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Maintenance of Endoscopic and Histologic Efficacy with Guselkumab for Ulcerative Colitis at Week 92 of the QUASAR Long-Term Extension Study

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October 7, 2025, Berlin

This presentation was sponsored by Johnson & Johnson.

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Disclosure of Conflicts of Interest

I, **Fernando Magro**, herewith declare the following paid or unpaid consultancies, business interests, or sources of honoraria payments for the past three years, and anything else which could potentially be viewed as a conflict of interest:

Consulting fees from AbbVie, Arena, Celltrion, Eli Lilly and Company, Ferring, Fresenius, Galapagos, GlaxoSmithKline, Johnson & Johnson, Merck, Pfizer, Prometheus Biosciences, Roche, Sandoz, Tillots, Takeda, and Teva.

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Background and Objective

Guselkumab (GUS)

- GUS is a selective, dual-acting IL-23p19 subunit inhibitor that potently blocks IL-23 and binds to CD64, a receptor on immune cells that produce IL-23¹

QUASAR Program

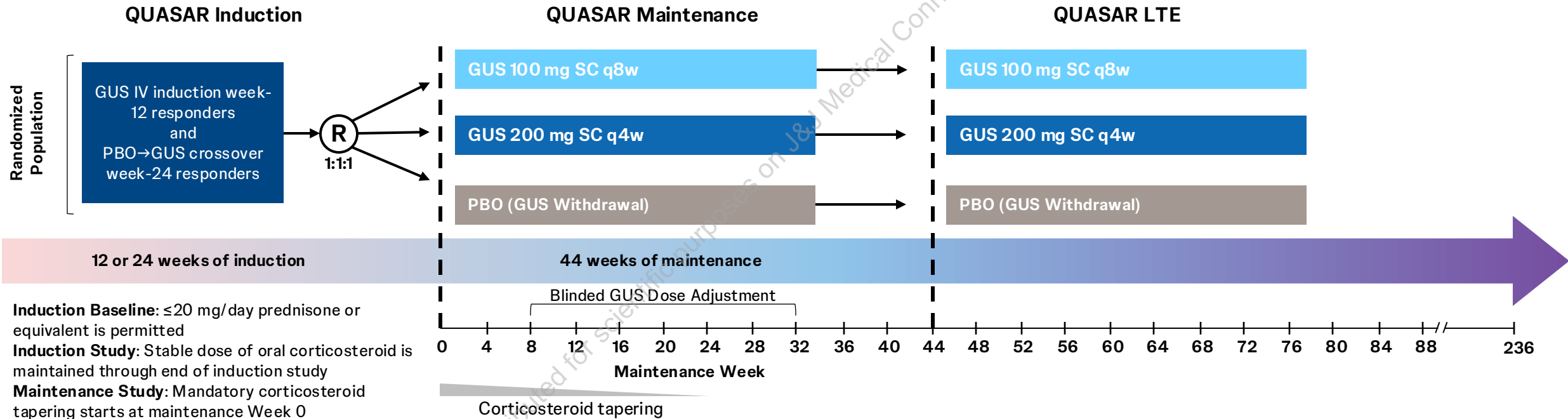
- Positive results for the QUASAR Phase 2b/3 induction studies (GUS IV) and Phase 3 maintenance study (GUS SC) in UC have been reported^{2,3}
- An ongoing LTE is evaluating symptomatic, endoscopic, and histologic efficacy of continued treatment with GUS⁴

Objective

- To describe long-term maintenance of endoscopic and histologic efficacy of GUS through 2 years (Week 92)

Study Design

Target Participant Population: Adults with moderately to severely active UC^a who were in clinical response 12 weeks following GUS IV induction



^aDefined as induction baseline modified Mayo score of 5-9 with a Mayo rectal bleeding subscore ≥1 and a Mayo endoscopic subscore ≥2 based on central review. GUS=guselkumab, IV=intravenous, LTE=long-term extension, PBO=placebo, q4w=every 4 weeks, q8w=every 8 weeks, R=randomized, SC=subcutaneous, UC=ulcerative colitis.




Efficacy Endpoints

Endoscopic improvement	Endoscopic subscore of 0 or 1
Histologic improvement	Neutrophil infiltration in <5% of crypts, no crypt destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system
HEMI	Histologic improvement <i>and</i> endoscopic improvement
Histologic remission	Absence of neutrophils from the mucosa (both lamina propria and epithelium), no crypt destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system (equivalent to a Robarts Histopathology Index ≤ 3 , with subscores of 0 for lamina propria neutrophils and neutrophils in the epithelium and without ulcers or erosion)
Endpoint maintenance at Week 92: Proportion of participants achieving the endpoint at Week 92 among those who achieved the corresponding endpoint at Week 0 or Week 44	

- **Population:** LTE participants who continued to receive their randomized GUS regimen assigned at Week 0 of the maintenance study
- **Efficacy data analyzed by 2 methods:**
 1. NRI approach to account for participants with intercurrent events^a or missing data
 2. “As observed” approach

