The Efficacy and Safety of Guselkumab as Maintenance Therapy in Patients with Moderately to Severely Active Ulcerative Colitis: Results from the Phase 3 QUASAR Maintenance Study

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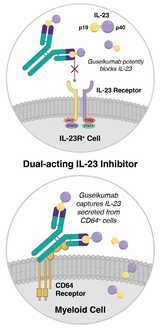
Key Takeaways

- **The dual-acting IL-23 inhibitor guselkumab was statistically superior to placebo (GUS Withdrawal) for the primary endpoint of clinical remission at Week 44. All 9 major secondary endpoints were also met, including:**
  - **Clinical and symptomatic outcomes**
  - **Endoscopic and histologic outcomes**
  - **Additional patient-reported outcomes of IBDQ remission and fatigue response**
- **Both guselkumab SC maintenance dose regimens were efficacious**
- **Safety results through Week 44 were consistent with the known and favorable safety profile of GUS in approved indications**

Background

- Guselkumab (GUS) is a dual-acting interleukin-23 p19 (IL-23p19) subunit inhibitor that blocks IL-23 and binds to CD64, a receptor on cells that produce IL-23[1]
- Results of the QUASAR Phase 2b and Phase 3 Induction Studies of intravenous (IV) GUS in patients with moderately to severely active ulcerative colitis (UC) have been previously presented[2,3]
  - GUS subcutaneous (SC) induction is also being evaluated in inflammatory bowel disease (IBD)
- The Phase 3 QUASAR Maintenance Study (NCT04033445) is a randomized-withdrawal, double-blind, placebo-controlled study



IL=Interleukin; JAK=Janus kinase; STAT=Signal transducer and activator of transcription; TYK=Tyrosine kinase.

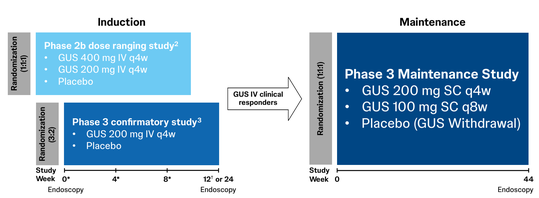
Objective

- **To report the efficacy and safety results of GUS SC maintenance treatment from the QUASAR Maintenance Study in patients with moderately to severely active UC who achieved clinical response to GUS IV induction**

Methods

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 based on central review

QUASAR Program Overview (N=1064, Enrolled)



*All studies were double-blinded. * = Study treatment administered; † = Study treatment administered to Week 12 clinical nonresponders. GUS=Guselkumab; IV=Intravenous; q4w=Every 4 weeks; q8w=Every 8 weeks; SC=Subcutaneous; UC=Ulcerative colitis.*

Primary Endpoint (Week 44)

- Clinical remission

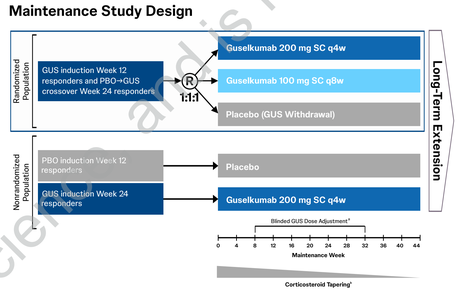
Major Secondary Endpoints (Week 44)

Clinical
- Corticosteroid-free clinical remission
- Maintenance of clinical remission
- Maintenance of clinical response
- Symptomatic remission

Endoscopic and Histologic
- Endoscopic improvement
- Histo-endoscopic mucosal improvement
- Endoscopic remission (normalization)

Patient-reported outcomes
- Inflammatory Bowel Disease Questionnaire (IBDQ) remission
- Fatigue response

Maintenance Study Design



Between Week 8 and Week 32, randomized patients meeting loss of clinical response criteria (based on the modified Mayo score and required an endoscopic assessment) were eligible for a blinded dose adjustment as follows: Placebo SC → GUS 200 mg SC q4w, GUS 100 mg SC q8w → GUS 200 mg SC q4w, GUS 200 mg SC q4w → GUS 200 mg SC q4w (sham adjustment). †Patients receiving corticosteroids upon maintenance entry were to begin tapering at Maintenance Week 0. Other UC-specific therapies were to be continued at stable doses unless indicated by the investigator. Tapering of corticosteroids may be paused for patients meeting clinical flare criteria. GUS=Guselkumab; IV=Intravenous; PBO=Placebo; q4w=Every 4 weeks; q8w=Every 8 weeks; R=Randomization; SC=Subcutaneous; UC=Ulcerative colitis.

