

Deep Remission in Guselkumab-Treated Participants With Moderately to Severely Active Crohn's Disease Through 3 Years: Results From the GALAXI 2 & 3 Studies

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Background

Crohn's disease (CD) treatment goals have evolved from managing symptoms to achieving clinical remission and endoscopic healing¹

Guselkumab is a dual-acting IL-23p19 subunit inhibitor that potentially blocks IL-23 and binds to CD64, a receptor on cells that produce IL-23²

The Phase 3 GALAXI 2 & 3 studies evaluated guselkumab in participants with moderately to severely active Crohn's disease

Objective

To assess achievement of deep remission and other outcomes in guselkumab-treated participants from the pooled GALAXI 2/3 studies through Week 144

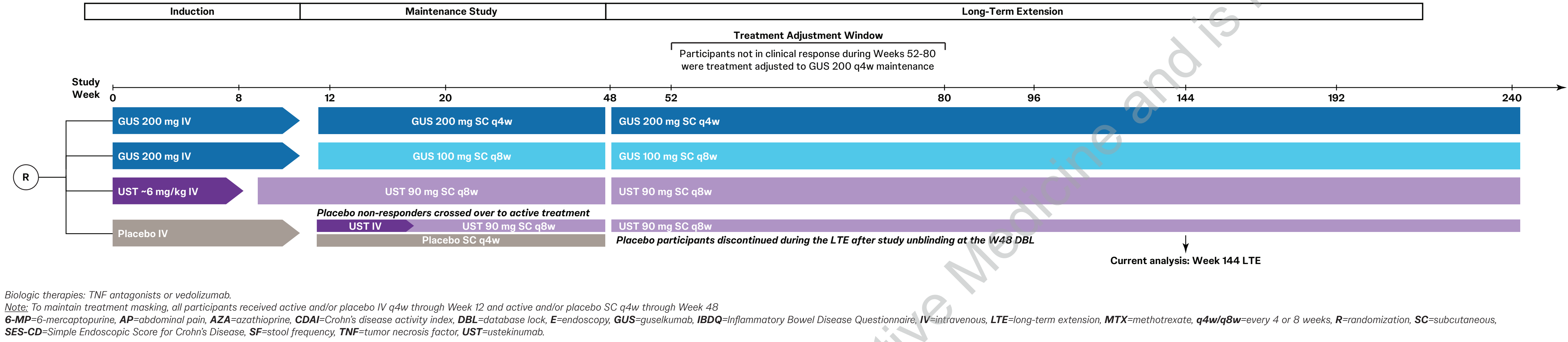
Methods

- A total of 582 participants received guselkumab in the pooled GALAXI 2/3 studies
- At Week 48, participants benefiting from study treatment (per the investigator) entered the long-term extension
- All participants with an inadequate response (not in clinical response and CDAI ≥ 220) from Weeks 52-80 could dose adjust once to guselkumab 200 mg every 4 weeks
- Deep remission (clinical remission [CDAI ≤ 150] AND endoscopic remission [SES-CD ≤ 4 and ≥ 2 -point reduction from Week 0 and no subscore >1] was evaluated in the overall, bionaive, and BIO-IR (inadequate response or intolerance to biologic therapies) populations at Weeks 48, 96, and 144
- IBDQ remission (IBDQ score ≥ 170), CD-related hospitalizations and/or surgeries rates, and dose adjustment were also assessed

Key eligibility criteria

- Moderately to severely active Crohn's disease: CDAI score 220–450 and mean daily SF count >3 or AP score >1 and SES-CD score ≥ 6 (or ≥ 4 for isolated ileal disease)
- Inadequate response/intolerance to oral corticosteroids or 6-MP/AZA/MTX, or biologic therapies or naïve to biologics

Figure 1. Identically-Designed, Double-Blind, Treat-Through Studies: GALAXI 2 & 3



Results

- Baseline demographics and disease characteristics were generally similar among groups (Table 1)

