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Understanding the long-term effects of Omvoh™ in moderately to severely active Crohn's disease:

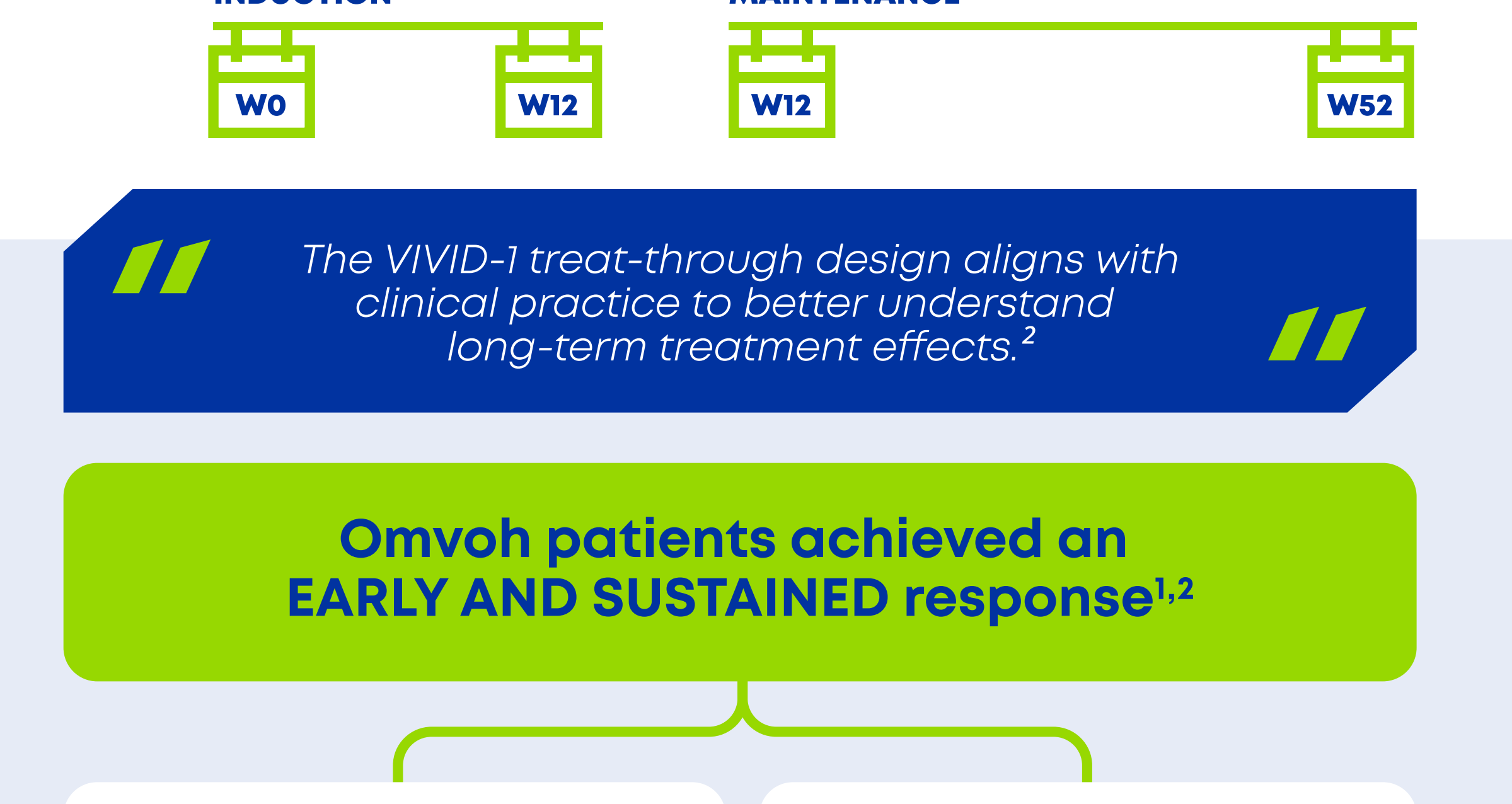
THE VIVID-1 STUDY

VIVID-1 trial design[1]:

A global Phase 3, randomised, double-blind, double-dummy, placebo-controlled, and active-controlled clinical trial with a treat-through design† for Crohn's disease over a 1-year period

The VIVID-1 trial evaluated adult patients with moderately to severely active Crohn's disease randomised to receive Omvoh or placebo.[1]

Omvoh was investigated using a treat-through design over 1 year, capturing both early response and response over time.[1]

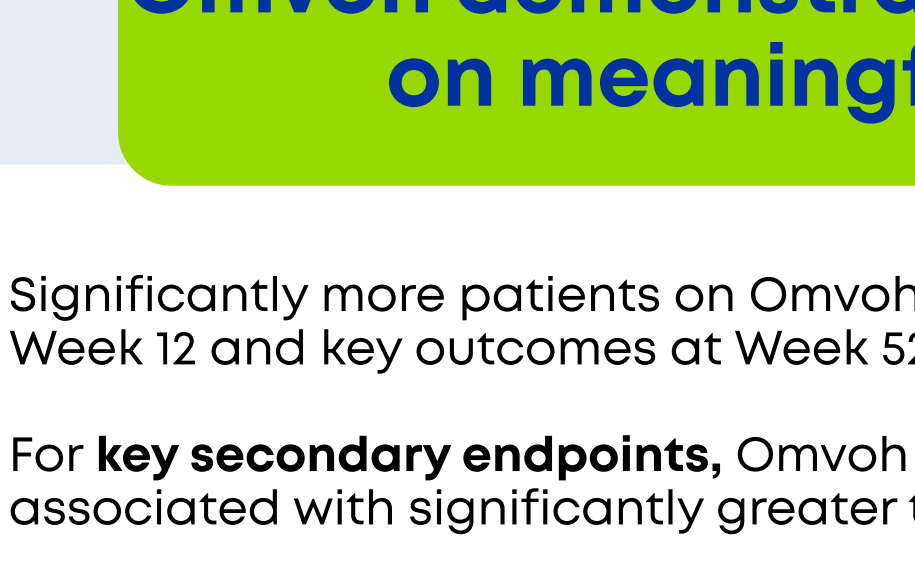


The VIVID-1 treat-through design aligns with clinical practice to better understand long-term treatment effects.[2]

Omvoh patients achieved an EARLY AND SUSTAINED response[1,2]

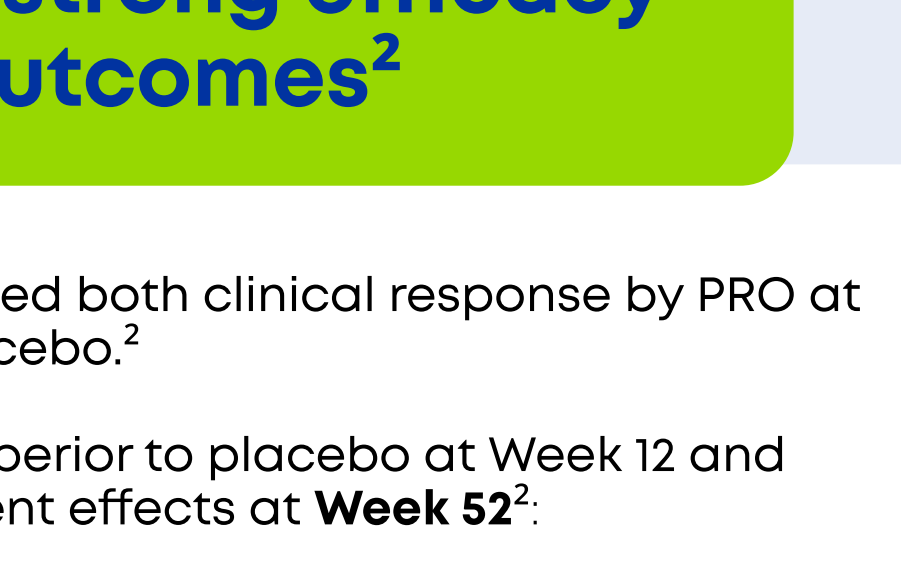
Omvoh was superior to placebo for the primary composite endpoint of clinical response by PRO† and clinical remission by CDAI[2,†]

