

Endoscopic Outcomes of Ulcer Size and Ulcerated Surface Over One Year Across Bowel Segments in Participants With Crohn's Disease Treated With Guselkumab: Pooled GALAXI 2 and 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 tract¹



Guselkumab (GUS)

- Fully human, dual-acting monoclonal antibody that selectively inhibits interleukin (IL)-23 by targeting its p19 subunit and binds CD64 on IL-23-producing inflammatory monocytes²
- Significantly improved overall endoscopic outcomes in moderately to severely active CD compared to placebo (PBO), achieving high rates of endoscopic response and remission in its Phase 3 trial program^{3,4}



Disease location may represent a key determinant of treatment effectiveness, but data describing segment-specific improvements in ulcer size and ulcerated surfaces across bowel segments remain limited

Objective



Post-hoc analyses of pooled GALAXI 2 & 3 data evaluating changes in ulcer presence/size and percentage of ulcerated surfaces across bowel segments through 1 year in GUS-treated participants with moderately to severely active CD

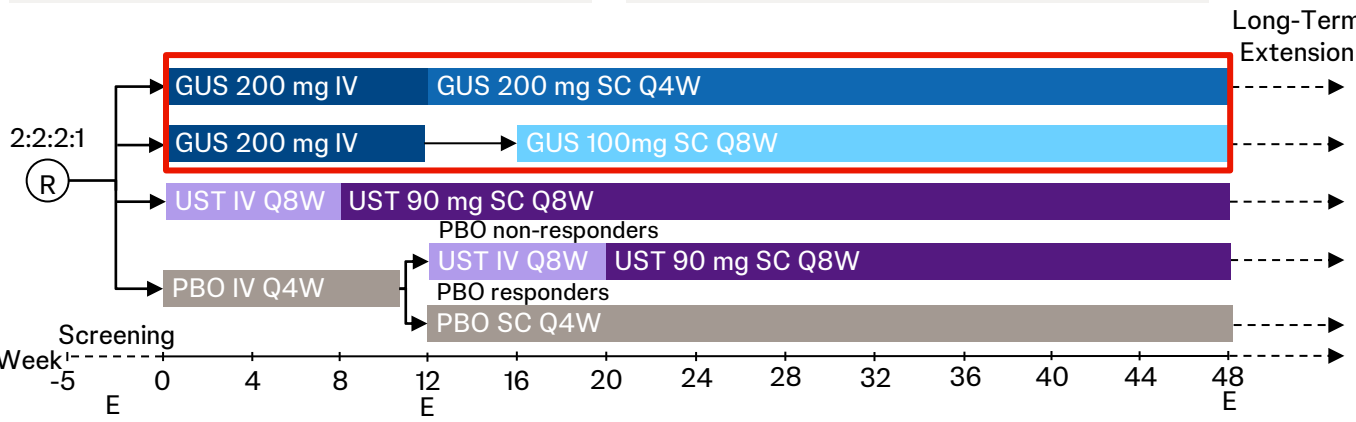
Analysis Cohort

GALAXI 2 & 3: Key inclusion criteria

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

Post hoc analysis cohort

- Pooled from GUS-treated (200 mg SC Q4W and 100mg SC Q8W) participants in the Phase 3 GALAXI 2 & 3 trials with ≥1 ulcer in the ileum, colon, and/or rectum at W0



^aNCT03466411. ^bCutoff score of ≥220-450 (inclusive). ^cCutoff score of ≥6 (or ≥4 for participants with isolated ileal disease). 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

- The SES-CD endoscopic scoring system (range, 0-56)⁵ includes assessment of ulcer size and percent ulcerated surface (each scored 0-3) across five bowel segments, as assessed by central reader

SES-CD Assessments at W0, W12, and W48		
Bowel Segments	Variable of interest	Categories
Ileum Right colon Transverse colon Left colon Rectum	Presence/ulcer size	None Aphthous (0.1-0.5cm) Large (0.5-2cm) Very large (>2cm)
	Percent Ulcerated Surface	None <10% 10-30% >30%

