omvoh™
mirikizumab
A Lilly Medicine

START

TOWARDS LONG-TERM COMPREHENSIVE MANAGEMENT IN CROHN'S DISEASE

NOW APPROVED FOR CD[1]

Omvoh® offers early and sustained control across a broad spectrum of outcomes in Crohn's disease[1-4]

Patients and clinicians may think differently over which **Crohn's disease symptoms** have the most **impact on quality of life**.[5]

The VIVID-1 study investigated a broad spectrum of disease outcomes including mucosal inflammation, inflammatory biomarkers, and patient-reported symptoms such as abdominal pain, stool frequency, bowel urgency, and fatigue.[2,3]

Symptomatic relief, measured by clinical response by PRO,† along with clinical remission by CDAI,† endoscopic response,† and histologic remission† are **key endpoints towards the goal of comprehensive management of Crohn's disease.**[6,7]

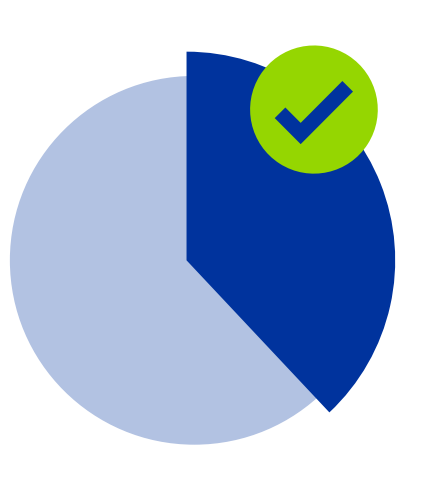
VIVID-1 enabled a **COMPREHENSIVE ASSESSMENT OF CROHN'S DISEASE** *outcomes to better achieve long-term control.*[2]

Omvoh offers comprehensive management for your patients with Crohn's disease[1-4]

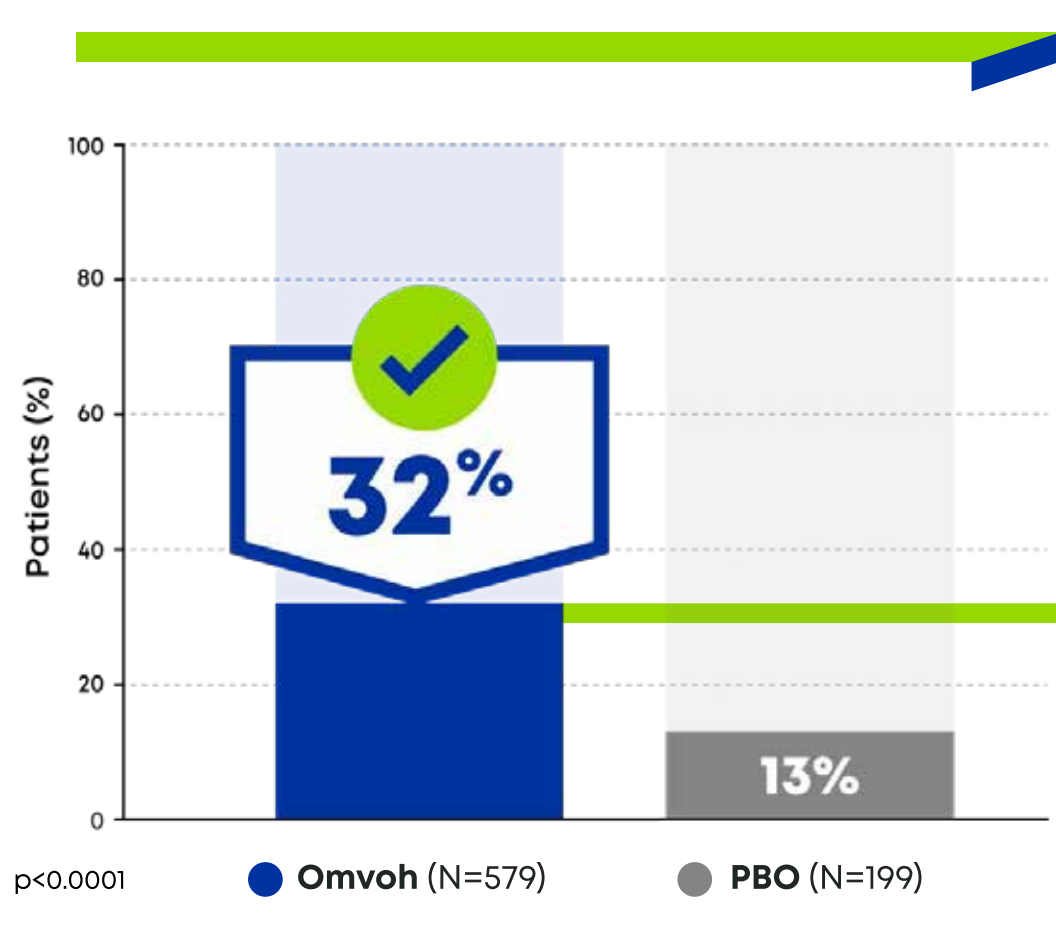
Following 1 year of treatment, **Omvoh demonstrated superiority** to placebo for the **co-primary composite endpoints** of clinical response by PRO at Week 12 and clinical remission by CDAI and endoscopic response at Week 52.[2]