Results

Patient Characteristics at Induction Baseline

	PBO (GUS Withdrawal)	GUS 100 mg q8w	GUS 200 mg q4w	Total
Randomized full analysis set, N	190	188	190	568
Age in years, mean (SD)	41.2 (13.58)	40.3 (13.00)	40.6 (14.66)	40.7 (13.75)
Male, n (%)	109 (57.4)	102 (54.3)	100 (52.6)	311 (54.8)
UC disease duration in years, mean (SD)	7.29 (6.338)	7.78 (8.463)	8.35 (8.397)	7.81 (7.791)
Modified Mayo score (0-9), mean (SD)[a]	7.0 (1.09)	6.8 (1.15)	6.9 (1.10)	6.9 (1.12)
Modified Mayo score of 7-9 (severe), n (%)	125 (65.8%)	114 (60.6%)	124 (65.3%)	363 (63.9%)
Mayo endoscopic subscore of 3 (severe), n (%)	129 (67.9%)	125 (66.5%)	123 (64.7%)	377 (66.4%)
Extensive UC, n (%)	95 (50.0%)	79 (42.0%)	83 (43.7%)	257 (45.2%)
C-reactive protein, median in mg/L (IQR)[b]	4.2 (1.6; 8.4)	3.9 (1.4; 10.4)	3.6 (1.4; 9.1)	3.9 (1.5; 9.2)
Fecal calprotectin, median in mg/kg (IQR)[c]	1642.0 (663.0; 3498.0)	1675.0 (806.0; 3543.5)	1487.0 (603.0; 3019.0)	1605.0 (669.0; 3337.0)
Oral corticosteroid use at baseline, n (%)	77 (40.5%)	74 (39.4%)	76 (40.0%)	227 (40.0%)
Immunosuppressant use at baseline, n (%)[d]	43 (22.6%)	41 (21.8%)	42 (22.1%)	126 (22.2%)
History of inadequate response or intolerance to biologic and/or JAK inhibitor therapy, n (%)[e,f]	75 (39.5%)	77 (41.0%)	88 (46.3%)	240 (42.3%)
One biologic or JAK inhibitor, n (%)	36 (48.0%)	36 (46.8%)	52 (59.1%)	124 (51.7%)
Two or more biologics and/or JAK inhibitors, n (%)	39 (52.0%)	41 (53.2%)	36 (40.9%)	116 (48.3%)

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 endoscopic subscores) Mayo score without the physician's global assessment. [b]Based on PBO, N=190; GUS 100 mg, N=185; GUS 200 mg, N=187; Total, N=562. [c]Based on PBO, N=175; GUS 100 mg, N=169; GUS 200 mg, N=171; Total, N=506. [d]Immunosuppressants included azathioprine, 6-mercaptopurine, and methotrexate. [e]Biologic therapy included tumor necrosis factor–α antagonists and vedolizumab. f JAK inhibitor therapy included to focitinib. GUS=Guselkumab; IQR=Interquartile range; JAK=Janus kinase; PBO=Placebo; q4w=Every 4 weeks; q8w=Every 8 weeks; SD=Standard deviation; UC=Ulcerative colitis.

Disease Characteristics at Maintenance Baseline

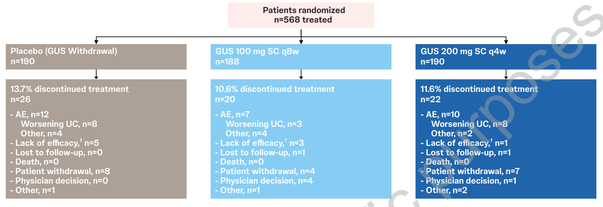
Induction Guselkumab IV Responders

	PBO (GUS Withdrawal)	GUS 100 mg q8w	GUS 200 mg q4w	Total
Randomized full analysis set, N	190	188	190	568
Clinical remission, n (%)[a]	59 (31.1%)	66 (35.1%)	69 (36.3%)	194 (34.2%)
Endoscopic improvement, n (%)[b]	68 (35.8%)	75 (39.9%)	79 (41.6%)	222 (39.1%)
Endoscopic remission, n (%)[c]	39 (20.5%)	41 (21.8%)	47 (24.7%)	127 (22.4%)
IBDQ remission, n (%)[d]	142 (75.5%)	134 (71.3%)	128 (67.7%)	404 (71.5%)
Modified Mayo score (0-9), mean (SD)	2.5 (1.57)	2.6 (1.51)	2.5 (1.50)	2.5 (1.53)
C-reactive protein, median in mg/L (IQR)	1.5 (0.6; 4.0)	1.4 (0.4; 4.0)	1.4 (0.6; 3.4)	1.5 (0.6; 3.8)
Fecal calprotectin (mg/kg), median in mg/kg (IQR)[e]	306.5 (82.5; 1077.0)	308.0 (71.0; 1310.0)	281.0 (89.0; 1233.0)	303.5 (79.5; 1194.0)

