DDW 2026:
Data reflow deck

Job code: CH_CP-581164 based on CP-580450
Date of preparation: May 2026

Janssen Cilag AG, a Johnson & Johnson company
Gubelstrasse 34, 6300 Zug, Switzerland

Immunology

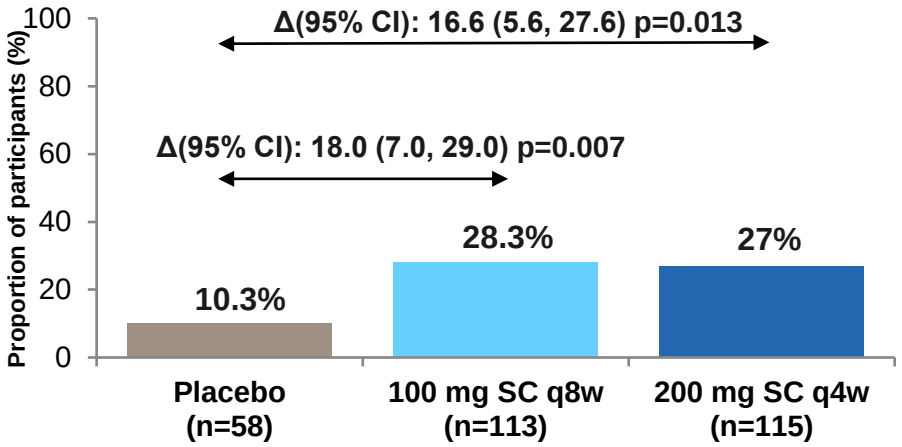
DDW 2026 GUS highlights

FUZION study (NCT05347095): Week 24 results from a Phase 3, randomised, double-blind, placebo-controlled, multicentre study evaluating the efficacy and safety of GUS in adults with active perianal fistulising CD

First successful international Phase 3 study with a combined clinical and MRI endpoint

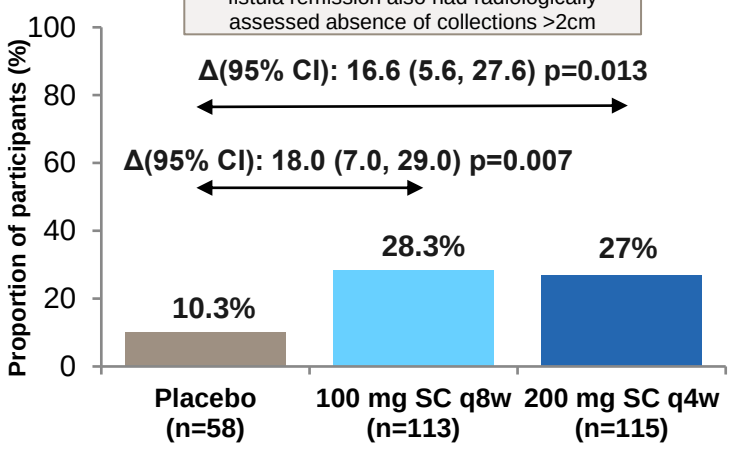
First study in more than two decades to show efficacy of an advanced therapy in perianal fistulising CD

Primary endpoint: Combined fistula remission at Week 24

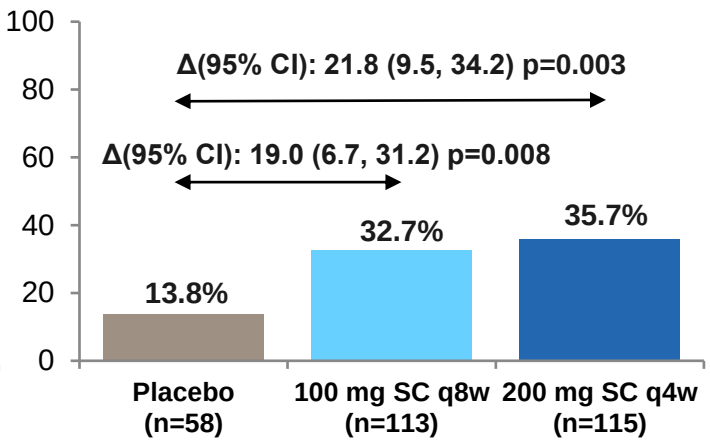


Multiplicity-controlled secondary endpoints at Week 24

Clinically assessed fistula remission



Clinically assessed fistula response



- GUS was efficacious through Week 24 in a study population that includes bio-naïve and bio-exposed patients with perianal fistulising CD
- GUS showed clinically meaningful difference versus placebo during induction
- Both GUS maintenance doses showed statistically significant and clinically meaningful benefit compared with placebo

Combined fistula remission: 100% closure of all treated external openings, without development of new fistulas or abscesses and without any drainage by the external openings, occurring spontaneously or after gentle finger compression AND absence of collections >2 cm of the perianal fistulas, confirmed by a blinded central review of the MRI results. Clinically assessed fistula remission: 100% closure of all treated external openings, without development of new fistulas or abscesses and without any drainage by the external openings, occurring spontaneously or after gentle finger compression. Clinically assessed fistula response: ≥50% reduction from baseline in number of open or draining perianal fistulas.
CD, Crohn's disease; CI, confidence interval; GUS, guselkumab; MRI, magnetic resonance imaging; q4w, every 4 weeks; q8w, every 8 weeks; SC, subcutaneous.
Peyrin-Biroulet L, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O1058b. Guselkumab is approved for adult moderate-severe CD patients. Full prescription information: swissmedicinfo-pro.ch.

CH_CP-581164 05/26

Contents (1/5)

All data		
FUZION: Guselkumab for perianal fistulising CD	Guselkumab for perianal fistulizing Crohn's disease: Week 24 results from the Phase 3, randomized, double-blind, placebo-controlled, multicenter FUZION study	Peyrin-Biroulet, et al.
DUET: JNJ-4804 in CD	Efficacy and safety of the first co-antibody therapy, JNJ-78934804, in patients with moderately to severely active Crohn's disease refractory to systemic therapies	Sands, et al.
DUET: JNJ-4804 in UC	Efficacy and safety of the first co-antibody therapy, JNJ-78934804, in patients with moderately to severely active ulcerative colitis refractory to systemic therapies	Abreu, et al.
QUASAR: Guselkumab in UC	Mayo Endoscopic Subscore changes in participants with moderately to severely active ulcerative colitis treated with guselkumab in the QUASAR long-term extension	Rubin, et al.
Guselkumab in IBD	Safety of guselkumab in patients aged ≥60 years with immune-mediated inflammatory diseases: a pooled analysis of registrational trials in UC, CD, PsA and PsO	Faye, et al.
	Pregnancy outcomes in maternal exposure to guselkumab: Review of cases reported to the company's global safety database	Mahadevan, et al.
ANTHEM: Icotrokinra in UC	Efficacy of icotrokinra, the first targeted oral peptide that selectively blocks the IL-23 receptor, in ulcerative colitis patients with or without prior intolerance or inadequate response to advanced therapies: results from the ANTHEM-UC study	Loftus, et al.

Contents (2/5)

Key data only		
UC and CD: Retrospective analyses of the Crohn's & Colitis Foundation Database	Impact of endoscopic remission on long-term outcomes and IBD-related surgery in patients with ulcerative colitis: a retrospective cohort analysis from the Crohn's & Colitis Foundation database	Truyers, et al.
	Long-term clinical outcomes, IBD-related surgery, and corticosteroid use in patients with Crohn's disease in endoscopic remission: a retrospective cohort analysis from the Crohn's & Colitis Foundation database	Truyers, et al.

All data

FUZION: Guselkumab for perianal fistulising CD

O1058b

Guselkumab for perianal fistulizing Crohn’s disease: Week 24 results from the Phase 3, randomized, double-blind, placebo-controlled, multicenter FUZION study

Laurent Peyrin-Biroulet, Vipul Jairath, Ailsa Hart, Geert D’Haens, Axel Dignass, Silvio Danese, Julian Panés, Susan J. Connor, Walter Reinisch, David A. Schwartz, Tadakazu Hisamatsu, Bram Verstockt, Antonino Spinelli, Anton Stift, André D’Hoore, Maciej Nazar, Jacqueline van Denderen, Talia Gramiccia, Takehiko Sakamoto, Stephen Xu, Ivana Bravatà, and Bruce E. Sands on behalf of the FUZION Study Group

CH_CP-581164 05/26

Perianal fistulising Crohn's disease

Severe manifestation of CD characterised by the development of abnormal epithelial connections between the anorectal canal and perianal skin[1,2]

PFCD affects up to **1/4** of patients and presence at diagnosis may indicate a more severe clinical course of CD[3]

PFCD is often accompanied by[1,2,4]

- Perianal abscesses
- Pain and persistent drainage/discharge
- Faecal incontinence
- Impaired QoL

CH_CP-581164 05/26

CD, Crohn's disease; GUS, guselkumab; IL, interleukin; MOA, mechanism of action; PFCD, perianal fistulising Crohn's disease; QoL, quality of life; RDBPC, randomised, double-blind, placebo-controlled.

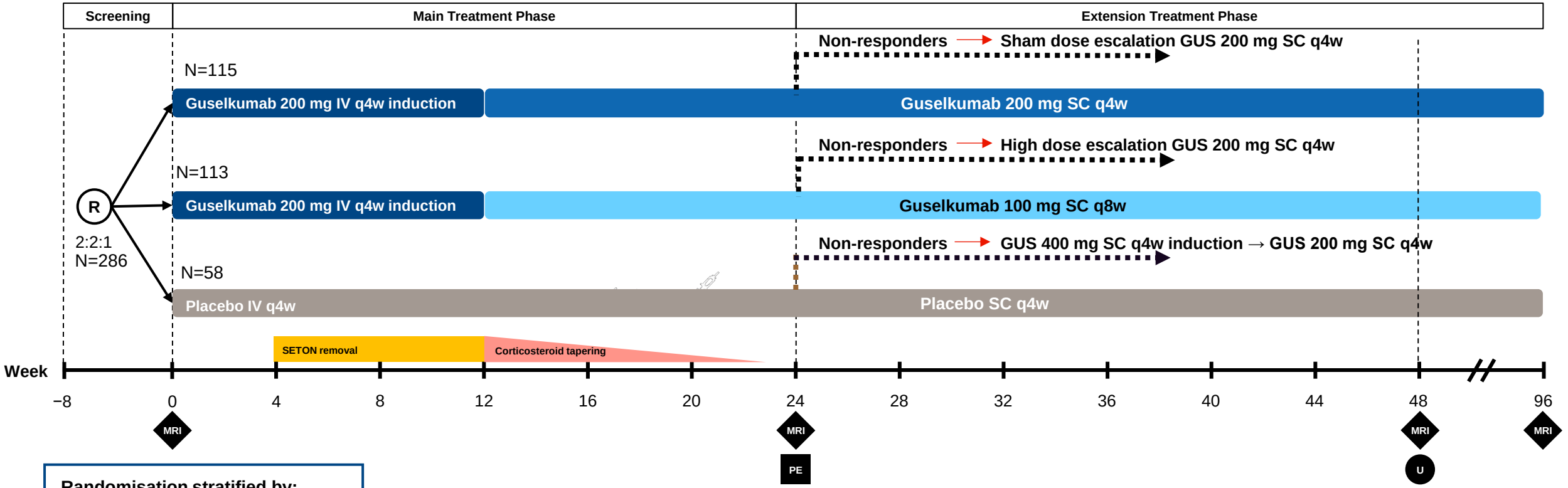
1. Lee JJ. *Clin Exp Gastroenterol*. 2025;18:291–303; 2. Anand E. *Tech Coloproctol*. 2025;29(1):102; 3. Lichtenstein GR. *Am J Gastroenterol*. 2025;120(6):1225–1264; 4. Hanna LN. *Clin Gastroenterol Hepatol*. 2025;23(6):914–926.