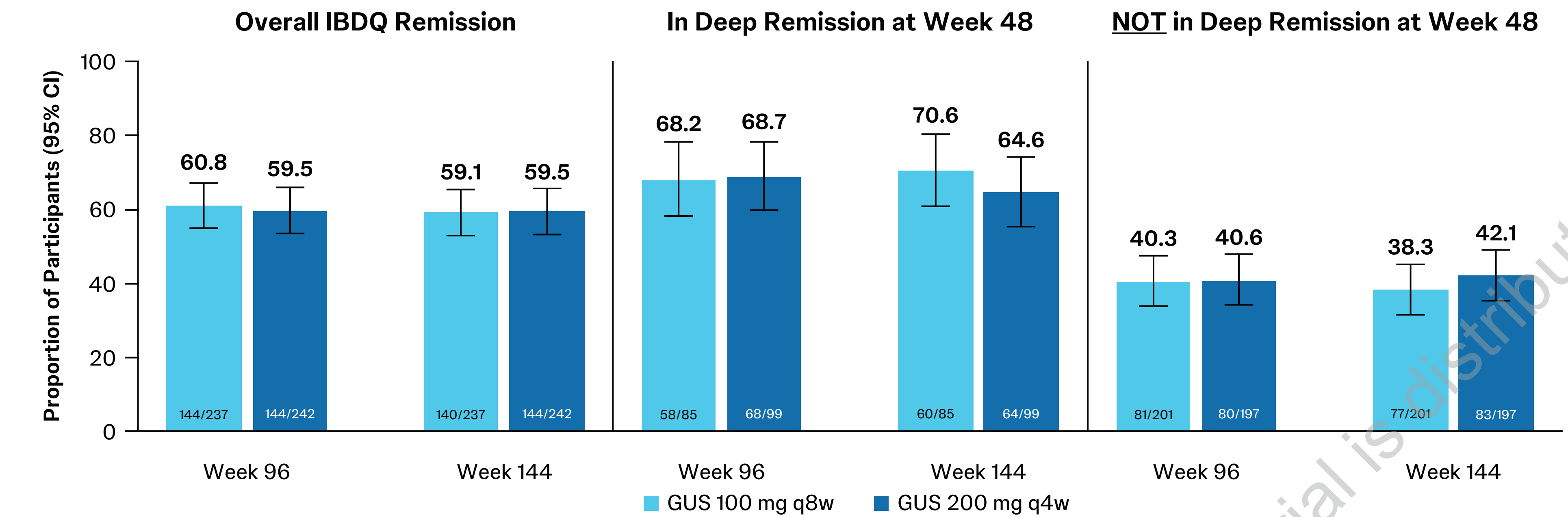
LTE Efficacy Analysis Set

	GUS 100 mg SC q8w*	GUS 200 mg SC q4w*	GUS Combined
Primary analysis set, N	251	256	507
Demographics			
Age in years, mean (SD)	35.8 (12.17)	36.6 (13.14)	36.2 (12.66)
Men, n (%)	141 (56.2%)	158 (61.7%)	299 (59.0%)
CD duration in years, mean (SD)	7.00 (6.44)	6.67 (6.60)	6.83 (6.52)
Characteristics, mean (SD)			
CDAI score	293.5 (53.47)	295.2 (53.28)	294.3 (53.33)
SES-CD	13.1 (7.54)	12.7 (7.38)	12.9 (7.46)
IBDQ score	126.8 (32.31)	128.6 (29.80)	127.7 (31.06)
Biomarkers, mean (SD)			
CRP, mg/L	16.0 (21.63)	15.8 (21.92)	15.9 (21.76)
Fecal calprotectin, µg/mL	1614.3 (1982.97)	1745.8 (3134.80)	1680.8 (2627.83)
Involved GI areas (as assessed by central reader), n (%)			
Ileum only	49 (19.5%)	66 (25.8%)	115 (22.7%)
Colon only	99 (39.4%)	98 (38.3%)	197 (38.9%)
Ileum and colon	103 (41.0%)	92 (35.9%)	195 (38.5%)

*Treatment group at the start of the LTE period. CD=Crohn's disease. CDAI=Crohn's Disease Activity Index. CRP=C-reactive protein. GI=gastrointestinal. GUS=guselkumab. IBDQ=Inflammatory Bowel Disease Questionnaire. IV=intravenous. LTE=long-term extension. q4w/q8w=every 4 or 8 weeks. SC=subcutaneous. SD=standard deviation. SES-CD=Simple Endoscopic Score-Crohn's Disease.