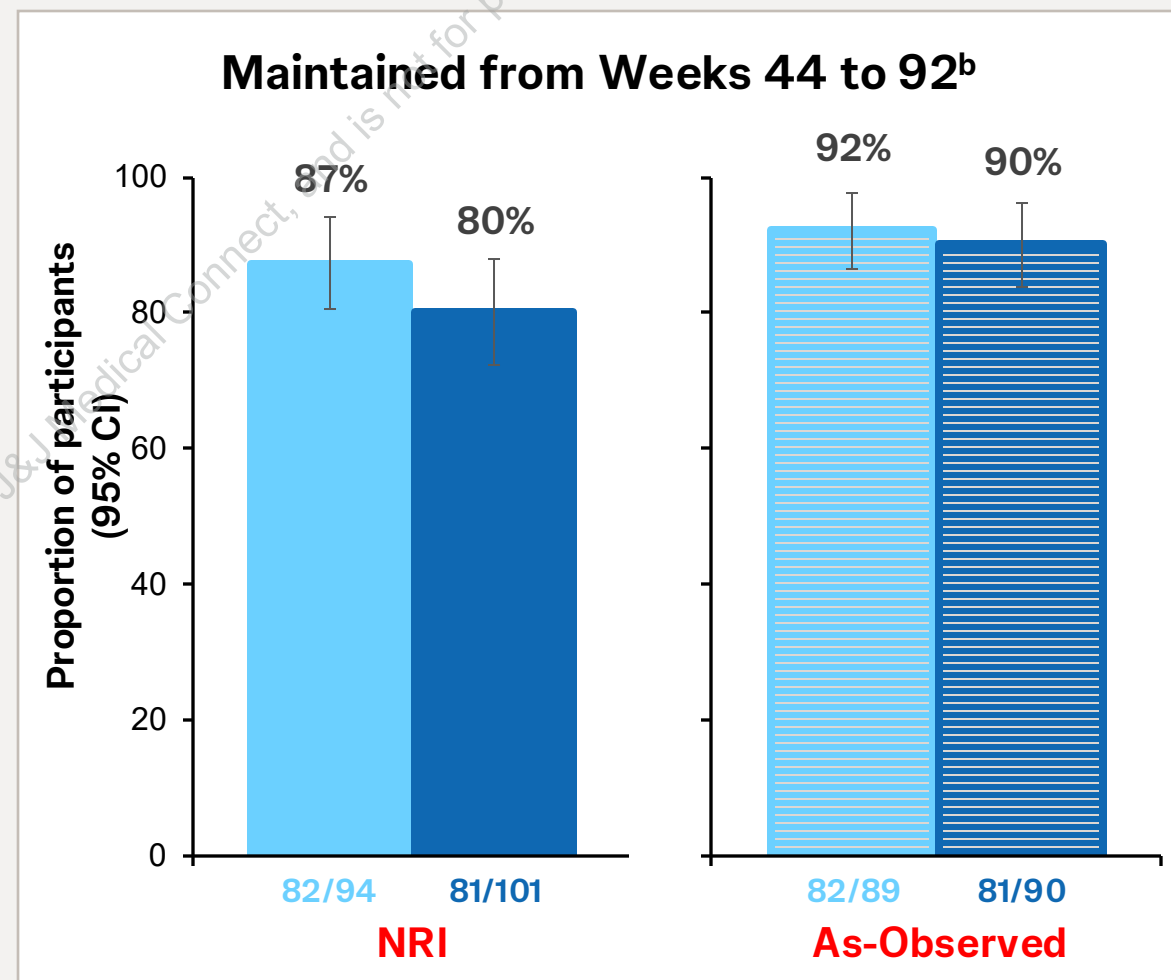
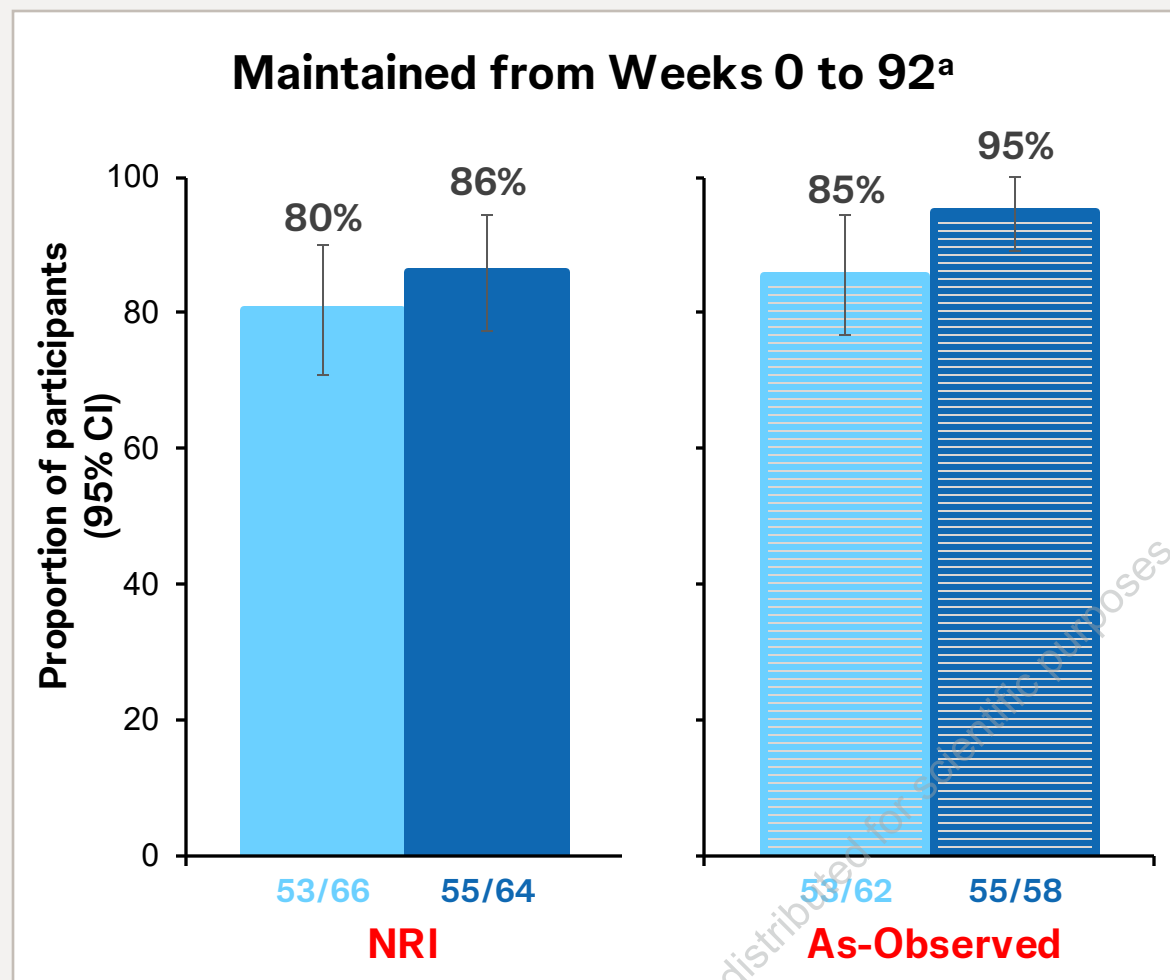
^aParticipants who had an ostomy or colectomy or discontinued study agent due to lack of therapeutic effect or an adverse event of worsening of UC before LTE week 92 were considered not to have achieved efficacy endpoints. For participants who discontinued study agent due to COVID-19–related reasons (excluding COVID-19 infection), regional crisis in Russia and Ukraine, or other reasons, observed values (if available) were used. **GUS**=guselkumab, **HEMI**=histologic-endoscopic mucosal improvement, **LTE**=long-term extension, **NRI**=non-responder imputation, **UC**=ulcerative colitis.