FUZION study design

Aim: Evaluate the efficacy and safety of GUS in adults with active perianal fistulising CD

Key eligibility criteria

- Adults with at least 1 active draining perianal fistula confirmed by blinded central MRI review
- Active Crohn's disease (CDAI score <350)
- Inadequate response or intolerance to oral corticosteroids, azathioprine, 6-mercaptopurine, methotrexate or up to 2 advanced therapy classes (anti-TNF, vedolizumab, JAK inhibitors) and be refractory to antibiotics (ie, ciprofloxacin, metronidazole)



CH_CP-581164 05/26

Randomisation stratified by:
- Proctitis (Y/N), assessed by MRI
- Prior bio-naïve status (Y/N)

Fistula-related surgery and the use of antibiotics were allowed, according to local practice, during screening

CD, Crohn's disease; CDAI, Crohn's Disease Activity Index; GUS, guselkumab; IL, interleukin; IV, intravenous; JAK, Janus kinase; MOA, mechanism of action; MRI, magnetic resonance imaging; PE, primary endpoint; qXw, every X weeks; RDBPC, randomised, double-blind, placebo-controlled; R, randomised; SC, subcutaneous; TNF, tumour necrosis factor; U, study unblinding.

Peyrin-Biroulet L, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O1058b. Guselkumab is approved for adult moderate-severe CD patients. Full prescription information: swissmedicinfo-pro.ch.

Endpoints through Week 24*

Aim: Evaluate the efficacy and safety of guselkumab in adults with active perianal fistulising CD

Primary endpoint*

Combined fistula **remission** at Week 24 (clinically and radiologically assessed)

Multiplicity-controlled secondary endpoints*

- Clinically assessed fistula **remission** at Week 24
- Clinically assessed fistula **response** at Week 24

Key secondary endpoints

- Clinically assessed fistula **response** at Week 12

Assessment Type	Outcome	Definition
Clinical	Clinically assessed fistula **remission**	100% closure of all treated external openings, without development of new fistulas or abscesses and without any drainage by the external openings, occurring spontaneously or after gentle finger compression
	Clinically assessed fistula **response**	≥50% reduction from baseline in number of open or draining perianal fistulas
Radiological	Absence of collections >2 cm	Absence of collections >2 cm of the perianal fistulas, confirmed by a blinded central review of the MRI results

*In the statistical testing procedure, guselkumab 200 mg q4w dose then the 100 mg q8w dose were sequentially tested versus placebo for the primary endpoint, then for the multiplicity-controlled secondary endpoints.
CD, Crohn's disease; GUS, guselkumab; IL, interleukin; MOA, mechanism of action; MRI, magnetic resonance imaging; qXw, every X weeks; RDBPC, randomised, double-blind, placebo-controlled.
Peyrin-Biroulet L, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O1058b. Guselkumab is approved for adult moderate-severe CD patients. Full prescription information: swissmedicinfo-pro.ch.

CH_CP-581164 05/26

Demographics and baseline disease characteristics

	100 mg SC q8w (n=113)	200 mg SC q4w (n=115)	Combined (n=228)	Placebo (n=58)	Total (N=286)
Age, mean (SD) (years)	36.2 (12.67)	36.0 (13.02)	36.1 (12.82)	38.0 (12.93)	36.5 (12.84)
Male, n (%)	79 (69.9)	85 (73.9)	164 (71.9)	41 (70.7)	205 (71.7)
Crohn's disease duration (years)					
Median	5.56	6.77	6.08	7.75	6.29
IQR	(1.90; 15.64)	(2.07; 15.93)	(1.94; 15.75)	(3.41; 17.59)	(2.07; 15.93)
CDAI score, N	113	108	221	56	277
Mean (SD)	154.6 (97.57)	143.2 (84.60)	149.0 (91.43)	147.6 (104.26)	148.7 (93.97)
>220	25 (22.1)	23 (21.3)	48 (21.7)	10 (17.9)	58 (20.9)
≤220	88 (77.9)	85 (78.7)	173 (78.3)	46 (82.1)	219 (79.1)
Participants with open or draining fistula, n (%)					
1 fistula	73 (64.6)	60 (52.2)	133 (58.3)	33 (56.9)	166 (58.0)
>1 fistulas	40 (35.4)	55 (47.8)	95 (41.7)	25 (43.1)	120 (42.0)
Previous biologic exposure, n (%)					
Bio-naïve	43 (38.1)	38 (33.0)	81 (35.5)	16 (27.6)	97 (33.9)
Bio-exposed	70 (61.9)	77 (67.0)	147 (64.5)	42 (72.4)	189 (66.1)
Proctitis at baseline, n (%)	31 (27.4)	37 (32.2)	68 (29.8)	16 (27.6)	84 (29.4)
Seton present at baseline, n (%)	23 (20.4)	21 (18.3)	44 (19.3)	10 (17.2)	54 (18.9)
≥1 fistula-related surgery during screening, n (%)	31 (27.4)	30 (26.1)	61 (26.8)	13 (22.4)	74 (25.9)
Patients with collections >2 cm at baseline, n (%)	0	4 (3.5)	4 (1.8)	2 (3.4)	6 (2.1)

CD, Crohn's disease; CDAI, Crohn's Disease Activity Index; GUS, guselkumab; IL, interleukin; IQR, interquartile range; MOA, mechanism of action; qXw, every X weeks; RDBPC, randomised, double-blind, placebo-controlled; SC, subcutaneous; SD, standard deviation.

Peyrin-Biroulet L, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O1058b. Guselkumab is approved for adult moderate-severe CD patients. Full prescription information: swissmedicinfo-pro.ch.

Prior and concomitant medications for CD

	100 mg SC q8w (n=113)	200 mg SC q4w (n=115)	Combined (n=228)	Placebo (n=58)	Total (N=286)
Inadequate response or intolerance, n (%)	70 (61.9)	77 (67.0)	147 (64.5)	42 (72.4)	189 (66.1)
Infliximab	52 (46.0)	58 (50.4)	110 (48.2)	32 (55.2)	142 (49.7)
Adalimumab	38 (33.6)	42 (36.5)	80 (35.1)	23 (39.7)	103 (36.0)
Certolizumab	1 (0.9)	2 (1.7)	3 (1.3)	1 (1.7)	4 (1.4)
Vedolizumab	8 (7.1)	6 (5.2)	14 (6.1)	3 (5.2)	17 (5.9)
Ustekinumab*	4 (3.5)	3 (2.6)	7 (3.1)	5 (8.6)	12 (4.2)
Only 1 anti-TNF agent	43 (38.1)	51 (44.3)	94 (41.2)	27 (46.6)	121 (42.3)
>1 anti-TNF agent	24 (21.2)	25 (21.7)	49 (21.5)	14 (24.1)	63 (22.0)
Only one mechanism of action	62 (54.9)	69 (60.0)	131 (57.5)	35 (60.3)	166 (58.0)
Concomitant medications for CD at baseline, n (%)					
5-ASA	27 (23.9)	27 (23.5)	54 (23.7)	19 (32.8)	73 (25.5)
Corticosteroids	10 (8.8)	9 (7.8)	19 (8.3)	3 (5.2)	22 (7.7)
Immunosuppressants (AZA, 6-MP, MTX)	34 (30.1)	35 (30.4)	69 (30.3)	16 (27.6)	85 (29.7)

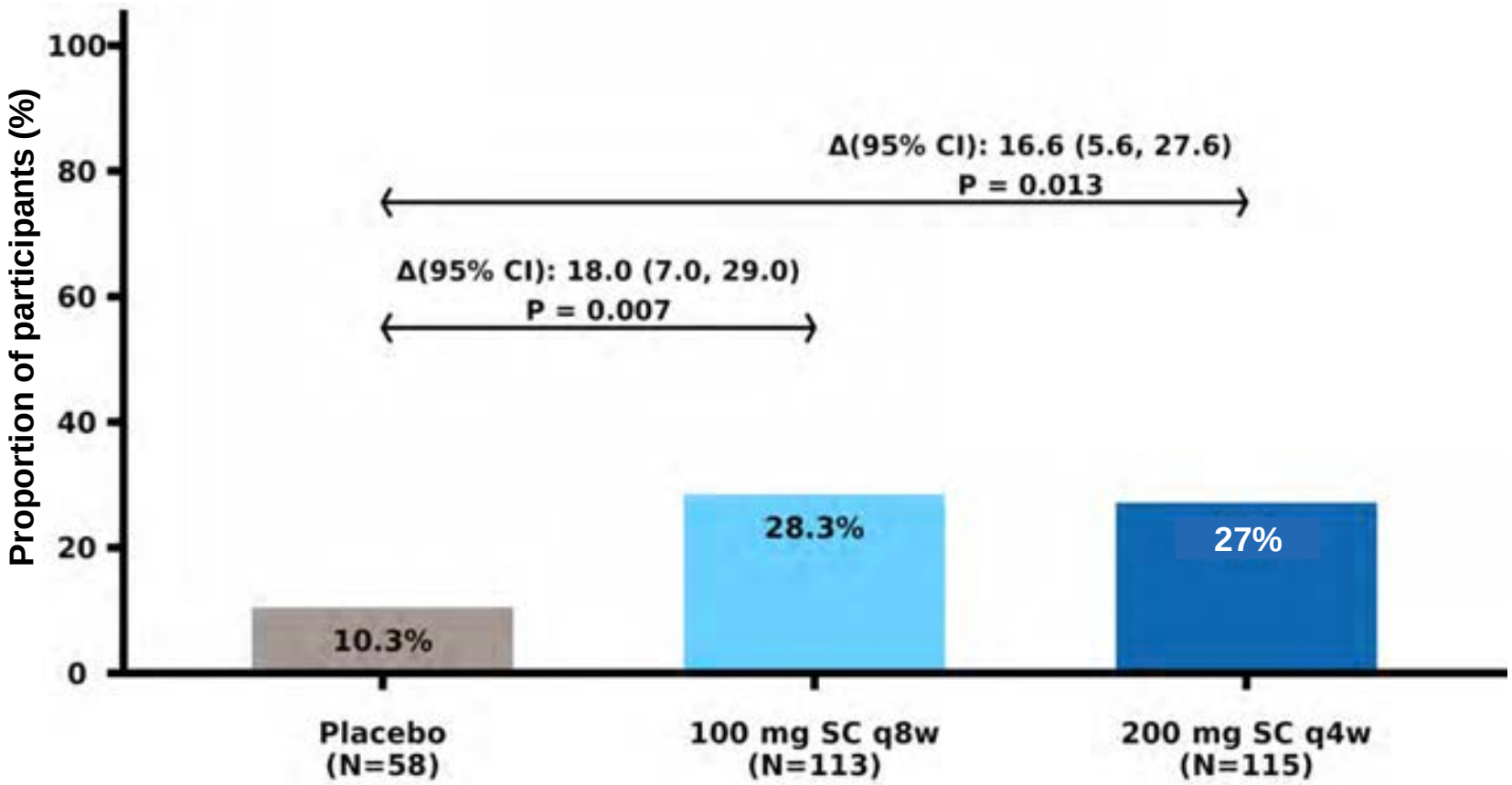
Participants with prior exposure to IL-12/23 or IL-23 agents were ineligible for study entry.
*Participants who were exposed to ustekinumab at its approved labelled dosage AND met the required washout criterion (16 weeks) AND had not demonstrated inadequate response or intolerance to ustekinumab AND received one IV induction dose of ~6 mg/kg and one SC maintenance dose of 90 mg.
ASA, aminosalicylates; AZA, azathioprine; CD, Crohn's disease; GUS, guselkumab; IL, interleukin; IV, intravenous; MOA, mechanism of action; MP, mercaptopurine; MTX, methotrexate; qXw, every X weeks; RDBPC, randomised, double-blind, placebo-controlled; SC, subcutaneous; TNF, tumour necrosis factor.
Peyrin-Biroulet L, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O1058b. Guselkumab is approved for adult moderate-severe CD patients. Full prescription information: swissmedicinfo-pro.ch.