[a]Clinical remission: A Mayo stool frequency subscore of 0 or 1 and not increased from baseline, a Mayo rectal bleeding subscore of 0, and a Mayo endoscopic subscore of 0 or 1 with no friability present. [b]Endoscopic improvement: A Mayo endoscopic subscore of 0 or 1 with no friability present. [c]Endoscopic remission (normalization): A Mayo endoscopic subscore of 0. [d]IBDQ remission: A total IBDQ score ≥ 170. Based on PBO, N=188; GUS 100 mg, N=188; GUS 200 mg, N=189; Total, N=565. [e]Based on PBO, N=188; GUS 100 mg, N=185; GUS 200 mg, N=187; Total, N=560. GUS=Guselkumab; IBDQ=Inflammatory Bowel Disease Questionnaire; IQR=Interquartile range; IV=Intravenous; PBO=Placebo; q4w=Every 4 weeks; q8w=Every 8 weeks; SD=Standard deviation.

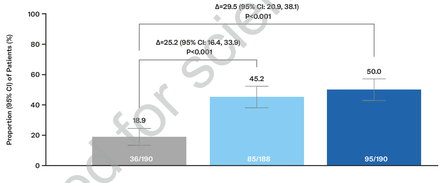
Treatment Disposition Through Week 44

- Overall rate of treatment discontinuation was low at 12.0%
- Discontinuation due to adverse event (AE) was reported in 5.1% of all patients treated
- Most common reasons overall for discontinuation: AEs of worsening UC (3.3%) and patient withdrawal (3.3%)



Randomized Full Analysis Set. As a result of an urgent site closure due to regional crisis in Russia and Ukraine, 3 patients did not have available treatment disposition status at Week 44. †As determined by the investigator. AE=Adverse event; GUS=Guselkumab; IV=Intravenous; q4w=Every 4 weeks; q8w=Every 8 weeks; SC=Subcutaneous; UC=Ulcerative colitis.

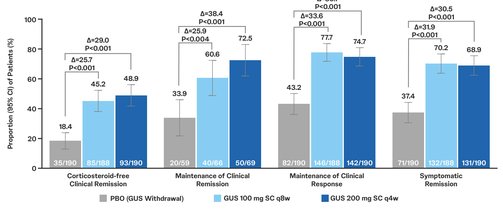
Primary Endpoint: Clinical Remission at Week 44



69% of GUS-treated patients in clinical remission were also in endoscopic remission (MES=0)

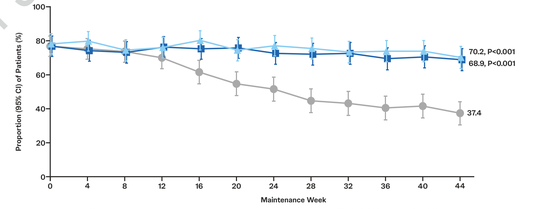
Randomized Full Analysis Set. Clinical remission: A Mayo stool frequency subscore of 0 or 1 and not increased from baseline, a Mayo rectal bleeding subscore of 0, and MES of 0 or 1 with no friability present. CI=Confidence interval; GUS=Guselkumab; MES=Mayo endoscopic subscore; PBO=Placebo; q4w=Every 4 weeks; q8w=Every 8 weeks; SC=Subcutaneous.

Major Secondary Clinical Endpoints At Week 44



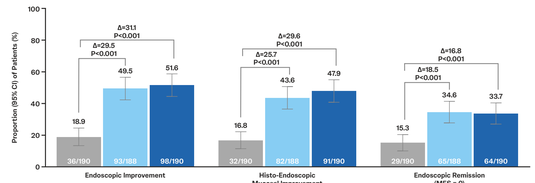
Randomized Full Analysis Set. Corticosteroid-free clinical remission: Not requiring any treatment with corticosteroids for ≥8 weeks prior to Week 44 and meeting the criteria for clinical remission at Week 44. Maintenance of clinical remission: Clinical remission at Week 44 among patients in clinical remission at maintenance baseline. Maintenance of clinical response: Clinical response at Week 44 among patients in clinical response at maintenance baseline. Symptomatic remission: A stool frequency subscore of 0 or 1 and not increased from induction baseline, and a rectal bleeding subscore of 0. CI=Confidence interval; GUS=Guselkumab; PBO=Placebo; q4w=Every 4 weeks; q8w=Every 8 weeks; SC=Subcutaneous.

