

Effect of Guselkumab Subcutaneous Induction and Maintenance on Bowel Urgency and Abdominal Pain as Measured by the UC-PRO/SS in Participants With Moderately to Severely Active Ulcerative Colitis: Results From the Phase 3 ASTRO Study

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Background

Guselkumab (GUS) is a selective dual-acting interleukin (IL)-23p19 subunit inhibitor that potently blocks IL-23 and binds to CD64, a receptor on cells that produce IL-23¹

Ulcerative colitis (UC) is a chronic inflammatory bowel disease (IBD); common bowel related symptoms include abdominal pain and cramping, diarrhea, rectal bleeding, and a feeling of urgency to defecate

GUS was recently approved to treat moderately to severely active UC and Crohn's disease

The Phase 3 ASTRO study (NCT05528510) evaluated the efficacy and safety of GUS subcutaneous (SC) induction and maintenance in participants with moderately to severely active UC

Objective

To evaluate bowel-related symptoms in participants with UC in the ASTRO study receiving GUS compared to placebo (PBO) through Week (W)24 via a validated instrument, the Ulcerative Colitis Patient-Reported Outcomes Signs and Symptoms instrument (UC-PRO/SS)²

Methods

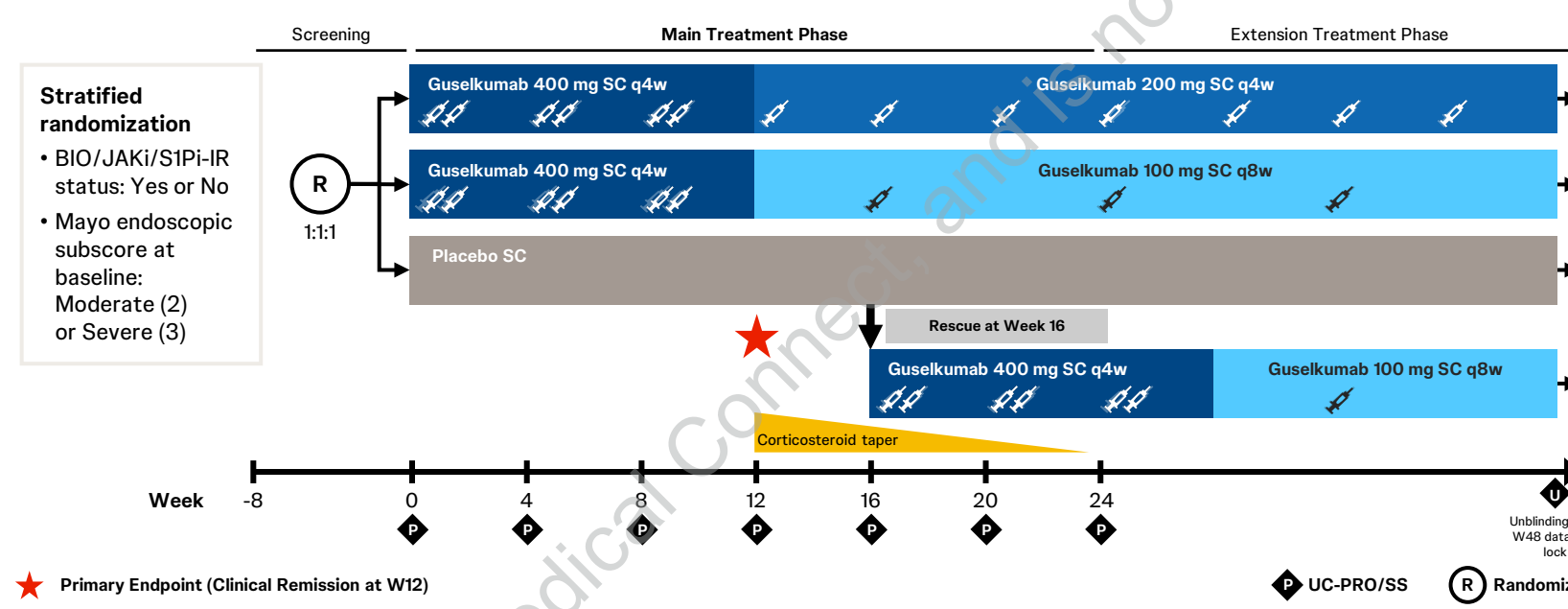
Statistical Considerations

- The prespecified analysis plan compared the combined GUS 400 mg SC group to PBO at W12 (both the GUS 100 mg every 8 weeks [q8w] and 200 mg every 4 weeks [q4w] groups received the same induction dosing regimen through W12) and each GUS group to PBO at W24
- Participants who, prior to the designated timepoint, had an ostomy or colectomy, a prohibited change in UC medications, met rescue criteria, or discontinued study intervention due to reasons other than COVID-19 or regional crisis had their baseline value carried forward from the time of the event onward or were considered not to have met the dichotomous endpoint
- The W16 rescue criteria were:
 - No improvement in Mayo endoscopic subscore at W12 compared with baseline AND
 - <2 point improvement in partial Mayo score at W12 and W16 compared with baseline
- Participants randomized to GUS who met rescue criteria at W16 continued their assigned treatment regimen and received blinded sham rescue with matching PBO SC injections at W16, W20, and W24. Rescue criteria were applied at W16 only