Discontinuation of study agent before Week 24

	100 mg SC q8w (n=113)	200 mg SC q4w (n=115)	Combined (n=228)	Placebo (n=58)	Total (N=286)
Completed 24 weeks of treatment, n (%)	100 (88.5)	111 (96.5)	211 (92.5)	50 (86.2)	261 (91.3)
Discontinued study treatment, n (%)	13 (11.5)	4 (3.5)	17 (7.5)	8 (13.8)	25 (8.7)
Reason for discontinuing study treatment, n (%)					
Discontinued due to AE	9 (8.0)	3 (2.6)	12 (5.3)	4 (6.9)	16 (5.6)
AE – Other	4 (3.5)	3 (2.6)	7 (3.1)	0	7 (2.4)
AE – Worsening of CD	5 (4.4)	0	5 (2.2)	4 (6.9)	9 (3.1)
Death	0	0	0	0	0
Lack of efficacy	0	0	0	1 (1.7)	1 (0.3)
Lost to follow-up	1 (0.9)	0	1 (0.4)	0	1 (0.3)
Physician decision	1 (0.9)	0	1 (0.4)	0	1 (0.3)
Protocol deviation	0	0	0	0	0
Pregnancy	0	0	0	0	0
Subject refused further study treatment	0	0	0	1 (1.7)	1 (0.3)
Withdrawal of consent	2 (1.8)	0	2 (0.9)	0	2 (0.7)
Prohibited CD-related surgery	0	0	0	0	0
Other	0	1 (0.9)	1 (0.4)	2 (3.4)	3 (1.0)

AE, adverse event; CD, Crohn's disease; GUS, guselkumab; IL, interleukin; MOA, mechanism of action; qXw, every X weeks; RDBPC, randomised, double-blind, placebo-controlled; SC, subcutaneous.
Peyrin-Biroulet L, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O1058b. Guselkumab is approved for adult moderate-severe CD patients. Full prescription information: swissmedicinfo-pro.ch.

Combined fistula remission at Week 24: Primary endpoint



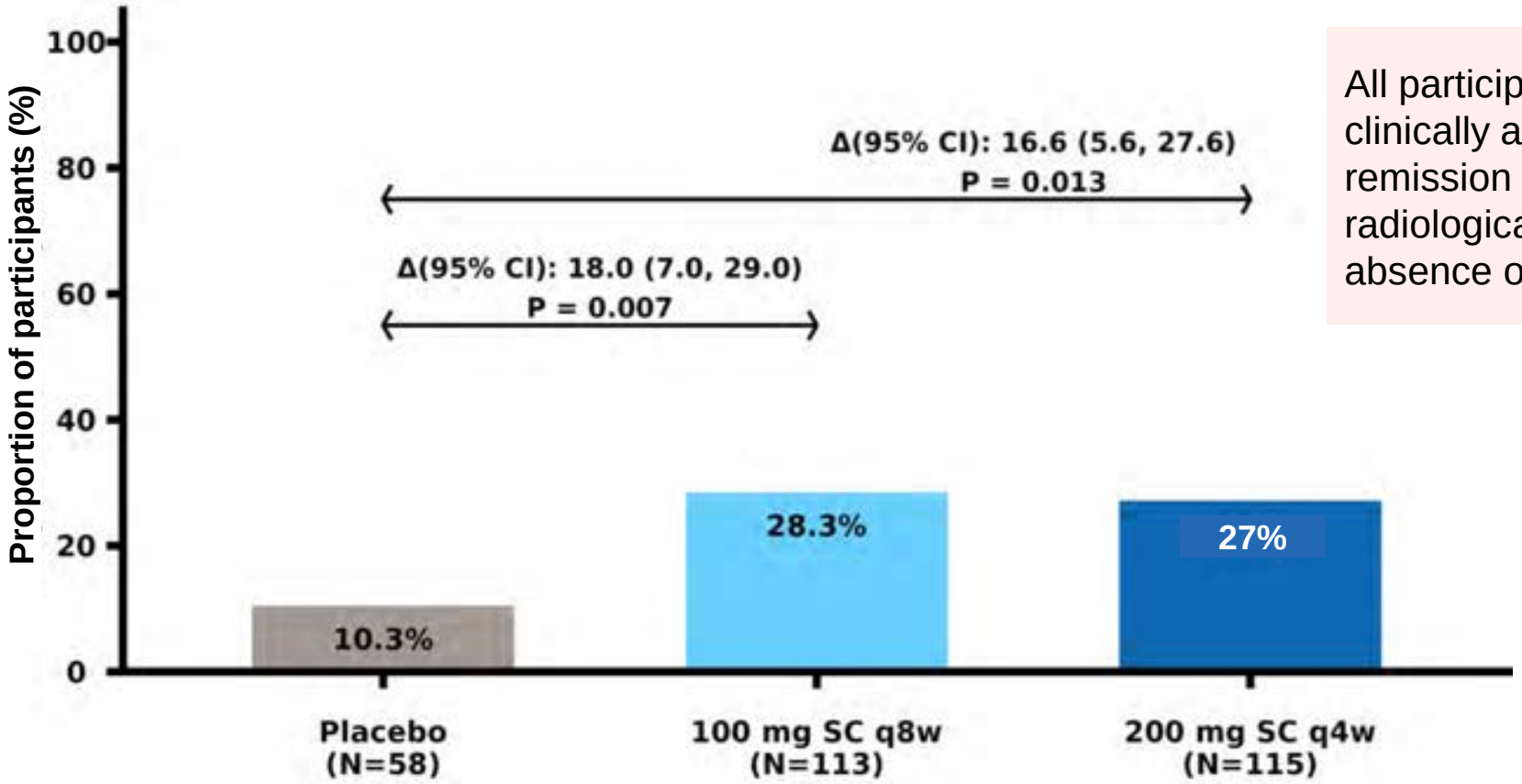
Combined fistula remission: 100% closure of all treated external openings, without development of new fistulas or abscesses and without any drainage by the external openings, occurring spontaneously or after gentle finger compression AND absence of collections >2 cm of the perianal fistulas, confirmed by a blinded central review of the MRI results

Missing Data Imputation: After applying the ICE strategy, missing data were imputed as not having achieved a combined fistula remission at Week 24. The adjusted risk difference and CI were based on Wald statistics using Mantel–Haenszel stratum weights stratified by baseline proctitis (yes, no) and baseline bio-naïve status (yes, no). The p-values are based on the CMH test, stratified by baseline proctitis (yes, no) and baseline bio-naïve status (yes, no).

CD, Crohn's disease; CI, confidence interval; CMH, Cochran–Mantel–Haenszel; GUS, guselkumab; ICE, intercurrent event; IL, interleukin; MOA, mechanism of action; MRI, magnetic resonance imaging; qXw, every X weeks; RDBPC, randomised, double-blind, placebo-controlled; SC, subcutaneous.

Peyrin-Biroulet L, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O1058b. Guselkumab is approved for adult moderate-severe CD patients. Full prescription information: swissmedicinfo-pro.ch.

Clinically assessed fistula remission at Week 24: Multiplicity-controlled secondary endpoint



All participants who had clinically assessed fistula remission also had radiologically assessed absence of collections >2 cm

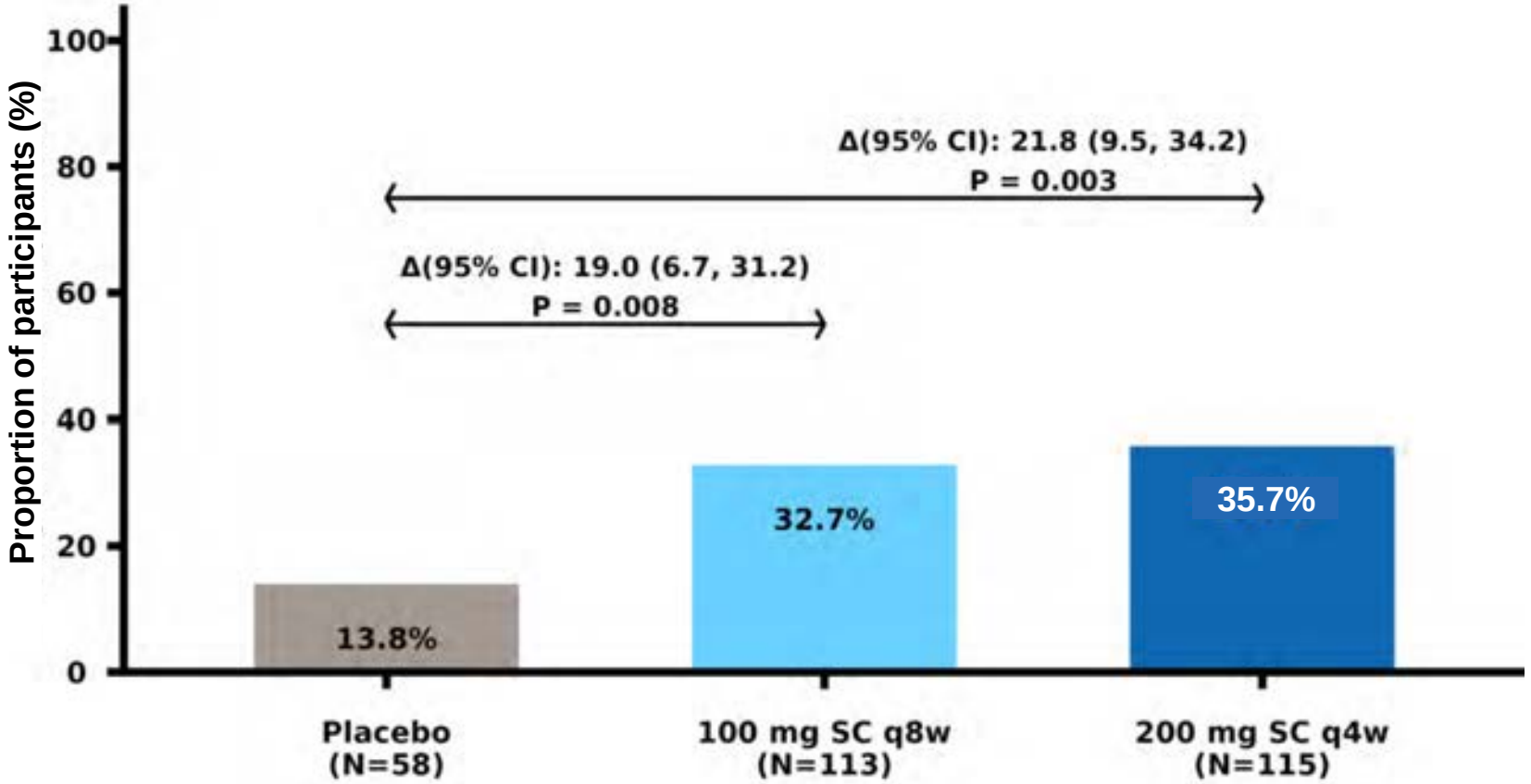
Clinically assessed fistula remission: 100% closure of all treated external openings, without development of new fistulas or abscesses and without any drainage by the external openings, occurring spontaneously or after gentle finger compression

Missing Data Imputation: After applying the ICE strategy, missing data were imputed as not having achieved a combined fistula remission at Week 24. The adjusted risk difference and CI were based on Wald statistics using Mantel–Haenszel stratum weights stratified by baseline proctitis (yes, no) and baseline bio-naïve status (yes, no). The p-values are based on the CMH test, stratified by baseline proctitis (yes, no) and baseline bio-naïve status (yes, no).

CD, Crohn's disease; CI, confidence interval; CMH, Cochran–Mantel–Haenszel; GUS, guselkumab; ICE, intercurrent event; IL, interleukin; MOA, mechanism of action; qXw, every X weeks; RDBPC, randomised, double-blind, placebo-controlled; SC, subcutaneous.

Peyrin-Biroulet L, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O1058b. Guselkumab is approved for adult moderate-severe CD patients. Full prescription information: swissmedicinfo-pro.ch.

Clinically assessed fistula response at Week 24: Multiplicity-controlled secondary endpoint



Clinically assessed fistula response: ≥50% reduction from baseline in number of open or draining perianal fistulas

Missing Data Imputation: After applying the ICE strategy, missing data were imputed as not having achieved a combined fistula remission at Week 24. The adjusted risk difference and CI were based on Wald statistics using Mantel–Haenszel stratum weights stratified by baseline proctitis (yes, no) and baseline bio-naïve status (yes, no). The p-values are based on the CMH test, stratified by baseline proctitis (yes, no) and baseline bio-naïve status (yes, no).

