Impact of Disease Duration on Clinical and Endoscopic Responses at 1 Year in Patients with Crohn's Disease Treated With Guselkumab: Pooled Analysis of the GALAXI 2 & 3 Studies

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Key Takeaways

- **Among GUS-randomized adults with moderately to severely active CD pooled from the Phase 3 GALAXI 2 & 3 trials:**
  - ✓ **GUS induction therapy was effective irrespective of disease duration, with W12 outcomes appearing similar across groups**
  - ✓ **GUS demonstrated clinical and endoscopic benefits through 1 year across disease duration groups, with lower endoscopic and deep remission rates in patients with LDD**
  - ✓ **Differences emerging at W48 may be partly driven by the more treatment-refractory profile of longer-duration groups, including a higher incidence of prior biologic failure**
- **Findings support improved therapeutic outcomes following earlier initiation of GUS treatment in CD**

Background

Crohn's disease (CD) is a chronic and progressive inflammatory bowel disease characterized by patchy and full thickness lesions affecting any part of the gastrointestinal tract[1]

Guselkumab (GUS) is a fully human, dual-acting interleukin (IL)-23 inhibitor, that selectively targets the p19 subunit and binds to CD64 on immune cells in inflamed tissues[2]

In GALAXI 2 & 3 trials, intravenous (IV) induction followed by subcutaneous (SC) GUS treatment was effective in moderately to severely active CD, demonstrating superior efficacy over placebo (PBO) and ustekinumab (UST) at week (W) 48, with a safety profile that was consistent with the well characterized safety profile of GUS in its approved indications[3]

Shorter disease duration at biologic treatment initiation has been associated with improved therapeutic outcomes in CD[4,5]

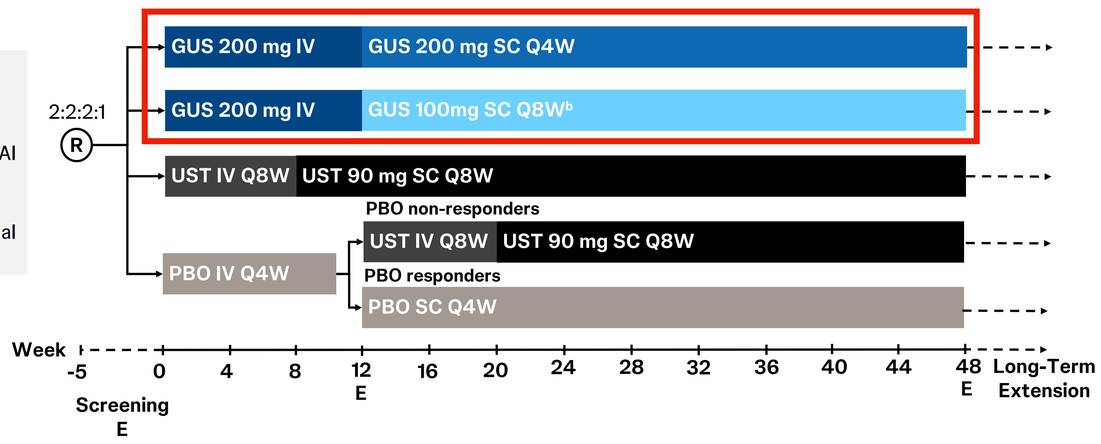
Objectives

Post-hoc analyses of pooled GALAXI 2 & 3 data evaluated the impact of disease duration on achievement of clinical and endoscopic outcomes in adults with moderately to severely active CD treated with GUS

Analysis Cohort

- The analysis cohort was pooled from Phase 3 GALAXI 2 & 3[a] studies of patients with moderate-to-severe CD treated with GUS

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



[a]NCT03466411. [b]First dose was administered at W16. *CDAI=Crohn's disease activity index, E=endoscopy, Q4W=every 4 weeks, Q8W=every 8 weeks, SES-CD=Simple Endoscopic Score for Crohn's disease.*

Endpoints and Analyses

Achievement of clinical and endoscopic outcomes at W12 and W48 across baseline disease duration

Endpoint	Definition
Clinical Response	100-point decrease from baseline in CDAI or CDAI<150
Clinical Remission	CDAI<150
Endoscopic Response	≥50% improvement from baseline in SES-CD or SES-CD≤2
Endoscopic Remission	SES-CD≤4, ≥2-point reduction from baseline in SES-CD, and no SES-CD sub-score >1
Deep Remission	Clinical and endoscopic remission

