Efficacy of Subcutaneous Guselkumab in Moderately to Severely Active Ulcerative Colitis by Induction Week 12 Clinical Response Status: Week 48 Results From the Phase 3 ASTRO Study

DOP105

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I, Silvio Danese, 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:

I report consultancy fees from AbbVie, Alimentiv, Allergan, Amgen, AstraZeneca, Athos Therapeutics, Biogen, Boehringer Ingelheim, Celgene, Celltrion, Lilly, Enthera, Ferring, Gilead, Hospira, Inotrem, Johnson & Johnson, MSD, Mundipharma, Mylan, Pfizer, Roche, Sandoz, Sublimity, Takeda, TiGenix, UCB, and Vifor; and report lecture fees from AbbVie, Amgen, Ferring, Gilead, Johnson & Johnson, Mylan, Pfizer, and Takeda.

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Background and Objective

Guselkumab

Guselkumab (GUS) is a selective dual-acting interleukin (IL)-23p19 inhibitor that potently blocks IL-23 and binds to CD64, a receptor on immune cells that produce IL-23[1]

ASTRO Study

The phase 3, randomised, double-blind, treat-through ASTRO study showed that a subcutaneous (SC) induction and maintenance treatment regimen with GUS was efficacious in patients with moderately to severely active ulcerative colitis (UC)[2,3]

Objective

This exploratory analysis of the ASTRO study evaluated clinical and endoscopic outcomes at Week 48 based on clinical response to GUS SC induction at Week 12

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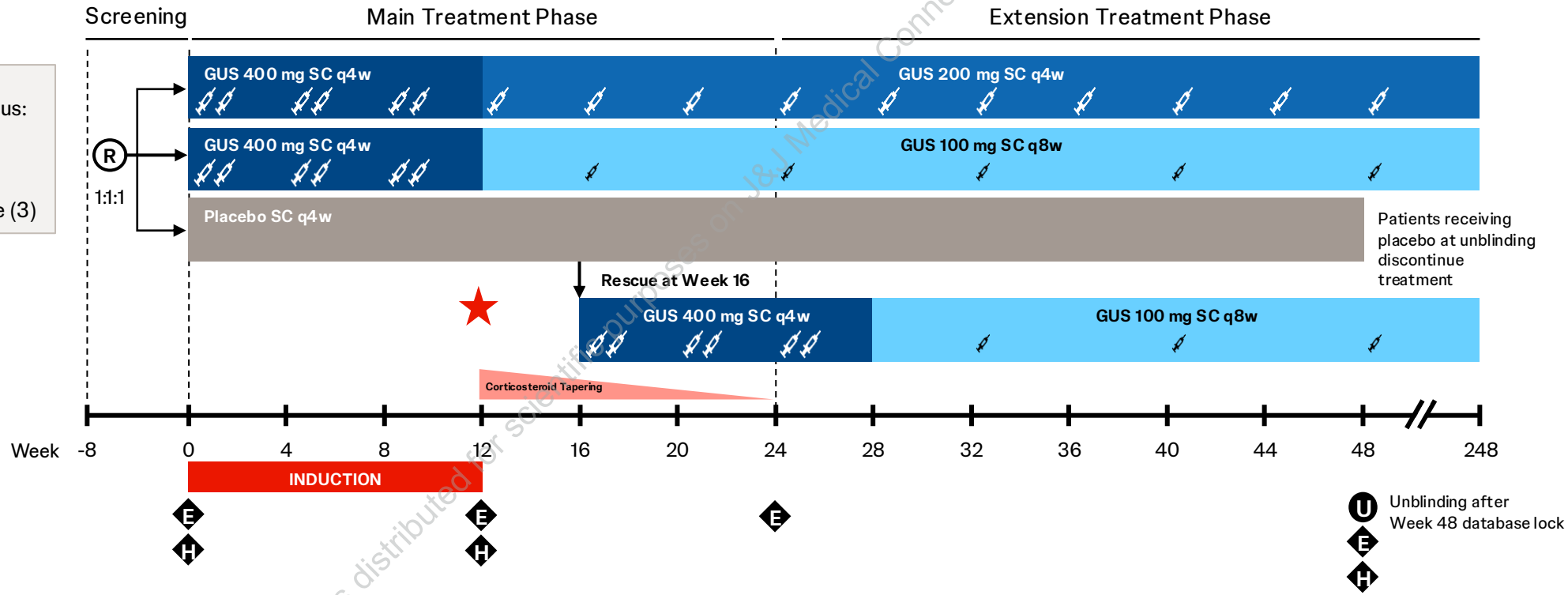
1. Sachen KL, et al. *Front Immunol*. 2025;16:1532852; 2. Allegretti J, et al. *UEG Journal*. 2025;13(Suppl):168; 3. Long, M, et al. *Lancet Gastroenterol Hepatol*. 2026;Jan 13:S2468-1253(25)00322-X.

