DDW 2025
Short Flow Deck

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Johnson&Johnson
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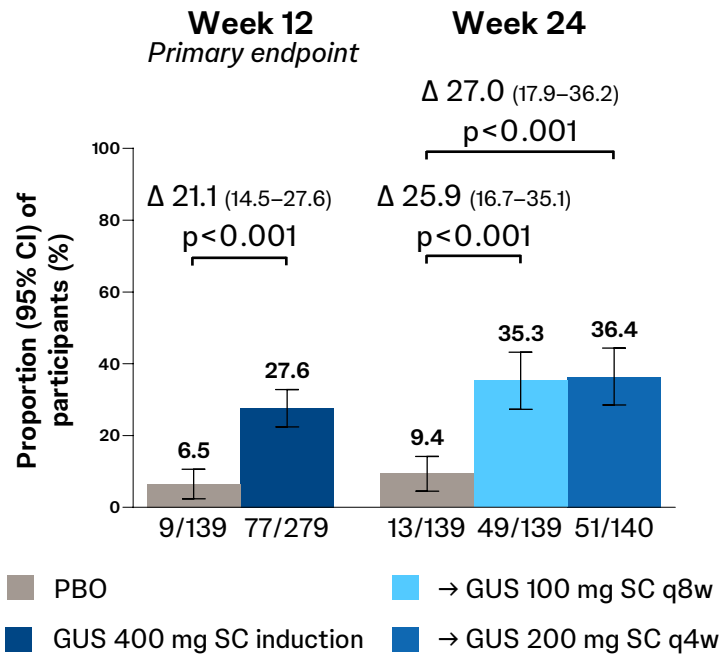
Immunology

DDW 2025 guselkumab highlights

Johnson&Johnson Innovative Medicine

ASTRO: Efficacy and safety through Week 24 in UC[1]

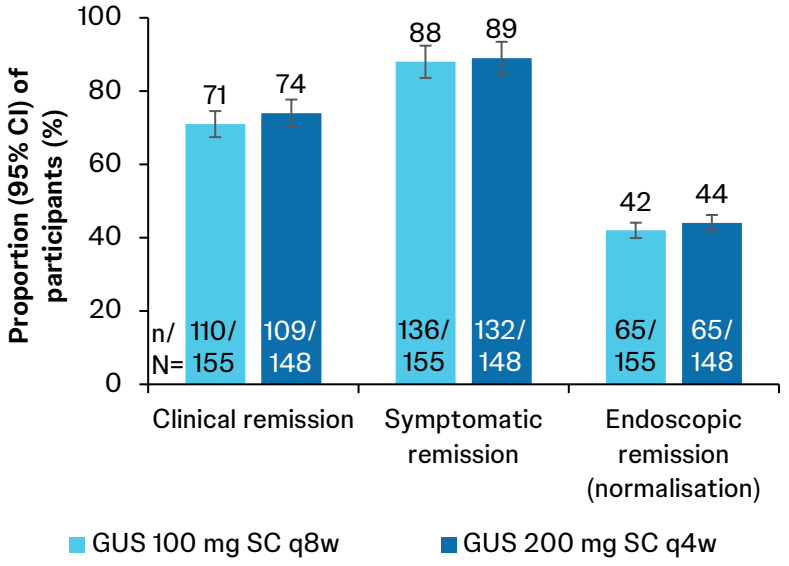
Clinical remission



- ASTRO results showed the efficacy of a fully SC induction and maintenance regimen through Week 24 with GUS in UC
- Clinically meaningful benefit was observed regardless of prior BIO/JAKi/S1Pi treatment history
- No new safety concerns were identified

QUASAR LTE: Efficacy and safety through Week 92 in UC[2]

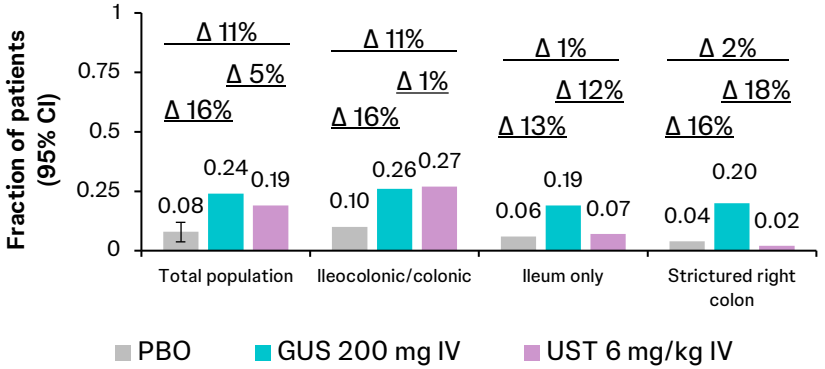
Efficacy outcomes at Week 92



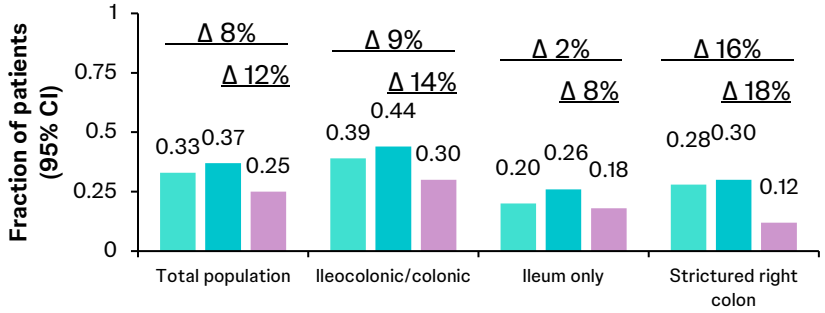
- Both GUS maintenance dose regimens sustained symptomatic, endoscopic and histologic efficacy in participants with UC through Week 92 of the LTE
- Efficacy was sustained regardless of prior biologic and/or JAKi treatment history
- No new safety concerns were identified

GRAVITI/GALAXI: Differential treatment effects of GUS and UST in CD[3]

Endoscopic remission rate Week 12



Endoscopic remission rate Week 48



- At Week 48, endoscopic remission was higher for patients receiving GUS than for patients receiving UST
- Improved narrowing characterised a subset of GUS responders at Week 12 and not UST
- Data-driven endoscopic patient clustering in CD can lead to stratified understanding of differential treatment effects between GUS and UST

Δ = adjusted treatment difference (95% CI) and p-value vs. PBO.
BIO, biologic; CD, Crohn's disease; CI, confidence interval; DDW, Digestive Disease Week; GUS, guselkumab; IV, intravenous; JAKi, Janus kinase inhibitor; LTE, long-term extension; PBO, placebo; qxw, every x weeks; S1Pi, sphingosine 1-phosphate inhibitor; SC, subcutaneous; UC, ulcerative colitis; UST, ustekinumab.

1. Long M, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. OP800; 2. Lichtenstein GR, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. Su1856; 3. Richards D, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. Su1861.

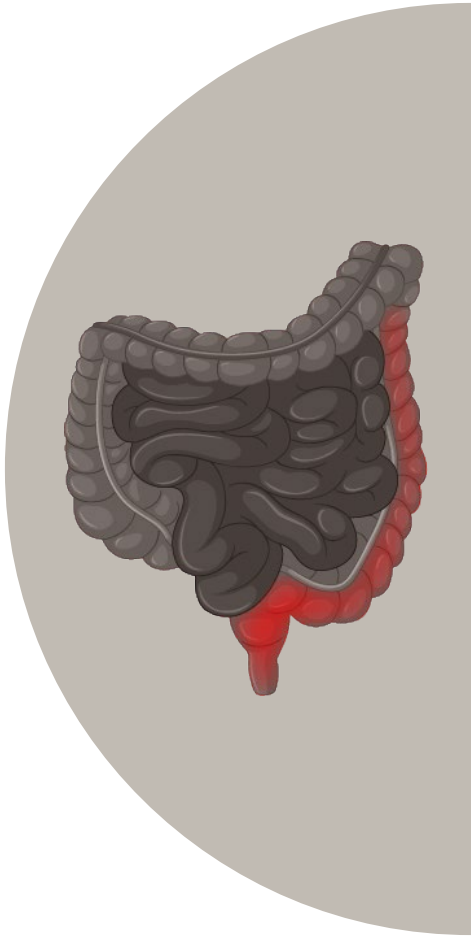
Overview

DDW 2025

ASTRO	*Long, et al.*: Efficacy and safety of subcutaneous GUS induction therapy in patients with moderately to severely active UC: Results through Week 24 from the Phase 3 ASTRO study
QUASAR	*Lichtenstein, et al.*: Efficacy and safety of GUS for UC through Week 92 during the QUASAR long-term extension study
GALAXI/GRAVITI	*Richards, et al.*: Endoscopic patient clustering to investigate differential treatment effects of GUS and UST in CD: *Post-hoc* analysis of GALAXI and GRAVITI trials
GALAXI/GRAVITI	*Afzali, et al.*: Efficacy of GUS intravenous and subcutaneous induction: Symptoms, HRQoL and inflammatory biomarker results from the GALAXI and GRAVITI studies

CD, Crohn's disease; DDW, Digestive Disease Week; GUS, guselkumab; HRQoL, health-related quality of life; UC, ulcerative colitis; UST, ustekinumab.

Guselkumab in ulcerative colitis



ASTRO

Efficacy and safety of subcutaneous guselkumab induction therapy in patients with ulcerative colitis: Results through Week 24 from the Phase 3 ASTRO study

Long M[1], Allegretti JR[2], Danese S[3], Germinaro M[4], Baker T[4], Alvarez Y[4], Jorgens S[4], Jiang L[4], Zhang H[4], Hisamatsu T[5], Rubin DT[6], Peyrin-Biroulet L[7]

