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Histologic and Combined Histologic and Endoscopic Outcomes After Guselkumab Maintenance Therapy in Patients With Moderately to Severely Active Ulcerative Colitis: Week 44 Results From the Phase 3 QUASAR Maintenance Study

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Key Takeaways

- In the QUASAR maintenance study, participants with ulcerative colitis receiving guselkumab SC maintenance showed clinically meaningful improvements in endoscopic and histologic outcomes compared with placebo (GUS withdrawal), including subpopulations:
  - Biologic/JAK inhibitor-naïve
  - Inadequate response or intolerance to biologics and/or JAK inhibitors
- Participants receiving guselkumab maintenance therapy showed improvement from maintenance baseline in combined histologic-endoscopic outcomes, while those who received placebo (GUS withdrawal) worsened

Background

Histologic healing is an emerging therapeutic target in ulcerative colitis (UC) and is associated with less clinical recurrence, reduced corticosteroid use, and lower hospitalization rates[1,2]

Guselkumab is a dual-acting IL-23p19 subunit inhibitor that potently neutralizes IL-23 and binds to CD64, a receptor on cells that produce IL-23[3]

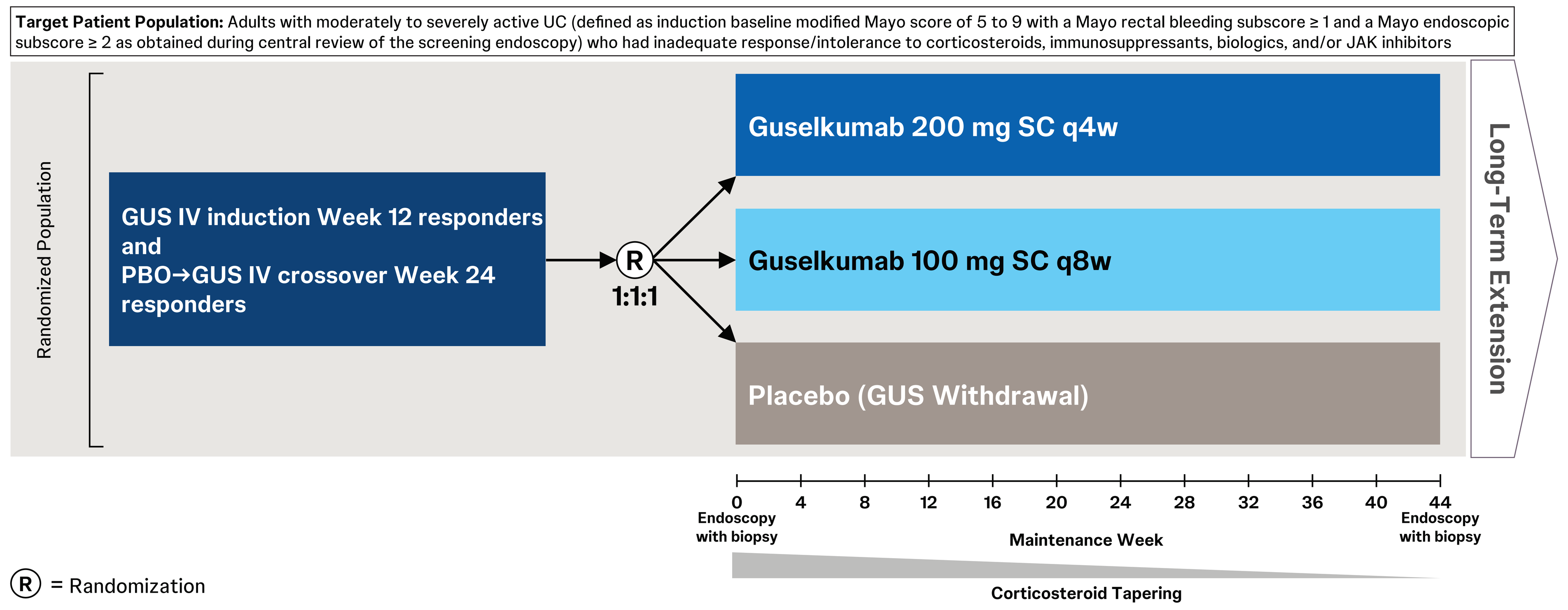
In the phase 3 QUASAR induction study (NCT04033445), participants with moderately to severely active ulcerative colitis treated with guselkumab 200 mg IV induction experienced clinically meaningful improvements in histologic and combined histologic and endoscopic outcomes at Week 12[4]