Demographic and Disease Characteristics at Induction Baseline

		GUS 100 mg SC q8w (N=155)	GUS 200 mg SC q4w (N=148)
Demographics			
	Age, mean (SD) yrs	40.2 (12.8)	40.6 (15.1)
	Male	54%	51%
UC Disease Characteristics			
	UC Disease Duration, mean (SD) yrs	8.2 (9.0)	8.2 (8.5)
	Modified Mayo Score (0-9), mean (SD)	6.8 (1.2)	6.9 (1.1)
	Modified Mayo Score of 7-9 (severe)	61%	66%
	Endoscopic Subscore of 3 (severe)	66%	64%
	Extensive UC	43%	47%
	CRP, mg/dL, median (IQR)	4.0 (1.4-10.4)	3.9 (1.5-9.5)
	Fecal Calprotectin, mg/kg, median (IQR)	1709.0 (815.0-3607.0)	1605.5 (596.0-3253.0)
Medication History			
	Oral Corticosteroid Use at Baseline	36%	36%
	Immunosuppressant Use at Baseline	25%	24%
	History of BIO/JAK-IR	39%	42%
	No History of BIO/JAK-IR	61%	58%
	Biologic and JAK Inhibitor-Naïve ^a	95%	94%

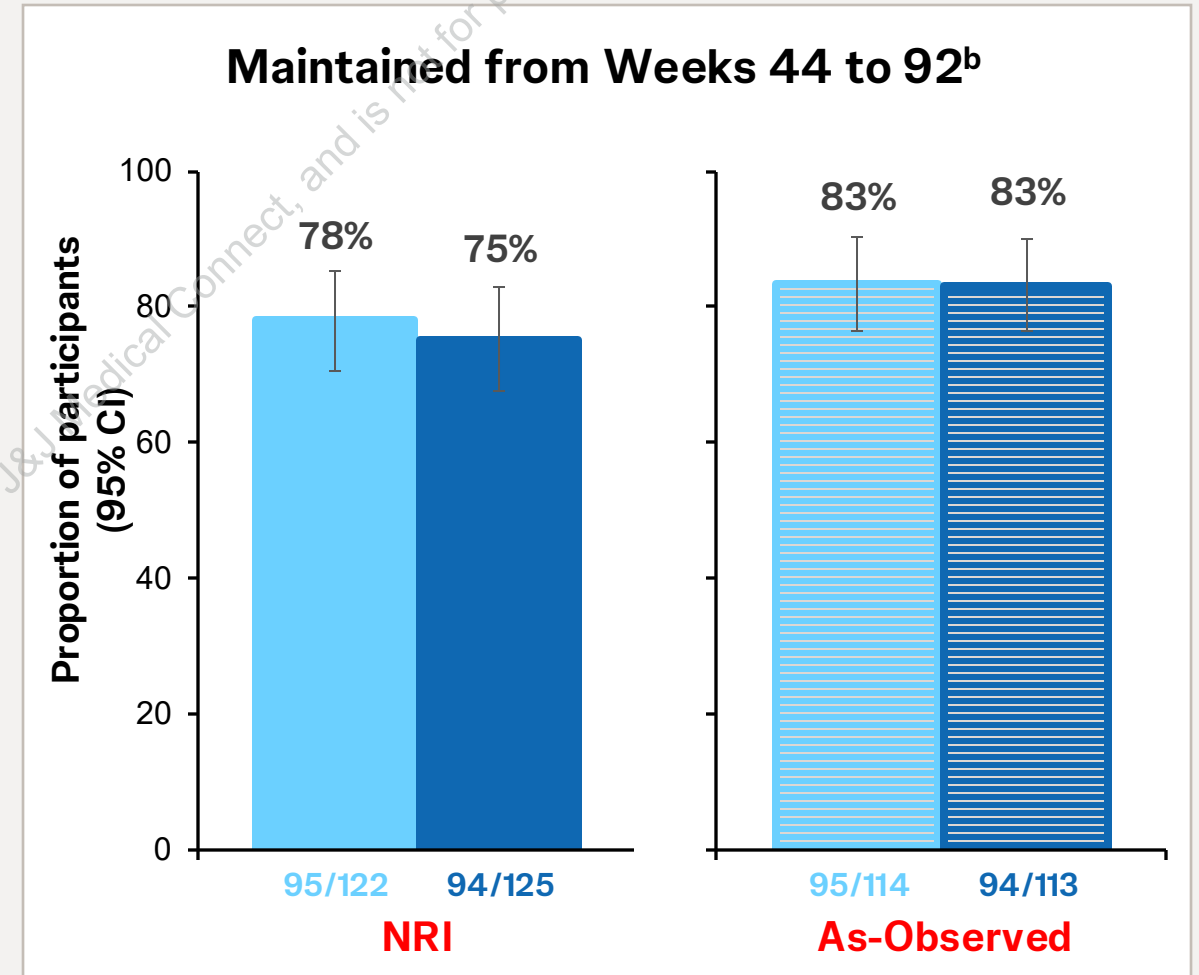
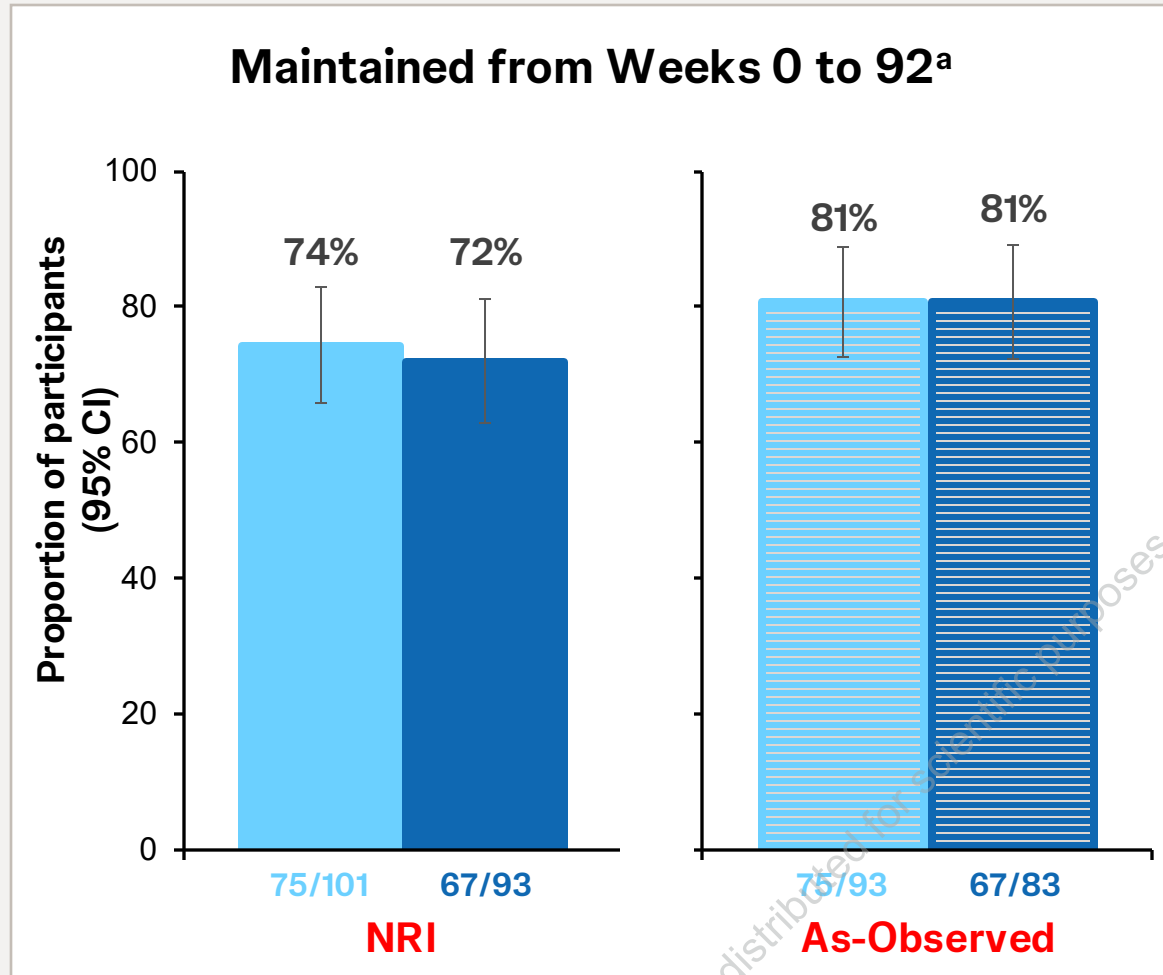
^aDenominator is participants without a history of BIO/JAK-IR. **BIO/JAK-IR**=inadequate response or intolerance to biologic and/or Janus kinase inhibitor, **CRP**=C-reactive protein, **GUS**=guselkumab, **IQR**=interquartile range, **JAK**=Janus kinase, **q4w**=every 4 weeks, **q8w**=every 8 weeks, **SC**=subcutaneous, **SD**=standard deviation, **UC**=ulcerative colitis.