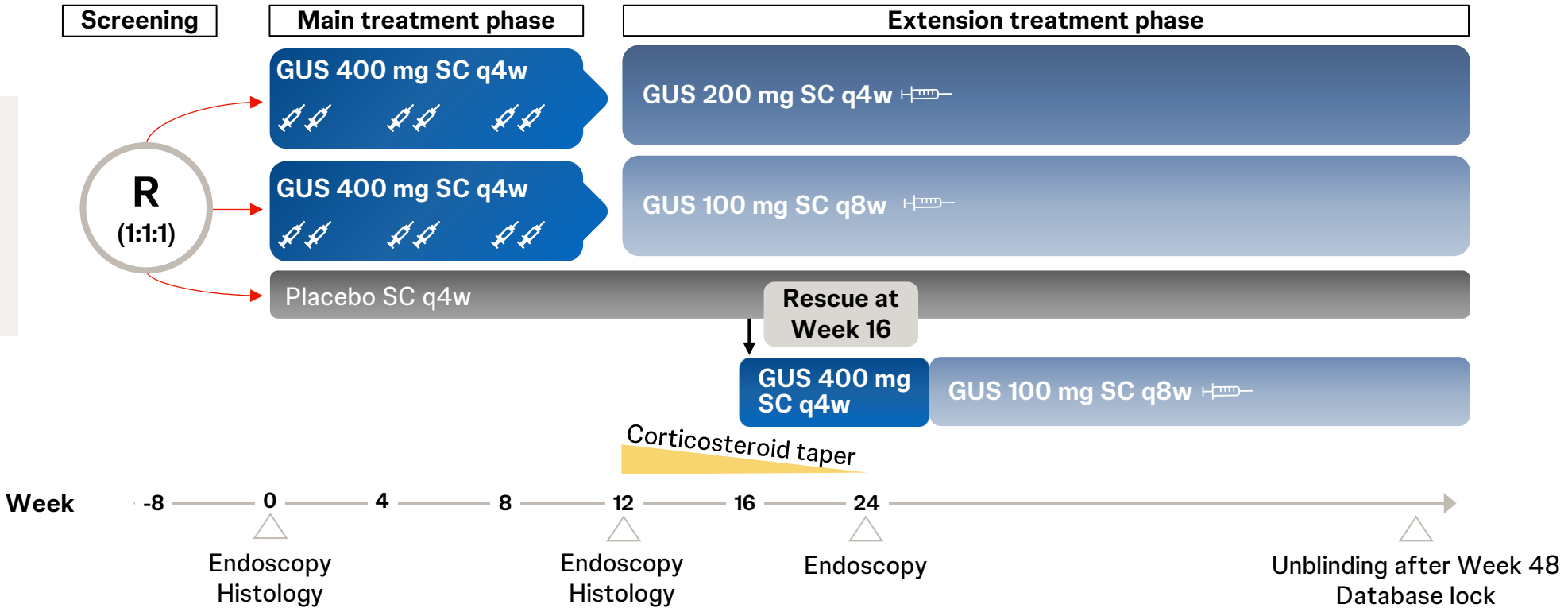
[1]UNC Division of Gastroenterology and Hepatology, Chapel Hill, NC, USA; [2]Division of Gastroenterology, Hepatology and Endoscopy, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA; [3]Gastroenterology and Digestive Endoscopy, IRCCS Ospedale San Raffaele and University Vita-Salute San Raffaele, Milan, Italy; [4]Janssen Research & Development, LLC, Spring House, PA, USA; [5]Kyorin University Faculty of Medicine, Tokyo, Japan; [6]University of Chicago Medicine Inflammatory Bowel Disease Center, Chicago, IL, USA; [7]University of Lorraine, Nutrition-Genetics and Exposure to Environmental Risks unit, F-54000 Nancy, France and Groupe Hospitalier privé Ambroise Paré-Hartmann, Paris IBD Centre, 92200 Neuilly sur Seine, France

Study design

ASTRO

Aim: To evaluate the efficacy and safety of GUS SC induction in participants with moderately to severely active UC

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



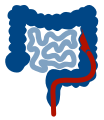
Key eligibility criteria
- Baseline (Week 0) modified Mayo score of 5–9
- Baseline Mayo rectal bleeding subscore ≥1, Mayo endoscopic subscore ≥2 (centrally reviewed)
- IR to TNFα blockers, vedolizumab, JAKi or S1Pi (BIO / JAKi / S1Pi-IR) **OR** naïve to BIO / JAKi / S1Pi (or exposed to BIO / JAKi / S1Pi without IR) and IR to CS, 6-MP or AZA

6-MP, mercaptopurine; AZA, azathioprine; BIO, biologic; CS, corticosteroid; GUS, guselkumab; IR, inadequate response/intolerance; JAKi, Janus kinase inhibitor; qxw, every x weeks; R, randomised; S1Pi, sphingosine-1-phosphate inhibitor; SC, subcutaneous; TNF, tumour necrosis factor; UC, ulcerative colitis.

Long M, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. OP800.

Baseline characteristics and UC medications

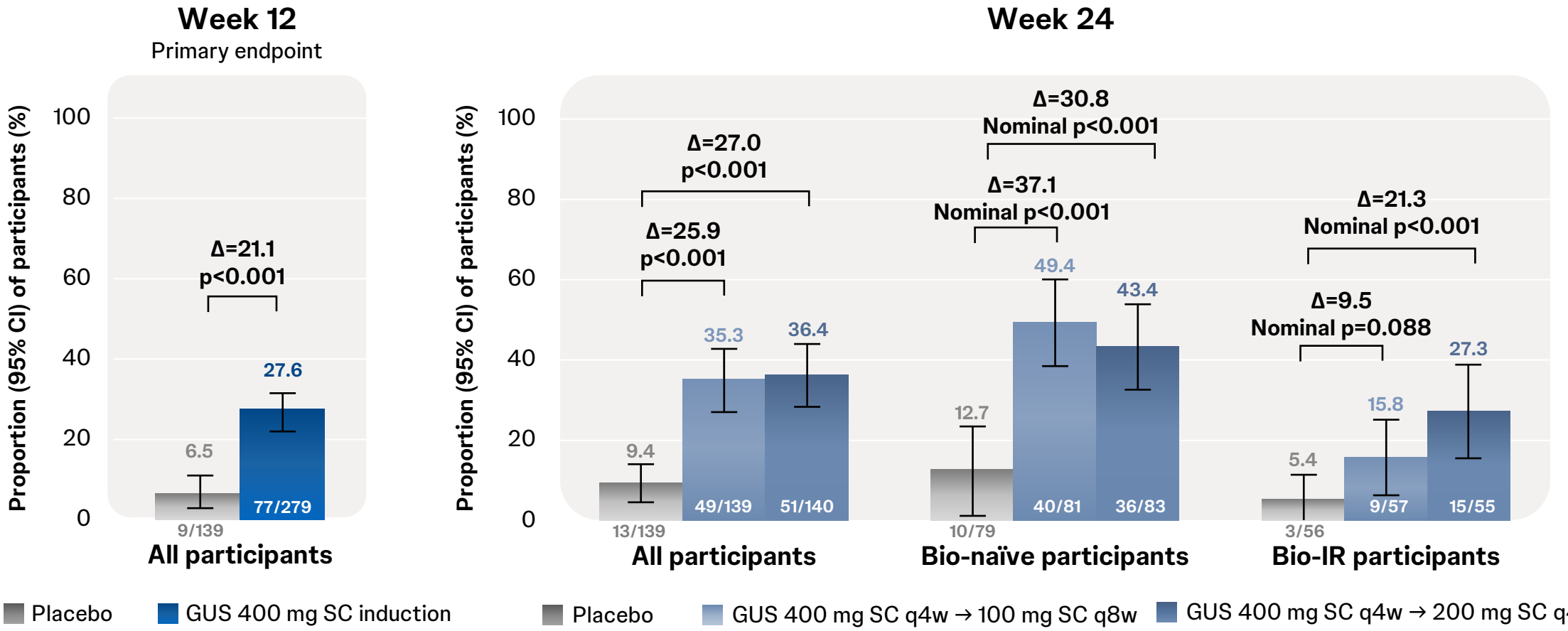
ASTRO



	Placebo (n=139)	GUS 400 mg SC → 100 mg SC q8w (n=139)	GUS 400 mg SC → 200 mg SC q4w (n=140)
UC disease duration in years, mean (SD)	6.61 (6.228)	8.39 (7.317)	7.69 (6.352)
Extensive UC, n (%)	73 (52.5%)	69 (49.6%)	82 (58.6%)
Modified Mayo score* (0–9), mean (SD)	6.8 (1.09)†	6.8 (1.20)	6.6 (1.15)
Modified Mayo score of 7–9 (severe), n (%)	87 (63.0%)†	95 (68.3%)	77 (55.0%)
Mayo endoscopic subscore of 3 (severe), n (%)	78 (56.1%)	78 (56.1%)	78 (55.7%)
C-reactive protein,‡ median in mg/l (IQR)	3.8 (1.2–10.9)	3.7 (1.3–7.2)	4.7 (1.7–9.1)
Faecal calprotectin, median in mg/kg (IQR)**	1749.0 (617.0–3202.0)	1351.5 (609.0–2805.0)	1594.0 (838.0–3336.0)
Baseline oral corticosteroid use, n (%)	46 (33.1%)	50 (36.0%)	41 (29.3%)
Naïve to BIO / JAKi / S1Pi, n (%)	79 (56.8%)	81 (58.3%)	83 (59.3%)
BIO / JAKi / S1Pi-IR, n (%)	56 (40.3%)	57 (41.0%)	55 (39.3%)
One class¶	39 (69.6%)	40 (70.2%)	38 (69.1%)
Two classes¶	13 (23.2%)	10 (17.5%)	11 (20.0%)
Three or more classes¶	4 (7.1%)	7 (12.3%)	6 (10.9%)

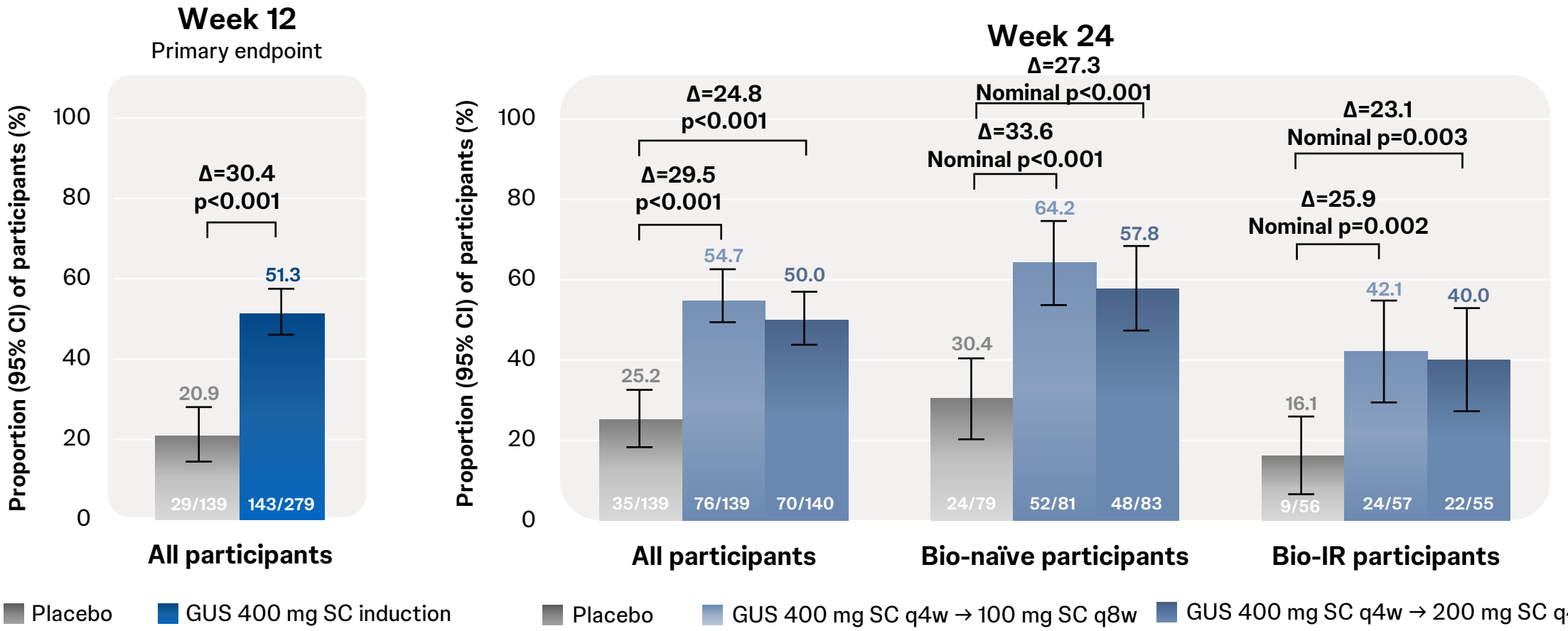
*Modified Mayo score: 3-component (stool frequency, rectal bleeding and endoscopy subscores) Mayo score without the physician's global assessment; †Based on n=138. ‡Based on n=138 for placebo, n=136 for GUS 400 mg SC→100 mg SC q8w, n=140 for GUS 400 mg SC→200 mg SC q4w; **Based on n=131 for placebo, n=126 for GUS 400 mg SC→100 mg SC q8w, n=128 for GUS 400 mg SC→200 mg SC q4w; ¶Denominator is participants who were BIO/JAKi/S1Pi-IR.
BIO, biologic; GUS, guselkumab; IQR, interquartile range; JAKi, Janus kinase inhibitor; qxw, every x weeks; S1Pi, sphingosine 1-phosphate inhibitor; SC, subcutaneous; SD, standard deviation; UC, ulcerative colitis.
Long M, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. OP800.