- Greater proportions of guselkumab-treated participants in deep remission at Week 48 achieved IBDQ remission at Week 96 and Week 144 vs participants not in deep remission (Figure 4)

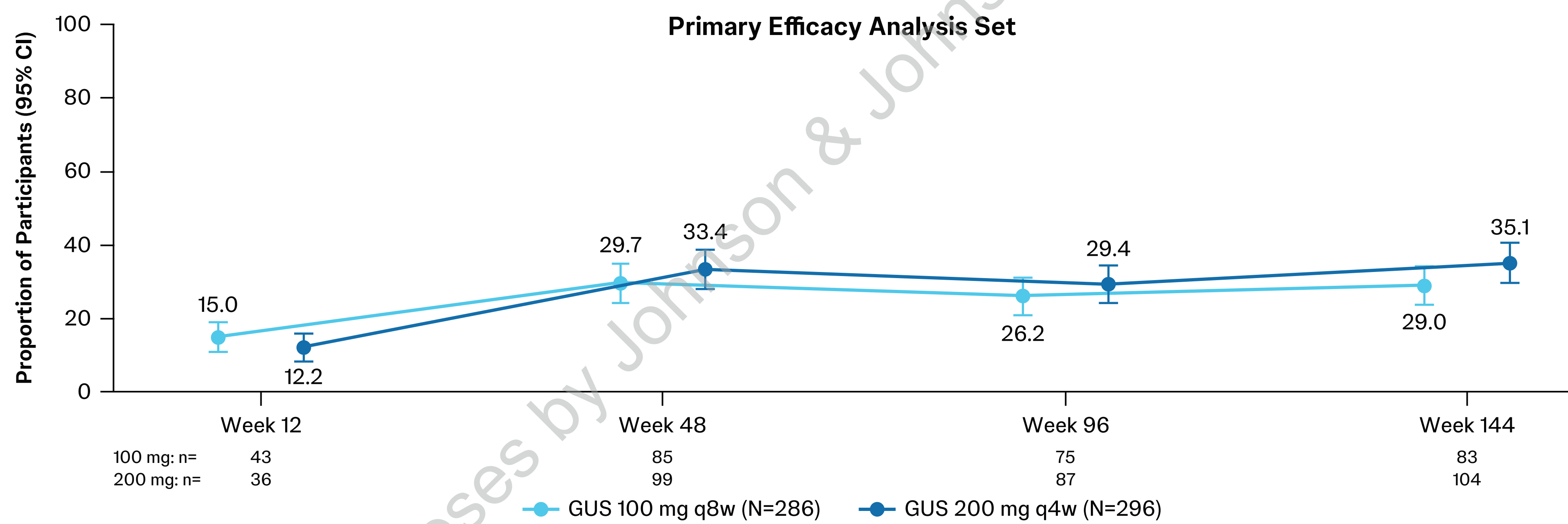
Figure 4. IBDQ Remission



IBDQ Remission: Total IBDQ score ≥ 170 .

- Deep remission was maintained in guselkumab-treated participants through Week 144 (Figure 2)

