Predictors of Endoscopic Remission at 1 Year in Patients with Ulcerative Colitis Treated With Guselkumab: Post-hoc Analyses of the QUASAR Trial

P0805

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Key Takeaways

- **Among patients with moderately to severely active UC who responded to GUS induction and were re-randomized to GUS in the QUASAR maintenance study:**
  - ✓ **Female sex, extensive UC, and oral aminosalicylate use at induction baseline were independently associated with ER at 1 year, irrespective of GUS dosing regimen**
  - ✓ **Endoscopic healing at maintenance baseline (i.e., after induction) was strongly associated with a higher likelihood of achieving ER at 1 year, regardless of GUS dosing regimen**
- **Collectively, these findings may provide insight into the long-term endoscopic benefits of GUS treatment in UC**

Background

- Ulcerative colitis (UC) is a chronic, immune-mediated, inflammatory bowel disorder involving the colon,[1] with management focused on sustained clinical remission and long-term endoscopic and histological healing[2-4]
- Guselkumab (GUS) is a fully human, dual acting, monoclonal antibody that inhibits interleukin (IL)-23 by selectively targeting the p19 subunit and binding to CD64 on immune cells,[5] and is approved for moderately to severely active UC
- In the Phase 2b/3 QUASAR trial of patients with moderately to severely active UC, GUS significantly improved clinical remission by Week (W) 44 of the maintenance (M) study, with one-third of patients achieving endoscopic remission (ER; Endoscopic Mayo subscore [EMS]=0)[6]

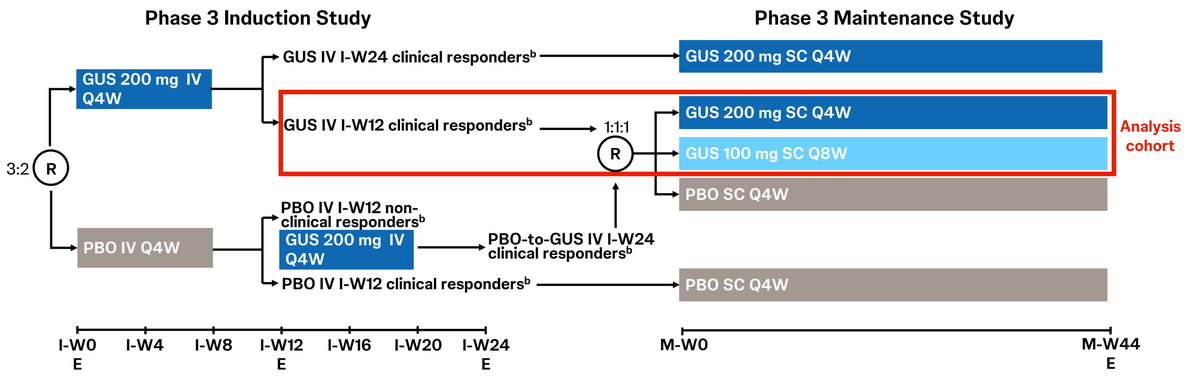
Objectives

- **Post-hoc analyses of QUASAR trial data evaluated baseline predictors of ER at 1 year of treatment in patients with moderately to severely active UC treated with GUS**

Analysis Cohort

Key inclusion criteria
- ≥18 years of age
- Moderately to severely active UC
- At induction baseline:
  - Modified Mayo score of 5 to 9
  - Mayo rectal bleeding subscore ≥1
  - Mayo Endoscopic subscore ≥2
- Inadequate response and/or intolerance to corticosteroids, immunosuppressants, biologics, or JAK inhibitors

QUASAR[a] trial design



[a]NCT04033445. [b]Clinical response defined as a decrease from induction baseline in the modified Mayo score by ≥ 30% and ≥ 2 points, with either a ≥ 1-point decrease from baseline in the rectal bleeding subscore or a rectal bleeding subscore of 0 or 1. E=endoscopy, I=induction, JAK=janus kinase IV=intravenous, PBO=placebo, Q4W=every 4 weeks, Q8W=every 8 weeks, R=randomization SC=subcutaneous.

Assessments and Analysis

Predictors of ER achievement at M-W44 of GUS treatment

Induction baseline predictors	Maintenance baseline predictors
Univariate logistic regression models for each induction baseline variable	Univariate logistic regression models for each maintenance baseline variable
↓ Variables with p<0.1 and GUS dosing regimen	↓ Variables with p<0.1 and GUS dosing regimen
Reduced multivariate logistic regression model using stepwise back selection based on the Wald method	Reduced multivariate logistic regression model using stepwise back selection based on the Wald method

- Data from GUS responders at W12 of the induction study that were re-randomized to GUS 100 mg SC Q8W or GUS 200 mg SC Q4W in the maintenance study were pooled

Results

Patients achieving ER at M-W44 of GUS treatment were slightly younger, more often female, and more likely to have extensive UC and concomitant oral aminosalicylate use, with higher CRP at induction baseline

- Of 378 GUS responders re-randomized to GUS SC Q8W or Q4W, 34% achieved ER at M-W44