Clinical remission



Clinical remission: A Mayo stool frequency subscore of 0 or 1 and not increased from baseline, a Mayo rectal bleeding subscore of 0 and a Mayo endoscopic subscore of 0 or 1 with no friability.
Δ=adjusted treatment difference and p-value vs. placebo. Subpopulation analyses were not multiplicity controlled (nominal p-values). Participants who, prior to the assessment timepoint, had an ostomy or colectomy, a prohibited change in concomitant UC medications, discontinued study agent due to lack of efficacy or an AE of worsening UC, or met rescue criteria per IWRS if applicable were considered not to meet the endpoint criteria. Participants who discontinued study agent due to COVID-19–related reasons (excluding COVID-19 infection) or regional crisis had their observed data used, if available. Participants who discontinued study agent for other reasons prior to the assessment timepoint were considered not to meet the endpoint criteria. After accounting for these scenarios, participants who were missing data necessary for calculation of the outcome measure at the assessment timepoint were considered not to have achieved that endpoint.
AE, adverse event; Bio, biologic; CI, confidence interval; GUS, guselkumab; IWRS, Interactive Web Response System; qxw, every x weeks; SC, subcutaneous; UC, ulcerative colitis.
Long M, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. OP800.

Symptomatic remission



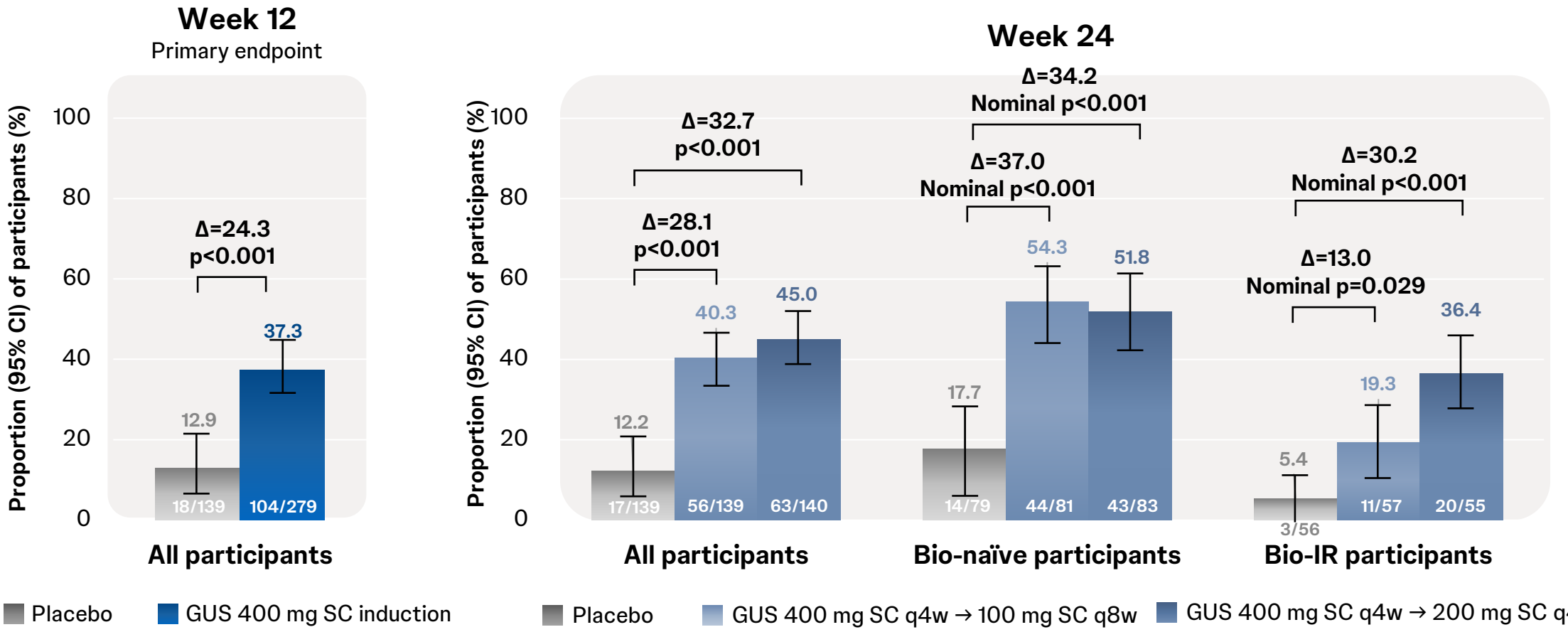
Symptomatic remission: A stool frequency subscore of 0 or 1 and not increased from baseline, and a rectal bleeding subscore of 0.

Δ=adjusted treatment difference and p-value vs. placebo. Subpopulation analyses were not multiplicity controlled (nominal p-values). Participants who, prior to the assessment timepoint, had an ostomy or colectomy, a prohibited change in concomitant UC medications, discontinued study agent due to lack of efficacy or an AE of worsening UC, or met rescue criteria per IWRS if applicable were considered not to meet the endpoint criteria. Participants who discontinued study agent due to COVID-19–related reasons (excluding COVID-19 infection) or regional crisis had their observed data used, if available. Participants who discontinued study agent for other reasons prior to the assessment timepoint were considered not to meet the endpoint criteria. After accounting for these scenarios, participants who were missing data necessary for calculation of the outcome measure at the assessment timepoint were considered not to have achieved that endpoint.

AE, adverse event; Bio, biologic; CI, confidence interval; GUS, guselkumab; IWRS, Interactive Web Response System; qxw, every x weeks; SC, subcutaneous; UC, ulcerative colitis.

Long M, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. OP800.

Endoscopic improvement



Endoscopic improvement: An endoscopic subscore of 0, or 1 with no friability.

Δ=adjusted treatment difference and p-value vs. placebo. Subpopulation analyses were not multiplicity controlled (nominal p-values). Participants who, prior to the assessment timepoint, had an ostomy or colectomy, a prohibited change in concomitant UC medications, discontinued study agent due to lack of efficacy or an AE of worsening UC, or met rescue criteria per IWRS if applicable were considered not to meet the endpoint criteria. Participants who discontinued study agent due to COVID-19–related reasons (excluding COVID-19 infection) or regional crisis had their observed data used, if available. Participants who discontinued study agent for other reasons prior to the assessment timepoint were considered not to meet the endpoint criteria. After accounting for these scenarios, participants who were missing data necessary for calculation of the outcome measure at the assessment timepoint were considered not to have achieved that endpoint.

AE, adverse event; Bio, biologic; CI, confidence interval; GUS, guselkumab; IWRS, Interactive Web Response System; qxw, every x weeks; SC, subcutaneous; UC, ulcerative colitis.

Long M, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. OP800.

Safety

ASTRO

AEs through Week 24

	Placebo* (n=139)	GUS 400 mg SC → 100 mg SC q8w (n=139)	GUS 400 mg SC → 200 mg SC q4w (n=140)
Average duration of follow-up, weeks	20.7	24.0	24.2
Deaths, n (%)	1 (0.7%)	0	0
Participants with 1 or more:			
AEs, n (%)	91 (65.5%)	74 (53.2%)	85 (60.7%)
Serious AEs, n (%)	17 (12.2%)	5 (3.6%)	6 (4.3%)
AEs leading to discontinuation of study agent, n (%)	12 (8.6%)	3 (2.2%)	4 (2.9%)
Infections,† n (%)	36 (25.9%)	33 (23.7%)	32 (22.9%)
Serious infections‡	1 (0.7%)	1 (0.7%)	3 (2.1%)

*Includes all placebo participants, excluding data after a participant is rescued with GUS; †Infections were defined as any adverse event coded to the MedDRA system organ class "Infections and infestations"; ‡Serious infections reported with GUS were appendicitis (n=2), pilonidal disease (n=1) and gastroenteritis (n=1).
AE, adverse event; GUS, guselkumab; MedDRA, Medical Dictionary for Regulatory Activities; qxw, every x weeks; SC, subcutaneous.
Long M, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. OP800.

Summary

- ASTRO results demonstrated the efficacy of a fully SC induction and maintenance regimen through Week 24 with GUS in UC
- Clinically meaningful benefit was observed both in participants naïve to BIO/JAKi/S1Pi and in those with prior IR to BIO/JAKi/S1Pi
- The safety of a fully SC treatment regimen was consistent with the well-characterised and favourable safety profile of GUS
- These results complement the QUASAR* data in UC and GUS data in CD,† demonstrating that both IV and SC induction with GUS are efficacious therapeutic options in IBD, providing simplicity for patients and healthcare providers

*Rubin DT, et al. *Lancet* 2025;405:33–49; †Hart A, et al. *Gastroenterology* 2025; doi: 10.1053/j.gastro.2025.02.033 and Panaccione R, et al. Presented at DDW, Washington, DC, US. 18–21 May 2024; DOP1057b.
BIO, biologic; CD, Crohn's disease; GUS, guselkumab; IBD, inflammatory bowel disease; IR, inadequate response or intolerance; IV, intravenous; JAKi, Janus kinase inhibitor; S1Pi, sphingosine 1-phosphate inhibitor; SC, subcutaneous; UC, ulcerative colitis.
Long M, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. OP800.