- Changes over time were analyzed as observed using the Wilcoxon signed-rank test
- All p-values are nominal

Results

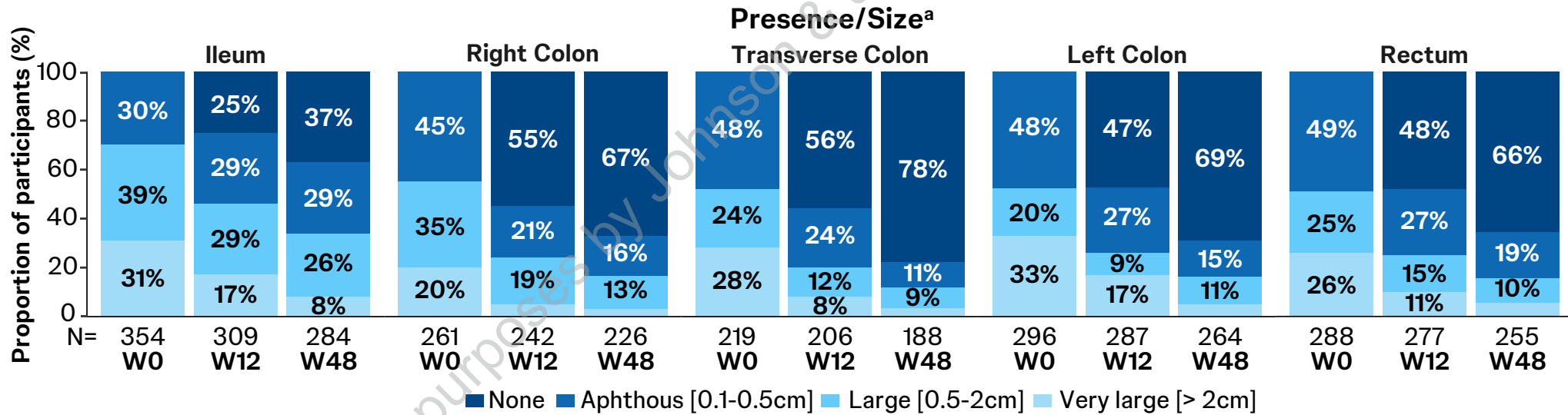
At baseline, higher proportions of participants had ulcers in the ileum (74%) than in the rectal (50%) and colonic (39%) segments

Baseline Participant and Disease Characteristics		GUS-treated (N = 582)
Demographics		
	Age, years	36.5 (12.8)
	Male	57%
	BMI, kg/m ²	23.2 (4.7)
Disease Characteristics		
	Disease duration, years	7.1 (7.0)
	CDAI, 0-600	296.1 (53.5)
	SES-CD, 0-56	12.8 (7.3)
	Involved GI areas ^a	
	Ileum only	23%
	Colon only	25%
	Ileum and Colon	51%
	CRP, mg/L	15.9 (21.6)
	Faecal calprotectin, µg/g	1788.6 (2974.1)
	≥1 failed biological therapy	53%
Ulcer Location		
	Ileum	74%
	Colonic	39%
	Rectal	50%

Data are % for categorical variables and mean (SD) for continuous variables. ^aAssessed by central reader. BMI=body mass index, CRP=C-reactive protein, GI=gastrointestinal, SD=standard deviation.

