INTRODUCING OMVOH (MIRIKIZUMAB)

A first-in-class IL-23p19 antagonist to treat adult patients with moderately to severely active ulcerative colitis (UC)[1,2]

omvoh™ mirikizumab infusion/injection

NOW APPROVED![2]

Omvoh (mirikizumab) is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.[2]

It is the first IL-23p19 targeted biologic to demonstrate efficacy and safety for induction and maintenance therapy of UC, regardless of biologic or tofacitinib failed status.[1] This was shown in the phase 3 trials, LUCENT-1 and LUCENT-2.[1]

Considering a different treatment for your UC patients?

Dr. Peter Irving discusses how patients achieved clinical remission with Omvoh in the LUCENT trial

WATCH NOW

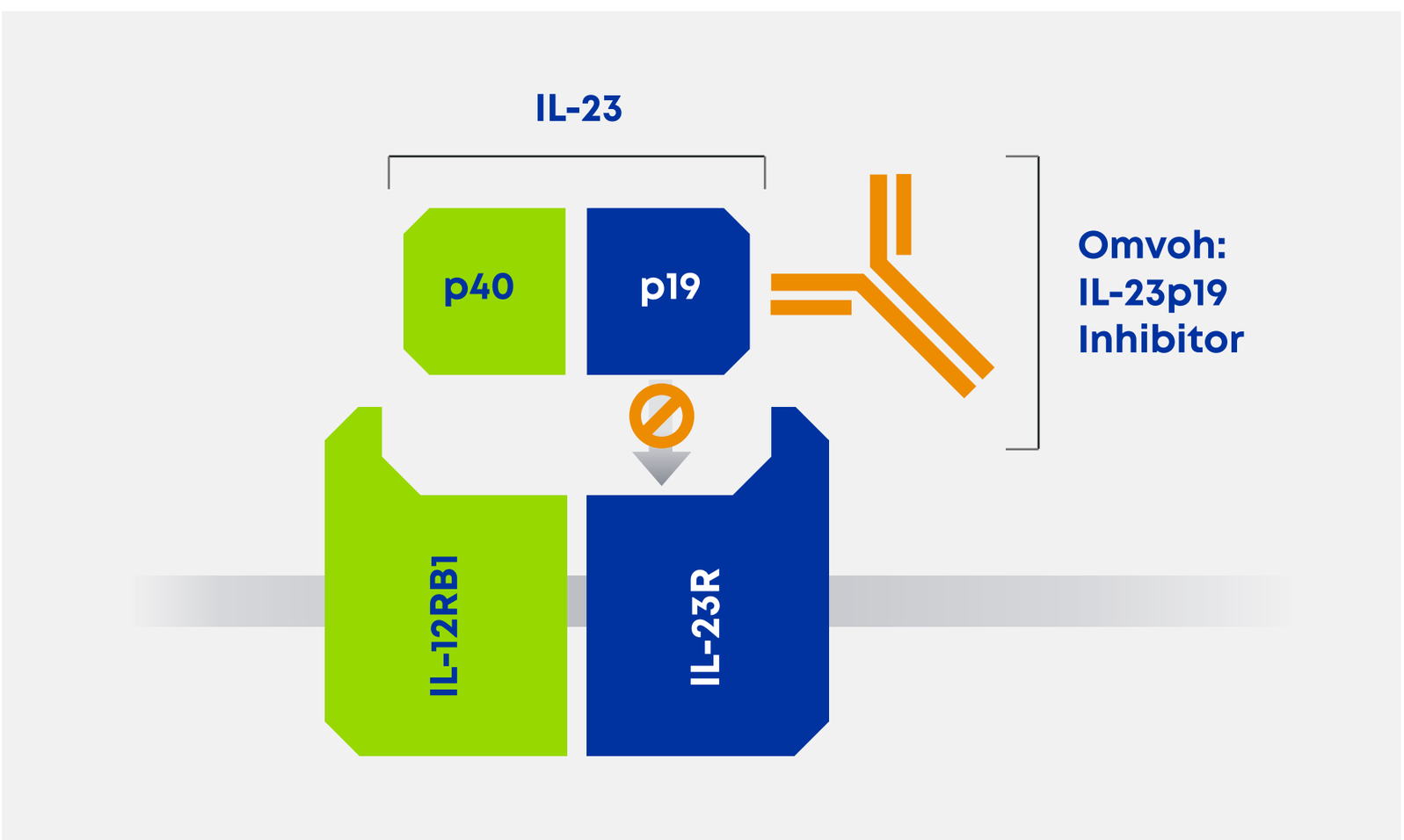
If you look at the efficacy data from the LUCENT trials, Omvoh demonstrated superiority compared to placebo on all primary and key secondary endpoints.