QUASAR

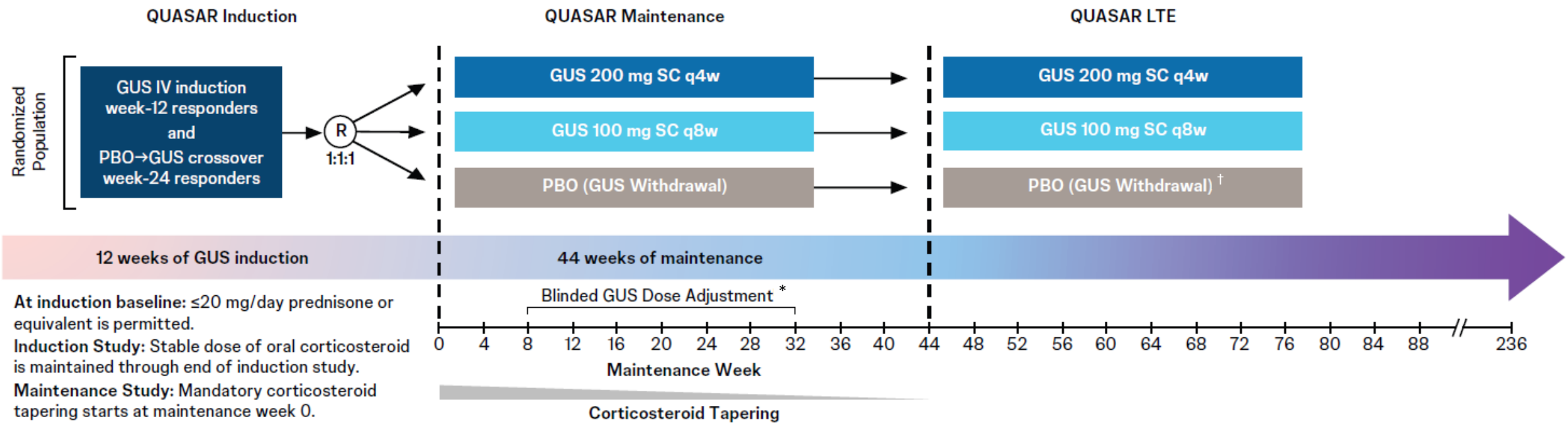
Efficacy and safety of guselkumab for ulcerative colitis through Week 92 during the QUASAR long-term extension study

Lichtenstein GR[1], Allegretti JR[2], Rubin DT[3], Feagan GF[4], Bressler B[5], Panés J[6], Afif W[7], Samaan MA[8], Ye BD[9], Yarandi S[10], Germinaro M[10], Shipitofsky N[10], Miao Y[10], Mistry P[10], Zhang H[10], Dignass A[11], Sands BE[12], Hisamatsu T[13], Peyrin-Biroulet L[14]

[1]University of Pennsylvania, Philadelphia, PA, USA; [2]Division of Gastroenterology, Hepatology and Endoscopy, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA; [3]University of Chicago Medicine Inflammatory Bowel Disease Center, Chicago, IL, USA; [4]Western University, London, ON, Canada; [5]University of British Columbia, Vancouver, BC, Canada; [6]Hospital Clínic de Barcelona, IDIBAPS, CIBERehd, Barcelona, Spain; [7]Division of Gastroenterology, McGill University Health Care, Montréal, QC, Canada; [8]Inflammatory Bowel Disease Unit, Guy's and St Thomas' NHS Foundation Trust, London, UK; [9]University of Ulsan College of Medicine, Asan Medical Center, Seoul, Republic of Korea; [10]Janssen Research & Development, LLC, Spring House, PA, USA; [11]Department of Medicine, Agaplesion Markus Hospital, Goethe University, Frankfurt, Germany; [12]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [13]Kyorin University Faculty of Medicine, Tokyo, Japan; [14]University of Lorraine, Inserm, Nutrition-Genetics and Exposure to Environmental Risks unit, F-54000 Nancy, France and Groupe Hospitalier Privé Ambroise Paré-Hartmann, Paris IBD Centre, 92200 Neuilly-sur-Seine, France

Study design

Aim: To understand the long-term efficacy and safety of GUS in patients with UC in the ongoing QUASAR LTE study through Week 92



Target patient population: Adults with moderately to severely active UC, defined as induction baseline modified Mayo score of 5–9 with a Mayo rectal bleeding subscore ≥1 and a Mayo endoscopy subscore ≥2 based on central review, who were in clinical response 12 weeks following GUS IV induction

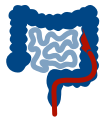
*Between maintenance Week 8 and Week 32, randomised patients meeting loss of clinical response criteria (based on the modified Mayo score and required and required an endoscopic assessment) were eligible for a blinded dose adjustment as follows: Placebo SC → GUS 200 mg SC q4w; GUS 100 mg SC q8w → GUS 200 mg SC q4w; GUS 200 mg SC q4w → sham adjustment; †The study blind was maintained during the LTE until the last participant in the maintenance study completed the maintenance Week 44 visit. After the maintenance study was unblinded to the investigative sites, participants receiving placebo were terminated from study participation.

GUS, guselkumab; IL, interleukin; IV, intravenous; LTE, long-term extension; MOA, mechanism of action; qxw, every x weeks; RDBPC, randomised, double blind, placebo controlled; SC, subcutaneous; UC, ulcerative colitis.

Lichtenstein GR, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. Su1856.

Baseline characteristics and UC medications

QUASAR LTE



	GUS 400 mg SC → 100 mg SC q8w (n=155)	GUS 400 mg SC → 200 mg SC q4w (n=148)
UC disease duration in years, mean (SD)	8.2 (9.0)	8.2 (8.5)
Extensive UC, n (%)	66 (43%)	69 (47%)
Modified Mayo score (0–9), mean (SD)	6.8 (1.2)	6.9 (1.1)
Modified Mayo score of 7–9 (severe), n (%)	94 (61%)	97 (66%)
Mayo endoscopic subscore of 3 (severe), n (%)	103 (66%)	95 (64%)
C-reactive protein, median in mg/l (IQR)*	4.0 (1.4–10.4)	3.9 (1.5–9.5)
Faecal calprotectin, median in mg/kg (IQR)†	1709.0 (815.0–3607.0)	1605.5 (596.0–3253.0)
Baseline oral corticosteroid use, n (%)	56 (36%)	54 (36%)
Naïve to BIO / JAKi , n (%)‡	90 (95%)	81 (94%)
BIO / JAKi -IR, n (%)	60 (39%)	62 (42%)
One BIO/JAKi**	33 (55%)	41 (66%)
Two or more BIO/JAKi**	27 (45%)	21 (34%)

Overall, 87% of participants randomised to GUS at maintenance Week 0 entered the LTE, and approximately 95% of participants in the LTE-randomised, GUS-treated population completed treatment through LTE Week 92

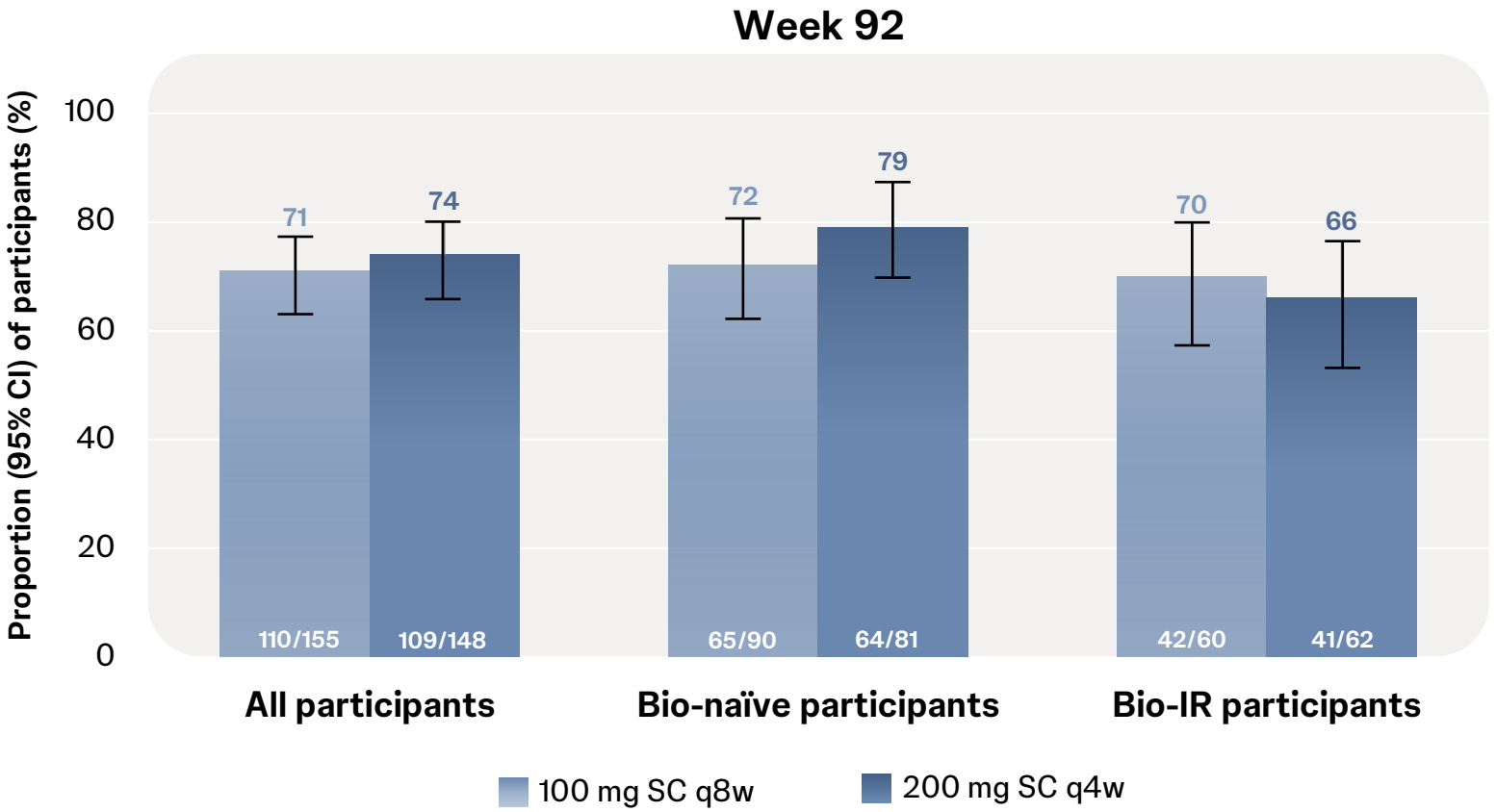
*Based on n=153 for GUS SC 100 mg q8w and n=145 for GUS SC 200 mg q4w; †Based on n=133 for GUS SC 100 mg q8w, and n=134 for GUS SC 200 mg q4w; ‡Denominator is participants without a history of biologic or JAKi IR; ** Denominator is participants with a history of biologic or JAKi IR.

BIO, biologic; GUS, guselkumab; IQR, interquartile range; IR, inadequate response or intolerance; JAKi, Janus kinase inhibitor; LTE, long-term extension; qxw, every x weeks; SC, subcutaneous; SD, standard deviation; UC, ulcerative colitis.

