omvoh™
mirikizumab
A Lilly Medicine

FLEXIBLE DOSING

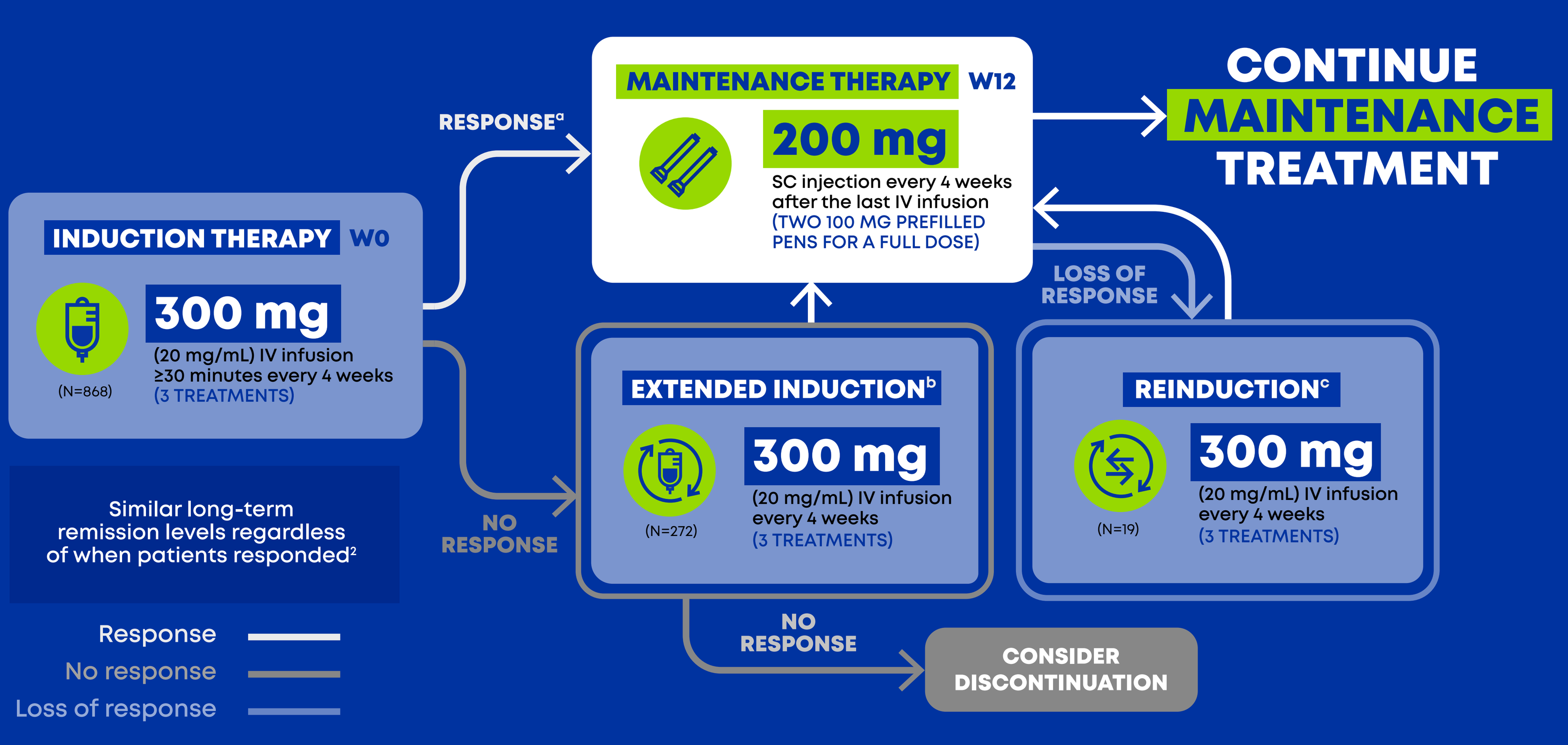
Omvoh offers in-label flexible dosing to help meet your patients' needs[1]

For patients with moderately to severely active UC, **OMVOH OFFERS IN-LABEL FLEXIBLE INDUCTION THERAPY TO HELP MORE PATIENTS ACHIEVE A RESPONSE[1-4]**

WHO MIGHT BENEFIT FROM OMVOH'S IN-LABEL FLEXIBLE DOSING?

