with a >1-point decrease from baseline; RB=0.[1,9] Symptomatic remission was measured as a gated secondary endpoint at Weeks 4 and 12, therefore statistical significance is shown for these time points only.[1]

RB, rectal bleeding; **SF**, stool frequency.

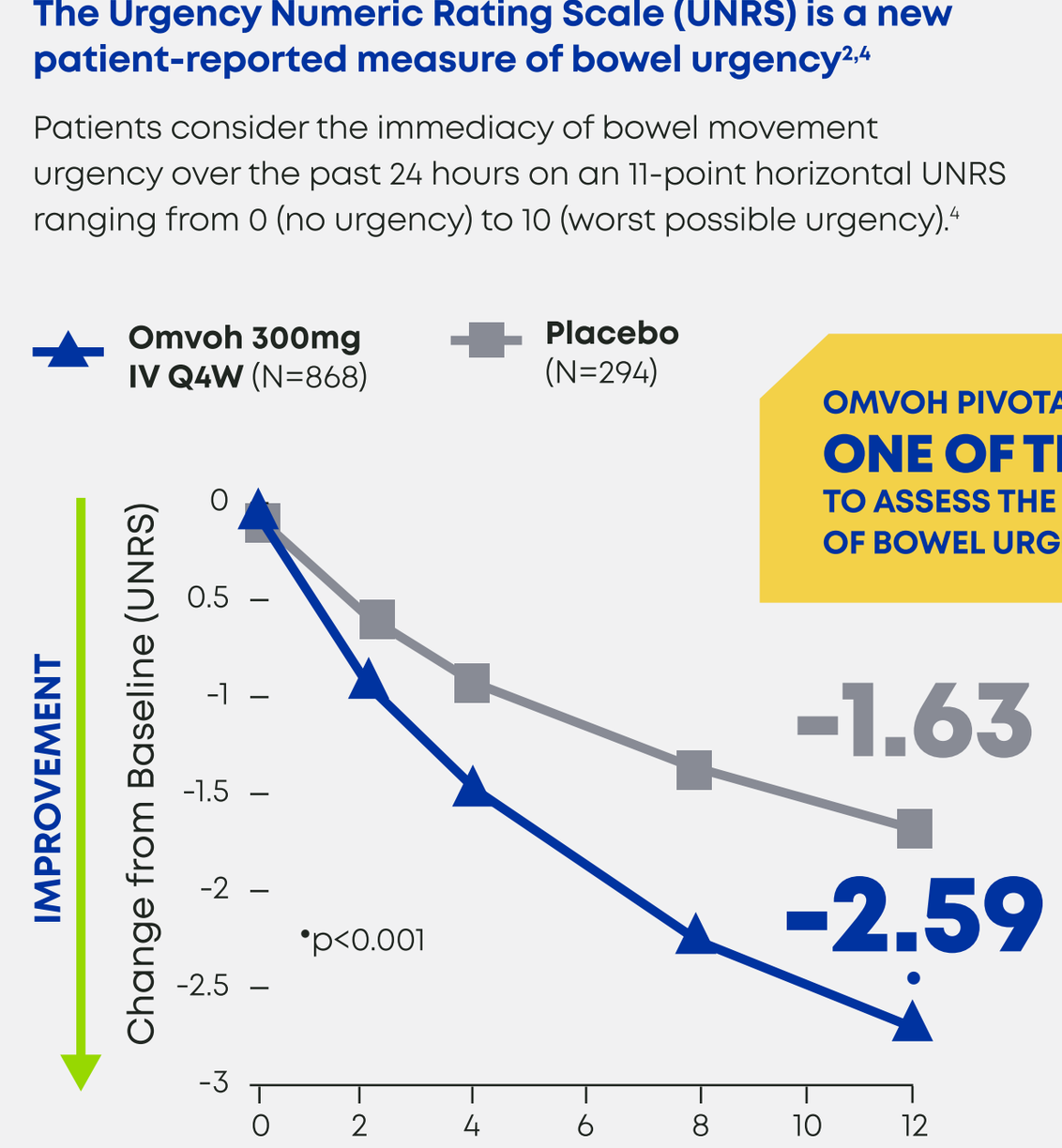
BOWEL URGENCY SEVERITY[9]

Reduction in bowel urgency severity

CHANGE IN BOWEL URGENCY SEVERITY[9]

The Urgency Numeric Rating Scale (UNRS) is a new patient-reported measure of bowel urgency[2,4]

Patients consider the immediacy of bowel movement urgency over the past 24 hours on an 11-point horizontal UNRS ranging from 0 (no urgency) to 10 (worst possible urgency).[4]



OMVOH PIVOTAL TRIALS ARE **ONE OF THE FIRST** TO ASSESS THE REDUCTION OF BOWEL URGENCY.[1,2]

Among patients in the LUCENT-1 induction trial, bowel urgency improvement was defined as a change from baseline in the urgency numerical rating scale (UNRS).[1]