- Mean change and clinically meaningful improvement (CMI) from baseline in bowel symptom domain (≥5.0) and abdominal symptom domain (≥1.5), and complete resolution of symptoms of urgency and abdominal pain (score of 0) from UC-PRO/SS were compared between GUS and PBO groups
- Statistical significance was defined as follows: *nominal p-value <0.05 GUS vs PBO; **nominal p-value <0.01 GUS vs PBO; ***nominal p-value <0.001 GUS vs PBO

Phase 3, Randomized, Double-blind, Placebo-controlled, Treat-through Design: ASTRO

Key Eligibility Criteria:

- Baseline (W0) modified Mayo score of 5 to 9
- Baseline Mayo rectal bleeding subscore ≥ 1, Mayo endoscopic subscore ≥ 2 (centrally reviewed)
- Inadequate response/intolerance (IR) to tumor necrosis factor alpha (TNF α) blockers, vedolizumab, Janus Kinase (JAK) inhibitors (i), or Sphingosine-1-phosphate (S1P) inhibitors (biologics [BIO]/JAKi/S1Pi-IR) OR naïve to BIO/JAKi/S1Pi (or exposed to BIO/JAKi/S1Pi without IR) and IR to corticosteroids, mercaptopurine (6-MP), or azathioprine (AZA)



Results

Demographics and baseline disease characteristics

	Placebo	GUS 400 mg SC → 100 mg SC q8w	GUS 400 mg SC → 200 mg SC q4w	GUS 400 mg SC combined
Full analysis set, N	139	139	140	279
Age in years, mean (SD)	39.5 (13.6)	42.1 (14.6)	43.6 (14.3)	42.9 (14.4)
Male, n (%)	90 (64.7)	79 (56.8)	87 (62.1)	166 (59.5)
UC disease duration in years, mean (SD)	6.6 (6.2)	8.4 (7.3)	7.7 (6.4)	8.0 (6.8)
Modified Mayo score ^a (0-9), mean (SD)	6.8 (1.1) ^b	6.8 (1.2)	6.6 (1.2)	6.7 (1.2)
Modified Mayo score of 7-9 (severe), n (%)	87 (63.0) ^b	95 (68.3)	77 (55.0)	172 (61.6)
Mayo endoscopic subscore of 3 (severe), n (%)	78 (56.1)	78 (56.1)	78 (55.7)	156 (55.9)
Extensive UC, n (%)	73 (52.5)	69 (49.6)	82 (58.6)	151 (54.1)
C-reactive protein, ^c median in mg/L (IQR)	3.8 (1.2; 10.9)	3.7 (1.3; 7.2)	4.7 (1.7; 9.1)	4.1 (1.5; 8.2)
C-reactive protein ^e >3 mg/L, n (%)	77 (55.8)	75 (55.1)	86 (61.4)	161 (58.3)
Fecal calprotectin, ^d median in mg/kg (IQR)	1749.0 (617.0; 3202.0)	1351.5 (609.0; 2805.0)	1594.0 (838.0; 3336.0)	1494.5 (678.0; 2963.0)
Fecal calprotectin ^d >250 mg/kg, n (%)	119 (90.8)	107 (84.9)	119 (93.0)	226 (89.0)