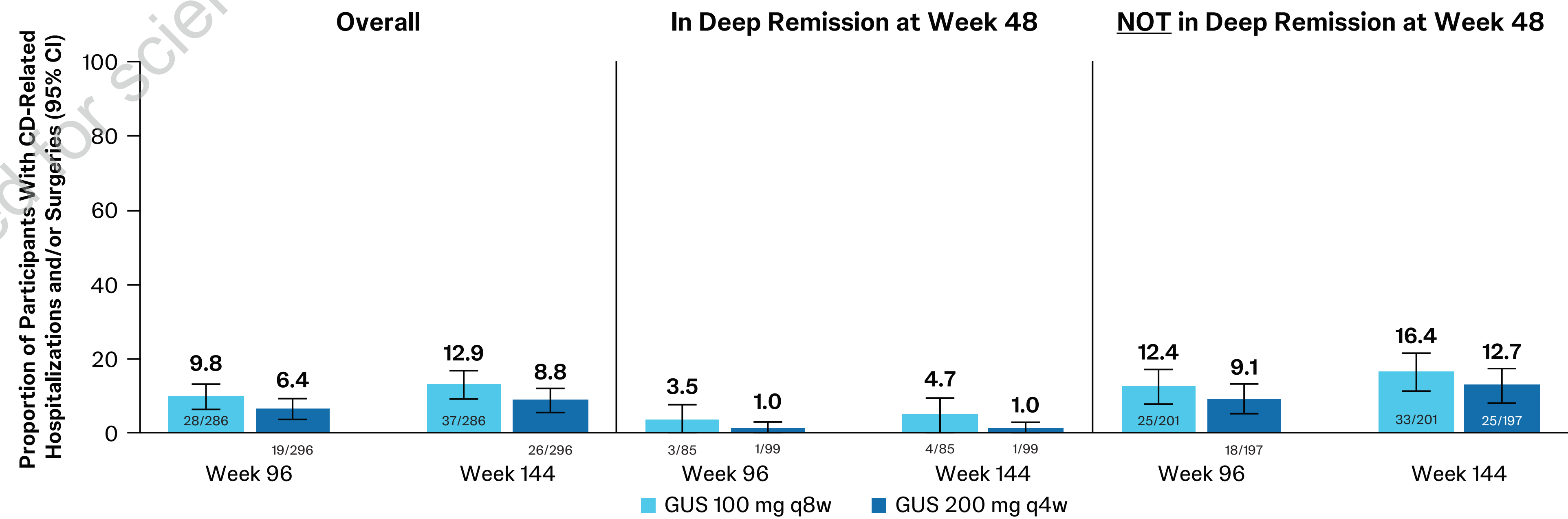
Figure 2. Deep Remission Through 3 Years



Deep remission: Composite endpoint of clinical remission (CDAI score ≤ 150) AND endoscopic remission (SES-CD score ≤ 4 and ≥ 2 -point reduction in SES-CD score and no subscore >1).

- Fewer guselkumab-treated participants in deep remission at Week 48 had CD-related hospitalizations and/or surgeries at Week 96 and Week 144 vs participants not in deep remission (Figure 5)

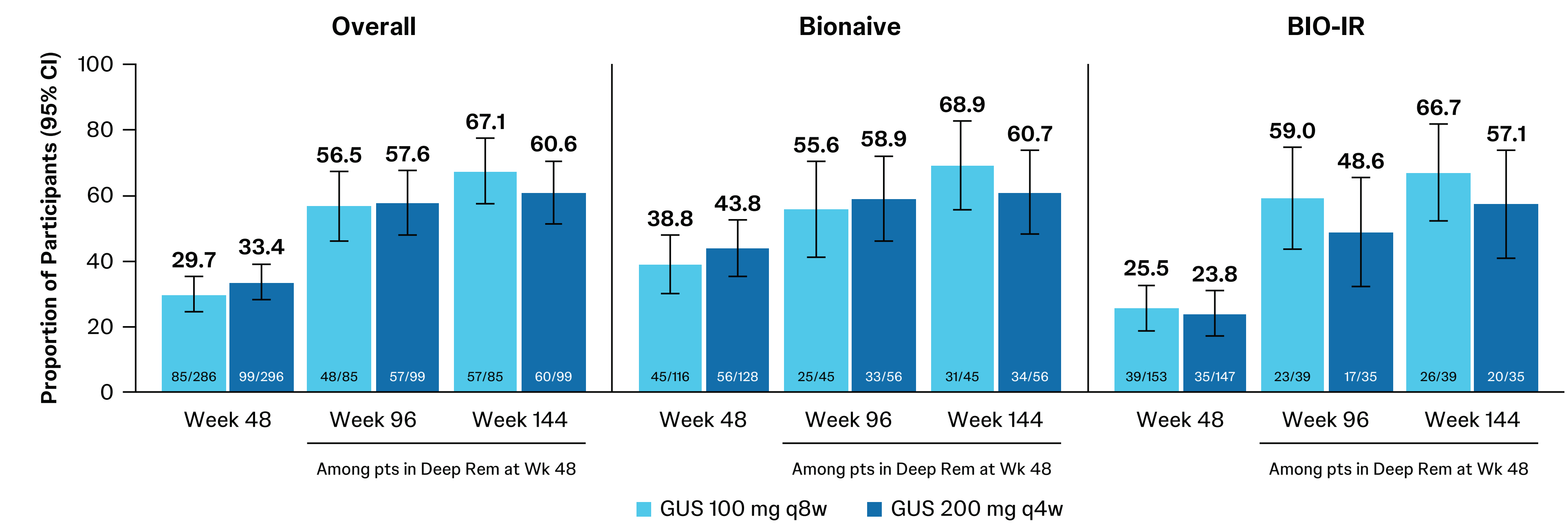
Figure 5. CD-Related Hospitalizations and/or Surgeries



Includes GUS participants in the Primary Efficacy Analysis set with a CD-related hospitalization and/or surgery.

