Early Improvement of Inflammatory Biomarkers Predicts 1-Year Outcomes in Adults with Crohn's Disease Treated with Guselkumab: Pooled GALAXI 2 & GALAXI 3, Phase 3 Trials Analysis

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Background

Crohn's disease (CD) is a chronic, progressive inflammatory bowel disease marked by segmental, transmural lesions affecting the gastrointestinal[1]

In the GALAXI 2 & 3 trials, intravenous (IV) induction followed by subcutaneous (SC) guselkumab (GUS) showed superior efficacy vs placebo (PBO) and ustekinumab (UST) at Week (W) 48 in participants with moderately to severely active CD, with a safety profile consistent with the established safety profile of GUS[2]

C-reactive protein (CRP) and faecal calprotectin (FC) are routinely used biomarkers in CD that reflect systemic and intestinal inflammation, respectively[3,4]

- Identifying early biomarker responses may predict long-term clinical and endoscopic outcomes, improving treatment, and disease management

Objective

Post-hoc analyses of pooled GALAXI 2 & 3 data evaluating the association between early serum and faecal biomarker response and 1-year clinical/endoscopic outcomes in participants with moderately to severely active CD treated with GUS

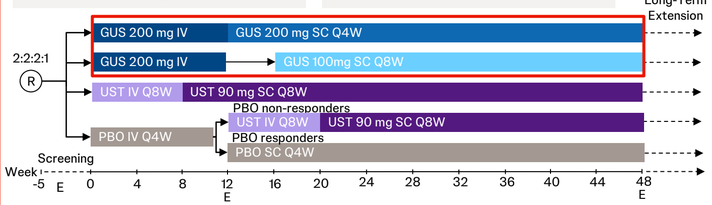
Analysis Cohort

GALAXI 2 & 3: Key inclusion criteria

- ≥18 years of age
- Moderately to severely active CD (based on CDAI[a] and SES-CD[b] scoring)
- Inadequate response or intolerant to conventional or biologic therapies

Post hoc analysis cohort

- Data were pooled from GUS-treated (200 mg SC Q4W and 100mg SC Q8W) participants in the Phase 3 GALAXI 2 & 3[c] trials with abnormal CRP (>3 mg/L) or FC (>250 µg/g) at W0



[a]Cutoff score of 220–450 (inclusive). [b]Cutoff score of ≥6 (or ≥4 for participants with isolated ileal disease). [c]NCT03466411. ***CDAI***=Crohn's disease activity index, ***E***=endoscopy, ***Q4W***=every 4 weeks, ***Q8W***=every 8 weeks, ***R***=randomization, ***SES-CD***=Simple Endoscopic Score for Crohn's disease.

Outcomes and Analyses

Definitions	
Early Biomarker Response at W4, W8, and W12	
CRP Response	CRP ≤3mg/L or ≥50% reduction from W0
FC Response	FC ≤250µg/g or ≥50% reduction from W0
Clinical and Endoscopic Outcomes at W48	
Clinical Remission	CDAI score <150
Endoscopic Remission	SES-CD ≤4, ≥2-point reduction from W0 in SES-CD, and no SES-CD sub-score >1
Deep Remission	Clinical and endoscopic remission

- For biomarker response, patients with missing data at W4, W8 and W12 were excluded from analysis at the corresponding time point
- For clinical outcomes, participants with missing data after applying intercurrent event rules were considered as non-responders
- Association between early biomarker response and W48 clinical/endoscopic outcomes were assessed using:
  - **Unadjusted models:** Chi-squared tests
  - **Adjusted models:** Multivariate logistic regression adjusted for age, sex, GUS maintenance regimen, and prior biologic treatment failure status