- Patients with more severe disease[2]
- Patients with prior exposure to biologics that may impact response to subsequent treatment[3]

DOSING SCHEME[1,4]



[a]Omvoh responders in LUCENT-1=551/868 (63.5%); 544 entered LUCENT-2.[1,4]

[b]For patients who do not achieve adequate therapeutic benefit at Week 12 of induction dosing, Omvoh 300 mg by IV infusion may be continued at Weeks 12, 16, and 20 (extended induction therapy). If therapeutic benefit is achieved with the additional IV therapy, patients may initiate Omvoh subcutaneous maintenance dosing (200 mg) every 4 weeks, starting at Week 24. Omvoh should be discontinued in patients who do not show evidence of therapeutic benefit from extended induction therapy by Week 24.[1]

[c]Patients with loss of therapeutic response during maintenance treatment may receive Omvoh 300 mg by IV infusion every 4 weeks for a total of 3 doses (reinduction). If clinical benefit is achieved from this additional IV therapy, patients may resume Omvoh SC dosing every 4 weeks. The efficacy and safety of repeated reinduction therapy have not been evaluated.[1]

EXTENDED INDUCTION WITH OMVOH[1]

Some patients may need extended induction therapy following initial induction to achieve clinical response.[1,†] If patients have not yet reached clinical response after 12 weeks of Omvoh, Omvoh can be continued for an additional 12 weeks (a total of 24 weeks of Omvoh).[1]

8 IN 10 Omvoh-treated patients achieved **CLINICAL RESPONSE following induction[4]**

RESULTS

CLINICAL RESPONSE after extended induction at Week 24 (total population)[4,†]

Clinical RESPONSE at WEEK 12

INDUCTION
Induction population (N=551/868)

63.5%

Over **50%** of Week 12 induction non-responders achieved **CLINICAL RESPONSE at Week 24** after 12 weeks of extended induction[4]

Clinical RESPONSE at WEEK 24

EXTENDED INDUCTION (N=272)

80.3%

Total population (N=697/868)

Over **70%** of induction non-responders achieved **SYMPTOMATIC RESPONSE[4,†]** after extended induction

Over **50%** of induction non-responders achieved clinically meaningful **IMPROVEMENT IN BOWEL URGENCY[†]** after extended induction[4]

Baseline characteristics of Week 12 induction non-responders showed **numerically higher numbers of pancolitis, more severe endoscopic disease, and prior biologic or tofacitinib failure.[4]**

Therefore, extended induction can be useful for patients who have:
1. More severe disease at baseline[4] **2.** Prior exposure to biologics, which can influence subsequent treatments.[3]

REINDUCTION TREATMENT WITH OMVOH

If a patient loses response during maintenance therapy, reinduction therapy may help them regain response.[1,2]

Over **60%** of patients who showed loss of response to treatment achieved **SYMPTOMATIC RESPONSE[4,†]** after reinduction

Over **35%** of patients achieved **SYMPTOMATIC REMISSION[†]** after reinduction[4]

KEY TAKEAWAYS

Omvoh offers:

EXTENDED INDUCTION
In-label flexible dosing with Omvoh offers patients with moderately to severely active UC another opportunity to achieve[1,4-7]:

- Clinical response[4,†]
- Symptomatic response[4,†]
- Clinically meaningful improvement in bowel urgency[4,†]
- Consistent safety profile with no new safety signals up to 4 years[5-7]

INDICATIONS
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]

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]

SAFETY INFORMATION
Ulcerativecolitis
The safety of Omvoh was evaluated in three Phase 3 trials. The most common adverse events (occurring in ≥5% of patients) were COVID-19, ulcerative colitis, nasopharyngitis, headache, pyrexia, and arthralgia.[5,7]

Crohn'sdisease
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.[8,9]

Please refer to the Omvoh SmPC for the complete adverse event profile.[1]

FOOTNOTES
†**Clinical response:** ≥2-point and ≥30% decrease in MMS from baseline; RB=0 or 1 or, RB ≥1-point decrease from baseline; **Symptomatic response**: At least a 30% decrease from baseline in the composite clinical endpoint of the sum of SF and RB subscores; **Bowel urgency CMI:** Change from baseline in urgency NRS ≥3, in patients with urgency NRS ≥3 at induction baseline; **Symptomatic remission:** SF=0 or SF=1 with ≥1-point decrease in MMS from baseline; RB=0.[4]

ABBREVIATIONS
CMI, clinically meaningful improvement; **COVID-19,** coronavirus disease of 2019; **HCP,** healthcare professional; **IV,** intravenous; **MMS,** modified Mayo score; **NRS,** numeric rating scale; **RB,** rectal bleeding; **SC,** subcutaneous; **SF,** stool frequency; **SmPC,** Summary of Product Characteristics; **UC,** ulcerative colitis; **W,** week.

REFERENCES

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