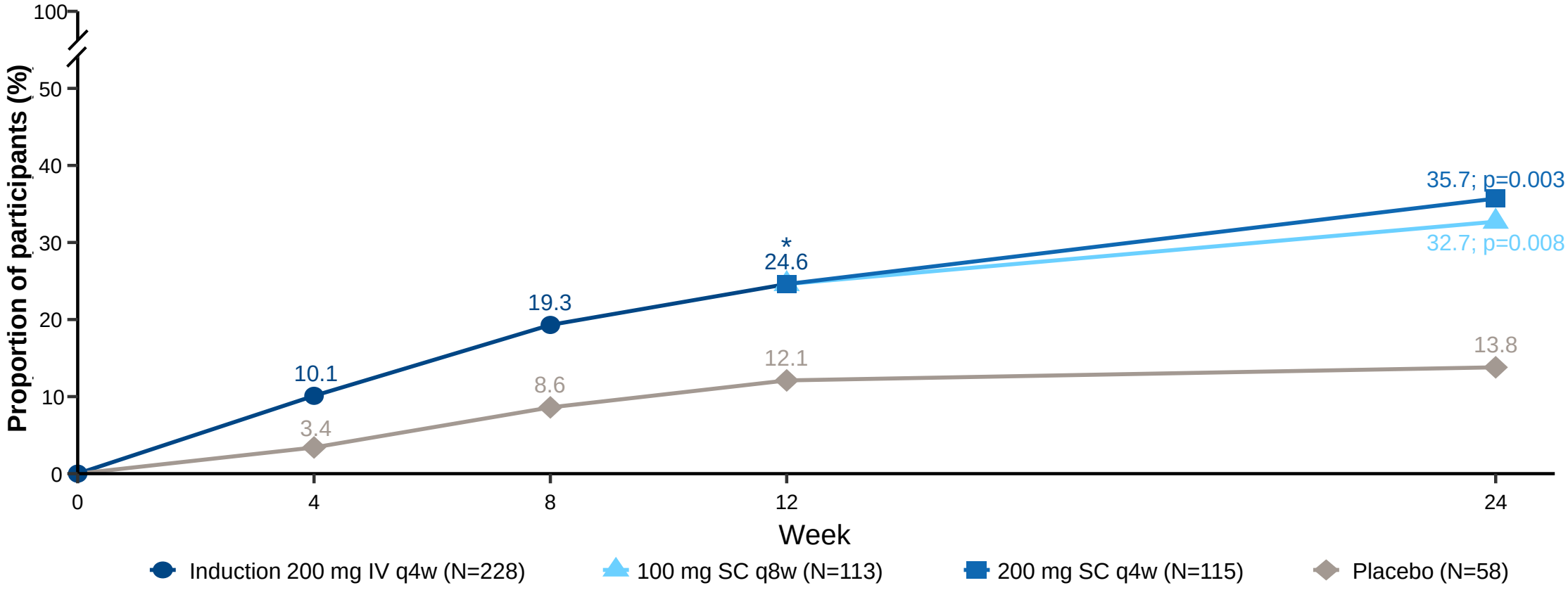
CD, Crohn's disease; CI, confidence interval; CMH, Cochran–Mantel–Haenszel; GUS, guselkumab; ICE, intercurrent event; IL, interleukin; MOA, mechanism of action; qXw, every X weeks; RDBPC, randomised, double-blind, placebo-controlled; SC, subcutaneous.

Peyrin-Biroulet L, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O1058b. Guselkumab is approved for adult moderate-severe CD patients. Full prescription information: swissmedicinfo-pro.ch.

CH_CP-581164 05/26

Clinically assessed fistula response through Week 24

Guselkumab showed clinically meaningful difference versus placebo during induction



Clinically assessed fistula response: ≥50% reduction from baseline in number of open or draining perianal fistulas

*Nominal p=0.041.
Missing Data Imputation: After applying the ICE strategy, missing data were imputed as not having achieved a combined fistula remission at Week 24. The adjusted risk difference and CI were based on Wald statistics using Mantel–Haenszel stratum weights stratified by baseline proctitis (yes, no) and baseline bio-naïve status (yes, no). The p-values are based on the CMH test, stratified by baseline proctitis (yes, no) and baseline bio-naïve status (yes, no).
CD, Crohn's disease; CI, confidence interval; CMH, Cochran–Mantel–Haenszel; GUS, guselkumab; ICE, intercurrent event; IL, interleukin; IV, intravenous; MOA, mechanism of action; qXw, every X weeks; RDBPC, randomised, double-blind, placebo-controlled; SC, subcutaneous.
Peyrin-Biroulet L, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O1058b. Guselkumab is approved for adult moderate-severe CD patients. Full prescription information: swissmedicinfo-pro.ch.

AEs through Week 24

	100 mg SC q8w (n=113)	200 mg SC q4w (n=115)	Combined (n=228)	Placebo (N=58)
Mean duration of follow-up (weeks)	24.0	24.0	24.0	23.8
Mean exposure (number of study agent administrations)	5.7	5.8	5.8	5.6
Subjects with ≥1 AE	76 (67.3%)	80 (69.6%)	156 (68.4%)	48 (82.8%)
Subjects with ≥1 SAE	12 (10.6%)	7 (6.1%)	19 (8.3%)	8 (13.8%)
Subjects with ≥1 AE leading to discontinuation of study agent	8 (7.1%)	3 (2.6%)	11 (4.8%)	5 (8.6%)
Subjects with ≥1 infection	45 (39.8%)	31 (27.0%)	76 (33.3%)	27 (46.6%)
Subjects with ≥1 serious infection	8 (7.1%)	2 (1.7%)	10 (4.4%)	2 (3.4%)

- No opportunistic infection, anaphylactic reactions or serum sickness reactions, MACE, clinically important hepatic disorders and VTE or deaths were reported
- **1 malignancy** (a B-cell lymphoma) was reported through Week 24 **(not related to study drug as assessed by investigator)**
- Injection-site reactions were **mild** and did not lead to discontinuation

Infections are based on MedDRA system organ class “Infections and Infestations”. Subjects are counted only once for any given event under specific column, regardless of the number of times they actually experienced the event. Adverse events are coded using MedDRA Version 28.0.
AE, adverse event; CD, Crohn’s disease; GUS, guselkumab; IL, interleukin; MACE, major adverse cardiovascular event; MedDRA, Medical Dictionary for Regulatory Activities; MOA, mechanism of action; qXw, every X weeks; RDBPC, randomised, double-blind, placebo-controlled; SAE, serious adverse event; SC, subcutaneous; VTE, venous thrombo-embolic event.
Peyrin-Biroulet L, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O1058b. Guselkumab is approved for adult moderate-severe CD patients. Full prescription information: swissmedicinfo-pro.ch.

Conclusions

- FUZION is the first successful international Phase 3 study that assessed a combined clinical and MRI primary endpoint and the first in more than two decades that showed efficacy of an advanced therapy in perianal fistulising Crohn's disease

- Guselkumab was efficacious through Week 24 in a study population that includes bio-naïve and bio-exposed patients with perianal fistulising CD
  - ✓ Guselkumab showed clinically meaningful difference versus placebo during induction
  - ✓ Both guselkumab maintenance doses showed statistically significant and clinically meaningful benefit compared with placebo

- The guselkumab benefit–risk profile was favourable, with no new safety signals identified

CH_CP-581164 05/26

CD, Crohn's disease; GUS, guselkumab; IL, interleukin; MOA, mechanism of action; MRI, magnetic resonance imaging; RDBPC, randomised, double-blind, placebo-controlled.
Peyrin-Biroulet L, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O1058b. Guselkumab is approved for adult moderate-severe CD patients. Full prescription information: swissmedicinfo-pro.ch.

DUET: JNJ-4804 in CD

Efficacy and safety of the first co-antibody therapy, JNJ-78934804, in patients with moderately to severely active Crohn's disease refractory to systemic therapies

Bruce E. Sands,[1] Geert D'Haens,[2] Iris Dotan,[3] Nat A. Terry,[4] Monica Walker,[4] Vanessa Bundy,[4] Hayley Perry,[5] Marion L. Vetter,[4] Taku Kobayashi,[6] Stefan Schreiber,[7] Vipul Jairath[8]

[1]Dr. Henry D Janowitz Division of Gastroenterology, Icahn School of Medicine at Mount Sinai, New York, NY, USA; [2]Department of Gastroenterology, Amsterdam University Medical Centers, Amsterdam, The Netherlands; [3]Division of Gastroenterology, Rabin Medical Center, Petah Tikva and the Gray Faculty of Medical and Health Sciences, Tel Aviv University, Israel; [4]Johnson & Johnson, Spring House, PA, USA; [5]Johnson & Johnson Innovative Medicine UK, High Wycombe, England; [6]Center for Advanced IBD Research and Treatment, Kitasato University Kitasato Institute Hospital, Tokyo, Japan; [7]Department of Internal Medicine I – Gastroenterology, Hepatology, Nutrition and Geriatric Medicine, University Hospital Schleswig-Holstein, Campus Kiel, Germany; [8]Department of Medicine, Schulich School of Medicine & Dentistry I, Western University, London, ON, Canada

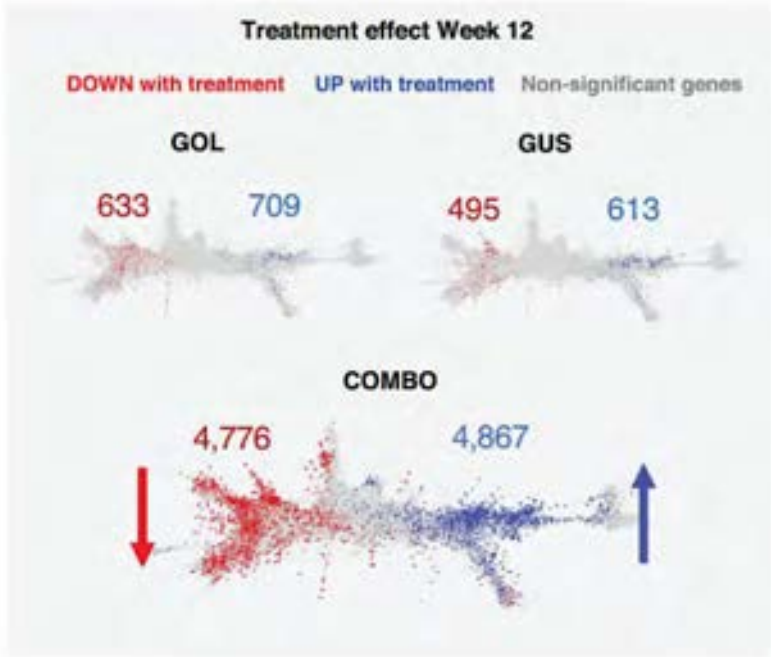
DUET-CD: Study background and objective[1]

In the Phase 2a VEGA study in ulcerative colitis, guselkumab and golimumab combination therapy showed higher efficacy over either monotherapy[2]*

This combination was informed by preclinical evidence of complementary and distinct IL-23 and TNF-α activity,[2] with molecular synergy demonstrated in VEGA[3]

JNJ-4804 (JNJ-78934804; guselkumab and golimumab fixed-dose combination), the first co-antibody therapy in IBD, aims to address the high unmet need in patients with disease refractory to current systemic therapies[1]

Molecular synergy observed in VEGA



Combination associated with reduced inflammation and restoration of epithelial-related processes[3]

Objective: The Phase 2b DUET-CD trial (NCT05242471) evaluated the efficacy and safety of **JNJ-4804** compared with the component monotherapies in patients with moderately to severely active CD that was refractory to systemic therapies†

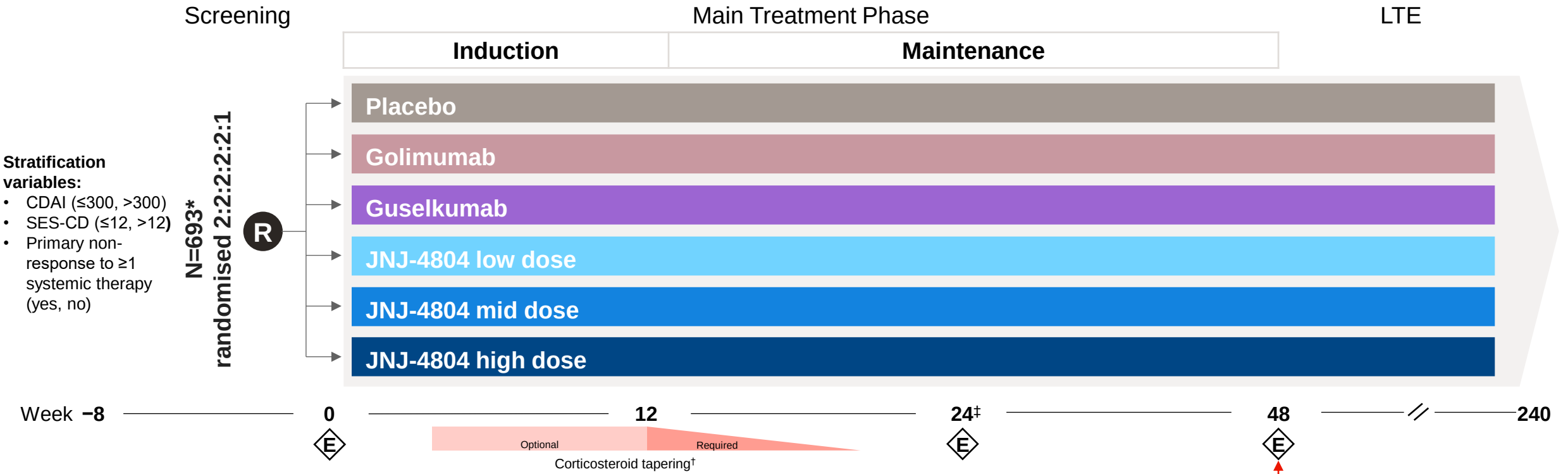
*VEGA was an anti-TNF-naïve study population[2]; †"Systemic therapies" are also referred to as "advanced therapies" (biologics and small molecules).
CD, Crohn's disease; GOL, golimumab; GUS, guselkumab; IL, interleukin; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor.
1. Sands BE, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 979f; 2. Feagan BG, et al. *Lancet Gastroenterol Hepatol.* 2023;8(4):307–320; 3. Desai P, et al Presented at EULAR, Milan, Italy 31 May – 3 June 2023. POS1606. Full prescribing information for guselkumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 and golimumab are not approved for CD by Swissmedic.