Key Takeaways

- **In the Phase 3 GALAXI 2 & 3 trials, participants with moderately to severely active CD and abnormal baseline biomarker levels were treated with GUS**
  - ✓ **Early serum and faecal biomarker responses with GUS were associated with significantly higher rates of W48 clinical, endoscopic, and deep remission**
  - ✓ **These associations were observed as early as W4 for CRP and W8 for FC**
- **Among participants without a CRP response during GUS induction, prior GALAXI 2 & 3 analyses showed greater W48 benefit with GUS 200 mg SC Q4W vs 100 mg SC Q8W maintenance[5]**
- **Findings support the potential utility of early biomarker changes to inform longer-term outcomes and treatment optimization in CD**

Results

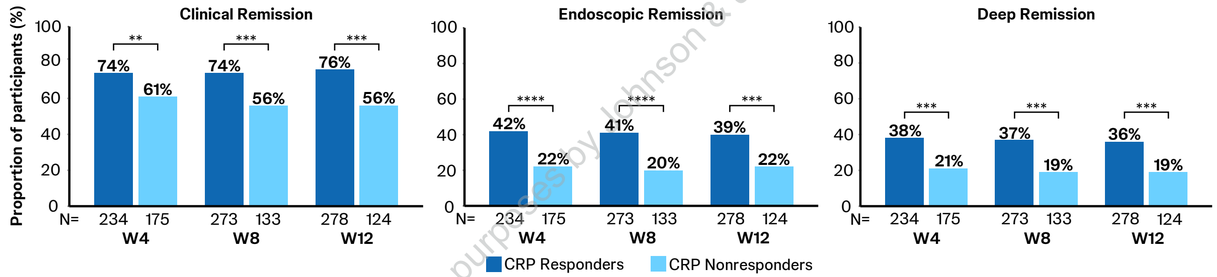
At baseline, 72% and 81% of participants had abnormal CRP and FC levels, respectively

Baseline Patient and Disease Characteristics	GUS-treated (N = 582)
Demographics	
Age, years	36.5 (12.8)
Male	57%
BMI, kg/m²	23.2 (4.7)
Disease Characteristics	
Disease duration	7.1 (7.0)
CDAI, 0-600	296.1 (53.5)
SES-CD, 0-56	12.8 (7.3)
CRP, mg/L	15.9 (21.6)
CRP Abnormal (>3mg/L)	72%
FC, µg/g	1788.6 (2974.1)
FC Abnormal (>250µg/g)	81%
≥1 failed biological therapy	53%
Involved GI areas[a]	
Ileum	23%
Colon	25%
Ileum and Colon	51%

Data shown are mean (SD) unless otherwise noted. [a]*Assessed by central reader.* ***BMI***=*body mass index,* ***SD***=*standard deviation.*

Early CRP response with GUS was observed as early as W4 and was associated with higher W48 rates of clinical, endoscopic and deep remission

Unadjusted models: W48 Clinical, Endoscopic, and Deep Remission by Early CRP Response[a]

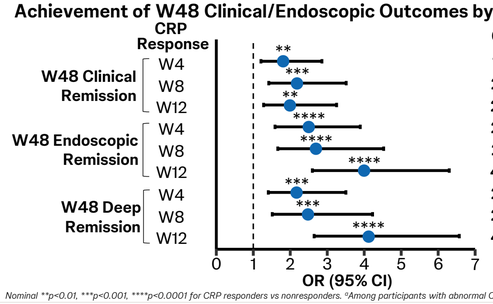


*Nominal **p<0.01, ***p<0.001, **** p<0.0001 for CRP responders vs nonresponders.* [a]*Among participants with abnormal CRP (>3 mg/L) at W0.*

CRP response from W4 onward was significantly associated with W48 outcomes in GUS-treated participants

Adjusted models:

Achievement of W48 Clinical/Endoscopic Outcomes by Early Biomarker Response[a]