UC-related medication history and baseline UC medications

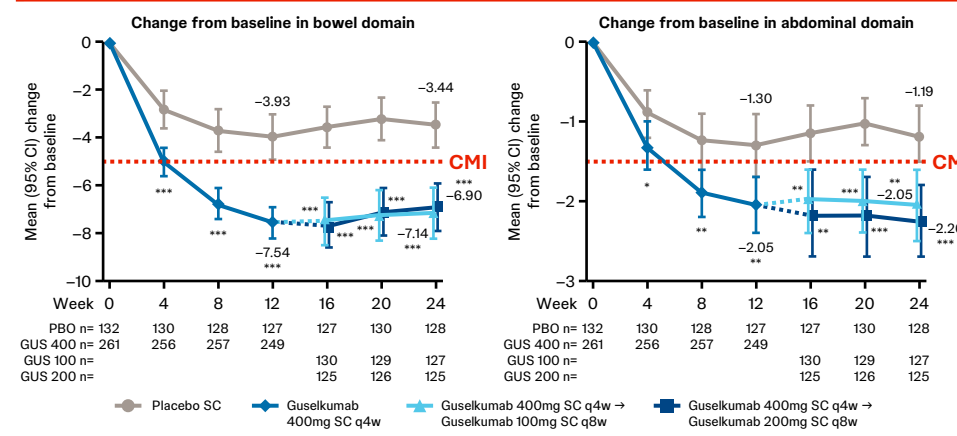
	Placebo	GUS 400 mg SC → 100 mg SC q8w	GUS 400 mg SC → 200 mg SC q4w	GUS 400 mg SC combined
Full analysis set, N	139	139	140	279
Naïve to BIO/JAKi/S1Pi, n (%)	79 (56.8)	81 (58.3)	83 (59.3)	164 (58.8)
BIO/JAKi/S1Pi-IR, n (%)	56 (40.3)	57 (41.0)	55 (39.3)	112 (40.1)
At least one anti-TNF ^a (regardless of other BIO/JAKi/S1Pi)	39 (69.6)	42 (73.7)	46 (83.6)	88 (78.6)
Vedolizumab ^b (regardless of other BIO/JAKi/S1Pi)	25 (44.6)	30 (52.6)	19 (34.5)	49 (43.8)
JAK inhibitors ^c (regardless of other BIO/S1Pi)	11 (19.6)	9 (15.8)	10 (18.2)	19 (17.0)
S1P inhibitors ^d (regardless of other BIO/JAKi)	2 (3.6)	0	3 (5.5)	3 (2.7)
History of IR or dependence on corticosteroids, n (%)	104 (74.8)	108 (77.7)	100 (71.4)	208 (74.6)
History of IR to 6-MP or AZA, n (%)	56 (40.3)	50 (36.0)	58 (41.4)	108 (38.7)
Baseline oral corticosteroid use, n (%)	46 (33.1)	50 (36.0)	41 (29.3)	91 (32.6)
Baseline use of 6-MP, AZA, or MTX, n (%)	28 (20.1)	26 (18.7)	30 (21.4)	56 (20.1)

