

3Y
SUSTAINED
REMISSION NOW
ESTABLISHED
IN CD¹⁻⁴

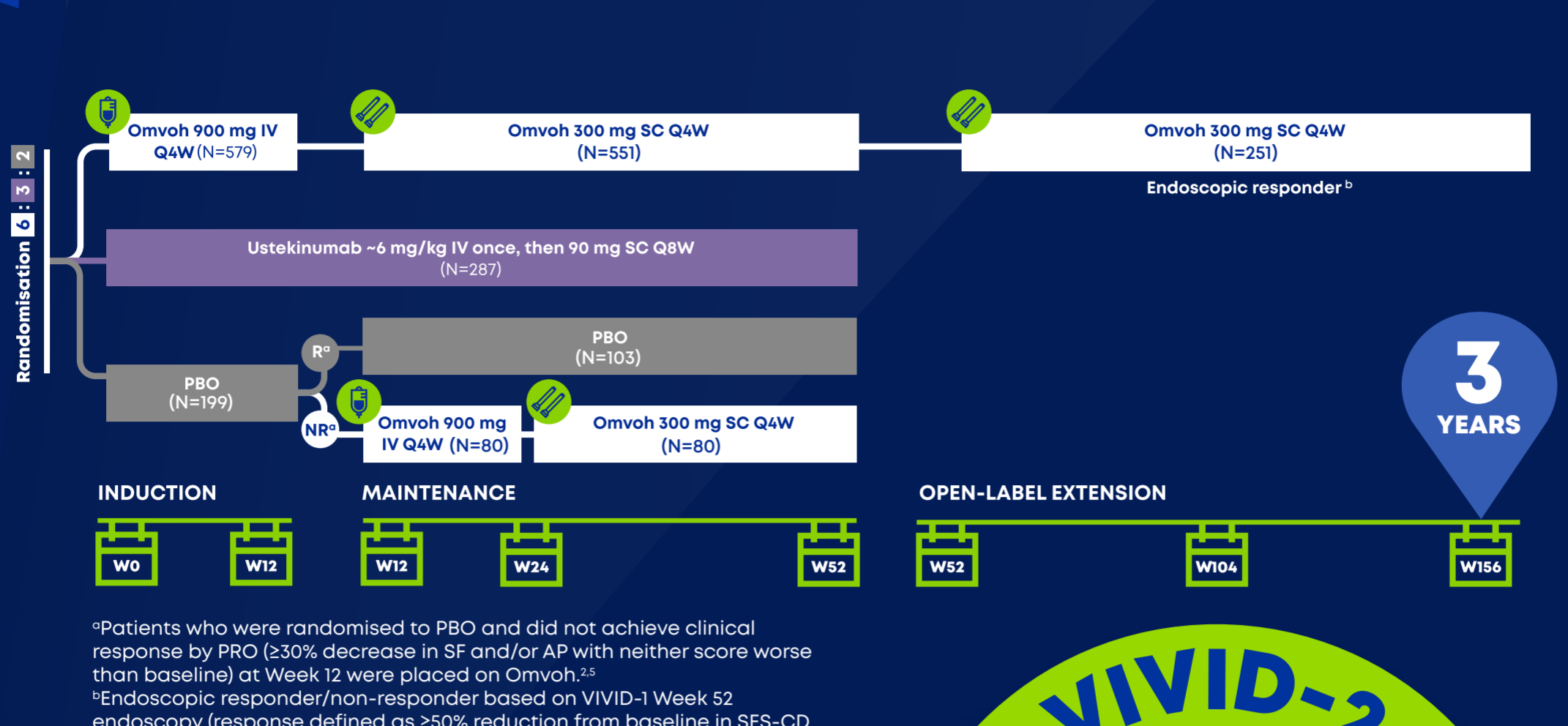
OMVOH™: SUSTAINED 3-YEAR EFFICACY IN CROHN'S DISEASE

Results from the VIVID-2
open-label extension study^{2,4}

VIVID-2 TRIAL DESIGN²

VIVID-2 is an ongoing, Phase 3, open-label extension study in patients with moderately to severely active Crohn's disease, evaluating the **long-term efficacy and safety of Omvoh (mirikizumab) after 3 years of continuous treatment.**^{1,2,4}

VIVID-1 and VIVID-2 trial design^{2,5}



¹Patients who were randomised to PBO and did not achieve clinical response by PBO (≥30% decrease in SF and/or AP with neither score worse than baseline) at Week 12 were placed on Omvoh.^{1,5}

²Endoscopic responder/non-responder based on VIVID-1 Week 52 endoscopy (response defined as ≥50% reduction from baseline in SES-CD total score) for Omvoh-treated patients only.^{1,2}