Clinical response by PRO at Week 12 and clinical remission by CDAI at Week 52‡



Omvoh was superior to placebo for the primary composite endpoint of clinical response by PRO and endoscopic response[2,†]

Clinical response by PRO at Week 12 and endoscopic response at Week 52‡

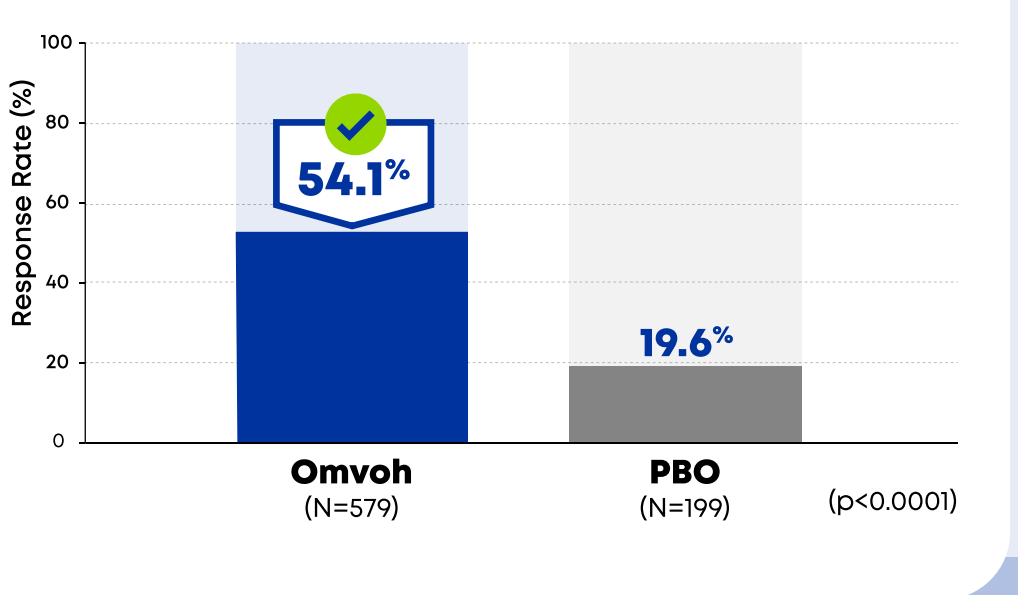


Omvoh demonstrated strong efficacy on meaningful outcomes[2]