ASTRO – Study Design

Key Inclusion Criteria:

- Baseline (Week 0) modified Mayo (mMayo) score of 5 to 9
- Baseline Mayo rectal bleeding subscore ≥1, Mayo endoscopic subscore ≥2 (centrally reviewed)
- Inadequate response/intolerance (IR) to tumour necrosis factor alpha (TNFα) blockers, vedolizumab, Janus Kinase (JAK) inhibitors, or Sphingosine-1-phosphate (S1P) inhibitors (biologics [BIO]/JAKi / S1Pi-IR)
  OR naïve to BIO/JAKi / S1Pi (or exposed to BIO/JAKi / S1Pi without IR) and IR to corticosteroids, mercaptopurine (6-MP), or azathioprine (AZA)

Stratified randomisation
- BIO/JAKi / S1Pi-IR status: Yes or No
- Mayo endoscopic subscore at baseline: Moderate (2) or Severe (3)



q4w=every 4 weeks; q8w=every 8 weeks.

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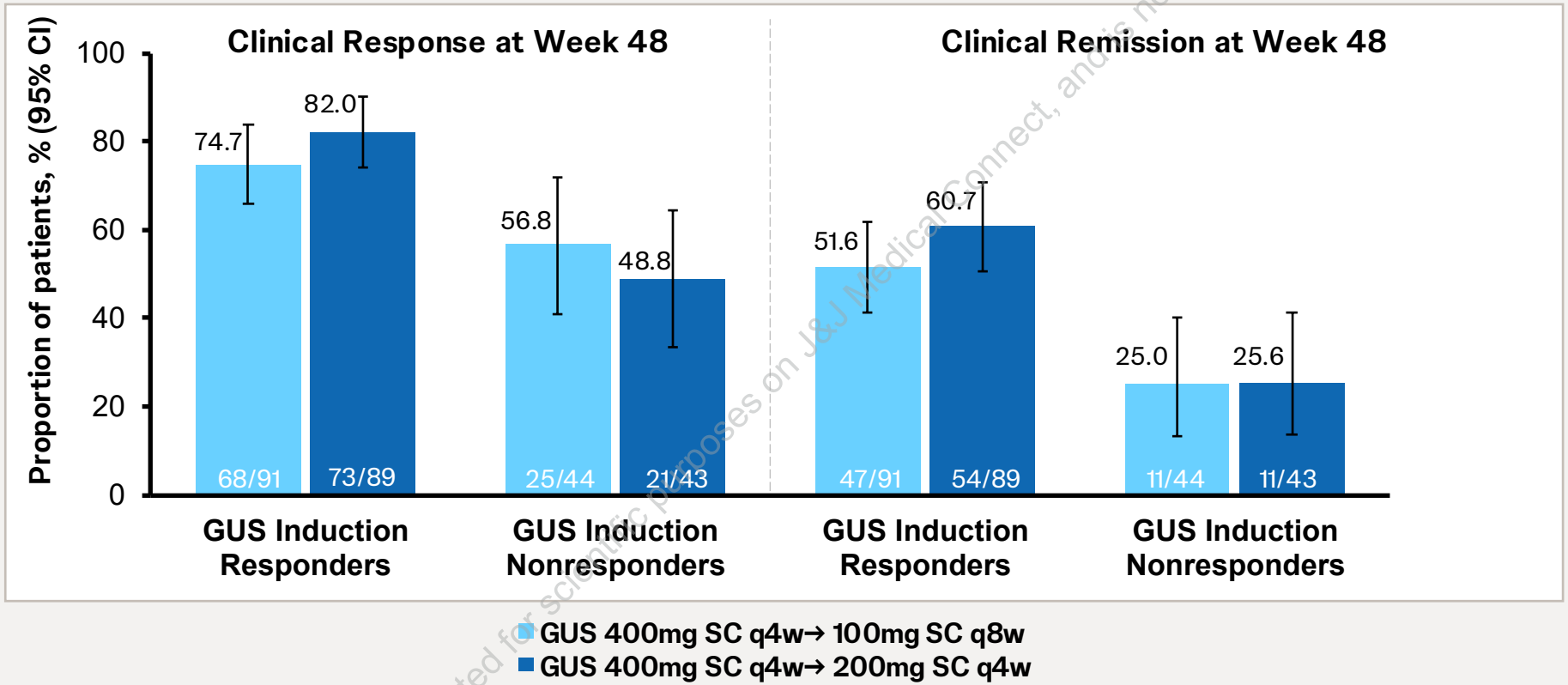
Week 48 Outcomes by Induction Response Status at Week 12