- Endpoints were evaluated at W12 and W48 among pooled GUS-randomized (100mg Q8W, 200mg Q4W) patients
- Endpoints were analyzed by baseline disease duration groups: **ultrashort (USDD; ≤1 year)**, **intermediate-short (ISDD; >1 to ≤2 years)**, **intermediate-long (ILDD; >2 to ≤5 years)**, and **long (LDD; >5 years)** disease duration
- Non-responder imputation was applied for missing data

ILDD=intermediate-long disease duration, ISDD=intermediate-short disease duration, LDD=long disease duration, USDD=ultrashort disease duration.

Results

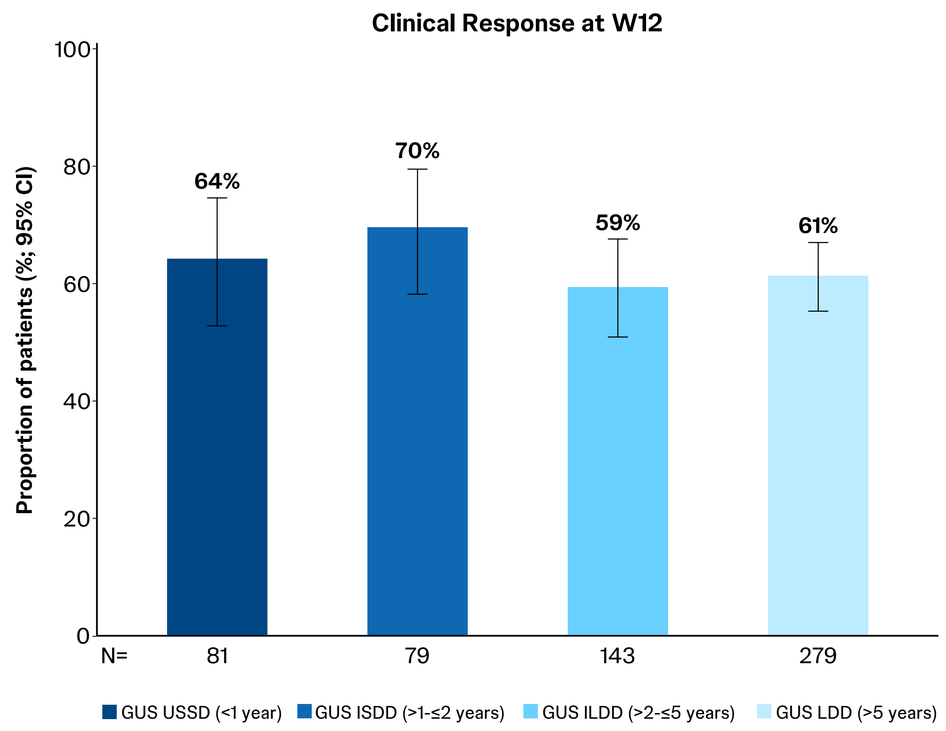
Despite numerical differences, baseline characteristics were generally well balanced across disease duration groups

- As expected, increasingly higher proportions of patients with a history of inadequate response or intolerance to biologic therapies were observed with longer disease duration