CH_CP-581164 05/26

DUET-CD study design

Phase 2b randomised, double-blind, active- and placebo-controlled treat-through study in a refractory population

- Moderately to severely active CD
- Inadequate response or intolerance to ≥1 systemic therapy mechanism (anti-TNF, IL-12/23, IL-23p19, integrin or JAK inhibitors)
- Caps for prior systemic therapy mechanisms: 1 (50%), 2 (35%), >2 (15%)
- All study medications were administered subcutaneously



CH_CP-581164 05/26

*Full Analysis Set; †All participants taking corticosteroids at Week 0 could begin tapering as early as Week 4 but no later than Week 12; ‡Patients who met inadequate response criteria, regardless of treatment assignment, received a JNJ-4804 regimen based on their initial study intervention group assignment.

CD, Crohn's disease; CDAI, Crohn's Disease Activity Index; E, endoscopy; GOL, golimumab; GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; JAK, Janus kinase; JNJ-4804, guselkumab and golimumab fixed-dose combination; LTE, long-term extension; MOA, mechanism of action; R, randomised; RDBAPC, randomised, double-blind, active- and placebo-controlled; SC, subcutaneous; SES-CD, Simple Endoscopic Score for Crohn's Disease; TNF, tumour necrosis factor.

Sands BE, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 979f. Full prescribing information for guselkumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 and golimumab are not approved for CD by Swissmedic.

Endpoints and statistical considerations

Co-primary endpoints

- Clinical remission at Week 48
- Endoscopic response at Week 48

Other key endpoints

- Corticosteroid-free clinical remission at Week 48
- Endoscopic remission at Week 48
- Deep remission at Week 48

Study powering and statistical considerations

- The study had >80% power to detect >20% difference in both co-primary endpoints for high-dose JNJ-4804 vs both monotherapies
- Participants who met prespecified treatment failure rules or had missing data were considered not to have met endpoints*
- Participants who met rescue criteria were considered treatment failures at Week 48*
- Analyses of subpopulations by systemic therapy history were prespecified† but not multiplicity controlled

CH_CP-581164 05/26

*Participants were considered not to have met the Week 48 endpoint if any of the following occurred prior to Week 48: CD-related surgery (except minor procedures such as drainage of a superficial abscess or seton placement); prohibited change in CD medication; treatment escalation due to inadequate response at Week 24; discontinuation of study treatment due to lack of efficacy or an AE of worsening CD; discontinuation of study treatment due to COVID-19 infection or any other reason. Participants who discontinued study treatment for COVID-19-related reasons (excluding COVID-19 infection) had their observed data used, if available. After accounting for these conditions, participants with a missing CDAI score (for clinical remission, corticosteroid-free clinical remission and deep remission) or SES-CD (for endoscopic response, endoscopic remission and deep remission) were considered not to have met the endpoint; †Analyses of subpopulations with 1, 2 and >2 prior systemic therapy mechanisms-IR were prespecified; the combined ≥2 systemic therapy mechanisms-IR subpopulation was evaluated based on these results.

AE, adverse event; CD, Crohn's disease; CDAI, Crohn's Disease Activity Index; GOL, golimumab; GUS, guselkumab; IL, interleukin; IR, inadequate response or intolerance; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; SES-CD, Simple Endoscopic Score for Crohn's Disease; TNF, tumour necrosis factor.

Sands BE, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 979f. Full prescribing information for guselkumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 and golimumab are not approved for CD by Swissmedic.

Baseline demographics, disease characteristics and concomitant medications

		Placebo	Golimumab	Guselkumab	JNJ-4804 low dose	JNJ-4804 mid dose	JNJ-4804 high dose	Total
Full analysis set		64	126	127	127	123	126	693
Age in years, mean (SD)		36.8 (13.47)	37.1 (12.25)	35.2 (11.33)	37.7 (12.26)	36.7 (11.50)	36.6 (12.73)	36.7 (12.15)
Sex, n (%)	**Male**	43 (67.2)	74 (58.7)	68 (53.5)	72 (56.7)	75 (61.0)	65 (51.6)	397 (57.3)
CD duration, years	Mean (SD)	10.7 (8.80)	10.2 (7.61)	10.3 (7.56)	12.0 (8.94)	10.1 (8.15)	11.4 (9.46)	10.8 (8.42)
	>10 years	25 (39.1)	50 (39.7)	51 (40.2)	57 (44.9)	49 (39.8)	54 (42.9)	286 (41.3)
Disease location	Ileum only	15 (23.4)	36 (28.6)	30 (23.6)	23 (18.1)	27 (22.0)	32 (25.4)	163 (23.5)
	Colon only	16 (25.0)	43 (34.1)	40 (31.5)	50 (39.4)	37 (30.1)	37 (29.4)	223 (32.2)
	Ileum and colon	33 (51.6)	47 (37.3)	57 (44.9)	54 (42.5)	59 (48.0)	57 (45.2)	307 (44.3)
CDAI score, mean (SD)*		322.2 (56.17)	322.5 (60.75)	327.8 (56.89)	320.8 (62.12)	321.4 (61.83)	325.4 (63.05)	323.5 (60.37)
SES-CD, mean (SD)		13.5 (7.98)	13.4 (7.52)	14.2 (8.41)	13.7 (7.82)	13.4 (7.34)	13.6 (8.31)	13.7 (7.88)
Concomitant medications at baseline								
Immunomodulators		9 (14.1)	24 (19.0)	26 (20.5)	25 (19.7)	26 (21.1)	21 (16.7)	131 (18.9)
Oral corticosteroid drugs		20 (31.3)	40 (31.7)	35 (27.6)	38 (29.9)	38 (30.9)	34 (27.0)	205 (29.6)
CRP (mg/L), median†		6.9	9.7	8.1	8.8	8.1	9.3	8.2
Faecal calprotectin (mg/kg), median‡		1214.0	1554.7	1362.0	1689.5	1070.0	1260.0	1362.0

*Means are based on the following numbers of participants with non-missing data: 64 (PBO), 124 (GOL), 125 (GUS), 125 (JNJ-4804 low dose), 122 (JNJ-4804 mid dose), 125 (JNJ-4804 high dose), 685 (total); †Medians are based on the following numbers of participants with non-missing data: 64 (PBO), 123 (GOL), 127 (GUS), 127 (JNJ-4804 low dose), 123 (JNJ-4804 mid dose), 125 (JNJ-4804 high dose), 689 (total); ‡Medians are based on the following numbers of participants with non-missing data: 57 (PBO), 111 (GOL), 113 (GUS), 108 (JNJ-4804 low dose), 109 (JNJ-4804 mid dose), 115 (JNJ-4804 high dose), 613 (total).

CD, Crohn's disease; CDAI, Crohn's Disease Activity Index; CRP, C-reactive protein; GOL, golimumab; GUS, guselkumab; IL, interleukin; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; PBO, placebo; RDBAPC, randomised, double-blind, active- and placebo-controlled; SD, standard deviation; SES-CD, Simple Endoscopic Score for Crohn's Disease; TNF, tumour necrosis factor.

Sands BE, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 979f. Full prescribing information for guselkumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 and golimumab are not approved for CD by Swissmedic.

Highly treatment-refractory population with inadequate response or intolerance to systemic therapies

		Placebo	Golimumab	Guselkumab	JNJ-4804 low dose	JNJ-4804 mid dose	JNJ-4804 high dose	Total
Analysis set, n		64	126	127	127	123	126	693
Participants with inadequate response to 1 or more systemic therapy mechanisms,* n (%)								
Number of systemic therapy mechanisms – inadequate responders, n (%)†	**1**	29 (45.3%)	61 (48.4%)	72 (56.7%)	53 (42.1%)	68 (55.3%)	63 (50.0%)	346 (50.0%)‡
	≥2	35 (54.7%)	65 (51.6%)	55 (43.3%)	73 (57.9%)	55 (44.7%)	63 (50.0%)	346 (50.0%)

50% were refractory to 2 or more systemic therapy mechanisms

History of inadequate response or intolerance by systemic therapy mechanism in the overall population:

- Anti-TNF: 90% (82% of the 1 systemic therapy-IR subgroup)
- Anti-IL-12/23: 47% (8% of the 1 systemic therapy-IR subgroup)
- Anti-integrin: 26% (8% of the 1 systemic therapy-IR subgroup)
- JAK inhibitor: 3%
- Anti-IL-23p19: 3%

*Anti-TNF, anti-IL-12/23, anti-IL-23p19, anti-integrin and JAK inhibitor; †Denominators are the numbers of participants with inadequate response to 1 or more systemic therapy mechanisms; ‡Among patients with inadequate response to 1 systemic therapy mechanism in DUET-CD, 17% had inadequate response to 2 anti-TNF agents.
CD, Crohn's disease; GOL, golimumab; GUS, guselkumab; IL, interleukin; IR, inadequate responder; JAK, Janus kinase; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor.
Sands BE, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 979f. Full prescribing information for guselkumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 and golimumab are not approved for CD by Swissmedic.