- Among the 184 participants in deep remission at Week 48, maintenance of deep remission at Weeks 96 and 144 was similar, and also similar across subgroups (Figure 3)

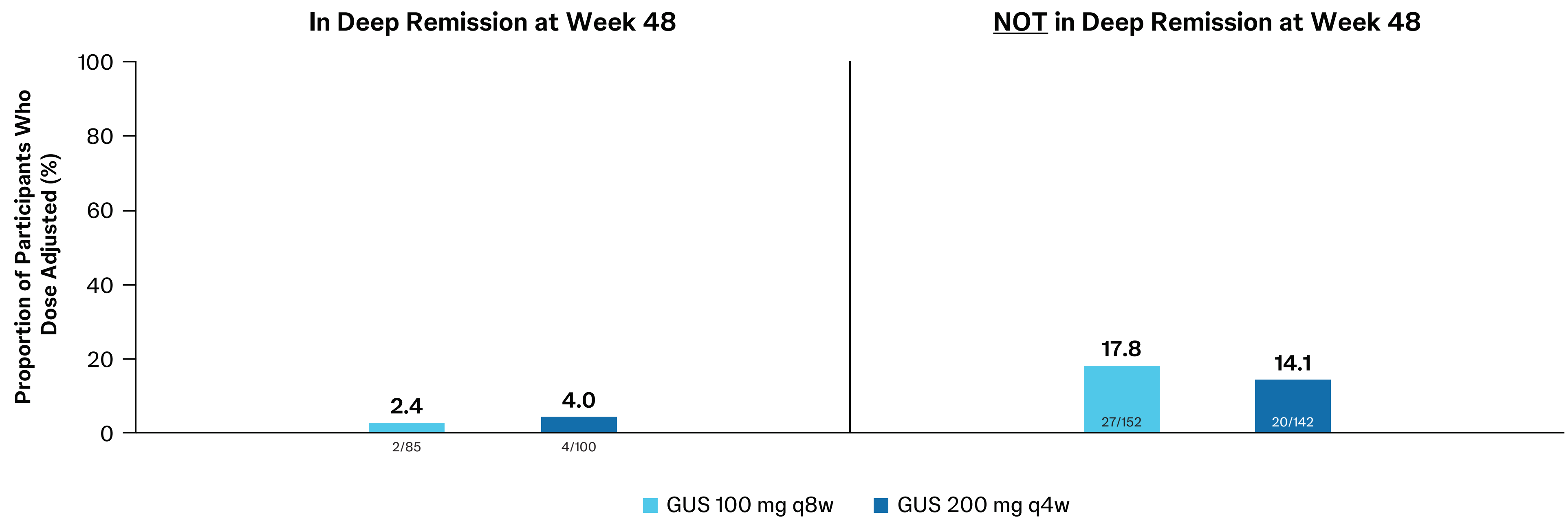
Figure 3. Deep Remission Among Participants in Deep Remission at Week 48



Pts=participants. Rem=remission. Wk=week.

- Fewer guselkumab-treated participants in deep remission at Week 48 required dose adjustment between Weeks 52-80 (Figure 6)

Figure 6. Dose Adjustment Between Weeks 52-80



Participants with an inadequate response (not in clinical response [≥ 100 -point reduction in CDAI from Week 0 or CDAI ≤ 150] AND CDAI ≥ 220) were eligible to dose adjust once to GUS 200 mg SC between Week 52 and Week 80. Overall, N=64 participants dose adjusted between weeks 52-80 (GUS 200 mg q4w from GUS 100 mg q8w [N=36] or GUS 200 mg q4w [N=28; sham dose adjustment]). Of these 64 pts, 53 were eligible for the efficacy analyses as 11 participants were excluded because they continued treatment and entered the LTE despite meeting discontinuation criteria prior to Week 48.