Endoscopic Improvement



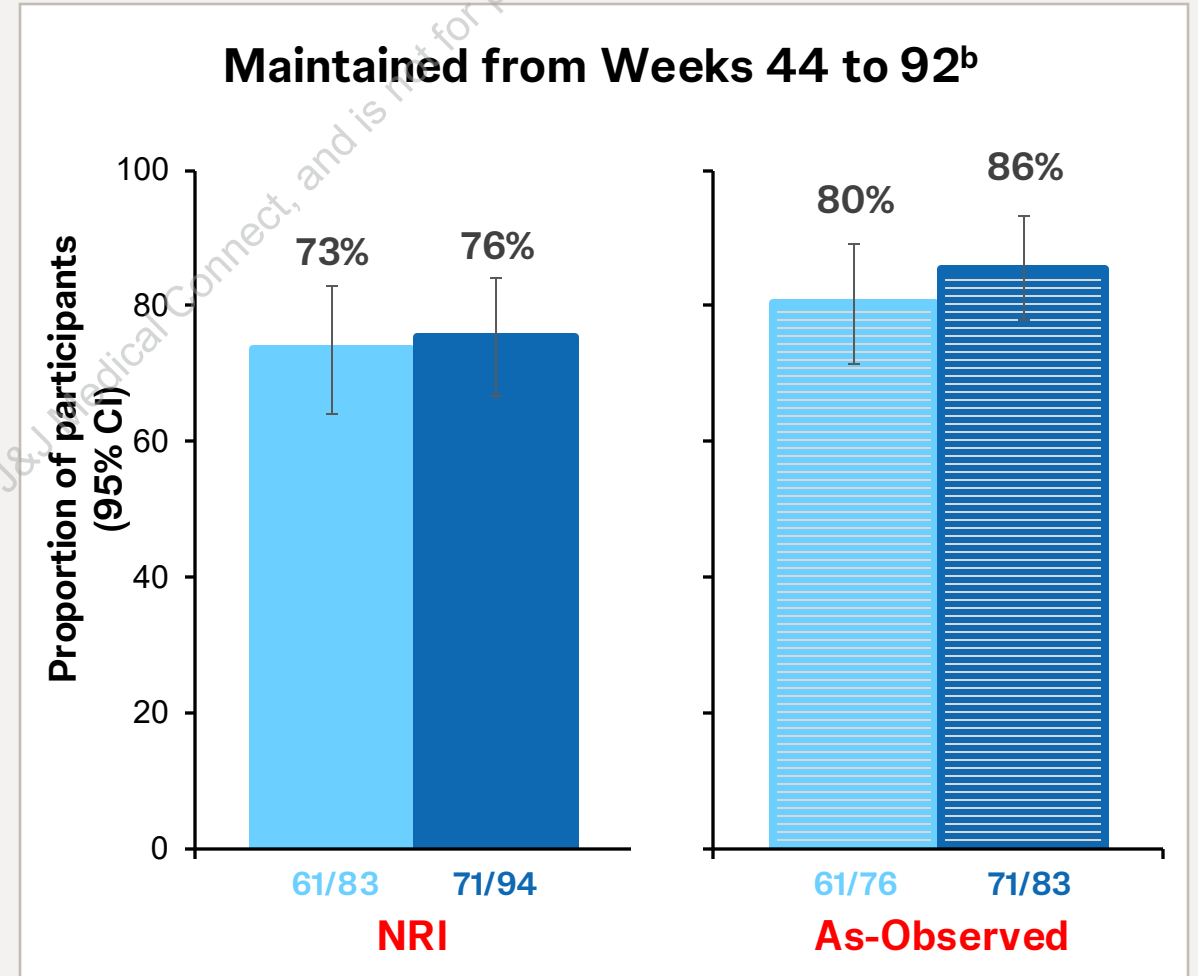
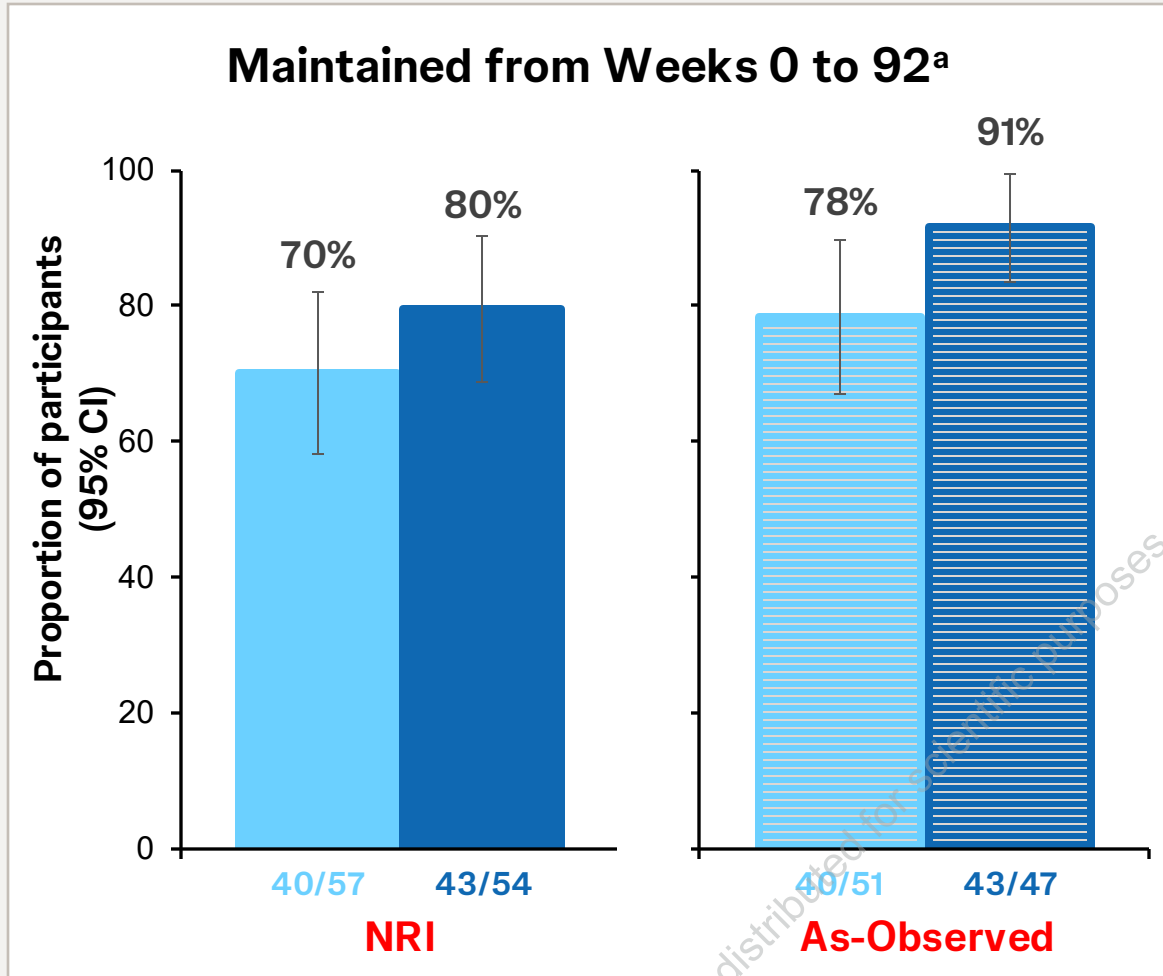
^aEndoscopic improvement is defined as an endoscopic subscore of 0 or 1. ^aEndoscopic improvement at week 92 among participants with endoscopic improvement at week 0 (maintenance baseline).
^bEndoscopic improvement at week 92 among participants with endoscopic improvement at week 44. CI=confidence interval, GUS=guselkumab, NRI=nonresponder imputation, q4w=every 4 weeks, q8w=every 8 weeks, SC=subcutaneous.

Histologic Improvement



Histologic Improvement is defined as neutrophil infiltration in <5% of crypts, no crypt destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system. ^aHistologic improvement at week 92 among participants with histologic improvement at week 0 (maintenance baseline). ^bHistologic improvement at week 92 among participants with histologic improvement at week 44. **CI**=confidence interval, **GUS**=guselkumab, **NRI**=nonresponder imputation, **q4w**=every 4 weeks, **q8w**=every 8 weeks, **SC**=subcutaneous.