Objective

Here we report the effects of guselkumab maintenance on histologic and combined histologic and endoscopic outcomes at Week 44 among clinical responders to guselkumab IV induction

Methods

QUASAR Maintenance Study Design


Target Patient Population: Adults with moderately to severely active UC (defined as induction baseline modified Mayo score of 5 to 9 with a Mayo rectal bleeding subscore ≥ 1 and a Mayo endoscopic subscore ≥ 2 as obtained during central review of the screening endoscopy) who had inadequate response/intolerance to corticosteroids, immunosuppressants, biologics, and/or JAK inhibitors
Randomized Population
GUS IV induction Week 12 responders and PBO→GUS IV crossover Week 24 responders
R
1:1:1
Guselkumab 200 mg SC q4w
Guselkumab 100 mg SC q8w
Placebo (GUS Withdrawal)
Long-Term Extension
0 4 8 12 16 20 24 28 32 36 40 44
Endoscopy with biopsy
Maintenance Week
Endoscopy with biopsy
Corticosteroid Tapering
R = Randomization

Outcomes Evaluated

- **Histologic improvement:** Neutrophil infiltration in <5% of crypts, no crypt destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system (ie, Geboes histologic score ≤3.1)
- **Histologic remission:** Absence of neutrophils from the mucosa [both lamina propria and epithelium], no crypt destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system (ie, Geboes histologic score ≤2 B.0)
- **Histo-endoscopic mucosal improvement:** Geboes histologic score ≤3.1 and Mayo endoscopy subscore of 0 or 1 with no friability
- **Histologic remission and endoscopic improvement:** Geboes histologic score ≤2 B.0 and Mayo endoscopy subscore of 0 or 1 with no friability
- **Histo-endoscopic mucosal remission:** Geboes histologic score ≤2 B.0 and Mayo endoscopy subscore of 0

Statistical Analysis and Data Handling

- The randomized full analysis set included all randomized patients in maintenance with a modified Mayo score of 5-9 at induction baseline who received at least 1 maintenance study treatment dose
- Patients who had a prohibited change in UC medication, an ostomy or colectomy, a dose adjustment (including sham dose adjustment), discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC, or due to other reasons except for COVID-19 related reasons (excluding COVID-19 infection) or regional crisis in Russia and Ukraine prior to Week 44 were considered not to have achieved the endpoint.
- Patients who had an unevaluable biopsy (ie, a biopsy that was collected, but could not be assessed due to sample preparation or technical errors) or were missing the endoscopy subscore (if applicable) or any of the histology components pertaining to an endpoint at Week 44 were considered not to have achieved the endpoint.

Results

Demographics, disease characteristics, and Crohn's disease medication history were similar across treatment groups at induction baseline

Table 1. Demographics, Disease Characteristics, and Medication History at Induction Baseline

Randomized full analysis set	Placebo (GUS withdrawal) (N=190)	Guselkumab 100 mg SC q8w (N=188)	Guselkumab 200 mg SC q4w (N=190)
Demographics			
Age in years, mean (SD)	41.2 (13.58)	40.3 (13.00)	40.6 (14.66)
Male, n (%)	109 (57.4%)	102 (54.3%)	100 (52.6%)
Characteristics			
UC disease duration in years, mean (SD)	7.3 (6.34)	7.8 (8.46)	8.4 (8.40)
Modified Mayo score[a] (0-9), mean (SD)	7.0 (1.09)	6.8 (1.15)	6.9 (1.10)
Modified Mayo score of 7-9 (severe), n (%)	125 (65.8%)	114 (60.6%)	124 (65.3%)
Mayo endoscopic subscore of 3 (severe), n (%)	129 (67.9%)	125 (66.5%)	123 (64.7%)
Extensive UC, n (%)	95 (50.0%)	79 (42.0%)	83 (43.7%)
Baseline histology scores,[b] mean (SD)			
Geboes total score (GS, range 0-22)[c]	12.3 (4.16)	12.1 (4.64)	11.7 (4.80)
Robarts histopathology index (RHI, range 0-33)	17.2 (7.33)	17.1 (8.04)	16.3 (7.99)
Nancy histological index (NHI, range 0-4)	2.9 (0.97)	2.8 (1.06)	2.7 (1.19)
Medication history			
Oral corticosteroid use, n (%)	77 (40.5%)	74 (39.4%)	76 (40.0%)
History of inadequate response/intolerance to biologic and/or JAK inhibitor therapy,[d,e] n (%)	75 (39.5%)	77 (41.0%)	88 (46.3%)

Randomized Full Analysis Set: Randomized patients in maintenance with modified Mayo score 5-9 at induction baseline who received at least 1 maintenance study treatment dose. [a]Modified Mayo score: 3-component (stool frequency, rectal bleeding, and endoscopy subscores) Mayo score without the physician's global assessment. [b]Based on N=187 for placebo, N=184 for guselkumab 100 mg SC q8w, and N=188 for guselkumab 200 mg SC q4w. [c]The continuous histology score is derived as the sum of all Geboes Grades and may take on values from 0 to 22. [d]Biologic therapy included tumor necrosis factor-α antagonists and vedolizumab. [e]JAK inhibitor therapy included tofacitinib.