— Dr. Peter Irving

WHAT IS OMVOH?

Omvoh is a first-in-class IL-23p19 antagonist for the treatment of moderately to severely active UC[1-3]

- Omvoh selectively targets the p19 subunit of IL-23 and inhibits the IL-23 pathway[1,4]
- Inflammation due to over-activation of the IL-23 pathway plays a critical role in the pathogenesis of UC[1,4]
- Omvoh spares the IL-12 pathway, preserving the protective role of IL-12 in immune responses[2,5]

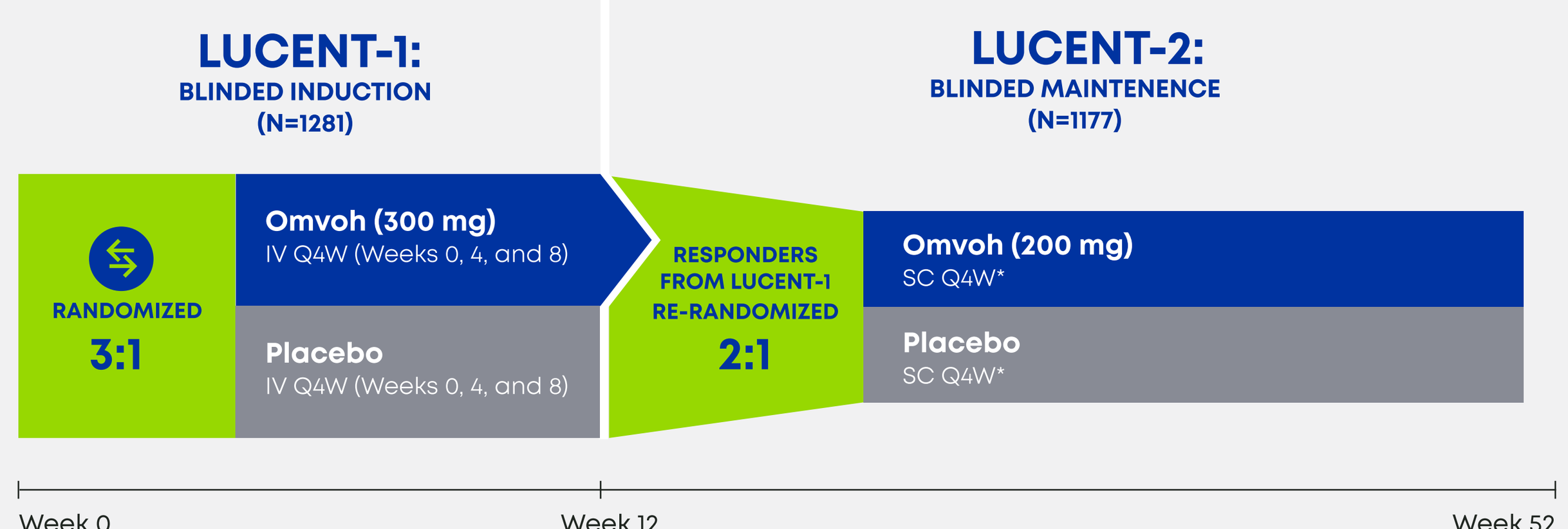


THE EFFICACY AND SAFETY OF OMVOH WAS EVALUATED IN ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE UC[1,2]