Baseline mean UC-PRO/SS domain and symptom scores

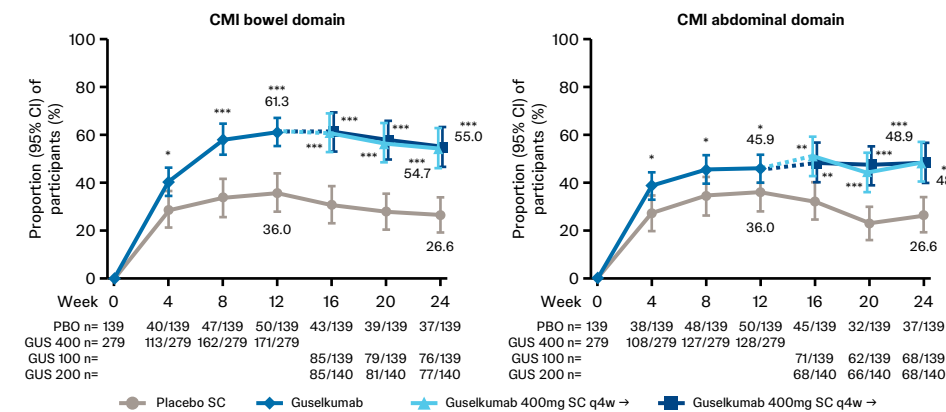
	Placebo	GUS 400 mg SC → 100 mg SC q8w	GUS 400 mg SC → 200 mg SC q4w	GUS 400 mg SC combined
Bowel domain score ^a , range 0-27, mean (SD)	13.2 (4.4)	13.1 (4.3)	13.1 (4.1)	13.1 (4.2)
Abdominal domain score ^a , range 0-12, mean (SD)	5.2 (2.5)	5.3 (2.5)	5.1 (2.5)	5.2 (2.5)
Bowel urgency score, range 0-4, mean (SD)	2.3 (1.1)	2.2 (1.1)	2.3 (1.0)	2.2 (1.1)
Abdominal pain score, range 0-4, mean (SD)	1.7 (1.1)	1.8 (1.1)	1.6 (1.1)	1.7 (1.1)

^a Bowel signs and symptoms domain score is defined as the weekly average of UC-PRO/SS item scores 1-5 and 7 over 7 days. ^b The abdominal (i.e., functional symptoms) domain score is defined as the weekly average of UC-PRO/SS item scores 6, 8 and 9 over 7 days.

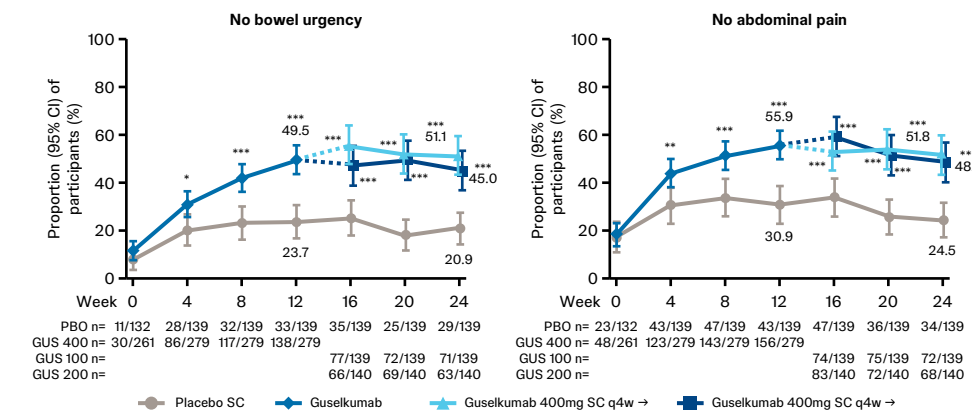
GUS-treated participants achieved greater improvements from baseline in UC-PRO/SS domain scores through W24 compared with PBO



Greater proportions of GUS-treated participants achieved clinically meaningful improvements from baseline in UC-PRO/SS domain scores through W24 compared with PBO

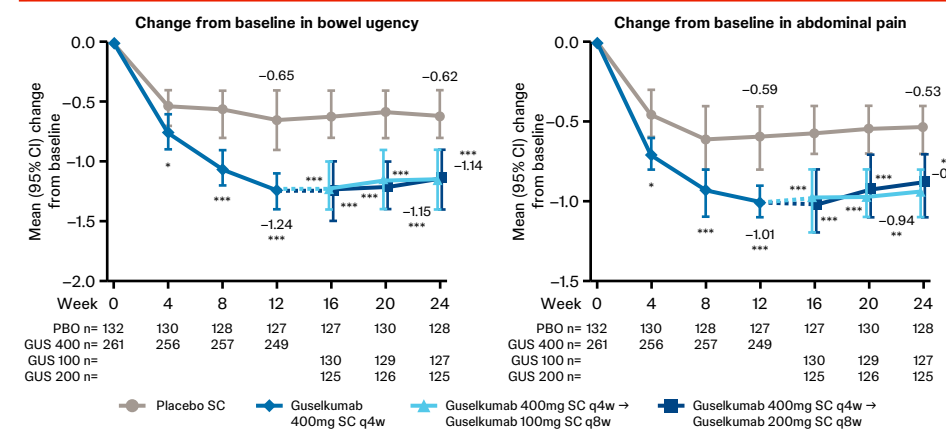


Proportions of GUS-treated participants without UC related symptoms increased through W24 compared with PBO