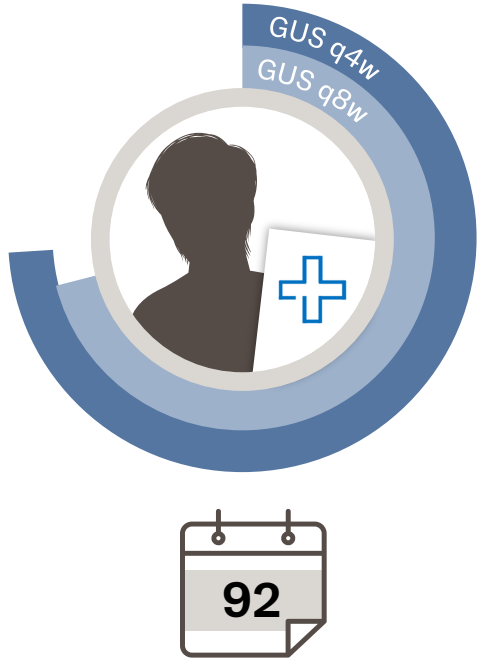
Lichtenstein GR, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. Su1856.

Clinical remission

A total of 218 out of 219 (99.5%) participants in clinical remission at Week 92 were corticosteroid free ≥8 weeks before Week 92

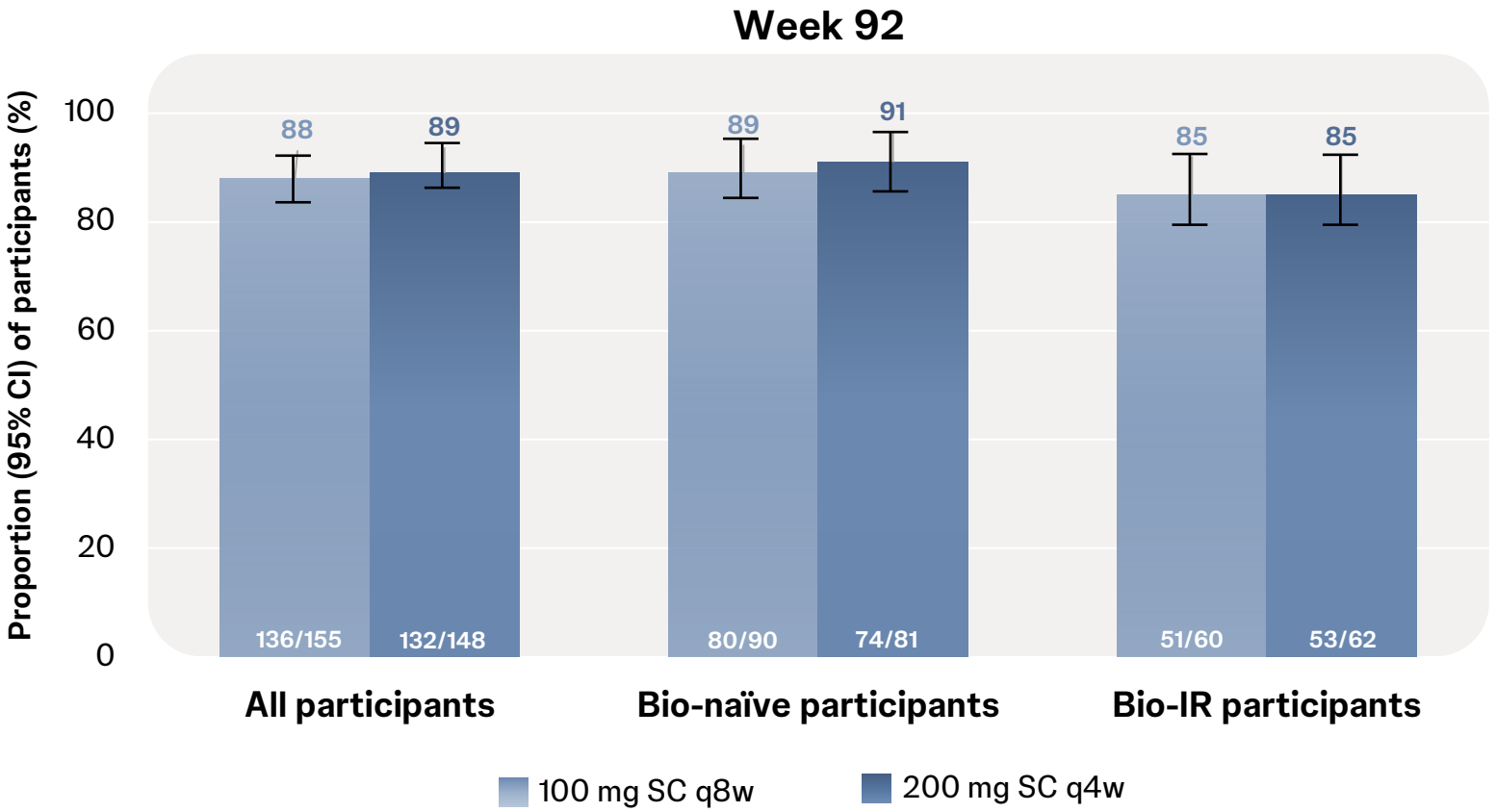


>70% of patients
in the overall population were in
clinical remission (NRI analysis)



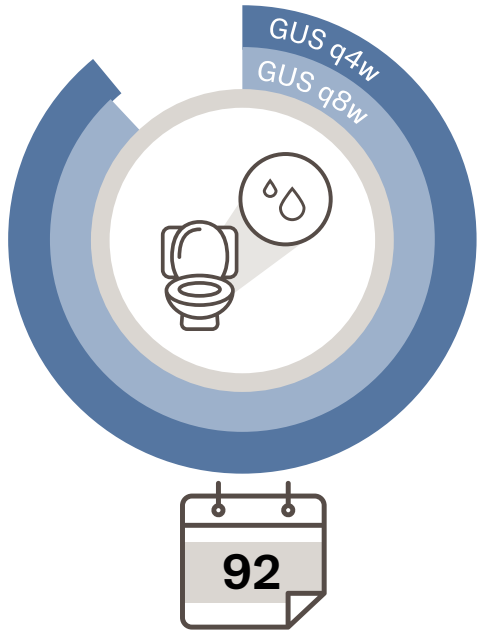
Clinical remission: Stool frequency subscore of 0 or 1 and not increased from induction baseline, rectal bleeding subscore of 0 and endoscopic subscore of 0 or 1.
Based on NRI analysis. Includes only participants with modified Mayo score 5–9 at induction baseline who were in clinical response to GUS IV induction, randomised to receive GUS maintenance treatment and did not experience a dose adjustment from maintenance Week 8 through Week 32.
CI, confidence interval; GUS, guselkumab; IV, intravenous; LTE, long-term extension; NRI, non-responder imputation; qxw, every x weeks; SC, subcutaneous; UC, ulcerative colitis.
Lichtenstein GR, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. Su1856.

Symptomatic remission



~90%

of patients in the overall population were in **symptomatic remission (NRI analysis)**



Symptomatic remission: Stool frequency subscore of 0 or 1, not increased from induction baseline and rectal bleeding subscore of 0.
Based on NRI analysis. Includes only participants with modified Mayo score 5–9 at induction baseline who were in clinical response to GUS IV induction, randomised to receive GUS maintenance treatment and did not experience a dose adjustment from maintenance Week 8 through Week 32.
CI, confidence interval; GUS, guselkumab; IV, intravenous; LTE, long-term extension; NRI, non-responder imputation; qxw, every x weeks; SC, subcutaneous; UC, ulcerative colitis.
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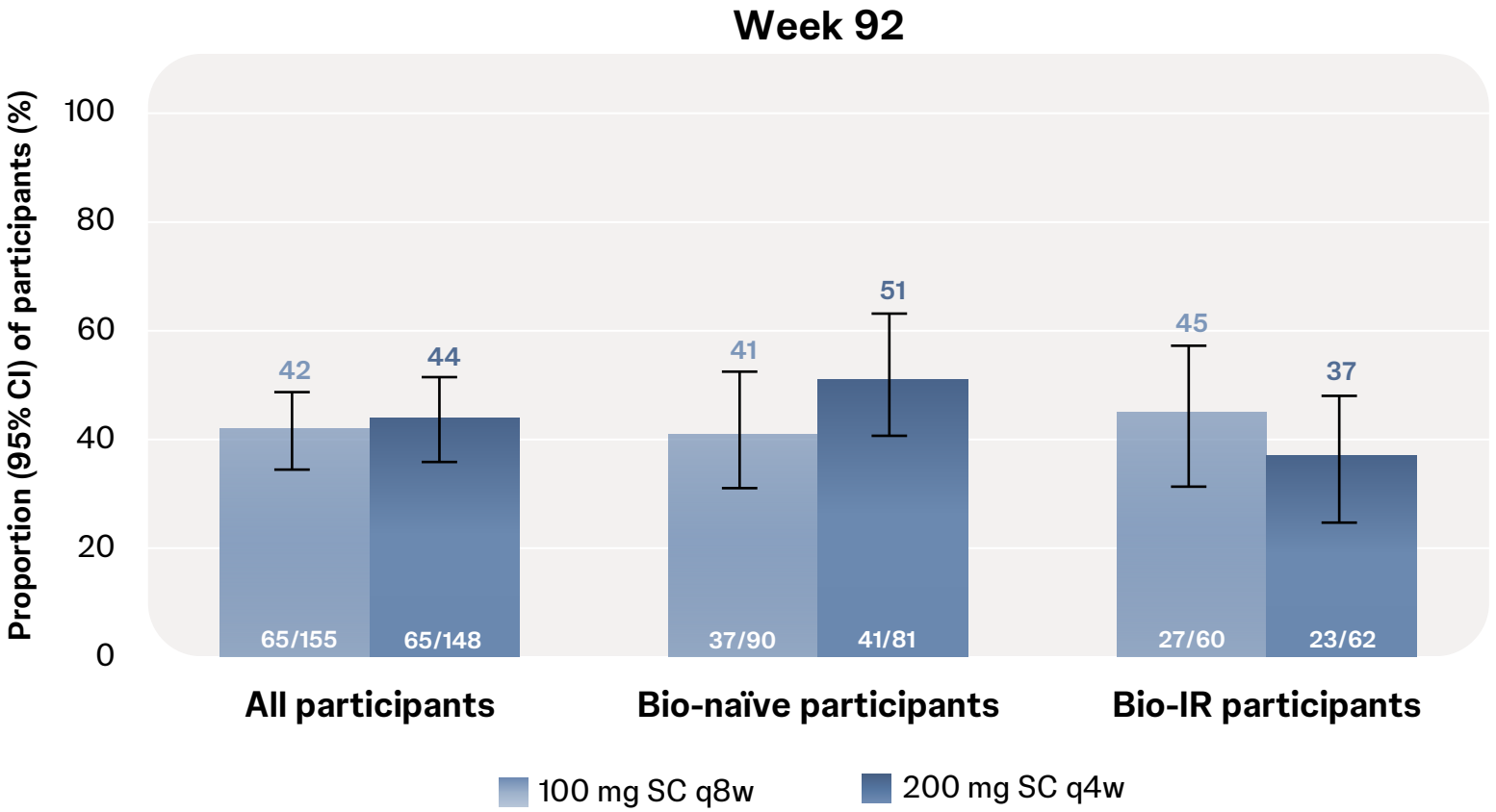
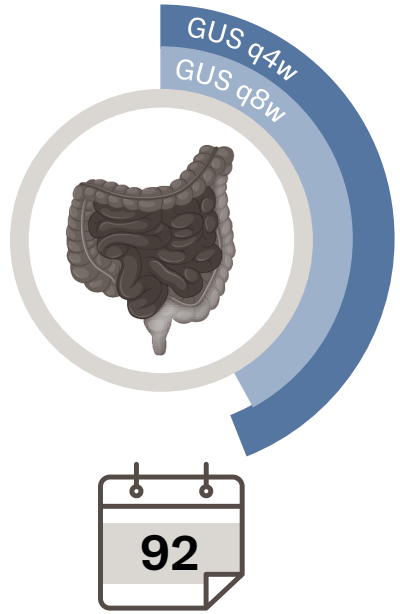
Endoscopic remission