LUCENT-1 was a 12-week blinded induction study with patients randomized to Omvoh (300 mg) IV or placebo every 4 weeks. In LUCENT-2, patients who achieved a clinical response with Omvoh in LUCENT-1, were re-randomized to Omvoh (200 mg) SC or placebo every 4 weeks for an additional 40 weeks.[1,6]

Patients enrolled in the study had moderately to severely active UC who had an inadequate response, loss of response, or intolerance to at least one corticosteroid, immunomodulator, biologic treatment, or tofacitinib for UC.[1,2]

TRIAL DESIGN[1]



PRIMARY ENDPOINT: **Clinical Remission at Week 12**[1]
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]

PRIMARY ENDPOINT: **Clinical Remission at Week 40 (52 weeks Omvoh Treatment) Among Responders from LUCENT-1**[1,6]
41% of patients in LUCENT-1 had failed at least one prior biologic and **3.9%** had failed a JAKi[1]

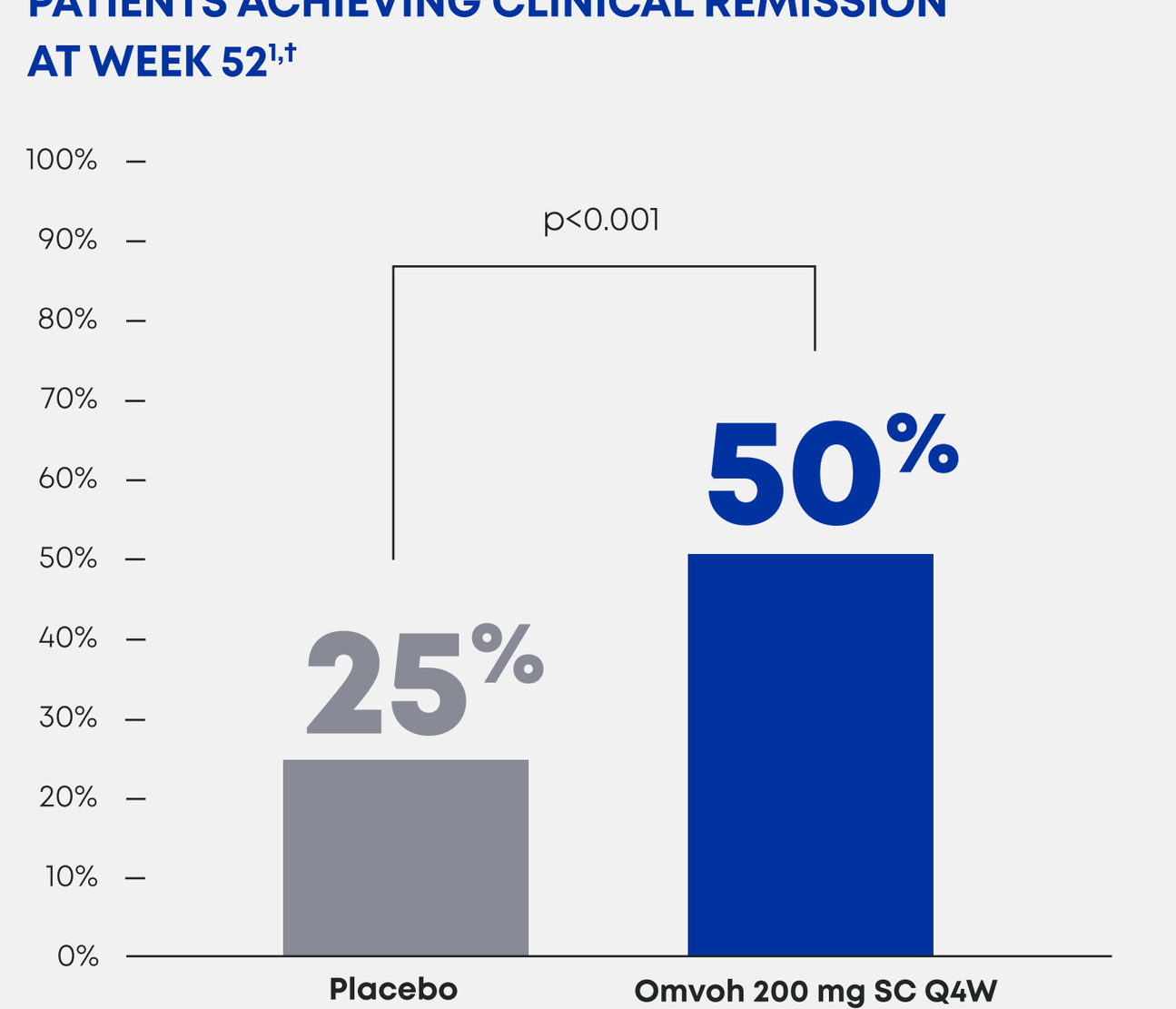
OMVOH PROVIDED SUSTAINED CLINICAL REMISSION AT WEEK 52[1,2]