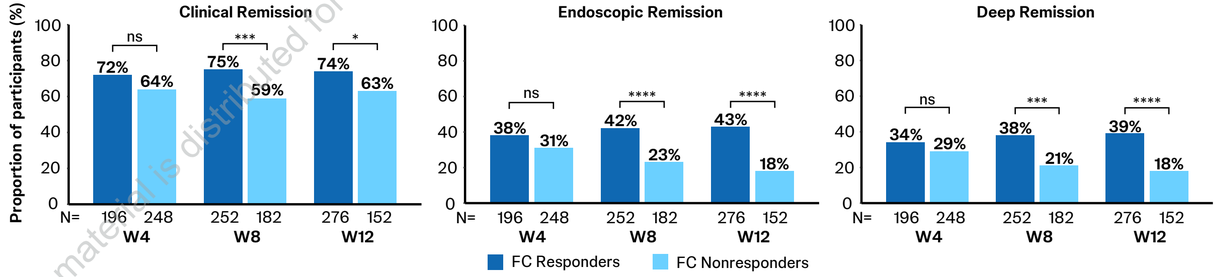


	OR	95% CI	P-value
W48 Clinical Remission W4	1.9	1.2, 2.9	0.0048
W48 Clinical Remission W8	2.2	1.4, 3.5	0.0005
W48 Clinical Remission W12	2.0	1.3, 3.3	0.0028
W48 Endoscopic Remission W4	2.5	1.6, 3.9	<0.0001
W48 Endoscopic Remission W8	2.7	1.7, 4.5	<0.0001
W48 Endoscopic Remission W12	4.0	2.6, 6.3	<0.0001
W48 Deep Remission W4	2.2	1.4, 3.5	0.0006
W48 Deep Remission W8	2.5	1.5, 4.2	0.0004
W48 Deep Remission W12	4.2	2.6, 6.6	<0.0001

*Nominal **p<0.01, ***p<0.001, ****p<0.0001 for CRP responders vs nonresponders.* [a]*Among participants with abnormal CRP (>3 mg/L) at W0. CI=confidence interval, OR=odds ratio.*

FC response with GUS was observed as early as W8 and was associated with higher W48 rates of clinical, endoscopic and deep remission

Unadjusted models: W48 Clinical, Endoscopic, and Deep Remission by Early FC Response[a]

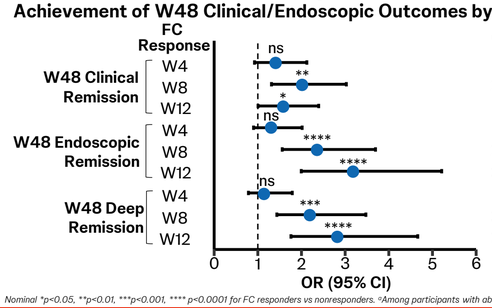


*Nominal *p<0.05, ***p<0.001, **** p<0.0001 for FC responders vs nonresponders.* [a]*Among participants with abnormal FC (>250 µg/g) at W0.* ***ns***=*not significant.*

FC response from W8 onward was significantly associated with W48 outcomes in GUS-treated participants

Adjusted models:

Achievement of W48 Clinical/Endoscopic Outcomes by Early Biomarker Response[a]



	OR	95% CI	P-value
W48 Clinical Remission W4	1.4	0.9, 2.1	0.1124
W48 Clinical Remission W8	2.0	1.3, 3.0	0.0012
W48 Clinical Remission W12	1.6	1.0, 2.4	0.0474
W48 Endoscopic Remission W4	1.3	0.9, 2.0	0.1451
W48 Endoscopic Remission W8	2.4	1.6, 3.7	<0.0001
W48 Endoscopic Remission W12	3.2	2.0, 5.2	<0.0001
W48 Deep Remission W4	1.2	0.8, 1.8	0.419
W48 Deep Remission W8	2.2	1.4, 3.5	0.0004
W48 Deep Remission W12	2.9	1.8, 4.7	<0.0001

*Nominal *p<0.05, **p<0.01, ***p<0.001, **** p<0.0001 for FC responders vs nonresponders.* [a]*Among participants with abnormal FC (>250 µg/g) at W0.*

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