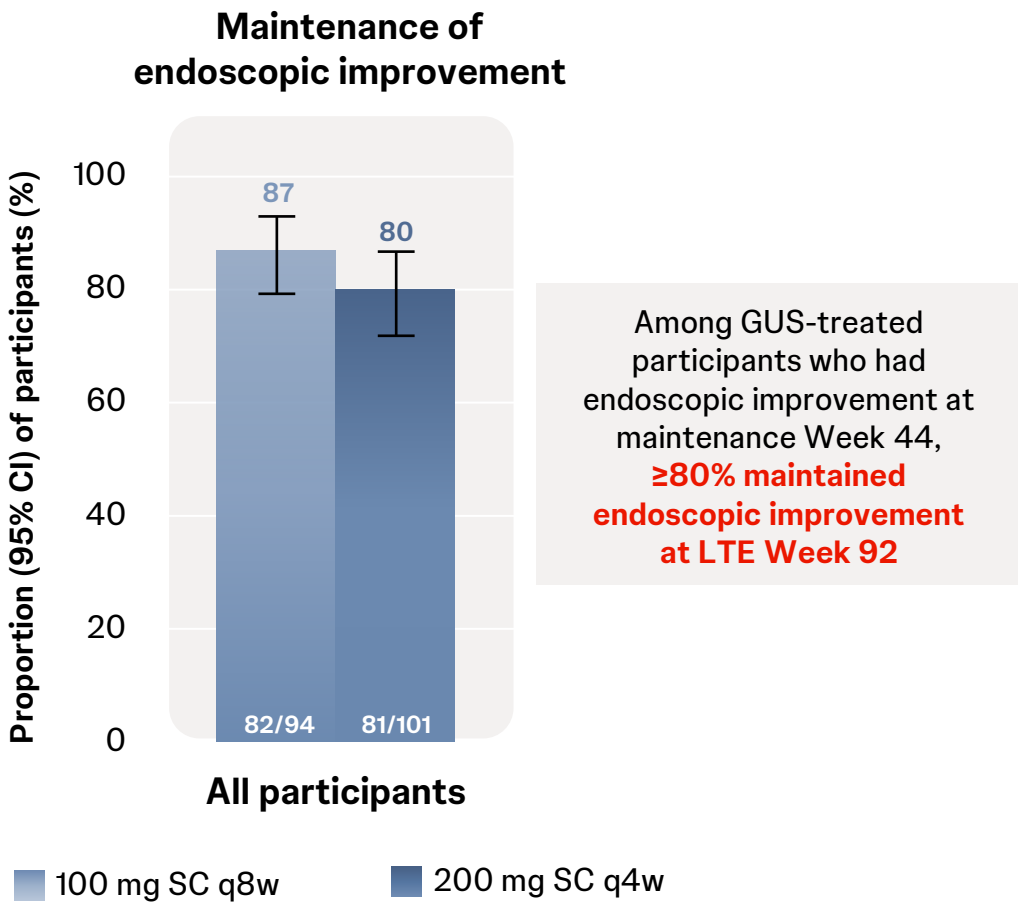
>40% of patients in the overall population were in **endoscopic remission (MES=0) (NRI analysis)**



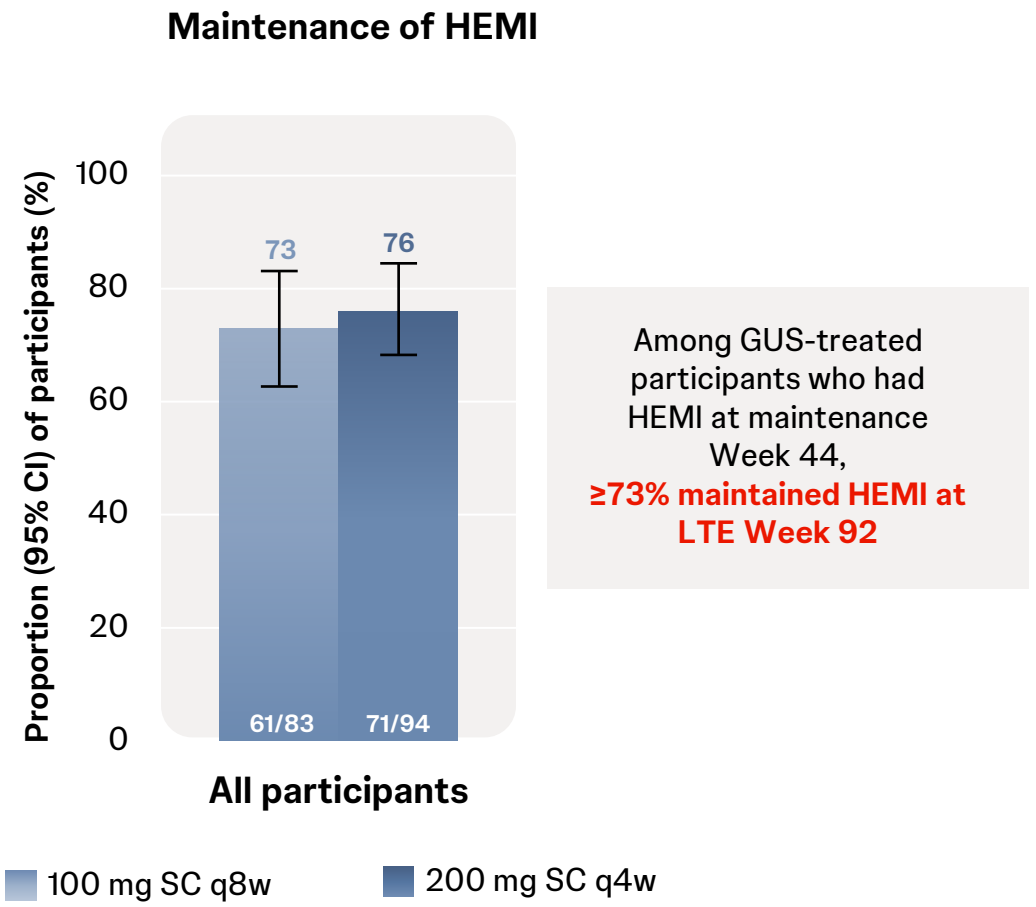
Endoscopic remission (normalisation): Endoscopic subscore of 0.
Based on NRI analysis. Includes only participants with modified Mayo score 5–9 at induction baseline who were in clinical response to GUS IV induction, randomised to receive GUS maintenance treatment and did not experience a dose adjustment from maintenance Week 8 through Week 32.
CI, confidence interval; GUS, guselkumab; IV, intravenous; LTE, long-term extension; NRI, non-responder imputation; qxw, every x weeks; SC, subcutaneous; UC, ulcerative colitis.
Lichtenstein GR, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. Su1856.

Maintenance of endoscopic improvement and HEMI

QUASAR LTE
WEEK 92



Among GUS-treated participants who had endoscopic improvement at maintenance Week 44, **≥80% maintained endoscopic improvement at LTE Week 92**



Among GUS-treated participants who had HEMI at maintenance Week 44, **≥73% maintained HEMI at LTE Week 92**

Endoscopic improvement: Endoscopic subscore of 0 or 1.
HEMI: Achievement of a combination of histological improvement (neutrophil infiltration in <5% of crypts, no crypt destruction and no erosions, ulcerations or granulation tissue according to the Geboes grading system) and endoscopic improvement.
Based on NRI analysis. Includes only participants with modified Mayo score 5–9 at induction baseline who were in clinical response to GUS IV induction and randomised to receive GUS maintenance treatment and did not experience a dose adjustment from maintenance Week 8 through Week 32.
CI, confidence interval; GUS, guselkumab; HEMI, histo-endoscopic mucosal improvement; LTE, long-term extension; NRI, non-responder imputation; qxw, every x weeks; SC, subcutaneous; UC, ulcerative colitis.
Lichtenstein GR, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. Su1856.

Safety

AEs from maintenance Week 44 through LTE Week 92

	Placebo (n=189)	GUS 100 mg SC q8w (n=162)	GUS 200 mg SC q4w (n=349)
Average duration of follow-up, weeks	40.8	46.9	46.5
Average exposure, weeks	9.4	10.9	11.4
Participants with event/100 PY of follow up (95% CI):			
AEs	81.8 (67.9–97.8)	71.5 (58.4–86.6)	75.9 (66.5–86.2)
Serious AEs	10.8 (6.2–17.6)	2.8 (0.8–7.0)	6.1 (3.7–9.5)
AEs leading to discontinuation of study agent	14.9 (9.3–22.5)	3.4 (1.1–8.0)	4.8 (2.7–8.0)
Infection*	41.2 (31.6–53.0)	37.1 (27.9–48.4)	40.5 (33.7–48.2)
Serious infection†	1.4 (0.2–4.9)	1.4 (0.2–5.0)	1.0 (0.2–2.8)

- No cases of death, active tuberculosis, opportunistic infection, anaphylaxis or serum sickness were reported in participants treated with GUS
- Serious infections were infrequent and similar across treatment groups

Includes all participants regardless of modified Mayo score at induction baseline who participated in the maintenance study and received any treatment in the LTE (LTE all-treated population). Data were summarised based on the study treatment participants were receiving upon entering the LTE.

*Infections were defined as any AE coded to the MedDRA system organ class 'Infections and infestations'; †Serious infections: (2 [1.1%] in the placebo group [1 chronic tonsillitis, 1 UTI], 2 [1.2%] in the GUS 100 mg group [1 epididymitis, 1 pneumonia], 3 [0.9%] in the GUS 200 mg group [1 pneumonia, 1 appendicitis, 1 *Clostridium difficile* infection]).

AE, adverse event; CI, confidence interval; GUS, guselkumab; LTE, long-term extension; MedDRA, Medical Dictionary for Regulatory Activities; PY, participant-years; qxw, every x weeks; SC, subcutaneous; UC, ulcerative colitis; UTI, urinary tract infection.