50% of all patients achieved clinical remission at Week 52[1]

Among patients who achieved a clinical response in the LUCENT-1 induction study (Omvoh 300 mg IV Q4W), **50%** achieved clinical remission at Week 52 (Omvoh 200 mg SC Q4W) compared to 25% in the placebo arm.[1]

In addition, efficacy was demonstrated in bio-failed and bio-naive patients, with 46% and 52% of patients respectively, achieving clinical remission at 1 year.[1]

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



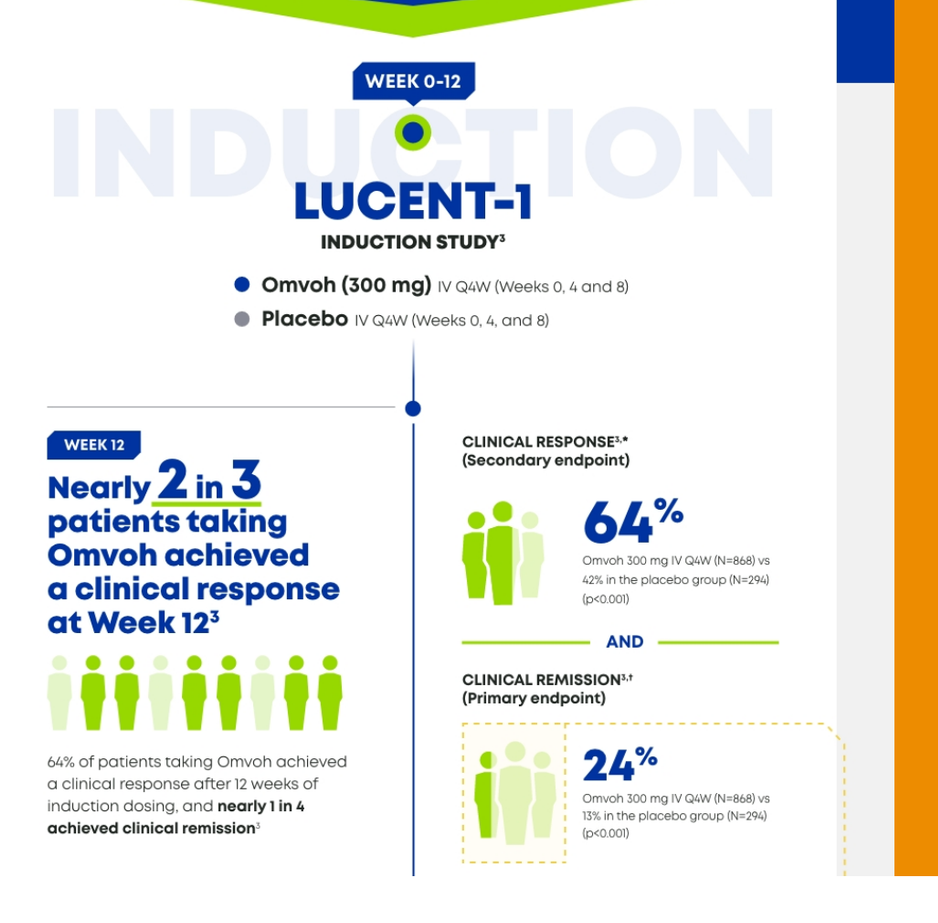
BIO-FAILED PATIENTS‡ achieved clinical remission at Week 52