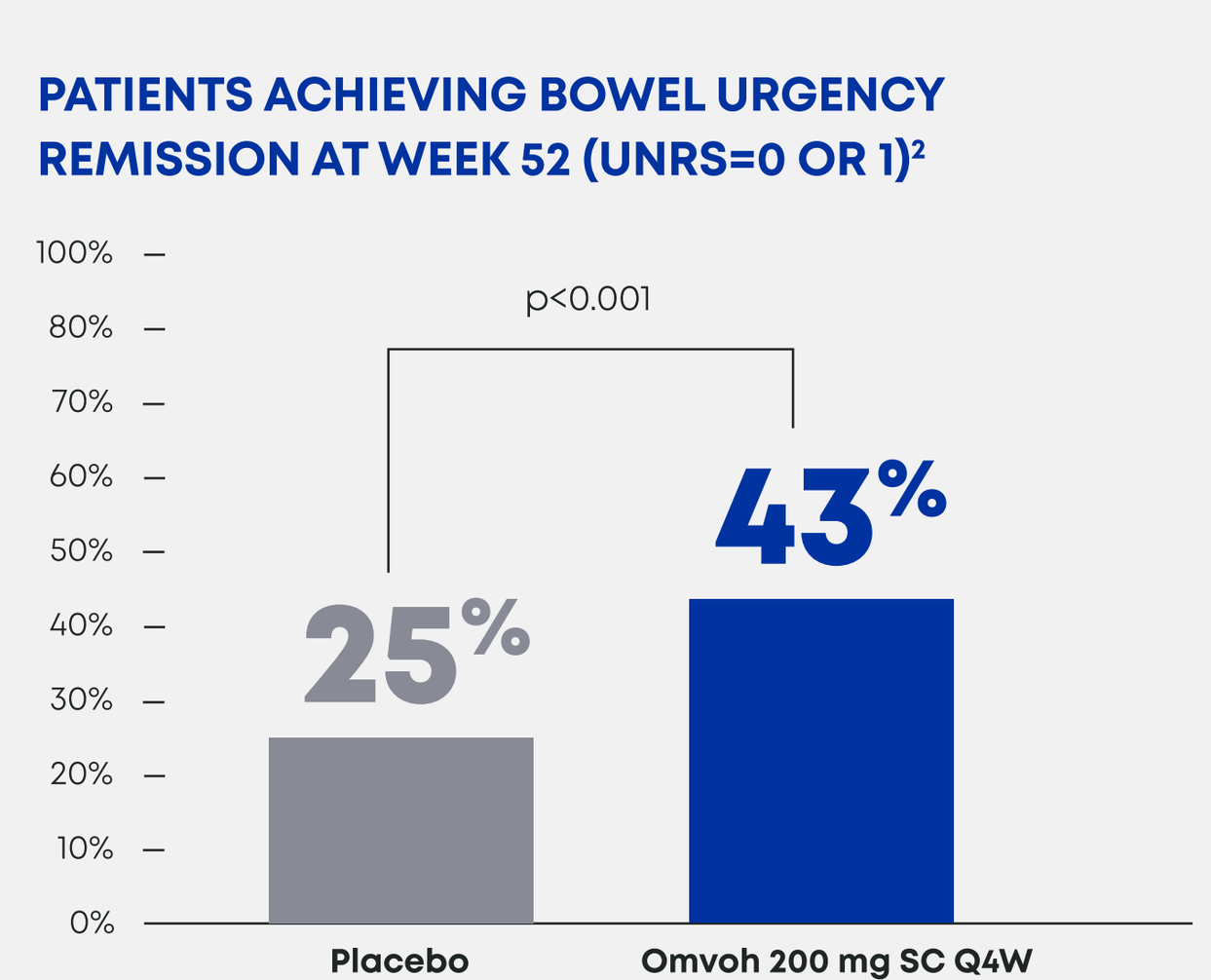
OMVOH REDUCED THE DISRUPTIVE IMPACT OF BOWEL URGENCY[2,10]

Omvoh demonstrated a significant impact on bowel urgency, one of the most disruptive symptoms for patients with UC.[2,10]

Among patients who achieved a clinical response with Omvoh in LUCENT-1, **43% achieved bowel urgency remission at Week 52.[2]**

BOWEL URGENCY SYMPTOM SEVERITY IS PERTINENT TO MEASURING UC DISEASE[4]

PATIENTS ACHIEVING BOWEL URGENCY REMISSION AT WEEK 52 (UNRS=0 OR 1)[2]



Patients included in this analysis had a UNRS score of ≥3 at baseline in LUCENT-1.[1]
Bowel urgency remission: Patients rating bowel urgency severity as 0 or 1 on UNRS (0-10).[1,4] No or minimal bowel urgency severity was defined as UNRS score of 0 or 1.[2]
The placebo arm is Omvoh induction (LUCENT-1) responders randomized to placebo.

Have you seen Omvoh's efficacy and safety data?