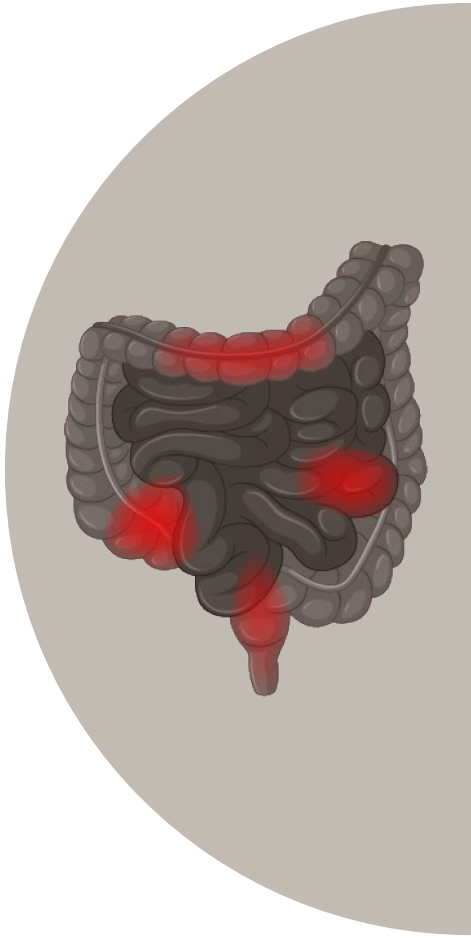
Lichtenstein GR, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. Su1856.

Summary

- Both GUS maintenance dose regimens sustained symptomatic, endoscopic and histologic efficacy in participants with UC through Week 92 of the LTE
- Efficacy was sustained regardless of prior biologic use and/or JAKi treatment history
- No new safety concerns were identified

GUS, guselkumab; JAKi, Janus kinase inhibitor; LTE, long-term extension; UC, ulcerative colitis.
Lichtenstein GR, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. Su1856.

Guselkumab in Crohn’s disease



Endoscopic patient clustering to investigate differential treatment effects of guselkumab and ustekinumab in Crohn's disease: *Post-hoc* analysis of GALAXI and GRAVITI trials

Richards D[1], Seridi L[1], Sohn K[1], Mcrae B[1], Terry NA[1], Vetter M[1], Cua D[1], Branigan P[1], Reinisch W[2], Atreya R[3]

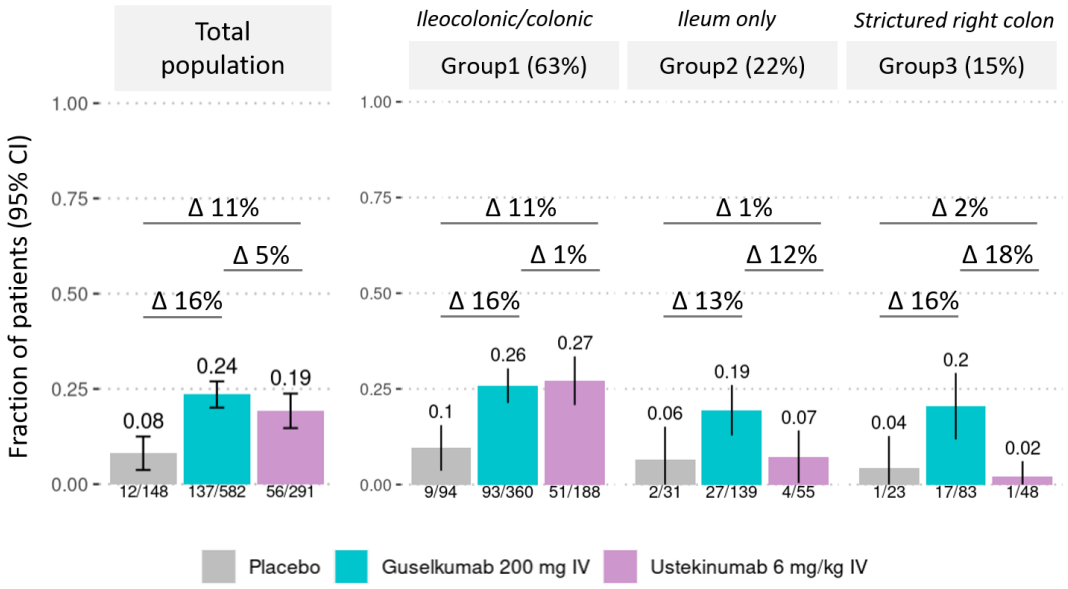
[1]Janssen Research & Development, LLC, Spring House, PA, USA; [2]Division Gastroenterology & Hepatology, Medical University of Vienna, Vienna, Austria; [3]Department of Medicine I, Gastroenterology, Endocrinology and Pneumology, University Hospital Erlangen, Friedrich-Alexander University Erlangen-Nuremberg, Erlangen, Germany

Endoscopic remission at Weeks 12 and 48

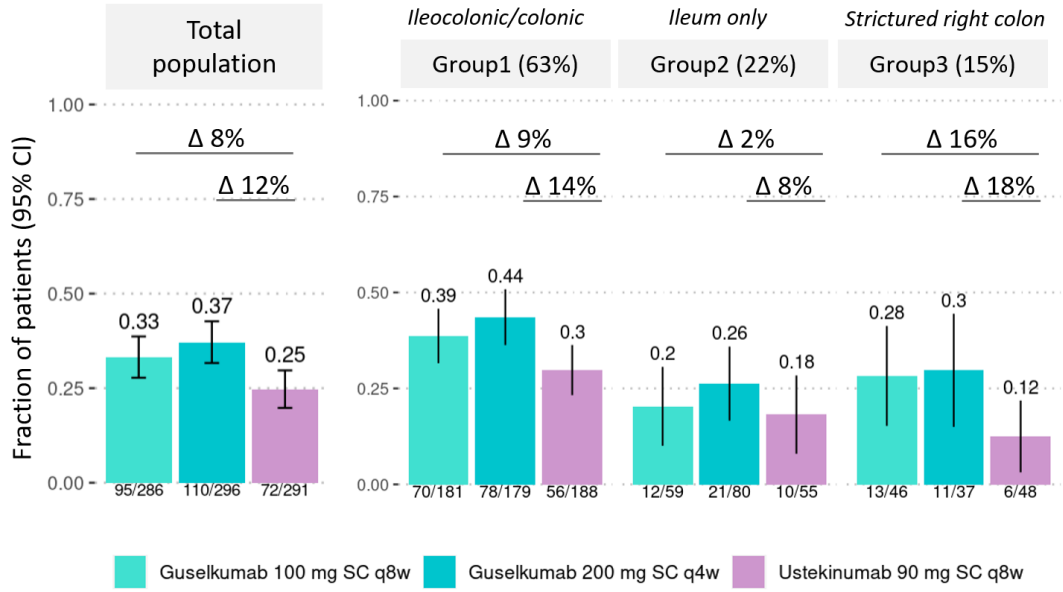
- GUS shows early Week 12 endoscopic remission for all patients
- Endoscopic characterisation indicates UST having placebo-like efficacy at Week 12 in “Ileum only” and “Strictured right colon”

- GUS shows higher endoscopic remission than UST in all patients at Week 48

Endoscopic remission rate: Week 12



Endoscopic remission rate: Week 48



Endoscopic remission: SES-CD ≤4 and a ≥2-point reduction from baseline, and no subscore greater than 1 in any individual component.
CD, Crohn’s disease; CI, confidence interval; GUS, guselkumab; IV, intravenous; qxw, every x weeks; SES-CD, Simple Endoscopic Score for CD; UST, ustekinumab; WK, week.
Richards D, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. Su1861.

GALAXI/GRAVITI

Efficacy of guselkumab intravenous and subcutaneous induction: Symptoms, heath-related quality of life, and inflammatory biomarker results from the GALAXI and GRAVITI studies

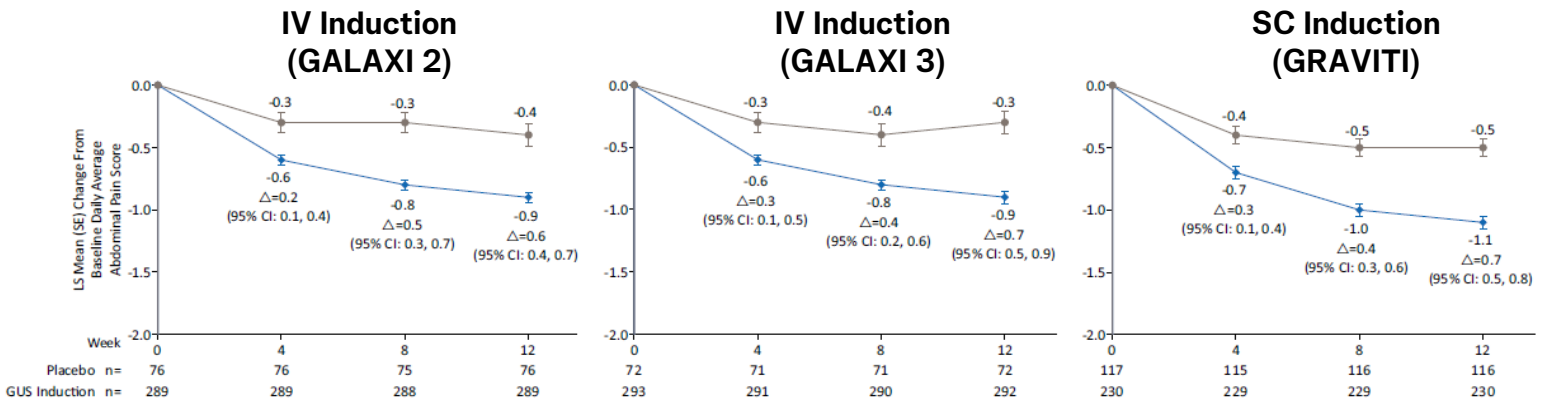
Afzali A[1], Panaccione R[2], Danese S[3], Hisamatsu T[4], D'Haens G[5], Terry NA[6], Olurinde M[6], Rampelbergh RV[7], Salese L[6], Merrall E[8], Wan KYY[9], Yang Z[6], Sands BE[10], Hart A[11]

[1]Division on Digestive Diseases, University of Cincinnati, College of Medicine, Cincinnati, OH, USA; [2]Inflammatory Bowel Disease Unit, Division of Gastroenterology and Hepatology, University of Calgary, Calgary, AB, Canada; [3]Gastroenterology and Endoscopy, IRCCS Ospedale San Raffaele and University Vita-Salute San Raffaele, Milano, Italy; [4]Department Gastroenterology and Hepatology, Kyorin University School of Medicine, Tokyo, Japan; [5]Department of Gastroenterology, Amsterdam University Medical Centers, Amsterdam, The Netherlands; [6]Johnson & Johnson, Spring House, PA, USA; [7]Johnson & Johnson, Beerse, Belgium; [8]Johnson & Johnson, Leiden, The Netherlands; [9]Johnson & Johnson, Allschwil, Switzerland; [10]Ichan School of Medicine at Mount Sinai, New York, NY, USA; [11]London North-West University Healthcare NHS Trust, London, UK