46% OMVOH 200 MG SC Q4W (N=128)
vs **16%** in the placebo group (N=16),

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).[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).[1]
†The placebo arm is Omvoh induction responders randomized to placebo.[1]
‡Bio-failed includes biologic-failed and tofacitinib-failed patients.[1] 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.[2]
§The data presented are from a post hoc analysis and were not type I error controlled. Therefore treatment di erences between Omvoh and placebo cannot be regarded as statistically significant.[1]

64% of patients who achieved clinical remission with Omvoh at Week 12 in LUCENT-1, **maintained clinical remission** through 1 year of continuous treatment with Omvoh.[1]



OMVOH DEMONSTRATED HISTOLOGIC-ENDOSCOPIC MUCOSAL REMISSION AT WEEK 52[1,2]

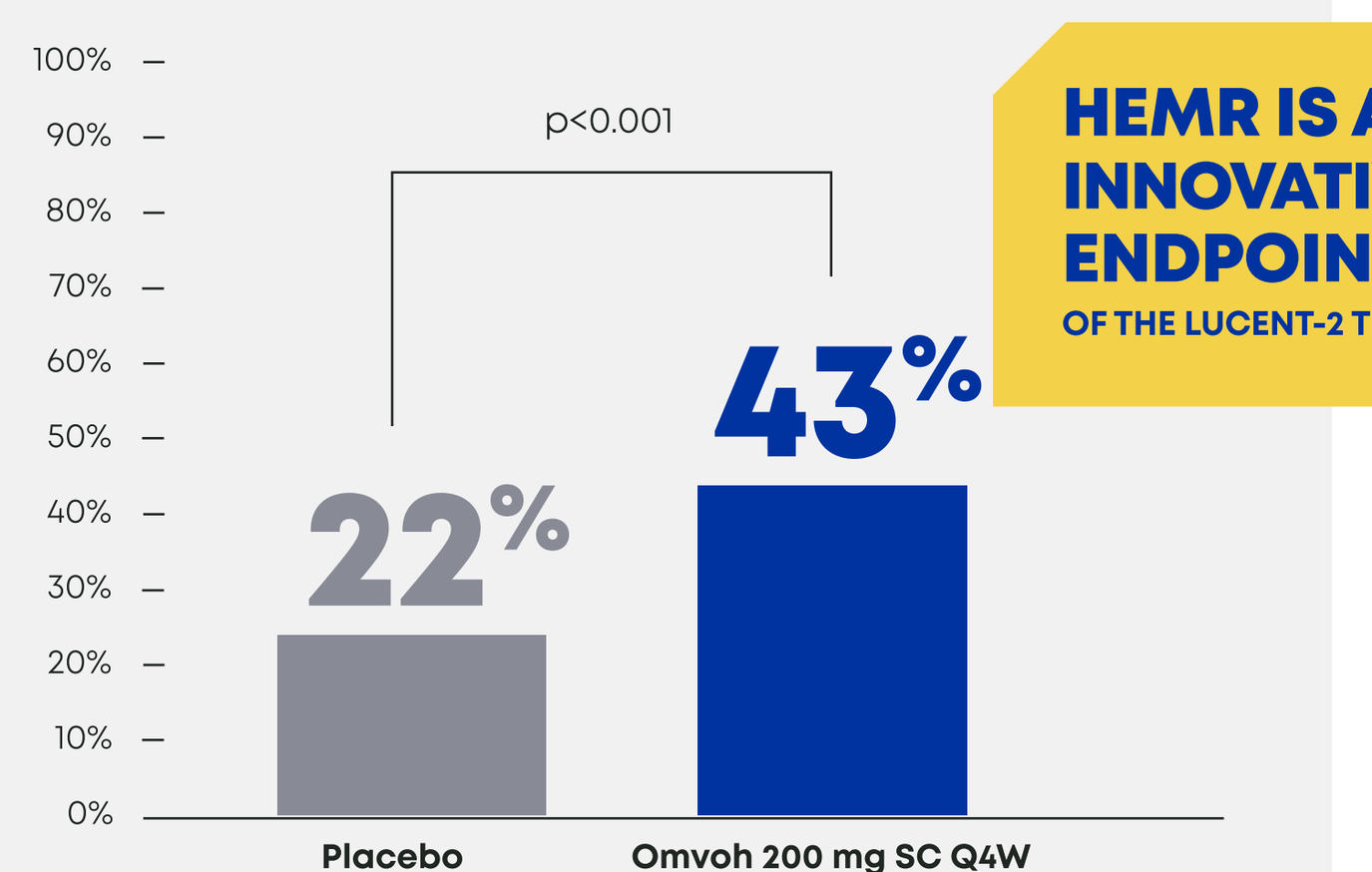
43% of patients achieved Histologic-Endoscopic Mucosal Remission (HEMR) at Week 52.[1,2]