Similar proportions of participants across all treatment groups achieved histologic and combined histologic/endoscopic outcomes after 12 weeks of induction with guselkumab

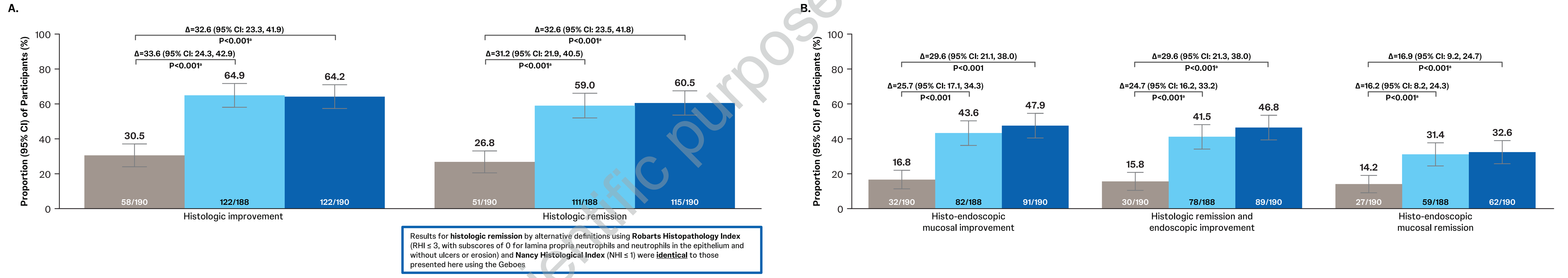
Table 2. Disease Characteristics at Maintenance Baseline

Randomized full analysis set	Placebo (GUS withdrawal) (N=190)	Guselkumab 100 mg SC q8w (N=188)	Guselkumab 200 mg SC q4w (N=190)
Histologic outcomes			
Histologic improvement,[a] n (%)	112 (58.9%)	114 (60.6%)	114 (60.0%)
Histologic remission,[b] n (%)	102 (53.7%)	104 (55.3%)	101 (53.2%)
Endoscopic outcomes			
Endoscopic improvement,[c] n (%)	68 (35.8%)	75 (39.9%)	79 (41.6%)
Endoscopic remission (normalization),[d] n (%)	39 (20.5%)	41 (21.8%)	47 (24.7%)
Combined histologic/endoscopic outcomes			
Histo-endoscopic mucosal improvement,[e] n (%)	57 (30.0%)	65 (34.6%)	67 (35.3%)
Histologic remission and endoscopic improvement, n (%)	52 (27.4%)	64 (34.0%)	63 (33.2%)
Histo-endoscopic mucosal remission,[f] n (%)	32 (16.8%)	30 (16.0%)	41 (21.6%)

Randomized Full Analysis Set: Randomized patients in maintenance with modified Mayo score 5-9 at induction baseline who received at least 1 maintenance study treatment dose. [a]Neutrophil infiltration in <5% of crypts, no crypt destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system (ie, Geboes histologic score ≤3.1). [b]Absence of neutrophils from the mucosa [both lamina propria and epithelium], no crypt destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system (ie, Geboes histologic score ≤2 B.0). [c]Mayo endoscopy subscore of 0 or 1 with no friability. [d]Mayo endoscopy subscore of 0. [e]Combination of histologic improvement and endoscopic improvement. [f]Combination of histologic remission and endoscopic remission.