Abdominal pain and stool frequency

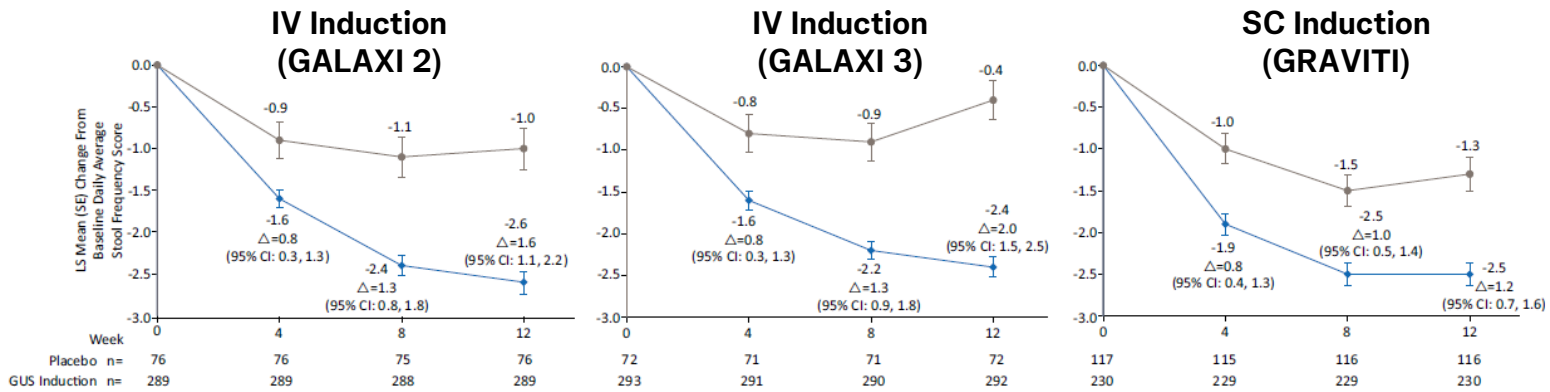
Compared with PBO, improvement in symptom-based outcomes was seen through Week 12 with both GUS IV and SC. Improvements with GUS were evident from the first assessment at Week 4

Abdominal pain



Placebo
GUS 200 mg IV q4w or GUS 400 mg SC q4w

Stool frequency



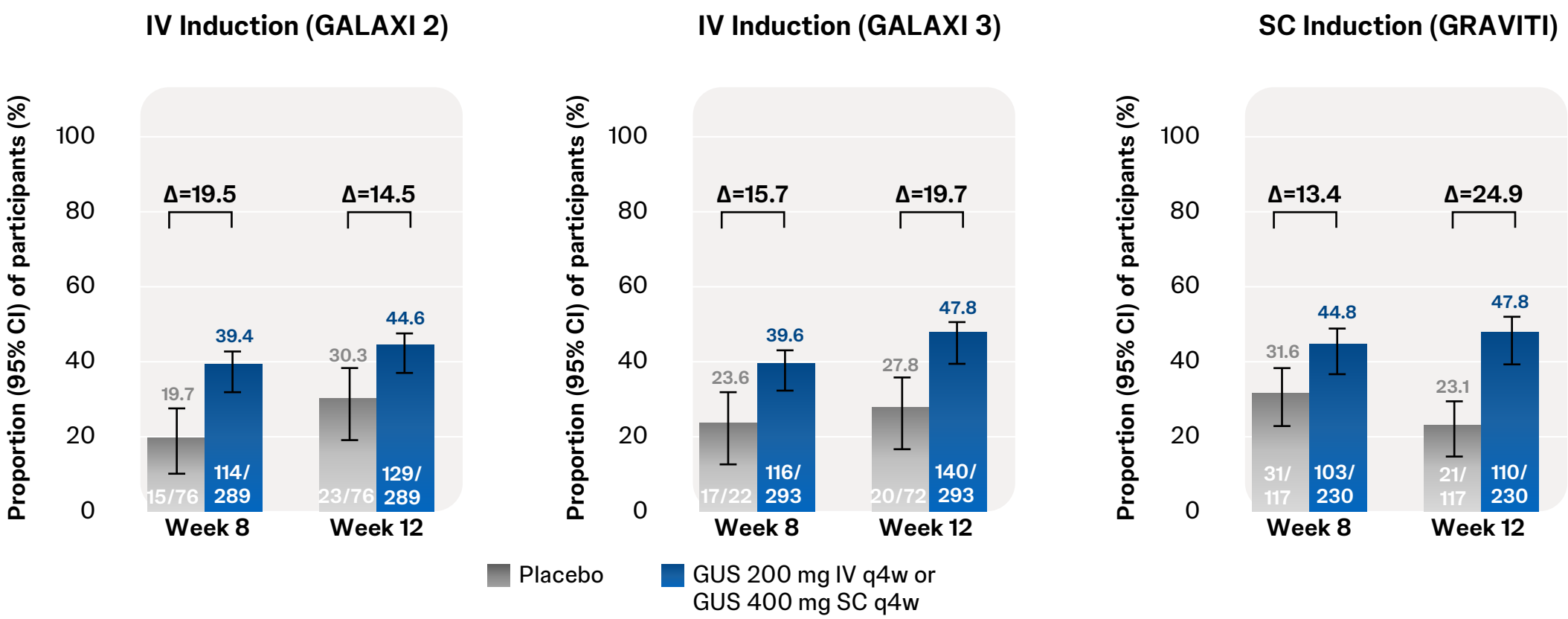
Placebo
GUS 200 mg IV q4w or GUS 400 mg SC q4w

CI, confidence interval; GUS, guselkumab; IV, intravenous; LS, least squares; PBO, placebo; qxw, every x weeks; SC, subcutaneous; SE, standard error.

Afzali A, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. Su1853.

IBDQ remission

Proportions of participants with IBDQ remission were higher for participants treated with GUS at both Weeks 8 and 12 compared with PBO



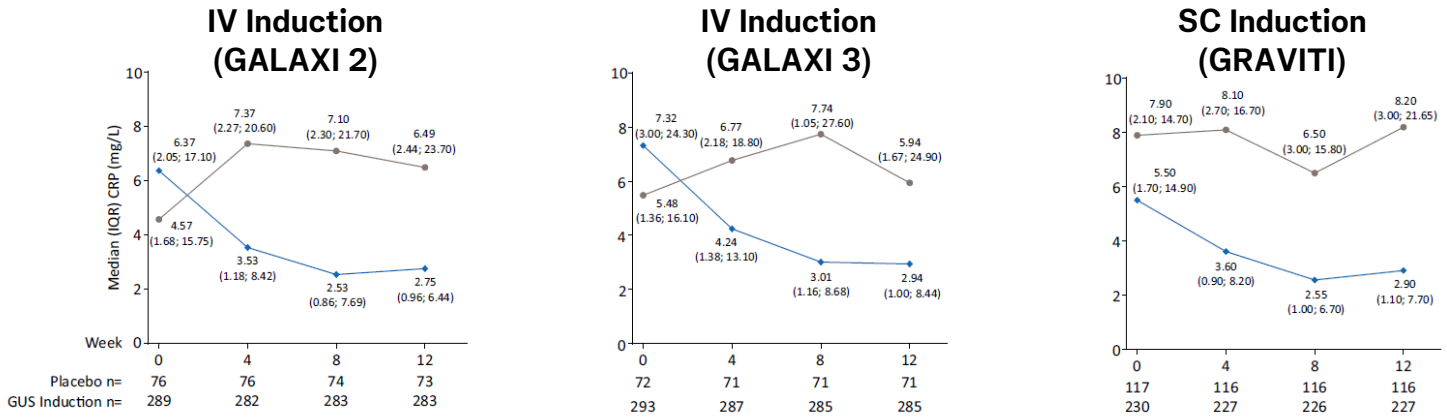
CD, Crohn's Disease; CI, confidence interval; GUS, guselkumab; IBDQ, Inflammatory Bowel Disease Questionnaire; IV, intravenous; PBO, placebo; qxw, every x weeks; SC, subcutaneous.

Afzali A, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. Su1853.

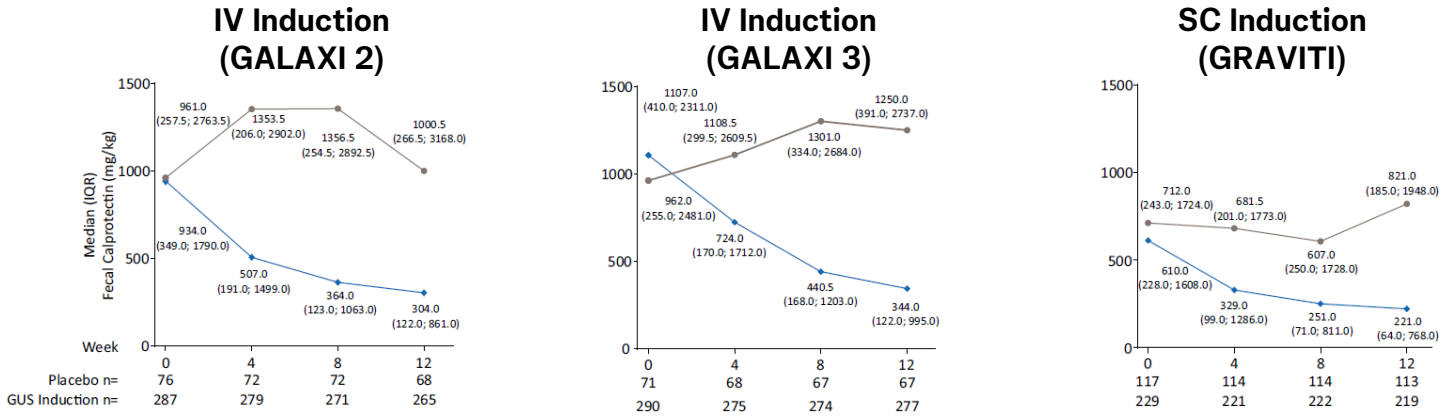
CRP and fCal levels

Median CRP and fCal levels decreased in GUS-treated participants starting at Week 4 following IV or SC induction, while levels increased or remained static in participants receiving PBO

CRP levels



fCal levels



Placebo
GUS 200 mg IV q4w or GUS 400 mg SC q4w

CI, confidence interval; CRP, c-reactive protein; fCal, faecal calprotectin; GUS, guselkumab; IQR, interquartile range; IV, intravenous; PBO, placebo; qxw, every x weeks; SC, subcutaneous.
Afzali A, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. Su1853.

Summary

- Induction treatment with either GUS IV or SC routes of administration provided rapid and robust improvements in symptoms and HRQoL as well as reductions in objective biomarkers of inflammation
- The differences between GUS and PBO were seen as early as the first assessment timepoint 4 weeks following the first IV or SC induction dose
- The rapidity and magnitude of the improvements were similar for IV and SC induction

GUS, guselkumab; HRQoL, health-related quality of life; IV, intravenous; PBO, placebo; SC, subcutaneous.
Afzali A, et al. Presented at DDW, San Diego, USA, 3–6 May 2025. Su1853.