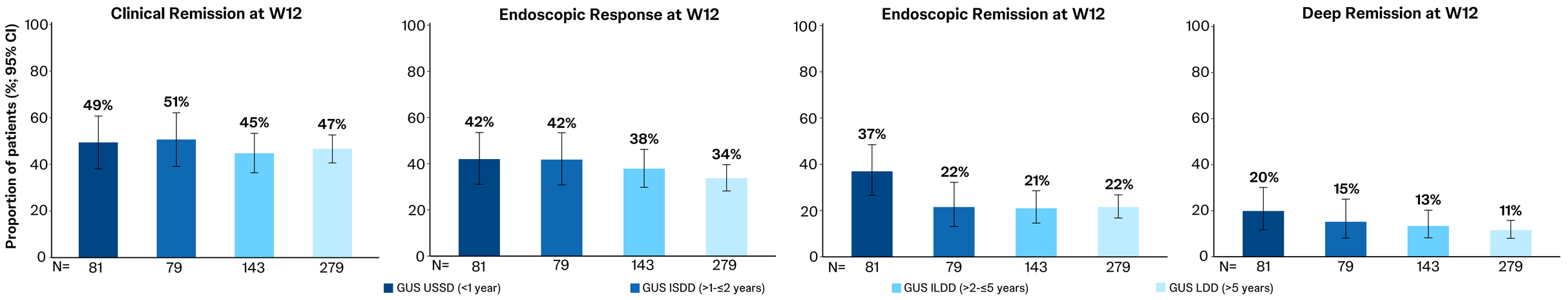
Baseline Characteristics	USSD (≤1 year) (N = 81)	ISDD (>1 to ≤2 years) (N = 79)	ILDD (>2 to ≤5 years) (N = 143)	LDD (>5 years) (N = 279)
Demographics				
Age, years	34.6 (12.8)	34.0 (14.7)	34.7 (12.5)	38.6 (12.0)
Male	52%	53%	64%	56%
Race, Asian/Black/White	22%/0%/78%	27%/0%/72%	23%/2%/71%	20%/1%/77%
Disease Characteristics				
CDAI	298.0 (54.3)	293.0 (53.2)	298.7 (55.6)	295.0 (52.4)
SES-CD	11.6 (7.4)	14.3 (8.3)	11.8 (6.2)	13.4 (7.5)
Involved GI areas[a]				
Ileum only	23%	27%	31%	19%
Colon only	28%	23%	27%	24%
Ileum and colon	47%	51%	41%	57%
Proximal small intestine	14%[b]	4%	13%	11%
≥1 open or draining fistula	14%	8%	11%	13%
>1 open or draining perianal fistula	11%[b]	8%	9%	11%
>1 open or draining perirectal fistula	1%	0%	0%	<1%
>1 extra-intestinal manifestation	20%	15%	24%	24%
CRP, mg/L	12.9 (17.4)	18.1 (22.7)	15.1 (18.9)	16.5 (23.6)
Faecal calprotectin, μg/g	1460.0 (1548.7)	1865.8 (2225.3)[c]	1570.3 (1724.5)[d]	1974.1 (3844.8)[e]
History of intolerance/inadequate response to biological therapy	19%	49%	53%	63%
Concomitant Medication Use				
Azathioprine, mercaptopurine, or methotrexate	35%	29%	30%	32%
Oral corticosteroids	49%	32%	33%	37%

Data are % for categorical variables and mean (SD) for continuous variables. [a]Assessed by central reader. [b]N=80. [c]N=78. [d]N=141. [e]N=277. CRP=C-reactive protein, GI=gastrointestinal.

At W12, ~60-70% of patients achieved clinical response with GUS induction across disease duration groups

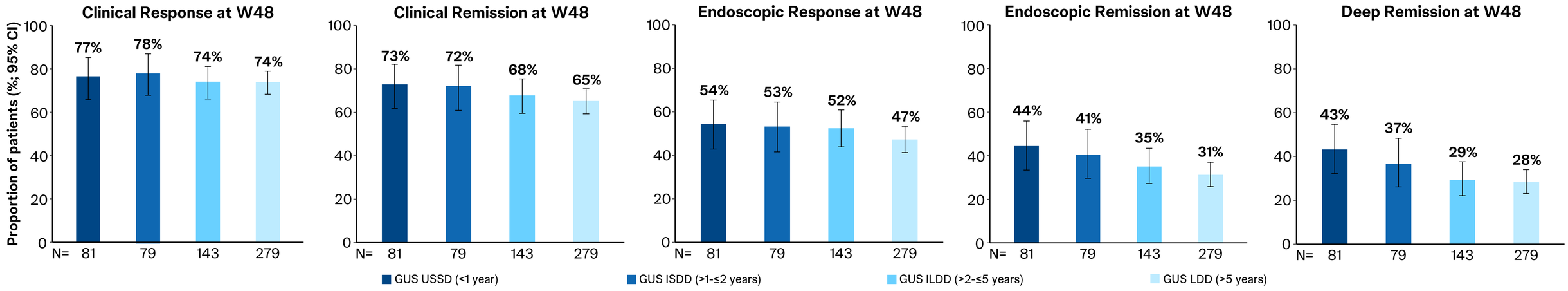


At W12, GUS induction therapy was effective irrespective of disease duration



GUS showed increased clinical and endoscopic response rates from W12 through W48 across disease duration groups

- Rates of clinical response, clinical remission, and endoscopic response at W48 were comparable across disease duration groups
- Clinically relevant decreases in endoscopic and deep remission rates with GUS were observed at W48 with longer disease duration



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