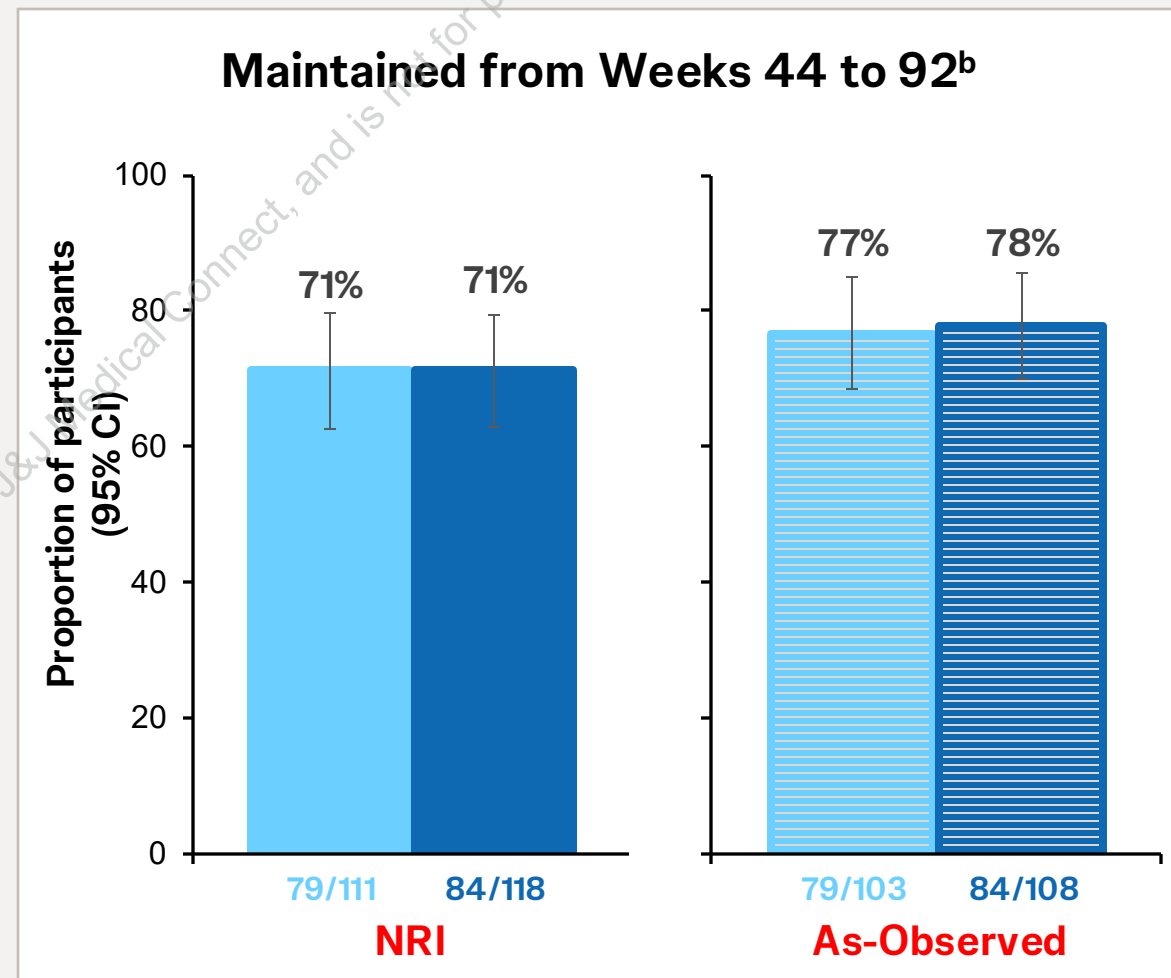
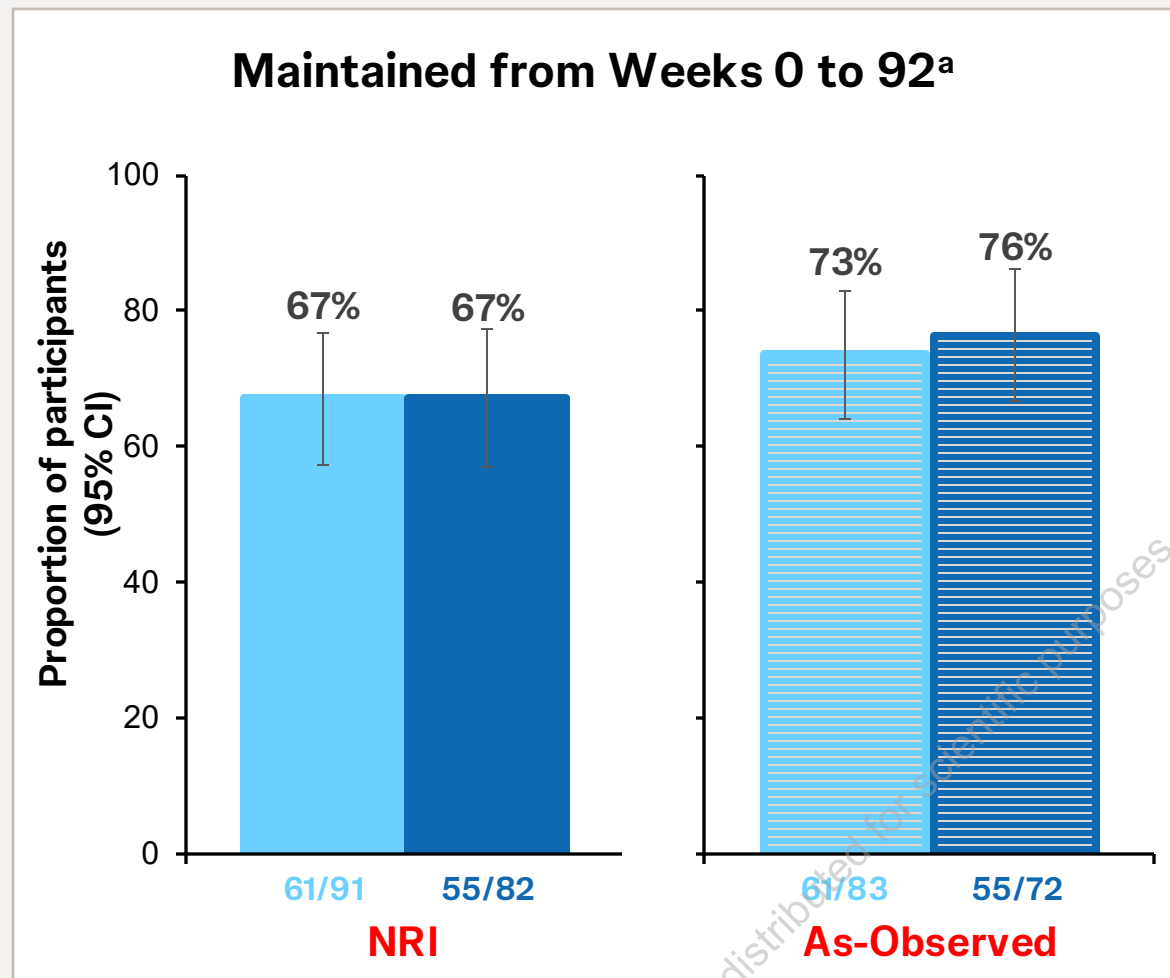
HEMI