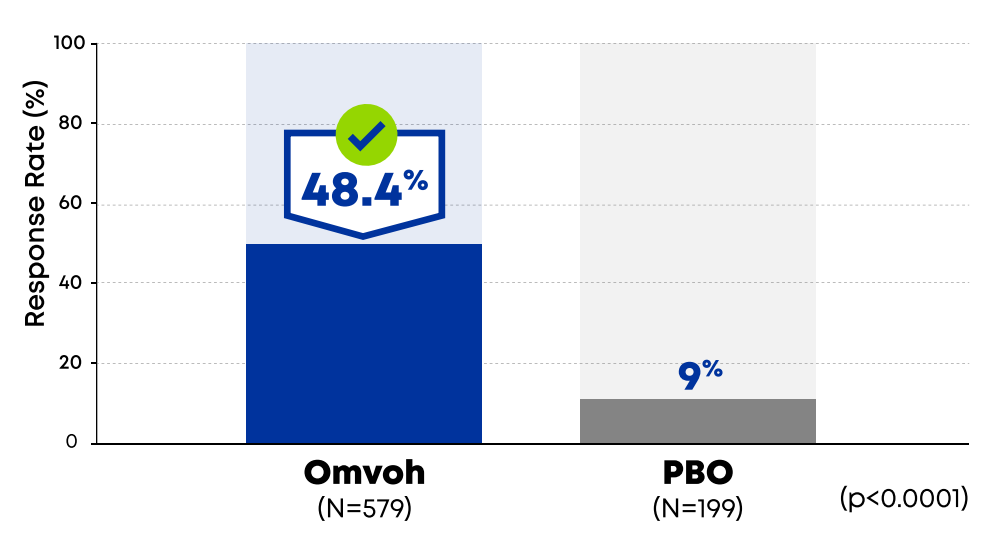
Significantly more patients on Omvoh achieved both clinical response by PRO at Week 12 and key outcomes at Week 52 vs placebo.[2]

For **key secondary endpoints,** Omvoh was superior to placebo at Week 12 and associated with significantly greater treatment effects at **Week 52**[2]:

Clinical remission by CDAI-TT‡



Endoscopic response-TT‡



Furthermore, Omvoh demonstrated significant treatment effects in patients, regardless of prior biologic experience, with consistent and significant response rates at Week 52.[2]

Watch Prof. Marc Ferrante review the VIVID-1 study results

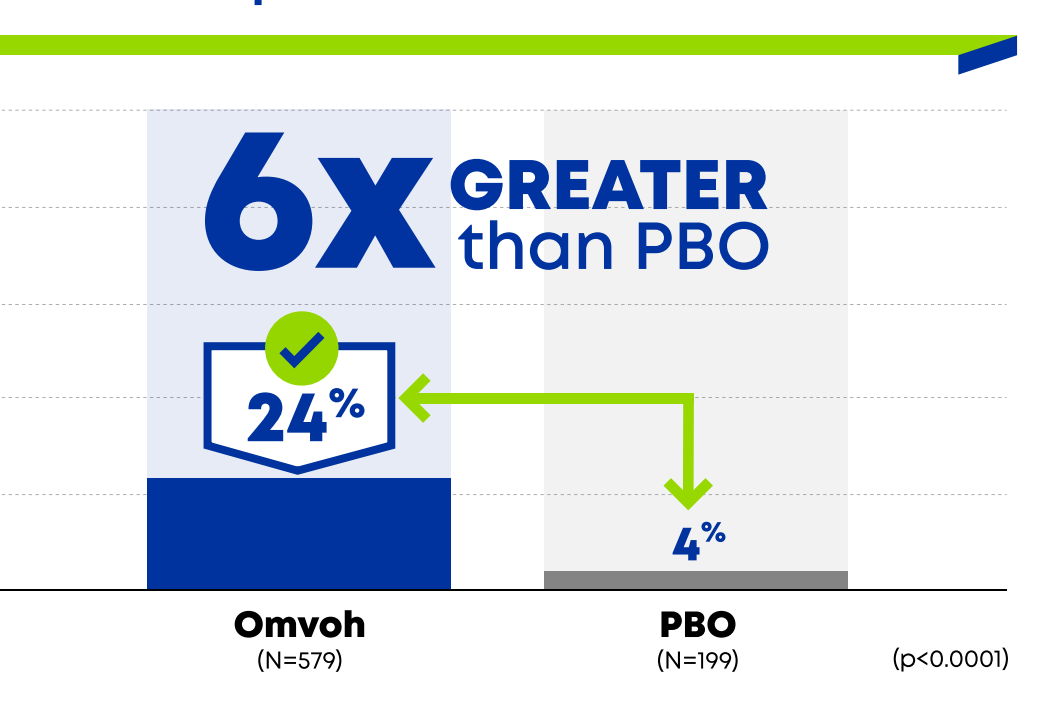
WATCH VIDEO

Significantly more Omvoh patients achieved endoscopic remission† at Week 52 vs placebo

To further evaluate the efficacy of Omvoh vs placebo, endoscopic remission was assessed at Week 52.