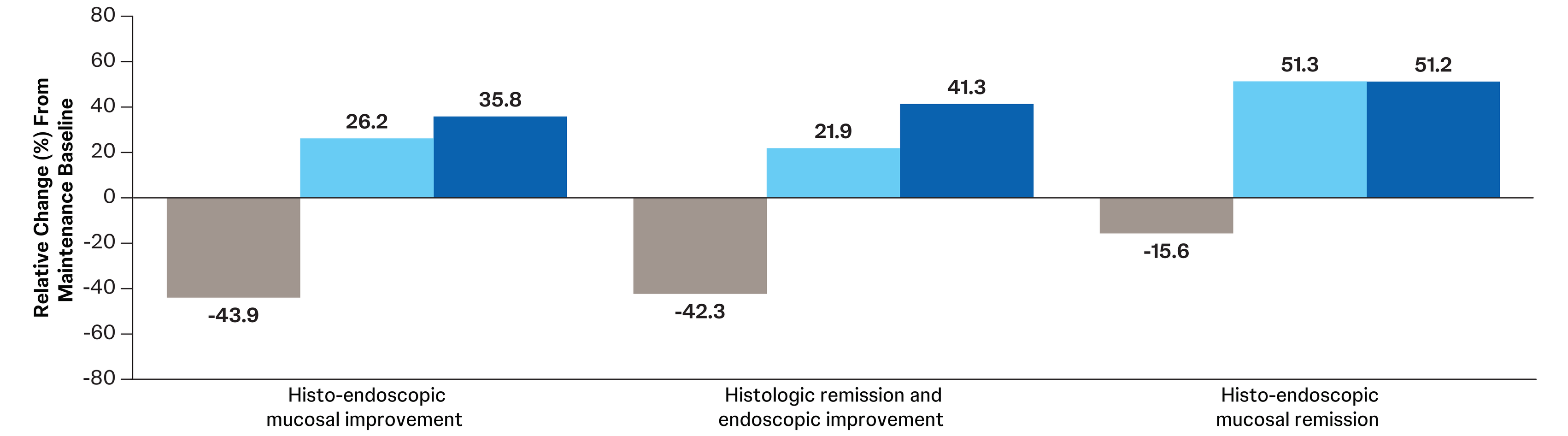
Greater proportions of participants treated with guselkumab achieved histologic and combined histologic/endoscopic outcomes at Week 44 than participants treated with placebo (guselkumab withdrawal)

Figure 1. Histologic (A) and Combined Histologic/Endoscopic (B) Outcomes at Week 44


A.
Proportion (95% CI) of Participants (%)
Δ=32.6 (95% CI: 23.3, 41.9)
P<0.001[a]
Δ=33.6 (95% CI: 24.3, 42.9)
P<0.001[a]
30.5
64.9
64.2
58/190
122/188
122/190
Histologic improvement
Δ=32.6 (95% CI: 23.5, 41.8)
P<0.001[a]
Δ=31.2 (95% CI: 21.9, 40.5)
P<0.001[a]
26.8
59.0
60.5
51/190
111/188
115/190
Histologic remission
Results for histologic remission by alternative definitions using Robarts Histopathology Index (RHI ≤ 3, with subscores of 0 for lamina propria neutrophils and neutrophils in the epithelium and without ulcers or erosion) and Nancy Histological Index (NHI ≤ 1) were identical to those presented here using the Geboes
B.
Δ=29.6 (95% CI: 21.1, 38.0)
P<0.001
Δ=25.7 (95% CI: 17.1, 34.3)
P<0.001
16.8
43.6
47.9
32/190
82/188
91/190
Histo-endoscopic mucosal improvement
Δ=29.6 (95% CI: 21.3, 38.0)
P<0.001[a]
Δ=24.7 (95% CI: 16.2, 33.2)
P<0.001[a]
15.8
41.5
46.8
30/190
78/188
89/190
Histologic remission and endoscopic improvement
Δ=16.9 (95% CI: 9.2, 24.7)
P<0.001[a]
Δ=16.2 (95% CI: 8.2, 24.3)
P<0.001[a]
14.2
31.4
32.6
27/190
59/188
62/190
Histo-endoscopic mucosal remission

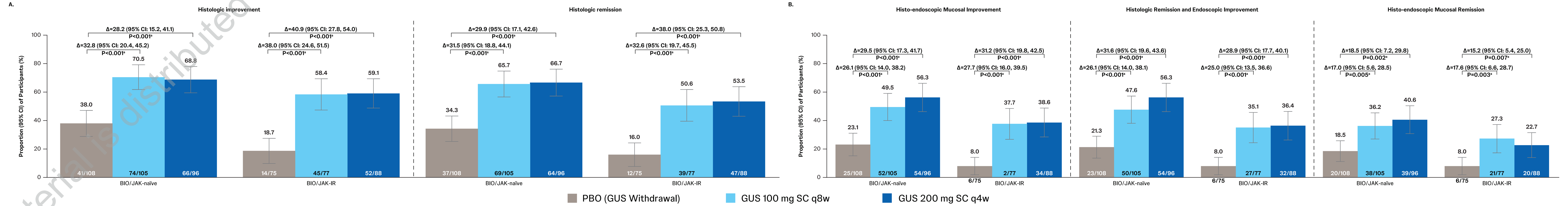
The proportions of participants achieving combined histologic/endoscopic outcomes increased from maintenance baseline to Week 44 for participants randomized to guselkumab at maintenance baseline, while participants randomized to placebo (guselkumab withdrawal) decreased