GUS significantly reduced ulcer size from W0 to W12 across all bowel segments, with sustained and enhanced reductions through W48

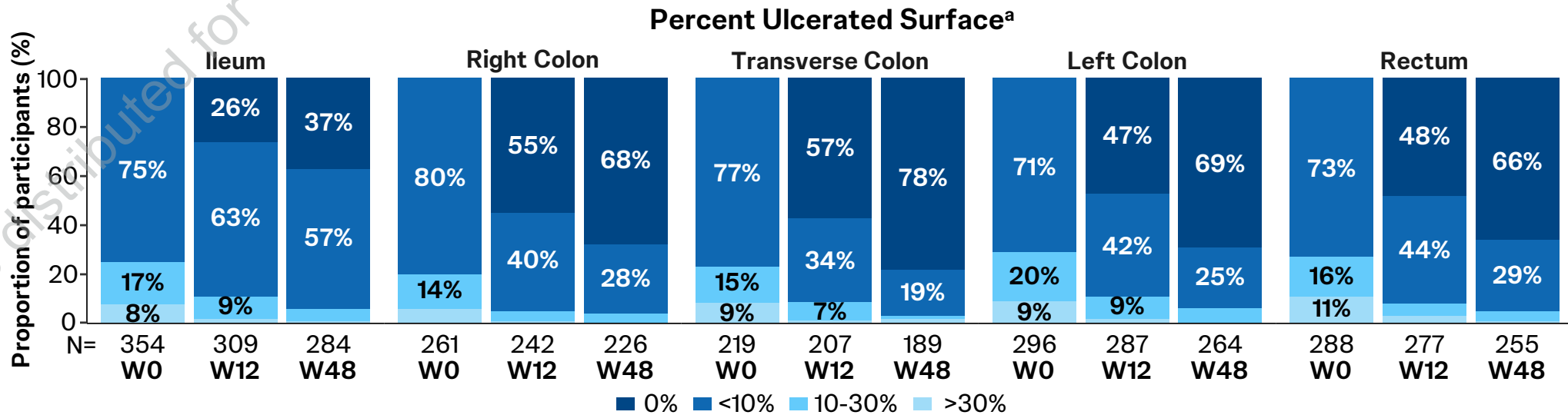
- Greater reductions in ulcer size were observed in colonic and rectal segments than in the ileum at W12 and W48



All nominal p<0.0001 for W12 vs W0, W48 vs W0, and W48 vs W12. Labels are not shown for the very large category at W12 (right colon) and W48 (right colon, transverse colon, left colon, and rectum) due to space limitation. ^aAmong participants with ulcers within a given bowel segment at W0.

GUS significantly reduced percentage of ulcerated surface from W0 to W12, with sustained and enhanced reductions through W48

- Greater reductions in percent of ulcerated surface were observed in colonic and rectal segments than in the ileum at W12 and W48



All nominal p<0.0001 for W12 vs W0, W48 vs W0, and W48 vs W12. Labels are not shown for the 10-30% and/or >30% categories at W12 (right colon, transverse colon, left colon, and rectum) and W48 (ileum, right colon, transverse colon, left colon, and rectum) due to space limitation. ^aAmong participants with ulcers within a given bowel segment at W0.