Clinical response by PRO at Week 12 and clinical remission by CDAI at Week 52[2,‡]

Clinical response by PRO at Week 12 and endoscopic response at Week 52[2,‡]



Endoscopic response at Week 12[2,‡]

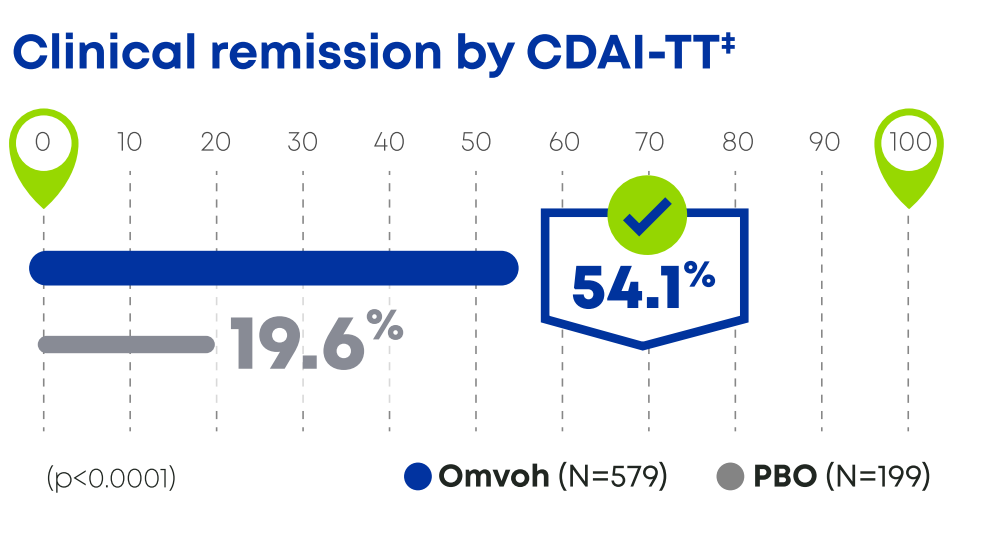


VIVID-1 focused on the comprehensive assessment of Crohn's disease outcomes, including mucosal inflammation, inflammatory biomarkers, and patient-reported symptoms.[2]

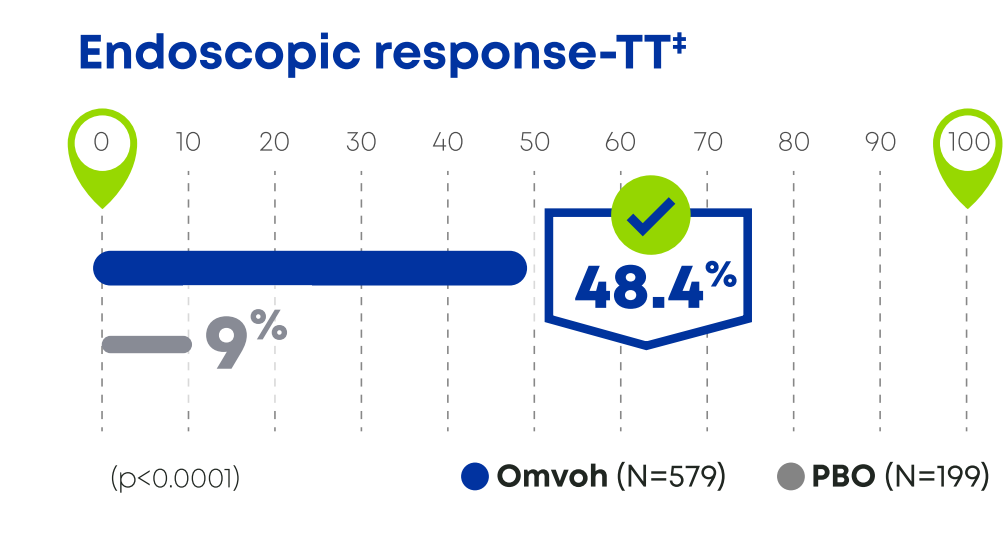
2.5X more patients receiving Omvoh achieved **EARLY ENDOSCOPIC RESPONSE** at Week 12 vs placebo[1]