HEMR was also achieved in 36% and 47% of bio-failed and bio-naive patients, respectively.[1,2]

HEMR:

- Includes histologic remission with resolution of mucosal neutrophils[1,2]
- Was defined as achieving both[1,2]:
  - Geboes subscores of 0 for grades: 2b (lamina propria neutrophils); 3 (neutrophils in epithelium); 4 (crypt destruction); 5 (erosion or ulceration)
  - Mayo endoscopic score 0 or 1 (excluding friability)

PROPORTION OF PATIENTS ACHIEVING HEMR AT WEEK 52[1,2,*]



HEMR IS AN INNOVATIVE ENDPOINT OF THE LUCENT-2 TRIAL[1]

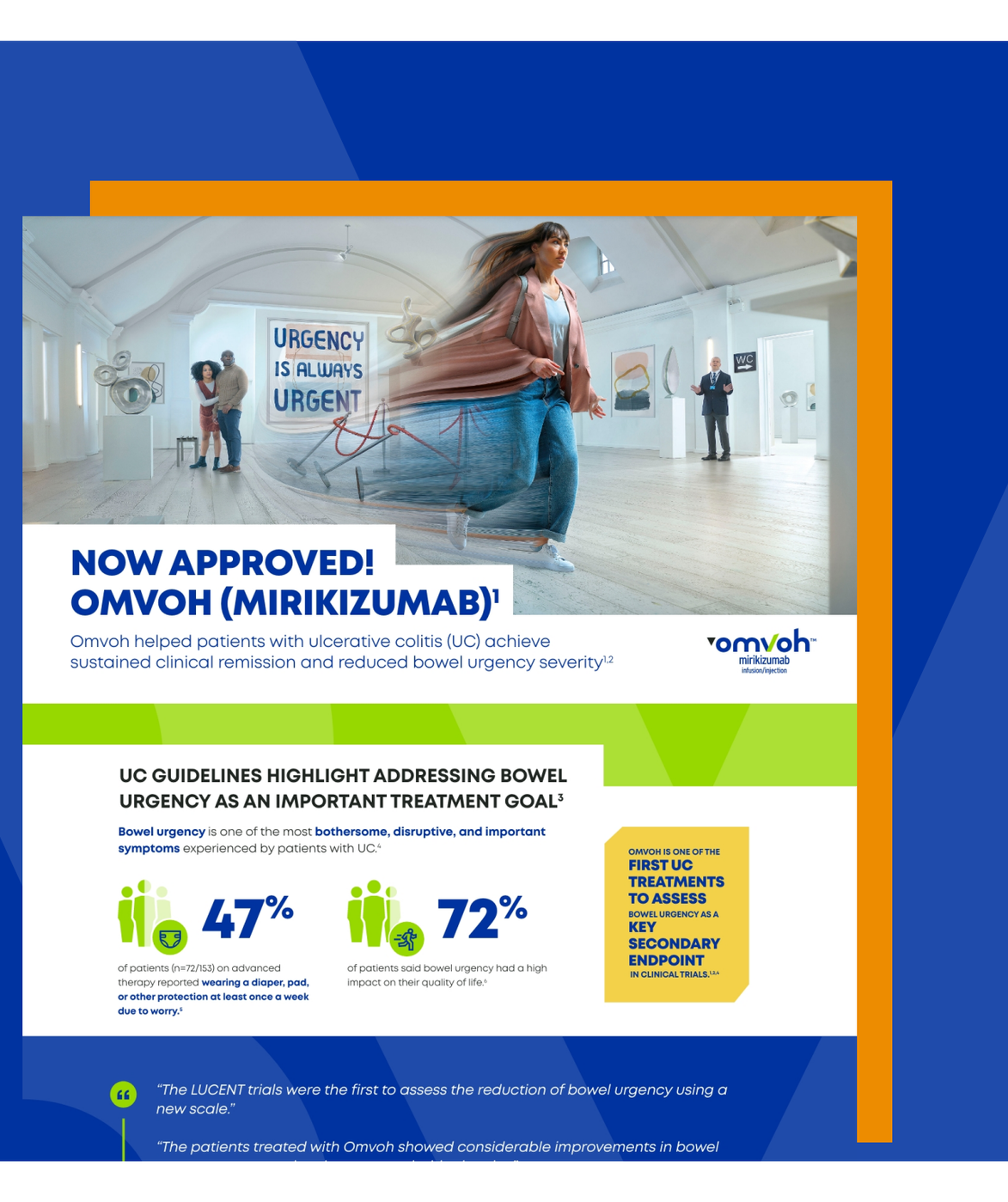
BIO-FAILED PATIENTS† achieved HEMR at Week 52