Get more details about Omvoh and the LUCENT-2 trial

LEARN MORE

SAFETY PROFILE FROM TWO PHASE 3 TRIALS[2,9]

Omvoh's overall safety profile was similar to that of previous mirikizumab studies in UC and **consistent with the known safety profile** of other anti-IL-23p19 antibodies.[2]

Omvoh was **well-tolerated**, with similar adverse events to placebo through 1 year. Rates of serious infections and malignancies were low and comparable to placebo.[2]

THE SAFETY OF OMVOH WAS EVALUATED IN TWO RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE 3 TRIALS[2,9]

ADVERSE DRUG REACTIONS THROUGH WEEK 12 IN LUCENT-1 (INDUCTION)[1,9]

ADVERSE DRUG REACTIONS IN ≥1% OF OMVOH-TREATED PATIENTS AND HIGHER THAN PLACEBO	OMVOH (N=958)	PLACEBO (N=321)
Upper respiratory tract infections**	7.9%	5.9%
Headache	3.3%	2.8%
Rash††	1.1%	0.6%

ADVERSE DRUG REACTIONS WEEKS 12–52 IN LUCENT-2[2] (MAINTENANCE)[2]

ADVERSE DRUG REACTIONS IN ≥1% OF OMVOH-TREATED PATIENTS AND HIGHER THAN PLACEBO	OMVOH (N=389)	PLACEBO (N=192)
Upper respiratory tract infections**	11.8%	9.9%
Injection site reactions‡‡	8.7%	4.2%
Headache	4.1%	1.0%
Rash††	3.6%	0%

The common adverse reactions were upper respiratory tract infections, headaches, rash and injection site reactions.[1]

THE MAJORITY OF INJECTION-SITE REACTIONS WERE MILD TO MODERATE AND DID NOT LEAD TO DISCONTINUATION OF OMVOH[2]

In the maintenance study (LUCENT-2) injection-site reactions were reported by 8.7% of patients taking Omvoh compared to 4.2% of patients taking placebo.[2]

The most frequently reported reactions were:

- Injection-site pain[1]
- Injection-site reaction[1]
- Injection-site erythema[1]

OMVOH HAD NUMERICALLY LOWER FREQUENCIES OF SERIOUS ADVERSE EVENTS AND DISCONTINUATIONS VS PLACEBO[2,9]

SERIOUS ADVERSE EVENTS AND DISCONTINUATIONS IN LUCENT-1 (INDUCTION) AND LUCENT-2 (MAINTENANCE)[2,9]

SERIOUS ADVERSE EVENTS AND DISCONTINUATIONS	LUCENT 1-(INDUCTION)[9]		LUCENT-2 (MAINTENANCE)[2]	
	OMVOH (N=958)	PLACEBO (N=321)	OMVOH (N=389)	PLACEBO (N=192)
Serious adverse events	2.8%	5.3%	3.3%	7.8%
Discontinuations due to adverse events	1.6%	7.2%	1.5%	8.3%

ADVERSE EVENTS OF SPECIAL INTEREST IN LUCENT-2 (MAINTENANCE)[2,9]

ADVERSE EVENTS OF SPECIAL INTEREST	LUCENT-2 (INDUCTION)[9]		LUCENT-2 (MAINTENANCE)[2]	
	OMVOH (N=389)	PLACEBO (N=192)	OMVOH (N=389)	PLACEBO (N=192)
Opportunistic Infection (narrow)§§	0.5%	0.3%	1.3%	0%
Hepatic events¶¶	1.6%	1.6%	3.1%	2.1%
Serious infection	0.7%	0.6%	0.8%	1.6%
Malignancy	0.2%	0%	0.3%	0.5%
Major adverse cardiac event	0%	0%	0%	0.5%

*Hypothetical patient

†Participants in the trial had completed the LUCENT-1 trial, a 12-week blinded induction study in which they were randomized to receive Omvoh (300 mg) IV or placebo IV every 4 weeks.[2] Clinical responders from week 12 of LUCENT-1 were re-randomized into LUCENT-2 to receive maintenance Omvoh therapy (200 mg) SC or placebo every 4 weeks for 40 weeks. At the end of LUCENT-2, these patients had received a total of 52 weeks of treatment.[1]

‡Clinical remission was defined as stool frequency (SF)=0, or SF=1 with a ≥1-point decrease from LUCENT-1 baseline; rectal bleeding = 0; endoscopic subscore = 0 or 1 (excluding friability).[2]

§The placebo arm is Omvoh induction responders randomized to placebo.[2]

¶Bio-failed includes biologic-failed and tofacitinib-failed patients.[2] 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-failed subgroup analysis.[1]

#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]

**Upper respiratory tract infections contain the preferred terms: acute sinusitis, nasopharyngitis, oropharyngeal discomfort, oropharyngeal pain, pharyngitis, rhinitis, sinusitis, tonsillitis, upper respiratory tract infection, and viral upper respiratory tract infection.[1]

††Rash contains the preferred terms: rash, rash macular, rash maculo-papular, rash papular, and rash pruritic.[1]

‡‡The most frequently reported events were injection site pain, injection site reaction, and injection site erythema.[1]

§§Excluding oral candidiasis and oral fungal infection.

¶¶Hepatic events include laboratory abnormalities reported as adverse events as well as any hepatobiliary disorder.

ACG, American College of Gastroenterology; **IV**, intravenous; **SC**, subcutaneous; **UC**, ulcerative colitis; **UNRS**, urgency numerical rating scale.

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OMVOH INDICATION

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

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