At Week 52, Omvoh was associated with SIGNIFICANTLY GREATER TREATMENT EFFECTS vs placebo, including[2]:

Clinical remission by CDAI-TT‡



Endoscopic response-TT‡



Histological activity can persist in patients with Crohn's disease who are in endoscopic remission,† with histologic improvement continuing to be an unrecognised target in the treatment of Crohn's disease.[7] **Omvoh was associated with significantly higher rates of histologic response† and remission** and greater decreases in RHI scores than placebo at Week 52.[4] After 1 year of treatment, differences were even **more pronounced in bio-failed patients** vs bio-naïve.[4]

Omvoh **IMPROVED CLINICAL OUTCOMES AND CONTROLLED INFLAMMATION** *in patients with moderately to severely active Crohn's disease.*[4]

Dive deeper into the concept of comprehensive management in Crohn's disease

WATCH VIDEO

Dr. Alissa Walsh

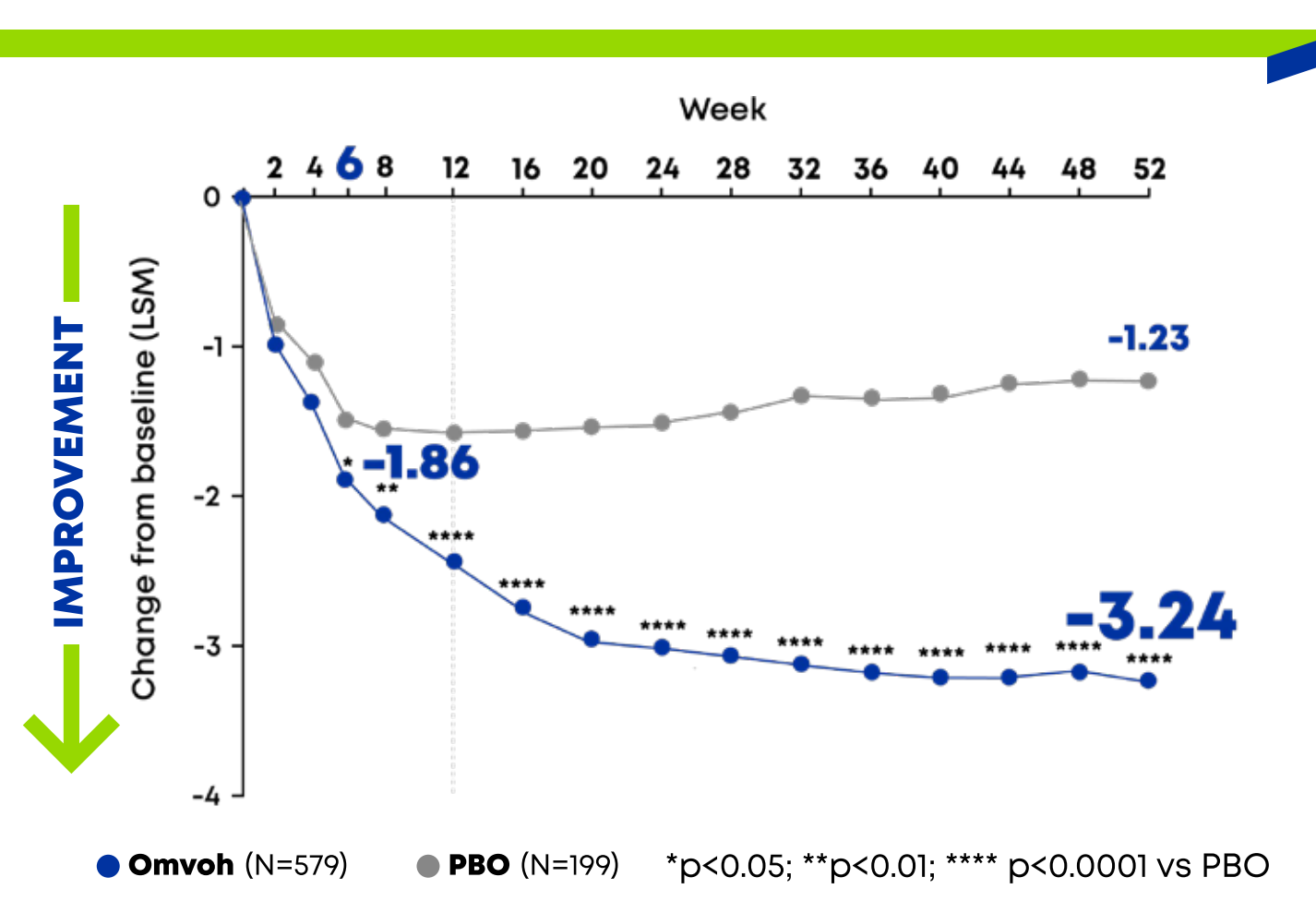
Omvoh significantly decreases the severity of bowel urgency.[3]