■ GUS 100 mg SC q8w
 ■ GUS 200 mg SC q4w

HEMI is defined as the combination of histologic improvement (neutrophil infiltration in <5% of crypts, no crypt destruction, and no erosions, ulcerations or granulation tissue per Geboes grading system) and endoscopic improvement (endoscopic subscore of 0 or 1). ^aHEMI at week 92 among participants with HEMI at week 0 (maintenance baseline). ^bHEMI at week 92 among participants with HEMI at week 44. CI=confidence interval, GUS=guselkumab, HEMI=histologic-endoscopic mucosal improvement, NRI=nonresponder imputation, q4w=every 4 weeks, q8w=every 8 weeks, SC=subcutaneous.

Histologic Remission



Histologic Remission is defined as the absence of neutrophils from the mucosa (both lamina propria and epithelium), no crypt destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system. ^aHistologic remission at week 92 among participants with histologic remission at week 0 (maintenance baseline). ^bHistologic remission at week 92 among participants with histologic remission at week 44. **CI**=confidence interval, **GUS**=guselkumab, **NRI**=nonresponder imputation, **q4w**=every 4 weeks, **q8w**=every 8 weeks, **SC**=subcutaneous.

Key Takeaways

- ✓ **Most GUS-treated participants who achieved endoscopic or histologic outcomes at maintenance baseline or Week 44 maintained these outcomes at Week 92**
- ✓ **The results were generally similar for the GUS 100 mg SC q8w and 200 mg SC q4w dose regimens**
- ✓ **The high retention rate in the LTE up to Week 92 enabled assessment of sustained outcomes in nearly all GUS participants who entered the LTE**

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Acknowledgements

- The authors thank the participants, investigators, and study personnel who made the QUASAR study possible
- Medical writing support was provided by Erin Bekes, PhD, of Certara, under the direction of the authors in accordance with Good Publication Practice guidelines (*Ann Intern Med.* 2022;175:1298-1304)
- This work was supported by Johnson & Johnson

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Back-Up Slides

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Treatment Disposition Through Week 92 for GUS Participants in the LTE

	GUS 100 mg SC q8w (N=155)	GUS 200 mg SC q4w (N=148)
Discontinued treatment prior to Week 92	7 (5%)	9 (6%)
Reasons for discontinuation, n		
Adverse event	2	2
Worsening of UC	1	1
Other than worsening of UC	1	1
Lack of efficacy	1	2
Lost to follow-up	0	0
Death	0	0
Pregnancy	2	0
Participant withdrew	2	3
Other	0	2
Completed treatment through Week 92	148 (95%)	139 (94%)