Induction baseline characteristics of GUS responders re-randomized to SC GUS Q8W or Q4W in the QUASAR maintenance study	Patients with ER at M-W44 (N=129)	Patients without ER at M-W44 (N=249)
Demographics		
Age, years	38.8 (13.9)	41.3 (13.8)
Female sex	57%	41%
Race, Asian/Black/White	20%/1%/77%	22%/1%/70%
Disease Characteristics		
Disease duration, years	7.8 (9.2)	8.2 (8.0)
UC type		
Extensive	53%	38%
Limited to left side of colon	47%	62%
Endoscopic Mayo score		
Moderate (endoscopy subscore=2)	37%	33%
Severe (endoscopy subscore=3)	63%	67%
CRP		
≤3 mg/L	37%[a]	48%[b]
Fecal calprotectin		
≤250 µg/g	15%[c]	10%[d]
Medication Use		
Prior ADT failure	35%	47%
Concomitant Use		
Oral corticosteroids	42%	39%
Immunomodulators	24%	21%
Oral aminosalicylates	84%	74%

Data are % for categorical variables and mean (SD) for continuous variables. [a]N=128. [b]N=244. [c]N=111. [d]N=220. ADT=advance drug therapy, CRP=C-reactive protein.

Patients achieving ER at M-W44 of GUS treatment had lower UC disease burden at maintenance baseline

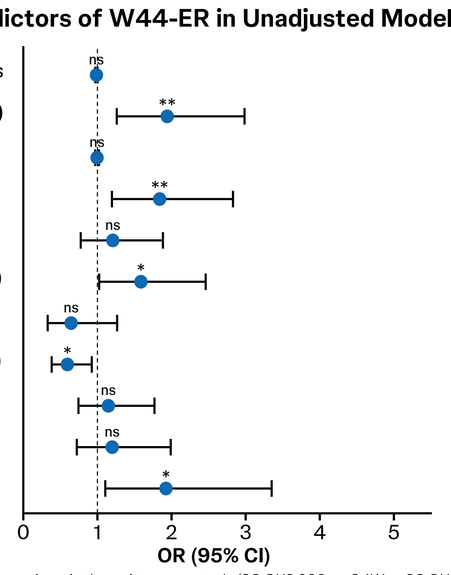
- Rates of ER achievement at M-W44 did not differ across GUS regimens

Maintenance baseline characteristics of GUS responders re-randomized to SC GUS Q8W or Q4W in the QUASAR maintenance study	Patients with ER at M-W44 (N=129)	Patients without ER at M-W44 (N=249)
Disease Characteristics		
CRP normalization[a]	86%[b]	75%[c]
Fecal calprotectin normalization[d]	78%[e]	66%[f]
Endoscopic healing[g]	58%	32%
GUS Dosing Regimen		
200 mg SC Q4W	50%	51%
100 mg SC Q8W	50%	49%

[a]Defined as ≤3 mg/L or 50% reduction from induction baseline. [b]N=128. [c]N=244. [d]Defined as ≤250 µg/g or 50% reduction from induction baseline [e]N=110. [f]N=218. [g]Defined as Endoscopic Mayo subscore of 0 or 1 and no friability.

<u>Unadjusted models:</u> Induction baseline predictors of ER at M-W44 of GUS treatment were female sex, extensive UC, concomitant oral aminosalicylate use, elevated CRP levels, and no prior ADT failure

Induction Baseline Predictors of W44-ER in Unadjusted Models[a]

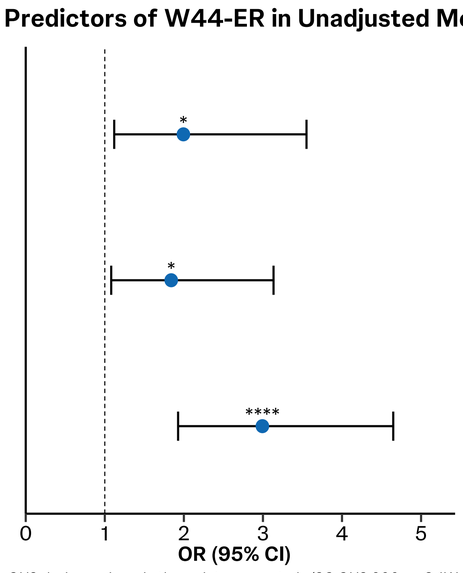


	OR	95% CI	p-value
Age, years	1.0	1.0, 1.0	0.0997
Sex (female vs male)	**1.9**	**1.3, 3.0**	**0.0026**
Disease duration, years	1.0	1.0, 1.0	0.7082
UC type (extensive vs limited to left side of colon)	**1.8**	**1.2, 2.8**	**0.0055**
Endoscopic Mayo Score (moderate vs severe)	1.2	0.8, 1.9	0.4047
CRP (>3 vs ≤3 mg/L)	**1.6**	**1.0, 2.5**	**0.0389**
Fecal calprotectin (>250 vs ≤250 µg/g)	0.6	0.3, 1.3	0.2025
Prior ADT failure (yes vs no)	**0.6**	**0.4, 0.9**	**0.0208**
Concomitant oral corticosteroids use (yes vs no)	1.1	0.7, 1.8	0.5326
Concomitant immunomodulators use (yes vs no)	1.2	0.7, 2.0	0.4832
Concomitant oral aminosalicylates use (yes vs no)	**1.9**	**1.1, 3.4**	**0.0206**