Bowel urgency is the sudden or immediate need for a bowel movement and is **often an unrecognized symptom of Crohn's disease** with a large QoL impact.[5,8-10]

In the VIVID-1 study, severity of **bowel urgency was assessed using the 11-point Urgency NRS.**[3,8,11]

Patients achieved a significantly greater improvement in Urgency NRS from baseline with Omvoh vs placebo.[3]

Urgency NRS[12,§]



W4

In addition, as early as Week 4, Omvoh was associated with a **significantly greater reduction in abdominal pain** vs placebo.[2]

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

Explore the importance of early and sustained control of bowel urgency with Omvoh

WATCH VIDEO

Dr. Alissa Walsh

Omvoh offers clinical remission by CDAI, including bowel urgency and endoscopic improvements, along with histologic improvement, aiming at comprehensive disease management.[1-4]

For patients with moderately to severely active Crohn's disease, Omvoh achieves and maintains:

- Clinical response by PRO
- Clinical remission by CDAI
- Endoscopic response
- Endoscopic remission

Omvoh demonstrated **improvements in bowel urgency severity** as early as Week 6 and **significantly greater remission rates** vs placebo.[3,12]

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.[13,14] The common reported adverse reactions were upper respiratory tract infections, arthralgia, headache, rash, and injection site reactions.[1]

Footnotes
†**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. **Histologic remission:** Complete absence of mucosal neutrophils (in epithelium and lamina propria), and no epithelial damage, erosions, and ulcers. **TT:** Week 52 parameter was assessed regardless of Week 12 PROs. **Endoscopic remission:** SES-CD Total Score ≤4 and at least a 2-point reduction versus baseline and no subscore >1 in any individual variable. **Histologic response:** absence of epithelial neutrophils, epithelial damage, erosions, and ulceration, or ≥50% decrease in both, active RHI and active GHAS.[2,4]
‡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]
§Data are LSM (95% CI), and comparisons were performed using ANCOVA with mBOCF.[12] For participants in the placebo group who switched to mirikizumab at Week 12, baseline values were carried forward to derive the change from baseline at Week 52.[3] A decrease in Urgency NRS score indicates improvement.[3]

Abbreviations
ANCOVA, analysis of covariance; **CD,** Crohn's disease; **CDAI,** Crohn's Disease Activity Index; **CI,** confidence interval; **GHAS,** Global Histological Disease Activity Score; **LSM,** least squares mean; **mBOCF,** modified baseline observation carried forward; **NRS,** numeric rating scale; **PBO,** placebo; **PRO,** patient-reported outcome; **QoL,** quality of life; **RHI,** Robarts Histopathology Index; **SES-CD,** Simple Endoscopic Score for Crohn's Disease; **SmPC,** Summary of Product Characteristics; **TT,** treat-through; **W,** Week.

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