Clinical response: A decrease in mMayo score from baseline by ≥30% and ≥2 points, with either a ≥1-point decrease from baseline in the rectal bleeding subscore or achieving a rectal bleeding subscore of 0 or 1

Clinical remission: A Mayo stool frequency subscore of 0 or 1 and no increase from baseline, a Mayo rectal bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1 with no friability

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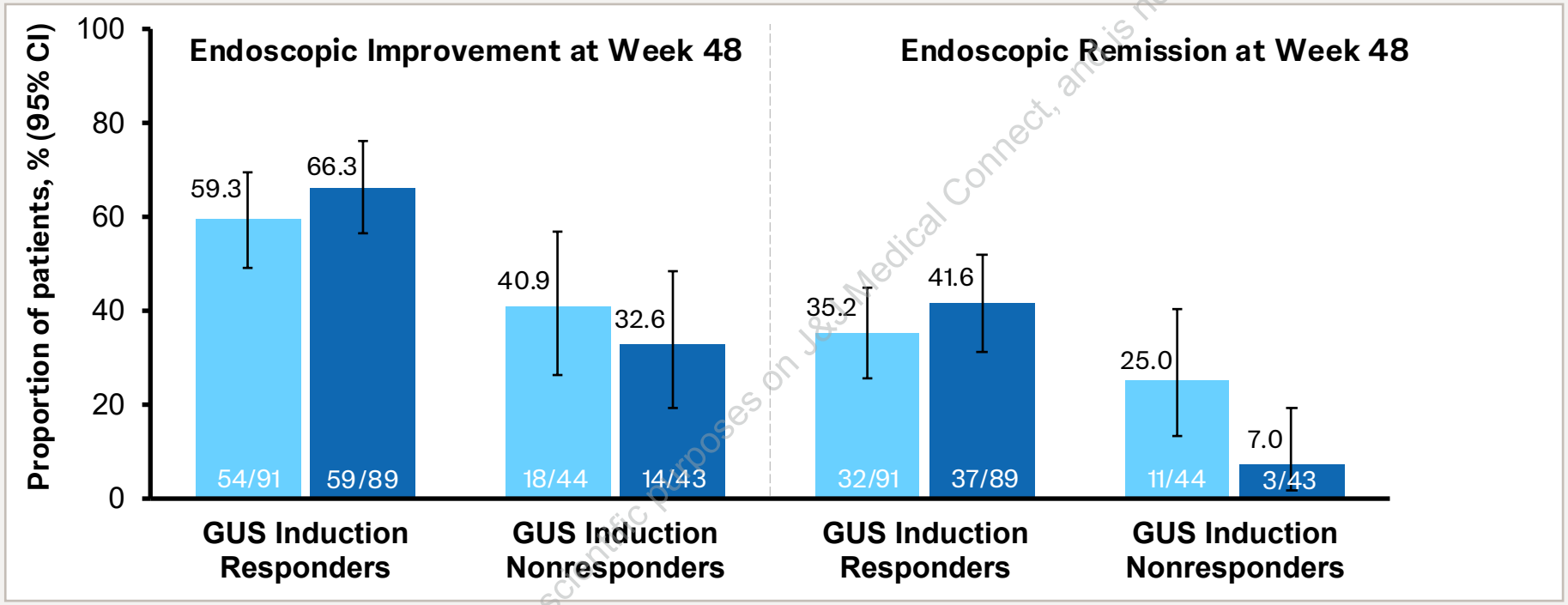
Note: Nonresponder imputation for patients who met rescue criteria in guselkumab groups at Week 12 and Week 16 was suspended in this analysis. CI=confidence interval.