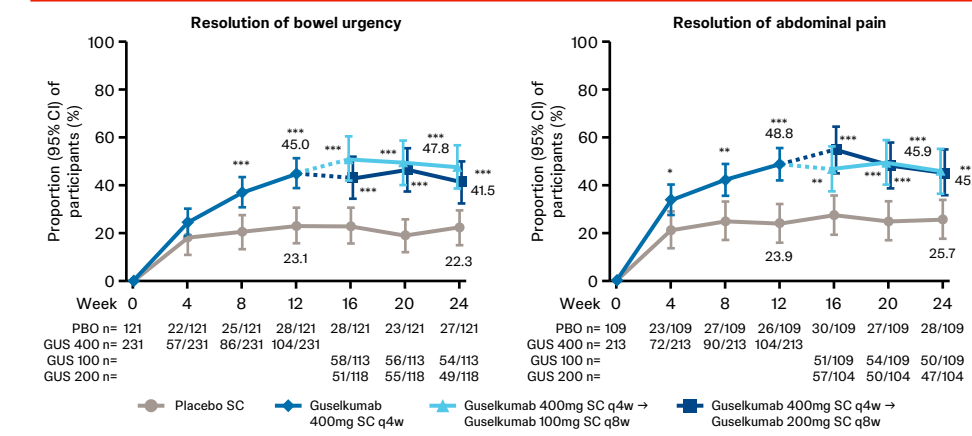


No bowel urgency is defined as the rounded weekly average UC-PRO/SS item 7 score = 0 over eligible days within 7 days prior to the designated timepoint. UC-PRO/SS Question 7: In the past 24 hours, did you feel the need to have a bowel movement right away? No abdominal pain is defined as the rounded weekly average UC-PRO/SS item 8 score = 0 over eligible days within 7 days prior to the designated timepoint. UC-PRO/SS Question 8: In the past 24 hours, did you feel pain in your belly?

GUS-treated participants achieved greater improvements from baseline in UC-PRO/SS symptom scores through W24 compared with PBO



Greater proportions of GUS-treated participants with UC symptoms at baseline achieved resolution of UC symptoms through W24 compared with PBO



Resolution of bowel urgency is defined as no bowel urgency (the rounded weekly average UC-PRO/SS item 7 score = 0 over eligible days within 7 days prior to the designated timepoint) among participants with bowel urgency at baseline (rounded weekly average item 7 score = 1 over eligible days within 7 days prior to baseline). Complete resolution of abdominal pain is defined as no abdominal pain (the rounded weekly average UC-PRO/SS item 8 score = 0 over eligible days within 7 days prior to the designated timepoint) among participants with abdominal pain at baseline (rounded weekly average item 8 score = 1 over eligible days within 7 days prior to baseline). Complete resolution of abdominal pain is defined as no abdominal pain (the rounded weekly average UC-PRO/SS item 8 score = 0 over eligible days within 7 days prior to the designated timepoint) among participants with abdominal pain at baseline (rounded weekly average item 8 score = 1 over eligible days within 7 days prior to baseline). Complete resolution of abdominal pain is defined as no abdominal pain (the rounded weekly average UC-PRO/SS item 8 score = 0 over eligible days within 7 days prior to the designated timepoint) among participants with abdominal pain at baseline (rounded weekly average item 8 score = 1 over eligible days within 7 days prior to baseline). Complete resolution of abdominal pain is defined as no abdominal pain (the rounded weekly average UC-PRO/SS item 8 score = 0 over eligible days within 7 days prior to the designated timepoint) among participants with abdominal pain at baseline (rounded weekly average item 8 score = 1 over eligible days within 7 days prior to baseline). Complete resolution of abdominal pain is defined as no abdominal pain (the rounded weekly average UC-PRO/SS item 8 score = 0 over eligible days within 7 days prior to the designated timepoint) among participants with abdominal pain at baseline (rounded weekly average item 8 score = 1 over eligible days within 7 days prior to baseline).

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