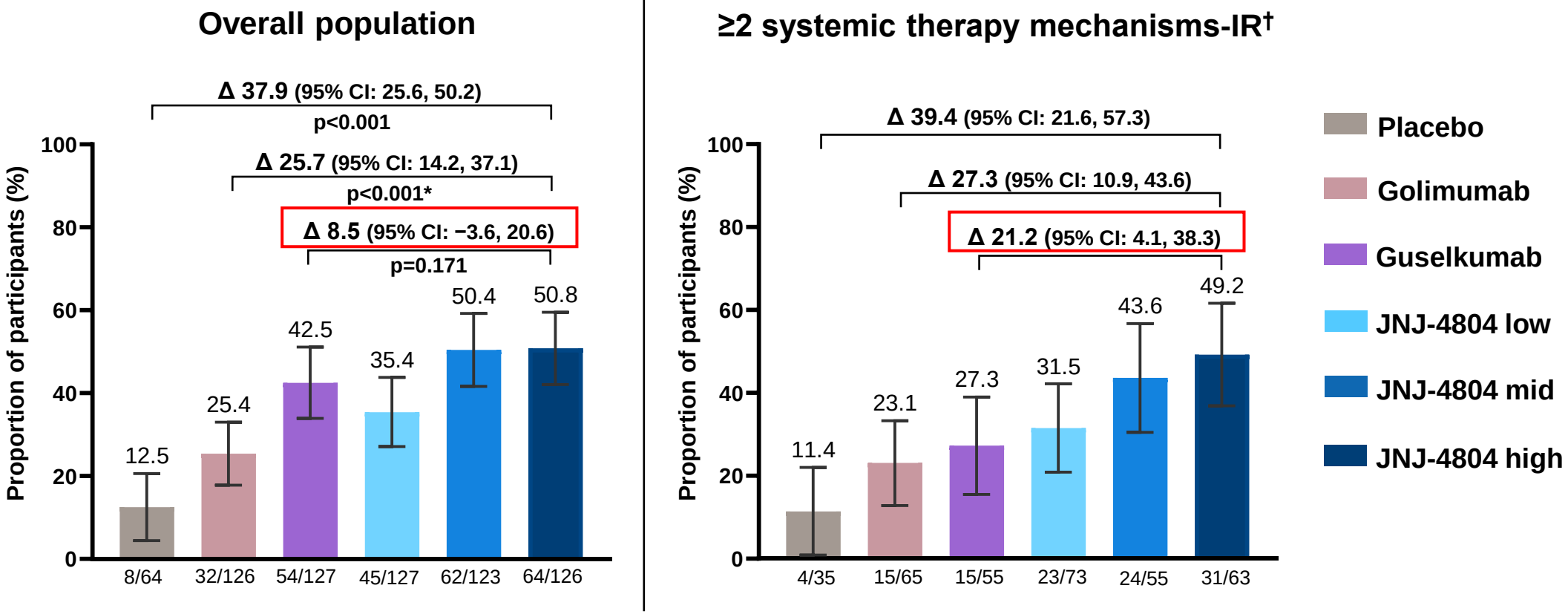
Treatment disposition through Week 48: Lowest discontinuation rates observed in JNJ-4804 mid-dose and high-dose groups

	Placebo	Golimumab	Guselkumab	JNJ-4804 low dose	JNJ-4804 mid dose	JNJ-4804 high dose	Total
Full analysis set	64	126	127	127	123	126	693
Number of participants who:							
Discontinued study treatment before Week 48	33 (51.6%)	51 (40.5%)	31 (24.4%)	37 (29.1%)	24 (19.5%)	24 (19.0%)	200 (28.9%)
Most common reasons for discontinuation							
Lack of efficacy	9 (14.1%)	15 (11.9%)	11 (8.7%)	13 (10.2%)	9 (7.3%)	6 (4.8%)	63 (9.1%)
Withdrawal by participant	9 (14.1%)	13 (10.3%)	4 (3.1%)	6 (4.7%)	4 (3.3%)	5 (4.0%)	41 (5.9%)
AE – worsening of CD	12 (18.8%)	10 (7.9%)	4 (3.1%)	6 (4.7%)	3 (2.4%)	5 (4.0%)	40 (5.8%)
AE – other	2 (3.1%)	5 (4.0%)	5 (3.9%)	7 (5.5%)	2 (1.6%)	5 (4.0%)	26 (3.8%)
Initiated prohibited medication	0	3 (2.4%)	3 (2.4%)	1 (0.8%)	3 (2.4%)	0	10 (1.4%)

CH_CP-581164 05/26

Note: Final dosing for the main treatment period was received 4 weeks prior to Week 48. Participants are presented in the treatment group assigned at Week 0.
AE, adverse event; CD, Crohn's disease; GOL, golimumab; GUS, guselkumab; IL, interleukin; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor.
Sands BE, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 979f. Full prescribing information for guselkumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 and golimumab are not approved for CD by Swissmedic.

Co-primary endpoint: Clinical remission at Week 48

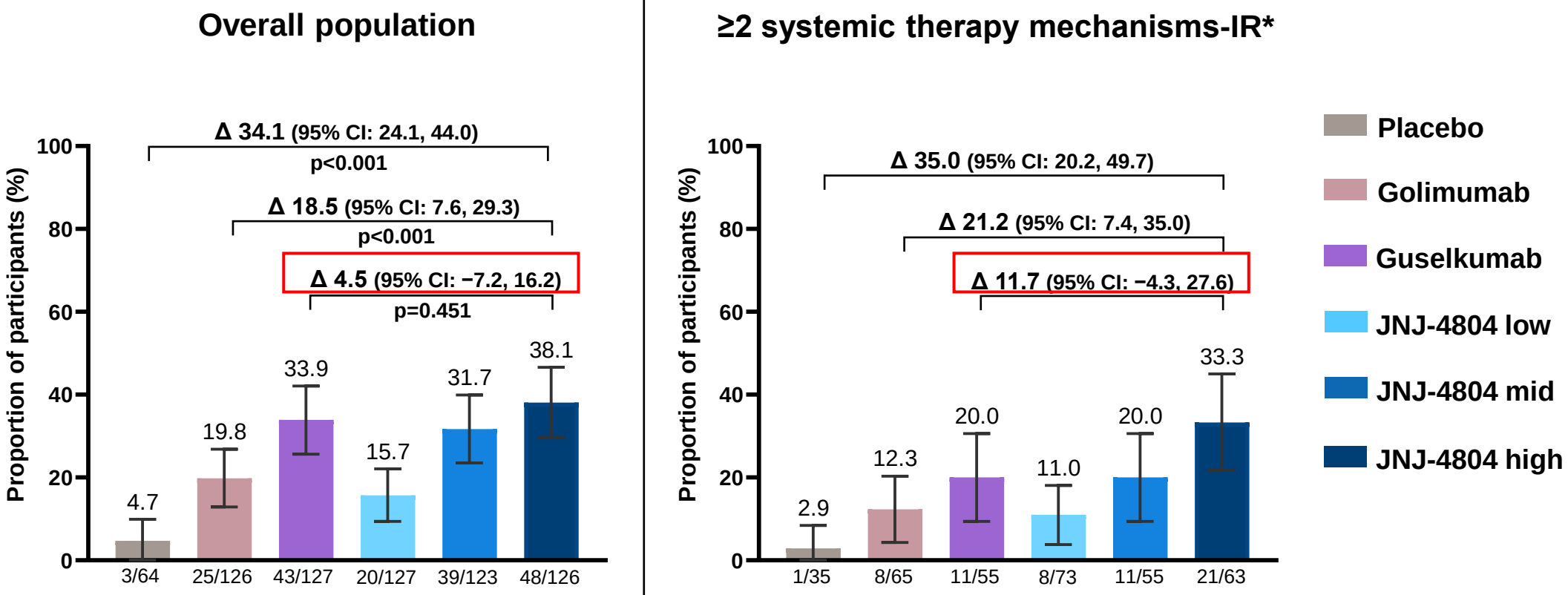


Clinical remission: CDAI score of <150

*Statistically significant. All other p-values are nominal; †Patients who were inadequate responders to two or more mechanisms of systemic therapies.
CD, Crohn's disease; CDAI, Crohn's Disease Activity Index; CI, confidence interval; GOL, golimumab; GUS, guselkumab; IL, interleukin; IR, inadequate responder; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor.
Sands BE, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 979f. Full prescribing information for guselkumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 and golimumab are not approved for CD by Swissmedic.

CH_CP-581164 05/26

Co-primary endpoint: Endoscopic response at Week 48



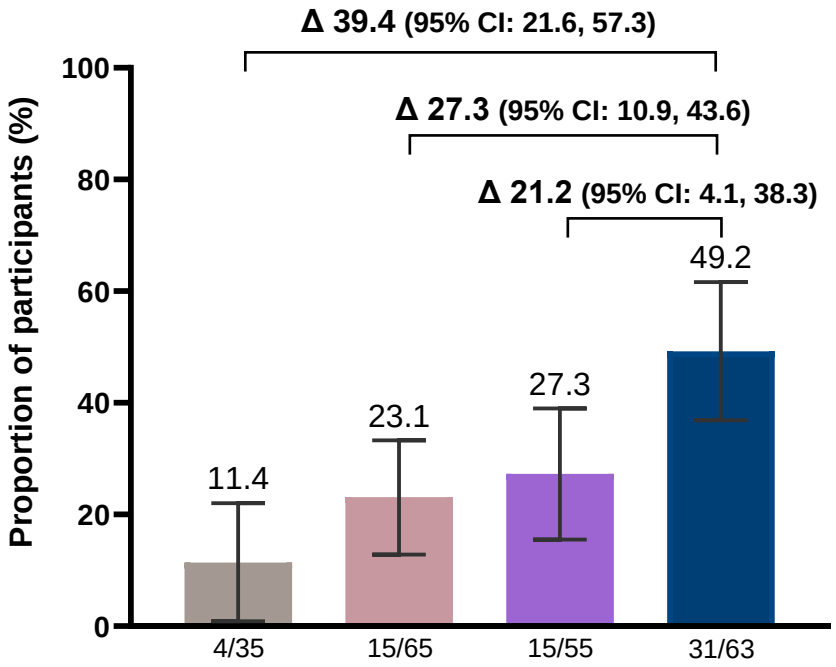
Endoscopic response: >50% improvement from baseline in SES-CD or an SES-CD ≤2, as assessed by central endoscopy reading

All p-values are nominal. *Patients who were inadequate responders to two or more mechanisms of systemic therapies.
CD, Crohn's disease; CI, confidence interval; GOL, golimumab; GUS, guselkumab; IL, interleukin; IR, inadequate responder; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; SES-CD, Simple Endoscopic Score for Crohn's Disease; TNF, tumour necrosis factor.
Sands BE, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 979f. Full prescribing information for guselkumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 and golimumab are not approved for CD by Swissmedic.

Key secondary endpoint: Corticosteroid-free clinical remission at Week 48 (≥2 systemic therapy mechanisms-IR population)

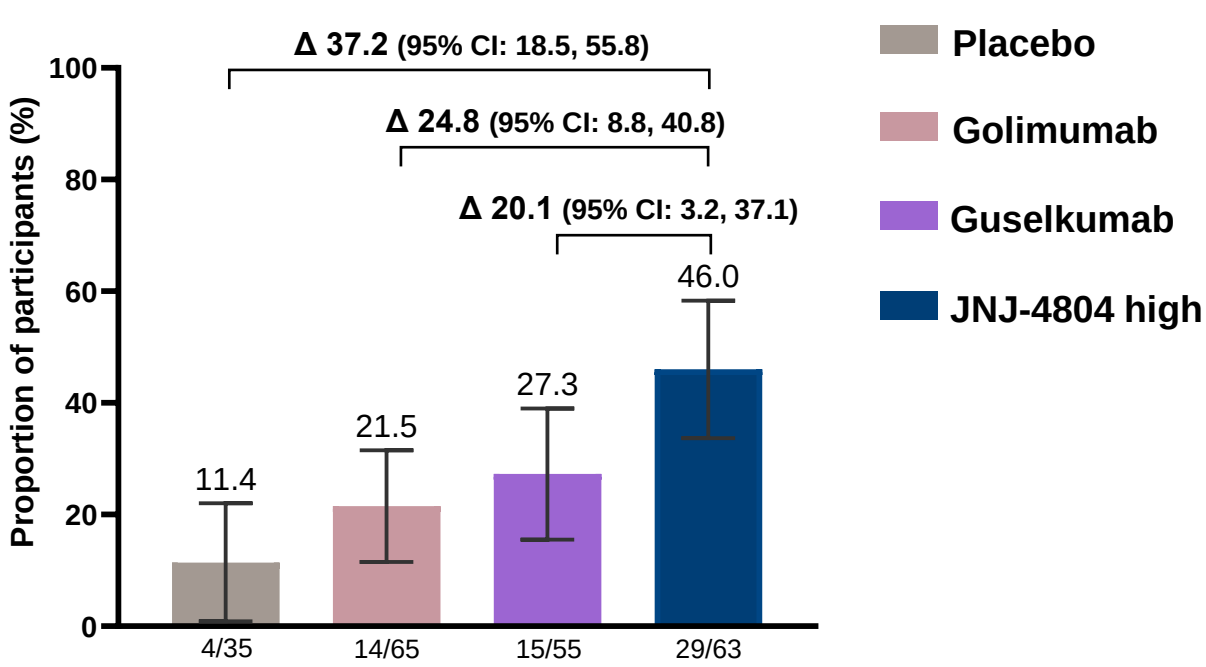
Clinical remission

≥2 systemic therapy mechanisms-IR*



Corticosteroid-free clinical remission

≥2 systemic therapy mechanisms-IR*



Corticosteroid-free (60-day) clinical remission: CDAI score <150, with no corticosteroids received for at least 60 days

Of the participants in clinical remission at Week 48 in the high-dose group, **29/31 (93.5%) were corticosteroid-free**

All p-values are nominal. *Patients who were inadequate responders to two or more mechanisms of systemic therapies.