VIVID-2
Designed to understand the
**SUSTAINED,
LONG-TERM EFFICACY
OF OMVOH**
in patients with
CD²⁻⁴
EXTENSION STUDY

SUSTAINED, 3-YEAR LONG-TERM EFFICACY OF OMVOH IN PATIENTS WITH CD²⁻⁴

CLINICAL REMISSION was maintained through
3 YEARS OF TREATMENT WITH OMVOH^{4,†}



92.4%
of patients maintained **CLINICAL
REMISSION BY CDAI AT 3 YEARS^{4,†}**

Observed data, Omvoh (N=131)

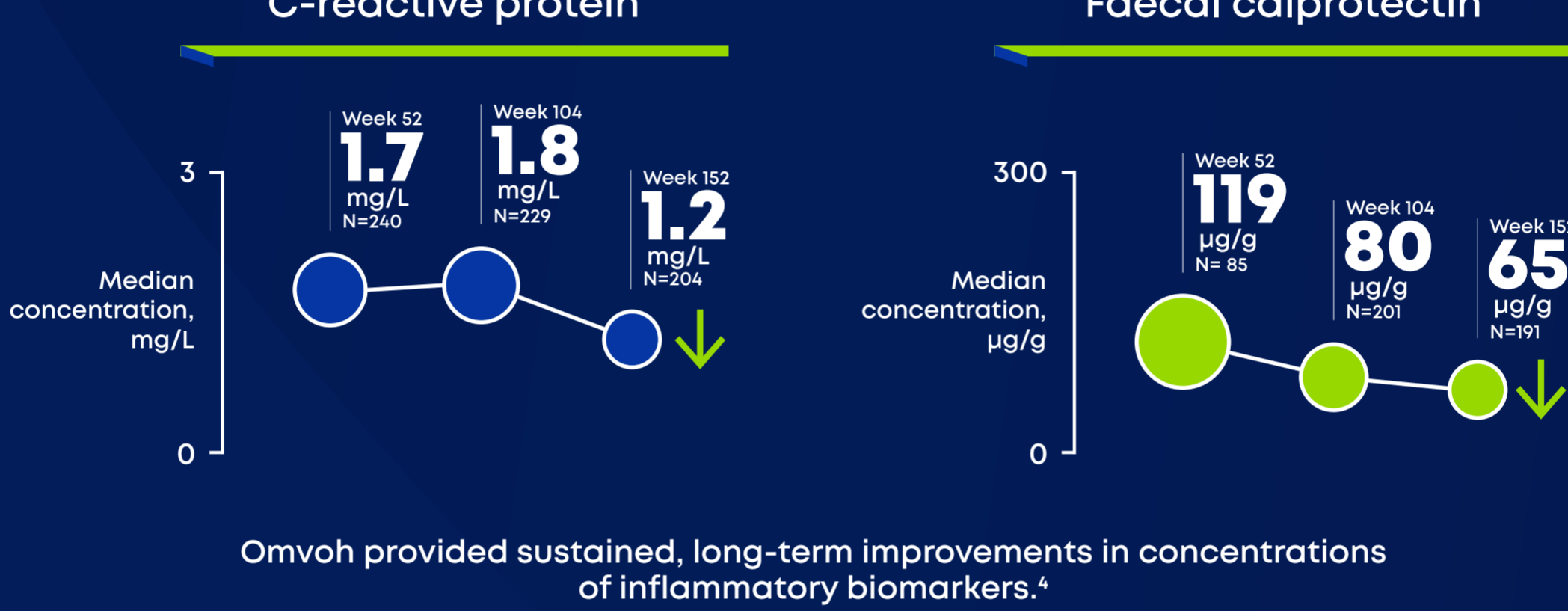


Out of the patients who achieved clinical remission at Week 52,
91.2% maintained **CORTICOSTEROID-FREE
CDAI CLINICAL REMISSION
AT 3 YEARS^{4,‡}**

Observed data, Omvoh (N=125)

Further **REDUCTIONS** in **CRP** and **fCLP** were observed
from Week 52[§] to Week 152[¶]

Biomarker improvements⁴



Omvoh provided sustained, long-term improvements in concentrations of inflammatory biomarkers.⁴



Omvoh significantly improved **BOWEL URGENCY** as early as **Week 6 (p<0.05)** and **MAINTAINED THROUGH 3 YEARS^{2,4,6}**