Patients treated with Omvoh achieved a rate of **x6 GREATER THE ENDOSCOPIC REMISSION** of patients who received placebo.[2]

Endoscopic remission at Week 52‡



Omvoh demonstrated a **favourable safety profile** with the majority of treatment-emergent adverse events being mild to moderate.[2]

The most common treatment-emergent adverse events (≥5% of patients) through 1 year of treatment with Omvoh were mild to moderate.[2] 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

Adverse events[a]	Weeks 0 to 52[2] Omvoh N=630	PBO N=211
COVID-19	16.5%	13.7%
Anaemia	6.7%	6.6%
Arthralgia	6.5%	5.2%
Headache	6.5%	4.3%
Upper respiratory tract infection	6.0%	4.3%
Nasopharyngitis	5.7%	4.3%

Adverse events of special interest	Weeks 0 to 52[2] Omvoh N=630	PBO N=211
Serious infection	2.2%	2.8%
Opportunistic infection (narrow)	1.1%	0%
Major adverse cardiac event	0%	0.9%
Malignancy		
Non-Melanoma Skin Cancer (NMSC)	0.2%	0.5%
Malignancies excluding NMSC	0.2%	0%
Infusion site reaction	0.2%	0%
Injection site reaction	10.8%	6.5%
Suicide/self-injury (narrow)[b]	0.3%	0%
Hepatic event (narrow)[c]	6.2%	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.[2]
[b]Both events were suicidal ideation; one participant had prior history of suicide attempt, the other had a history of anxiety.[2]
[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.[2]

Abbreviations
ALT, alanine aminotransferase; **AST,** aspartate aminotransferase; **PBO,** placebo; **TB,** total bilirubin; **ULN,** upper limit of normal.

Omvoh provides a favourable benefit-risk in clinical practice for patients with moderately to severely active Crohn's disease, regardless of their biologic experience.[2]

Omvoh achieves and maintains[2]:

- Symptomatic improvement
- Clinical remission by CDAI
- Endoscopic response
- Endoscopic remission

Omvoh demonstrates both early and long-term efficacy regardless of prior biologic experience.[2]

Omvoh demonstrated a favourable safety profile with the majority of treatment-emergent adverse events being mild to moderate.[2]

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.[1]

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.[1]

Click here to view the Omvoh SmPC for full indication.

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

Ulcerative colitis
The safety of Omvoh was evaluated in three Phase 3 trials.[3,4] The common reported adverse reactions were upper respiratory tract infections, arthralgia, headache, rash, and injection site reactions.[1]

Footnotes
†**Treat-through design:** Week 52 endpoints were controlled for multiplicity and 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:** ≥50% reduction from baseline in SES-CD Total Score.
Endoscopic remission: SES-CD Total Score ≤4 and at least a ≥2-point reduction from baseline and no subscore >1 in any individual variable.[2]
‡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.[2]

Abbreviations
CD, Crohn's disease; **CDAI,** Crohn's Disease Activity Index; **IV,** intravenous; **PBO,** placebo; **PRO,** patient-reported outcome; **Q4W,** every 4 weeks; **SC,** subcutaneous; **SES-CD,** Simple Endoscopic Score for Crohn's Disease; **SmPC,** Summary of Product Characteristics; **TT,** treat-through; **W,** Week.

References:

1. Omvoh Local Label
2. Ferrante M, et al. Lancet. 2024. doi: 10.1016/S0140-6736(24)01762-8.
3. D'Haens G, et al. N Engl J Med. 2023;388(26):2444–2455O
4. Sands BE, et al. Inflamm Bowel Dis. 2024:izae253. doi: 10.1093/ibd/izae253.

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