Figure 3. Relative Change in Combined Histologic/Endoscopic Outcomes From Week M-0 to Week 44



Regardless of previous biologic/JAK inhibitor history, participants treated with guselkumab achieved higher proportions of both histologic and combined histologic/endoscopic outcomes at Week 44 than participants treated with placebo (guselkumab withdrawal)

Figure 2. Histologic (A) and Combined Histologic/Endoscopic (B) Outcomes at Week 44 by BIO/JAK Inhibitor History


A.
Histologic improvement
Histologic remission
Proportion (95% CI) of Participants (%)
Δ=28.2 (95% CI: 15.2, 41.1)
P<0.001[a]
Δ=32.8 (95% CI: 20.4, 45.2)
P<0.001[a]
38.0
70.5
68.8
41/108
74/105
66/96
BIO/JAK-naïve
Δ=40.9 (95% CI: 27.8, 54.0)
P<0.001[a]
Δ=38.0 (95% CI: 24.6, 51.5)
P<0.001[a]
18.7
58.4
59.1
14/75
45/77
52/88
BIO/JAK-IR
Δ=29.9 (95% CI: 17.1, 42.6)
P<0.001[a]
Δ=31.5 (95% CI: 18.8, 44.1)
P<0.001[a]
34.3
65.7
66.7
37/108
69/105
64/96
BIO/JAK-naïve
Δ=38.0 (95% CI: 25.3, 50.8)
P<0.001[a]
Δ=32.6 (95% CI: 19.7, 45.5)
P<0.001[a]
16.0
50.6
53.5
12/75
39/77
47/88
BIO/JAK-IR
B.
Histo-endoscopic Mucosal Improvement
Histologic Remission and Endoscopic Improvement
Histo-endoscopic Mucosal Remission
Δ=29.5 (95% CI: 17.3, 41.7)
P<0.001[a]
Δ=26.1 (95% CI: 14.0, 38.2)
P<0.001[a]
23.1
49.5
56.3
25/108
52/105
54/96
BIO/JAK-naïve
Δ=31.2 (95% CI: 19.8, 42.5)
P<0.001[a]
Δ=27.7 (95% CI: 16.0, 39.5)
P<0.001[a]
8.0
37.7
38.6
6/75
2/77
34/88
BIO/JAK-IR
Δ=31.6 (95% CI: 19.6, 43.6)
P<0.001[a]
Δ=26.1 (95% CI: 14.0, 38.1)
P<0.001[a]
21.3
47.6
56.3
23/108
50/105
54/96
BIO/JAK-naïve
Δ=28.9 (95% CI: 17.7, 40.1)
P<0.001[a]
Δ=25.0 (95% CI: 13.5, 36.6)
P<0.001[a]
8.0
35.1
36.4
6/75
27/77
32/88
BIO/JAK-IR
Δ=18.5 (95% CI: 7.2, 29.8)
P=0.002[a]
Δ=17.0 (95% CI: 5.6, 28.5)
P=0.005[a]
18.5
36.2
40.6
20/108
38/105
39/96
BIO/JAK-naïve
Δ=15.2 (95% CI: 5.4, 25.0)
P=0.007[a]
Δ=17.6 (95% CI: 6.6, 28.7)
P=0.003[a]
8.0
27.3
22.7
6/75
21/77
20/88
BIO/JAK-IR
PBO (GUS Withdrawal)
GUS 100 mg SC q8w
GUS 200 mg SC q4w

Note: The adjusted treatment difference and confidence intervals were based on the Wald statistic with Cochran-Mantel-Haenszel (CMH) weight. The p-values were based on the CMH chi-square test, stratified by clinical remission status at maintenance baseline (Yes/No), and induction treatment (guselkumab 400 mg IV, guselkumab 200 mg IV, placebo IV crossover to guselkumab 200 mg IV). [a]Nominal p-value. **BIO/JAK**=biologic and/or JAK inhibitor. **IR**=history of inadequate response or intolerance.

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