Week 48 Outcomes by Induction Response Status at Week 12



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Endoscopic Improvement: A Mayo endoscopy subscore of 0 or 1 with no friability

Endoscopic remission: A Mayo endoscopy subscore of 0

Note: Nonresponder imputation for patients who met rescue criteria in guselkumab groups at Week 12 and Week 16 was suspended in this analysis.

Baseline Characteristics and Medication History of GUS Induction Week 12 Responders and Nonresponders

	GUS Induction Week 12 Responders (N=180)	GUS Induction Week 12 Nonresponders (N=87)
Demographics		
Age in years, mean (SD)	41.6 (14.0)	44.9 (15.1)
Male	56.7%	66.7%
Disease characteristics		
UC duration in years, mean (SD)	8.09 (7.02)	8.21 (6.72)
mMayo score (0-9), mean (SD)	6.7 (1.1)	6.7 (1.2)
mMayo score of 7-9 (severe)	57.2%	67.8%
Mayo endoscopy subscore of 3 (severe)	50.0%	65.5%
Extensive UC	48.9%	62.1%
UC-related concomitant medications		
Oral corticosteroid use	30.0%	36.8%
6-MP/AZA use	22.2%	16.1%
Oral 5-ASA compound use	78.9%	75.9%
BIO/JAKi/S1Pi naïve, n (%)	115 (63.9%)	43 (49.4%)
BIO/JAKi/S1Pi-IR, n (%)	63 (35.0%)	43 (49.4%)
One class[a]	47 (74.6%)	29 (67.4%)
≥2 classes[a]	16 (25.4%)	14 (32.6%)

[a]Denominator is patients who were BIO/JAKi/S1Pi-IR. 5-ASA=5-aminosalicylic acid; SD=standard deviation.

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Baseline Characteristics and Medication History of GUS Induction Week 12 Nonresponders by Remission Status at Week 48

	GUS Induction Week 12 Nonresponders	
	Achieved Clinical Remission at Week 48 (N=22)	Did Not Achieve Clinical Remission at Week 48 (N=65)
Demographics		
Age in years, mean (SD)	43.1 (16.4)	45.5 (14.8)
Male	68.2%	66.2%
Disease characteristics		
UC duration in years, mean (SD)	6.71 (5.93)	8.72 (6.93)
mMayo score (0-9), mean (SD)	6.9 (1.6)	6.6 (1.1)
mMayo score of 7-9 (severe)	77.3%	64.6%
Mayo endoscopy subscore of 3 (severe)	72.7%	63.1%
Extensive UC	54.5%	64.6%
UC-related concomitant medications		
Oral corticosteroid use	31.8%	38.5%
6-MP/AZA use	36.4%	9.2%
Oral 5-ASA compound use	90.9%	70.8%
BIO/JAKi/S1Pi naïve, n (%)	15 (68.2%)	28 (43.1%)
BIO/JAKi/S1Pi-IR, n (%)	7 (31.8%)	36 (55.4%)
One class[a]	5 (71.4%)	24 (66.7%)
≥2 classes[a]	2 (28.6%)	12 (33.3%)

[a]Denominator is patients who were BIO/JAKi/S1Pi-IR.

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Key Takeaways

Among patients with moderately to severely active UC in the ASTRO study:

- ✓ **Patients who achieved clinical response after GUS SC induction treatment had better clinical and endoscopic outcomes at Week 48 than those who did not achieve clinical response after induction**
- ✓ **A subset of patients who were not in clinical response after induction but continued GUS SC maintenance achieved clinical and endoscopic endpoints at Week 48**

Overall, these results suggest a benefit of continued GUS treatment after Week 12 regardless of induction clinical response status

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