Symptomatic Remission Through Week 44



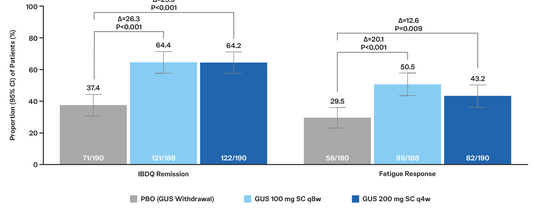
Randomized Full Analysis Set. Symptomatic remission: A stool frequency subscore of 0 or 1 and not increased from baseline, and a rectal bleeding subscore of 0. CI=Confidence interval; GUS=Guselkumab; PBO=Placebo; q4w=Every 4 weeks; q8w=Every 8 weeks.

Major Secondary Endoscopic and Histologic Endpoints at Week 44



Randomized Full Analysis Set. Endoscopic improvement: MES = 0 or 1 with no friability present. Histo-endoscopic mucosal improvement: Achieving a combination of histologic improvement (neutrophil infiltration in <5% of crypts, no crypt destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system) and endoscopic improvement. Endoscopic remission (normalization): MES = 0. CI=Confidence interval; GUS=Guselkumab; MES=Mayo endoscopic subscore; PBO=Placebo; q4w=Every 4 weeks; q8w=Every 8 weeks; SC=Subcutaneous.

Major Secondary Patient-Reported Outcome Endpoints at Week 44



Randomized Full Analysis Set. IBDQ remission: A total IBDQ score ≥ 170. Fatigue response: A ≥ 7-point improvement from induction baseline in the PROMIS Fatigue Short Form 7a. CI=Confidence interval; GUS=Guselkumab; IBDQ=Inflammatory Bowel Disease Questionnaire; PBO=Placebo; PROMIS, Patient-Reported Outcomes Measurement Information System; q4w=Every 4 weeks; q8w=Every 8 weeks; SC=Subcutaneous.

Summary of Adverse Events Through Week 44

	Randomized PBO (GUS withdrawal)	Randomized GUS 100 mg q8w	Randomized GUS 200 mg q4w
Randomized safety analysis set, N	192	186	190
Average duration of follow-up, weeks	34.0	40.5	39.2
Average exposure, number of administrations	8.2	9.9	9.6
Deaths	0	0	0
Patients with 1 or more, n (%):			
AEs	131 (68.2%)	120 (64.5%)	133 (70.0%)
Serious AEs	1 (0.5%)	5 (2.7%)	12 (6.3%)
AEs leading to discontinuation	13 (6.8%)	7 (3.8%)	5 (2.6%)
Infections	63 (32.8%)	59 (31.7%)	59 (31.1%)
Serious infections	0	1 (0.5%)	2 (1.1%)

Most common AEs among GUS-treated patients:	COVID-19	UC	Arthralgia
	14.1% PBO 11.2% GUS Combined	29.7% PBO 11.2% GUS Combined	6.8% PBO 6.1% GUS Combined

Includes only patients with modified Mayo score 5-9 at induction baseline who were randomized in the Maintenance Study and data up to the time of dose adjustment for patients who had a dose adjustment. AE=Adverse event; COVID-19=Coronavirus disease 2019; GUS=Guselkumab; PBO=Placebo; q4w=Every 4 weeks; q8w=Every 8 weeks; UC=Ulcerative colitis.

Summary of Targeted Adverse Events Through Week 44

	Randomized PBO (GUS withdrawal)	Randomized GUS 100 mg q8w	Randomized GUS 200 mg q4w
Randomized safety analysis set, N	192	186	190
Average duration of follow-up, weeks	34.0	40.5	39.2
Average duration of treatment, weeks	29.2	32.6	34.9
Patients with 1 or more, n (%):			
Active tuberculosis	0	0	0
Malignancies	4 (2.1%)	0	1 (0.5%)
Anaphylactic reactions	0	0	0
Serum sickness reactions	0	0	0
Opportunistic infections	0	0	0
Major adverse cardiovascular events	0	0	1 (0.5%)
Venous thromboembolism	0	0	1 (0.5%)
Clinically important hepatic disorders[a]	0	0	0

Includes only patients with modified Mayo score 5-9 at induction baseline who were randomized in the Maintenance Study and data up to the time of dose adjustment for patients who had a dose adjustment. Patients were counted only once for any given event. [a]Defined as hepatic disorder adverse events reported as serious adverse events or adverse events leading to discontinuation of study agent. GUS=Guselkumab; PBO=Placebo; q4w=Every 4 weeks; q8w=Every 8 weeks.

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