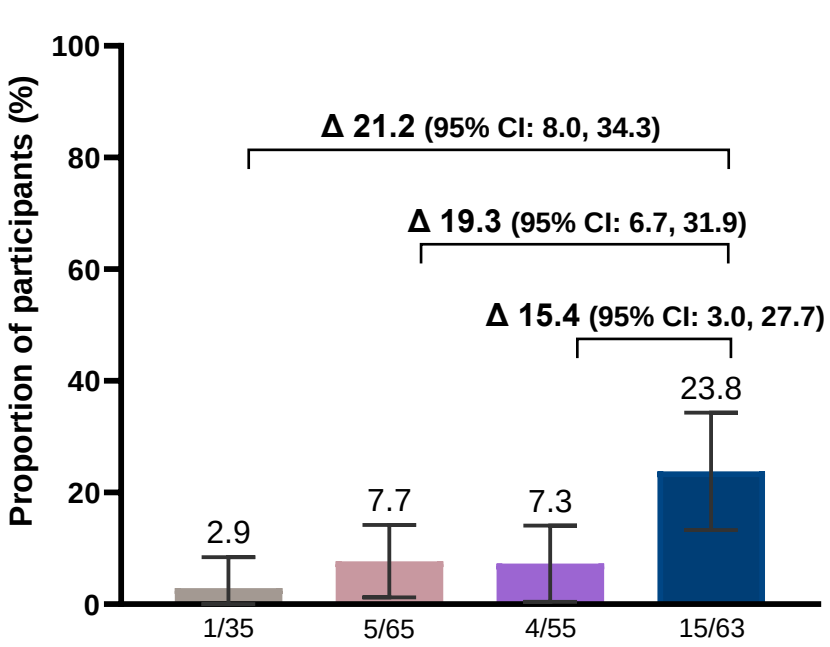
CD, Crohn's disease; CDAI, Crohn's Disease Activity Index; CI, confidence interval; GOL, golimumab; GUS, guselkumab; IL, interleukin; IR, inadequate responder; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor.

Sands BE, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 979f. Full prescribing information for guselkumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 and golimumab are not approved for CD by Swissmedic..

Key endpoints: Endoscopic remission and deep remission at Week 48 (≥2 systemic therapy mechanisms-IR population)

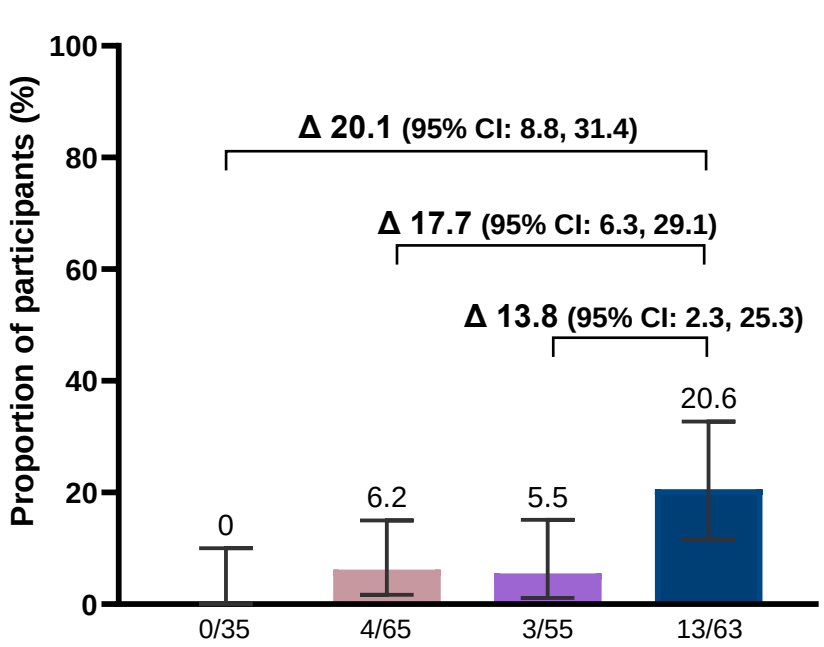
Endoscopic remission

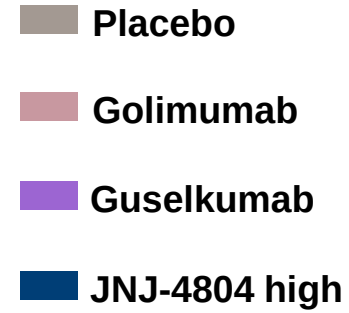
≥2 systemic therapy mechanisms-IR*



Deep remission

≥2 systemic therapy mechanisms-IR*





CH_CP-581164 05/26

Endoscopic remission: SES-CD ≤4, with at least a 2-point reduction from baseline and no sub-score greater than 1 on any individual component
Deep remission: Both clinical remission and endoscopic remission

All p-values are nominal. *Patients who were inadequate responders to two or more mechanisms of systemic therapies.
CD, Crohn's disease; CI, confidence interval; GOL, golimumab; GUS, guselkumab; IL, interleukin; IR, inadequate responder; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; SES-CD, Simple Endoscopic Score for Crohn's Disease; TNF, tumour necrosis factor.
Sands BE, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 979f. Full prescribing information for guselkumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 and golimumab are not approved for CD by Swissmedic..

Summary of exposure-adjusted AEs through Week 48* (Overall population)

	Placebo	Golimumab	Guselkumab	JNJ-4804 low dose	JNJ-4804 mid dose	JNJ-4804 high dose	JNJ-4804 Combined
Safety analysis set	64	126	127	127	123	126	376
Total patient-years of follow-up	38.5	86.0	98.6	97.6	98.6	104.3	300.5
Events per hundred patient-years [number of events]							
AEs	646.8 [249]	603.2 [519]	561.0 [553]	572.6 [559]	489.0 [482]	496.4 [518]	518.7 [1559]
SAEs	31.2 [12]	44.2 [38]	14.2 [14]	36.9 [36]	15.2 [15]	18.2 [19]	23.3 [70]
AEs leading to discontinuation of study treatment	41.6 [16]	23.2 [20]	11.2 [11]	12.3 [12]	6.1 [6]	10.5 [11]	9.6 [29]
Infections	127.3 [49]	122.0 [105]	95.4 [94]	134.2 [131]	102.5 [101]	116.9 [122]	117.8 [354]
Serious infections	2.6 [1]	7.0 [6]	4.1 [4]	8.2 [8]	3.0 [3]	2.9 [3]	4.7 [14]
Deaths†	0.0 [0]	1.2 [1]	0.0 [0]	0.0 [0]	0.0 [0]	0.0 [0]	0.0 [0]

Most infections were **mild or moderate** and **did not result in treatment discontinuation**

The most frequently reported treatment-emergent AEs (reported in ≥5% of participants for all groups) were nasopharyngitis, upper respiratory tract infection, CD, and pyrexia

*Excludes inadequate responder events after treatment escalation at Week 24; †One participant with a MACE of unwitnessed cardio-respiratory arrest/respiratory failure (golimumab).
AE, adverse event; CD, Crohn's disease; GOL, golimumab; GUS, guselkumab; IL, interleukin; JNJ-4804, guselkumab and golimumab fixed-dose combination; MACE, major adverse cardiovascular event; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; SAE, serious adverse event; TNF, tumour necrosis factor.
Sands BE, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 979f Full prescribing information for guselkumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 and golimumab are not approved for CD by Swissmedic.

Treatment-emergent AEs of interest through Week 48*

	Placebo	Golimumab	Guselkumab	JNJ-4804 low dose	JNJ-4804 mid dose	JNJ-4804 high dose
Safety analysis set	64	126	127	127	123	126
Major adverse cardiovascular events	0	1 (0.8%)	0	0	0	0
Venous thromboembolism	0	0	0	0	0	0
Clinically important hepatic disorders	0	2 (1.6%)	1 (0.8%)	2 (1.6%)	0	0
Opportunistic infection	1 (1.6%)	1 (0.8%)	0	3 (2.4%)	0	1 (0.8%)
Participants with ≥1 AE of special interest†						
Invasive fungal infection	0	0	0	0	0	0
Hepatitis B reactivation	0	0	0	0	0	0
Tuberculosis	0	0	0	1 (0.8%)	0	0
Malignancy	0	1 (0.8%)	0	2 (1.6%)	1 (0.8%)	1 (0.8%)
Hypersensitivity reaction	0	0	0	0	0	0
Congestive heart failure	0	0	0	0	0	0
Demyelinating disorders	0	0	0	0	0	0
Lupus-like syndrome	0	0	0	0	0	0

Malignancies were carcinoma in situ of the larynx (golimumab), dermatofibrosarcoma protuberans (low dose), squamous cell carcinoma (low dose and high dose) and basal cell carcinoma (mid dose)

Opportunistic infections were CMV infection (placebo and low dose), EBV reactivation (golimumab), oesophageal candidiasis (low dose), tuberculosis (low dose) and herpes zoster disseminated cutaneous (high dose)

*Excludes inadequate responder events after treatment escalation at Week 24; †Serious infections were also an AE of special interest and were presented in the previous slide.

AE, adverse event; CMV, cytomegalovirus; EBV, Epstein–Barr virus; GOL, golimumab; GUS, guselkumab; IL, interleukin; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor.

Sands BE, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 979f. Full prescribing information for guselkumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 and golimumab are not approved for CD by Swissmedic.

Conclusions

- JNJ-4804, the first co-antibody therapy in development for IBD, demonstrated clinically meaningful efficacy exceeding that of the monotherapies in patients with treatment-refractory CD
- In the overall population, efficacy of high-dose JNJ-4804 was superior to golimumab and numerically greater than guselkumab
- In patients with disease refractory to two or more systemic therapy mechanisms, high-dose JNJ-4804 exceeded golimumab and guselkumab monotherapy, with more than additive benefits in high-bar endoscopic and deep remission outcomes
- The safety profile of JNJ-4804 through 48 weeks was consistent with the well-established safety profiles of the component monotherapies
- Building on the molecular synergy seen in VEGA, the DUET-CD results support advancement to Phase 3 in the rapidly growing population of patients with disease refractory to systemic therapies

CH_CP-581164 05/26

CD, Crohn's disease; GOL, golimumab; GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor.
Sands BE, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 979f. Full prescribing information for guselkumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 and golimumab are not approved for CD by Swissmedic.

DUET: JNJ-4804 in UC

1058d

Efficacy and safety of the first co-antibody therapy, JNJ-78934804, in patients with moderately to severely active ulcerative colitis refractory to systemic therapies

Maria T. Abreu,[1] Bruce E. Sands,[2] Séverine Vermeire,[3] Remo Panaccione,[4] Gregory T Moore,[5] Raja Atreya,[6] John Lynch,[7] Melissa G. Marko,[7] Eun Suk Jung,[7] Siyka Alexandrova,[7] Hayley Perry,[8] Marion L. Vetter,[7] Julián Panés[9]

[1]Cedars-Sinai, Los Angeles, CA, USA; [2]Dr. Henry D Janowitz Division of Gastroenterology, Icahn School of Medicine at Mount Sinai, New York, NY, USA; [3]University Hospitals Leuven, Leuven, Belgium; [4]Inflammatory Bowel Disease Unit, Division of Gastroenterology and Hepatology, University of Calgary, Calgary, AB, Canada; [5]Monash Health, and Monash University, Melbourne, Australia; [6]Department of Medicine 1, Erlangen University Hospital, Friedrich-Alexander-Universität Erlangen-Nürnberg, Erlangen, Germany; [7]Johnson & Johnson, Spring House, PA, USA; [8]Johnson & Johnson Innovative Medicine UK, High Wycombe, England; [9]Hospital Clínic de Barcelona, IDIBAPS, CIBERehd, Barcelona, Spain