36% OMVOH 200 MG SC Q4W (N=128)
vs **14%** in the placebo group (N=64), respectively[1]

*The placebo arm in Omvoh induction (LUCENT-1) responders randomized to placebo.
†Prespecified subgroup analysis not controlled for multiplicity. 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.[2]

Learn more about how Omvoh can help your UC patients with their most burdensome symptom

LEARN MORE



SAFETY PROFILE FROM TWO PHASE 3 TRIALS[1,6]

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.[1,2]

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.[1,2]

THE SAFETY OF OMVOH WAS EVALUATED IN TWO RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE 3 TRIALS[1,6]

ADVERSE DRUG REACTIONS THROUGH WEEK 12 IN LUCENT-1 (INDUCTION)[1,6]

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 (MAINTENANCE)[1,2]

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.[2]
*Upper respiratory tract infections contains 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]

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.[1,2]

The most frequently reported reactions were:

- Injection-site pain[2]
- Injection site reaction[2]
- Injection-site erythema[2]

OMVOH HAD NUMERICALLY LOWER FREQUENCIES OF SERIOUS ADVERSE EVENTS AND DISCONTINUATIONS VS PLACEBO[1]

SERIOUS ADVERSE EVENTS AND DISCONTINUATIONS IN LUCENT-1 (INDUCTION) AND LUCENT-2 (MAINTENANCE)[1,6]

	LUCENT-1 (INDUCTION)[6]		LUCENT-2 (MAINTENANCE)[1]	
	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 INTERESTS IN LUCENT-2 (MAINTENANCE)[1]

ADVERSE EVENTS OF SPECIAL INTEREST	LUCENT-1 (INDUCTION)[6]		LUCENT-2 (MAINTENANCE)[1]	
	OMVOH (N=958)	PLACEBO (N=321)	OMVOH (N=389)	PLACEBO (N=192)
Serious infection	0.7%	0.6%	0.8%	1.6%
Opportunistic infection	0.5%	0.3%	1.3%	0%
Hepatic events	1.6%	1.6%	3.1%	2.1%
Malignancy	0.2%	0%	0.3%	0.5%
Major adverse cardiac event	0%	0%	0%	0.5%

IL-23p19, interleukin 23, subunit p19; **IV**, intravenous; **Q4W**, every 4 weeks; **SC**, subcutaneous; **UC**, ulcerative colitis.

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OMVOH INDICATION

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

PP-MR-AE-0078

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