82.1% maintained BU CMI^{4,†}

71.7% maintained BU remission^{4,‡}

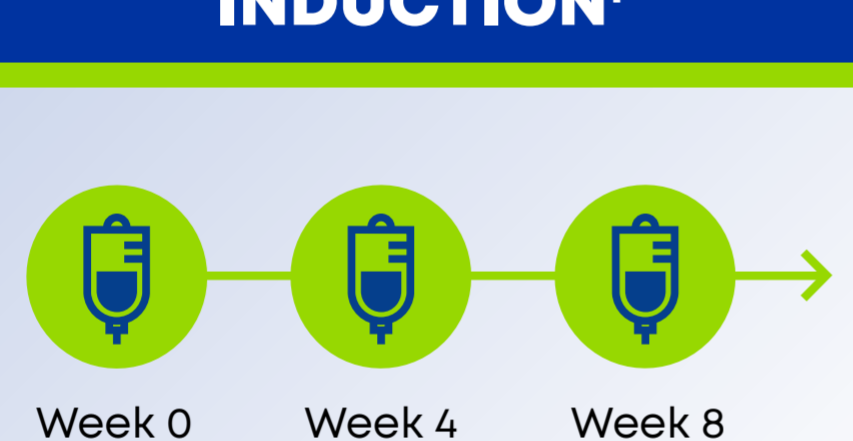
Observed data, Omvoh (N=117)

Observed data, Omvoh (N=92)

OMVOH'S SIMPLE DOSING SCHEME IN CROHN'S DISEASE^{2,5}

Indication-optimised dosing to meet the unique needs of patients with CD, allowing for injections every 4 weeks¹

INDUCTION¹



Omvoh 900 mg IV Q4W

Omvoh dosing begins with IV infusions during induction and transitions to self-injections for maintenance

MAINTENANCE¹



Omvoh 300 mg SC Q4W

Patients can take Omvoh with prefilled pens or prefilled syringes for maintenance dosing

- Easy-to-use prefilled pen ✓
- Simple dosing scheme ✓
- Q4W dosing ✓

Consistent once-monthly dosing across both IBD indications¹



**Consistent
SAFETY PROFILE
UP TO
3Y**^{2,4,5,7}

Omvoh demonstrated a favourable safety profile,^{††} with the majority of treatment-emergent adverse events through 3 years being mild to moderate.^{2-4,7}

In VIVID-2 (2-year results), 6.8% of patients experienced serious adverse events, and 0.8% of patients discontinued treatment due to an adverse event.⁷

**Omvoh demonstrated
SUSTAINED, LONG-TERM EFFICACY
ACROSS ENDPOINTS OVER 3 YEARS**
in patients with moderately to severely active CD,
regardless of previous biologic experience^{2,4}

KEY TAKEAWAYS

- Early and sustained control of symptoms, including BU²⁻⁵
- Long-term clinical remission[†] with continuous improvement in biomarkers^{2-5,8}
- Optimised, simple dosing scheme¹
- Consistent safety profile over 3 years^{1-5,7}

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. HCPs are asked to report any suspected adverse reactions.

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

SAFETY INFORMATION

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.^{2,5}

Ulcerative colitis

The safety of Omvoh was evaluated in three Phase 3 clinical trials. The most common adverse events (occurring in ≥5% of patients) were COVID-19, ulcerative colitis, nasopharyngitis, headache, pyrexia, and arthralgia.^{9,10}

FOOTNOTES

¹Clinical remission by CDAI: CDAI score <150.⁵

²CS-free CDAI remission: Clinical remission at Week 52 + CS-free from Weeks 40–52.⁵

³Data derived from VIVID-1 W52 endoscopic responders (N=251).⁴

⁴BU CMI: ≥3-point improvement in Urgency NRS from baseline at Week 152.⁴

⁵BU remission: Urgency NRS score ≤2 with a baseline Urgency NRS ≥3.^{3,11}

^{††}Safety data include exposure-adjusted incidence rates of MACE, malignancies, infections, and serious infections.⁴

ABBREVIATIONS

AP, abdominal pain; BU, bowel urgency; CD, Crohn's disease; CDAI, Crohn's Disease Activity Index; CMI, clinically meaningful improvement; CRP, C-reactive protein; CS, corticosteroid; fCLP, faecal calprotectin; HCP, healthcare professional; IBD, inflammatory bowel disease; IV, intravenous; MACE, major adverse cardiovascular event; NR, non-responder; NRS, Numeric Rating Scale; PBO, placebo; PRO, patient-reported outcome; Q4W, every 4 weeks; Q8W, every 8 weeks; R, responder; SC, subcutaneous; SES-CD, Simple Endoscopic Score for Crohn's Disease; SF, stool frequency; W, week; Y, year.

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