*Nominal *p<0.05, **p<0.01. [a]Univariate models were adjusted for GUS dosing regimen in the maintenance study (SC GUS 200mg Q4W vs SC GUS 100mg Q8W). CI=confidence interval, ns=not significant, OR=odds ratio.*

<u>Unadjusted models:</u> Maintenance baseline predictors of ER at M-W44 of GUS treatment were CRP normalization, fecal calprotectin normalization, and endoscopic healing

Maintenance Baseline Predictors of W44-ER in Unadjusted Models[a]



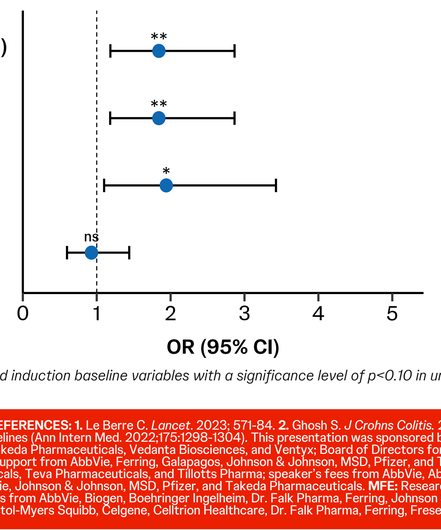
	OR	95% CI	p-value
CRP normalization[b] (yes vs no)	**2.0**	**1.1, 3.6**	**0.0192**
Fecal calprotectin normalization[c] (yes vs no)	**1.8**	**1.1, 3.1**	**0.0247**
Endoscopic healing[d] (yes vs no)	**3.0**	**1.9, 4.6**	**<0.0001**

*Nominal *p<0.05, ****p<0.0001. [a]Univariate models were adjusted for GUS dosing regimen in the maintenance study (SC GUS 200mg Q4W vs SC GUS 100mg Q8W). [b]Defined as ≤3 mg/L or 50% reduction from induction baseline. [c]Defined as ≤250 µg/g or 50% reduction from induction baseline. [d]Defined as Endoscopic Mayo subscore of 0 or 1 and no friability.*

<u>Adjusted models:</u> Female sex, extensive UC, and concomitant oral aminosalicylate use at induction baseline were independent predictors of ER at M-W44 of GUS treatment, irrespective of dosing regimen

- GUS regimen was not a baseline predictor of ER achievement at M-W44

Induction Baseline Predictors of W44-ER in Adjusted Models[a]



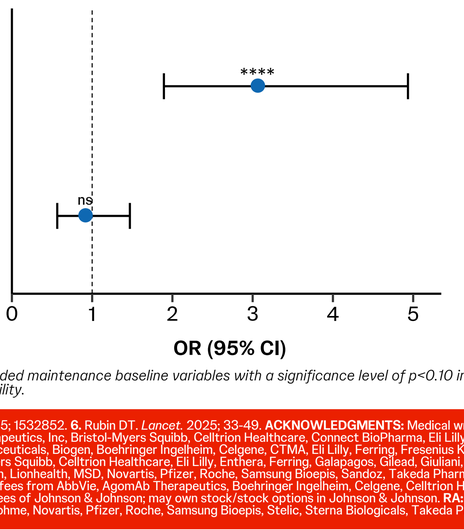
	OR	95% CI	p-value
Sex (female vs male)	**1.8**	**1.2, 2.9**	**0.0067**
UC type (extensive vs limited to left side of colon)	**1.8**	**1.2, 2.9**	**0.0069**
Concomitant oral aminosalicylates use (yes vs no)	**1.9**	**1.1, 3.4**	**0.0221**
GUS (200 mg SC Q4W vs 100 mg SC Q8W)	0.9	0.6, 1.4	0.7419

*Nominal *p<0.05, **p<0.01. [a]Backward selection multivariate models included induction baseline variables with a significance level of p<0.10 in univariate models and GUS dosing regimen.*

<u>Adjusted models:</u> Achievement of endoscopic healing at maintenance baseline was an independent predictor of ER at M-W44 of GUS treatment, irrespective of dosing regimen

- GUS regimen was not a baseline predictor of ER achievement at M-W44

Maintenance Baseline Predictors of W44-ER in Adjusted Models[a]



	OR	95% CI	p-value
Endoscopic healing[b] (yes vs no)	**3.1**	**1.9, 4.9**	**<0.0001**
GUS (200 mg SC Q4W vs 100 mg SC Q8W)	0.9	0.6, 1.5	0.7022

*Nominal ****p<0.0001. [a]Backward selection multivariate models included maintenance baseline variables with a significance level of p<0.10 in univariate models and GUS dosing regimen. [b]Defined as Endoscopic Mayo subscore of 0 or 1 and no friability.*

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