Key Takeaways



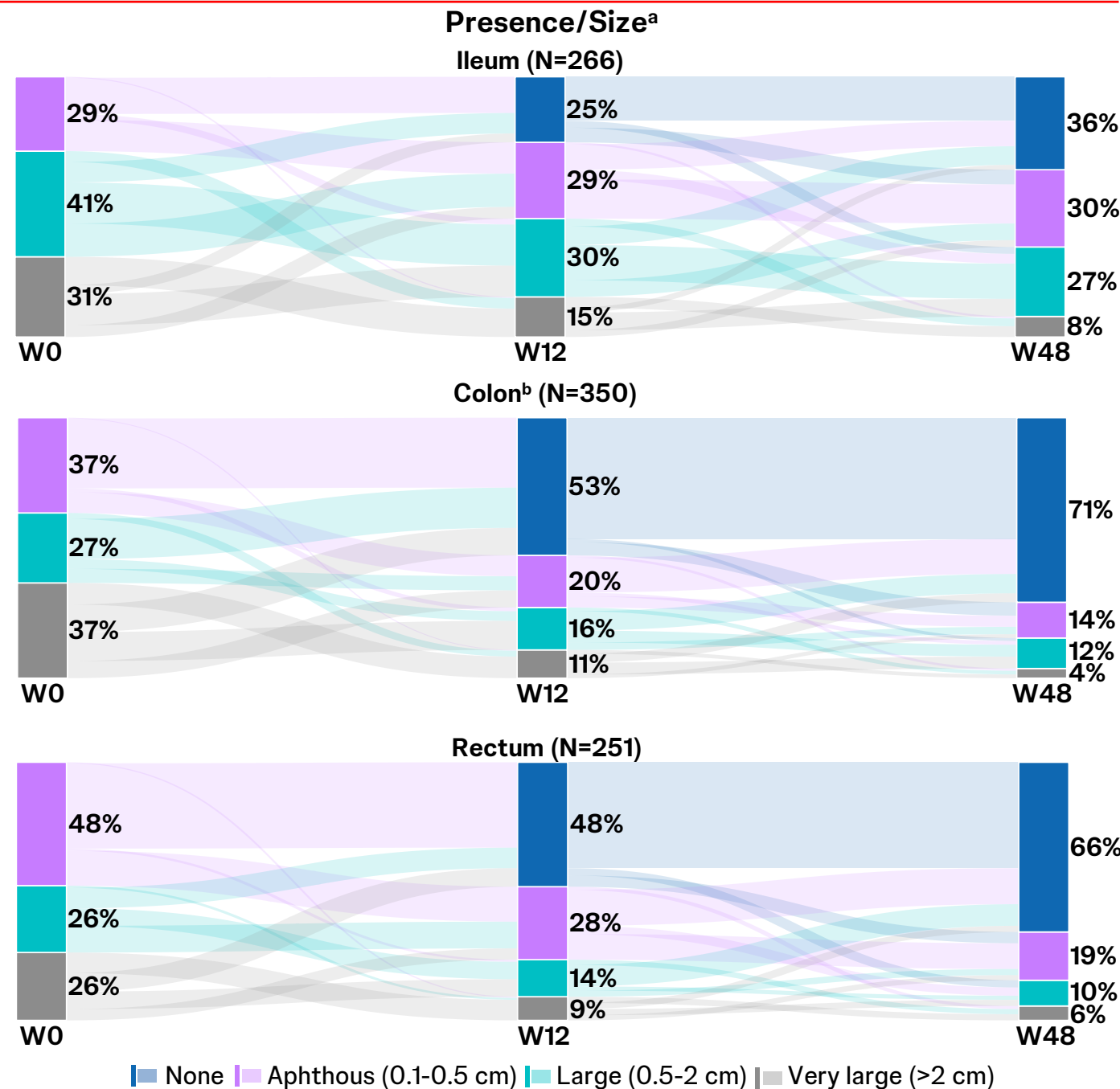
Among GUS-treated adults with moderately to severely active CD in the Phase 3 GALAXI 2 & 3 trials:

- ✓ Baseline ulcers were more common in the ileum (74%) than in the rectum (50%) and colon (39%), and were large or very large in 70% of ileal and ~50% of colonic and rectal ulcers
- ✓ Complete ulcer resolution at W48 was achieved by 37%, 67-78% and 66% of participants with baseline ileal, colonic, or rectal ulcers, respectively
- ✓ GUS markedly reduced ulcer size and ulcerated surface across all bowel segments as early as W12, with effects sustained through W48
- ✓ Improvements were greater in colonic and rectal than ileal segments



These findings suggest early and durable endoscopic improvement with GUS across bowel segments in moderately to severely active CD

GUS shifted ulcer size towards resolution across bowel segments through W48



^aAmong participants with ulcers within a given bowel segment at W0 and assessment available at each timepoint. ^bData from the three colonic segments (right colon, transverse colon, and left colon) were collapsed.

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