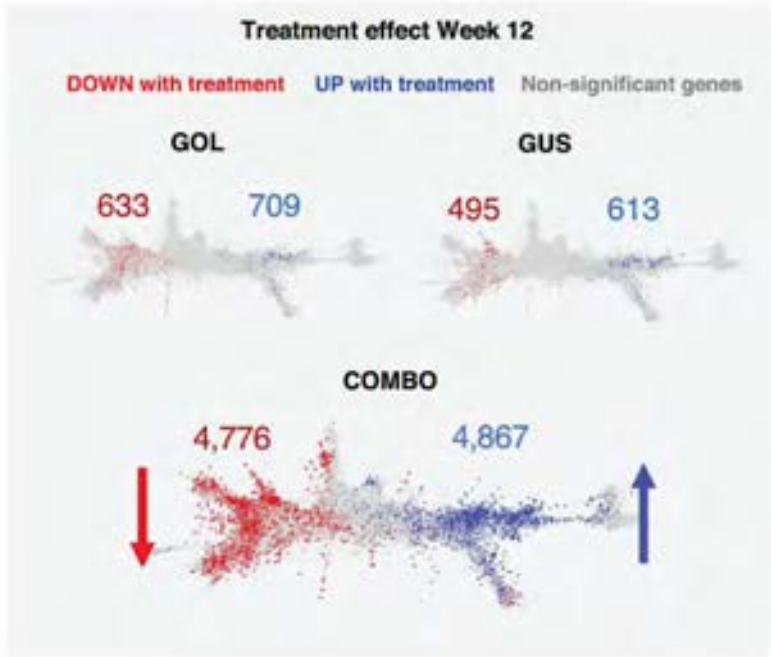
DUET-UC: Study background and objective[1]

In the Phase 2a VEGA study in ulcerative colitis, guselkumab and golimumab combination therapy showed higher efficacy over either monotherapy[2]*

This combination was informed by preclinical evidence of complementary and distinct IL-23 and TNF-α activity,[2] with molecular synergy demonstrated in VEGA[3]

JNJ-4804 (JNJ-78934804; guselkumab and golimumab fixed-dose combination), the first co-antibody therapy in IBD, aims to address the high unmet need in patients with disease refractory to current systemic therapies[1]

Molecular synergy observed in VEGA



Combination associated with reduced inflammation and restoration of epithelial-related processes[3]

Objective: The Phase 2b DUET-UC trial (NCT05242484) evaluated the efficacy and safety of **JNJ-4804** compared with the component monotherapies in patients with moderately to severely active ulcerative colitis refractory to systemic therapies†

*VEGA was an anti-TNF-naïve study population[2]; †"Systemic therapies" are also referred to as "advanced therapies" (biologics and small molecules).
CD, Crohn's disease; GOL, golimumab; GUS, guselkumab; IL, interleukin; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor.

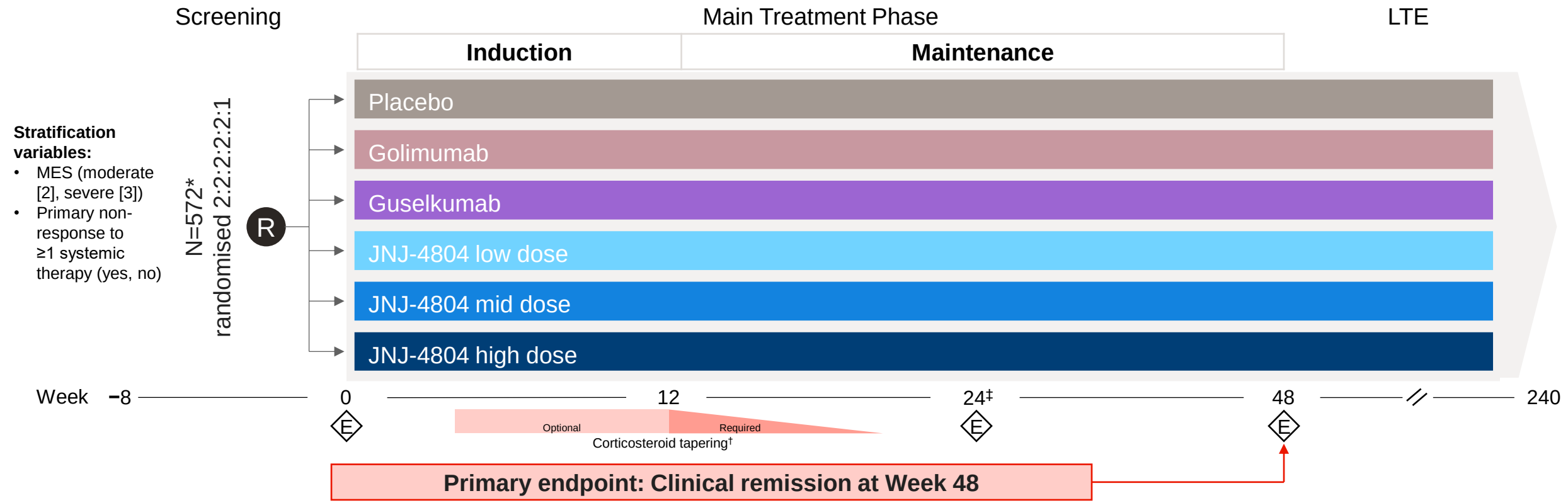
1. Sands BE, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 1058D; 2. Feagan BG, et al. *Lancet Gastroenterol Hepatol.* 2023;8(4):307–320; 3. Desai P, et al Presented at EULAR, Milan, Italy 31 May – 3 June 2023. POS1606. Full prescribing information for guselkumab and golimumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 is not approved by Swissmedic.

CH_CP-581164 05/26

DUET-UC study design

Phase 2b randomised, double-blind, active- and placebo-controlled treat-through study in a refractory population

- Moderately to severely active UC
- Inadequate response or intolerance to ≥1 systemic therapy mechanism (anti-TNF, IL-12/23, IL-23p19, integrin, JAK inhibitor or S1PR modulator)
- Caps for prior systemic therapy mechanisms: 1 (50%), 2 (35%), >2 (15%)
- All study medications were administered subcutaneously



*Full Analysis Set; 559 were included in the modified Full Analysis Set (13 did not meet mMayo inclusion criteria at baseline); †Participants taking corticosteroids at Week 0 could begin tapering as early as Week 4 but no later than Week 12; ‡Patients who met inadequate response criteria at Week 24 received a JNJ-4804 regimen (regardless of treatment assignment).
E, endoscopy; GOL, golimumab; GUS, guselkumab; IL, interleukin; JAK, Janus kinase; JNJ-4804, guselkumab and golimumab fixed-dose combination; LTE, long-term extension; MES, Mayo Endoscopic Subscore; mMayo, modified Mayo; MOA, mechanism of action; R, randomised; RDBAPC, randomised, double-blind, active- and placebo-controlled; S1PR, sphingosine-1-phosphate receptor; TNF, tumour necrosis factor; UC, ulcerative colitis.
Abreu MT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 1058d. Full prescribing information for guselkumab and golimumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 is not approved by Swissmedic..

Endpoints and statistical considerations

Primary endpoint

- Clinical remission at Week 48

Other key endpoints

- Endoscopic improvement at Week 48
- Histologic remission and endoscopic improvement at Week 48
- Corticosteroid-free clinical remission at Week 48

Statistical considerations

- Participants who met prespecified treatment failure rules or had missing data were considered not to have met endpoints*
- Participants who met rescue criteria were considered treatment failures at Week 48*
- Analyses of subpopulations by systemic therapy history were prespecified† but not multiplicity controlled

CH_CP-581164 05/26

*Participants were considered not to have met the Week 48 endpoint if any of the following occurred prior to Week 48: An ostomy or colectomy (partial or total); prohibited change in UC medication; treatment escalation due to inadequate response at Week 24; discontinuation of study treatment due to lack of efficacy or an AE of worsening UC; discontinuation of study treatment due to COVID-19 infection or any other reason. Participants who discontinued study treatment for COVID-19-related reasons (excluding COVID-19 infection) had their observed data used, if available. Missing data imputation: After accounting for these conditions, participants with missing Mayo subscores (any or all) at Week 48 (for clinical remission and corticosteroid-free clinical remission), missing endoscopy subscores at Week 48 (for endoscopic improvement and HREI), or missing histology data at Week 48 (for HREI) were considered not to have met the endpoint at Week 48; †Analyses of subpopulations with 1, 2 and >2 prior systemic therapy mechanisms-IR were prespecified; the combined ≥2 systemic therapy mechanisms-IR subpopulation was evaluated based on these results.

AE, adverse event; GOL, golimumab; GUS, guselkumab; HREI, histologic remission and endoscopic improvement; IL, interleukin; IR, inadequate responder; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor; UC, ulcerative colitis.

Abreu MT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 1058d. Full prescribing information for guselkumab and golimumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 is not approved by Swissmedic.

Baseline demographics, disease characteristics and concomitant medications

		Placebo	Golimumab	Guselkumab	JNJ-4804 low dose	JNJ-4804 mid dose	JNJ-4804 high dose	Total
Full Analysis Set		52	104	103	103	105	105	572
Age in years, mean (SD)		38.6 (11.51)	38.5 (12.86)	40.3 (12.32)	39.8 (13.44)	39.6 (13.27)	38.0 (12.05)	39.2 (12.66)
Sex, n (%)	**Male**	33 (63.5%)	59 (56.7%)	54 (52.4%)	57 (55.3%)	61 (58.1%)	62 (59.0%)	326 (57.0%)
UC disease duration, years	**Mean (SD)**	9.3 (6.95)	8.5 (7.40)	9.4 (6.81)	9.7 (8.21)	8.9 (7.23)	8.9 (8.24)	9.1 (7.52)
Extent of disease, n (%)	**Extensive**	22 (42.3%)	50 (48.1%)	56 (54.4%)	52 (50.5%)	48 (45.7%)	49 (46.7%)	277 (48.4%)
mMayo Score*	**Mean (SD)**	7.0 (1.24)	7.1 (1.02)	7.0 (1.28)	7.0 (1.09)	7.2 (1.30)	7.1 (1.13)	7.1 (1.17)
Severity of UC disease, n (%)*	**Severe (mMayo Score 7–9)**	37 (71.2%)	71 (68.9%)	69 (67.6%)	74 (72.5%)	72 (69.2%)	75 (72.1%)	398 (70.2%)
Mayo Endoscopic Subscore, n (%)	**Subscore of 3 (severe)**	37 (71.2%)	78 (75.0%)	73 (70.9%)	73 (70.9%)	76 (72.4%)	73 (69.5%)	410 (71.7%)
Abnormal faecal calprotectin (>250 mg/kg)†	**n (%)**	41 (85.4%)	92 (95.8%)	83 (89.2%)	86 (91.5%)	80 (89.9%)	81 (91.0%)	463 (91.0%)
Faecal calprotectin (mg/kg)†	**Median**	1551.7	1689.5	1789.8	2220.4	1798.3	1634.0	1744.0
Concomitant medications at baseline								
Immunomodulators		5 (9.6%)	16 (15.4%)	14 (13.6%)	20 (19.4%)	17 (16.2%)	11 (10.5%)	83 (14.5%)
Oral corticosteroids		20 (38.5%)	38 (36.5%)	45 (43.7%)	36 (35.0%)	52 (49.5%)	51 (48.6%)	242 (42.3%)

*Means or percentages are based on the following numbers of participants with non-missing data: 52 (PBO), 103 (GOL), 102 (GUS), 102 (JNJ-4804 low dose), 104 (JNJ-4804 mid dose), 104 (JNJ-4804 high dose), 567 (total); †Medians or percentages are based on the following numbers of participants with non-missing data: 48 (PBO), 96 (GOL), 93 (GUS), 94 (JNJ-4804 low dose), 89 (JNJ-4804 mid dose), 89 (JNJ-4804 high dose), 509 (total).

GOL, golimumab; GUS, guselkumab; IL, interleukin; JNJ-4804, guselkumab and golimumab fixed-dose combination; mMayo, modified Mayo; MOA, mechanism of action; PBO, placebo; RDBAPC, randomised, double-blind, active- and placebo-controlled; SD, standard deviation; TNF, tumour necrosis factor; UC, ulcerative colitis.

Abreu MT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 1058d. Full prescribing information for guselkumab and golimumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 is not approved by Swissmedic.

CH_CP-581164 05/26

Highly treatment-refractory population with inadequate response or intolerance to systemic therapies

		Placebo	Golimumab	Guselkumab	JNJ-4804 low dose	JNJ-4804 mid dose	JNJ-4804 high dose	Total
Full Analysis Set		52	104	103	103	105	105	572
Participants with inadequate response to 1 or more systemic therapy mechanisms*								
Number of systemic therapy mechanisms – inadequate responders, n (%)†	**1**	30 (58.8%)	56 (53.8%)	51 (49.5%)	63 (61.2%)	58 (55.2%)	58 (55.8%)	316 (55.4%)
	≥2	21 (41.2%)	48 (46.2%)	52 (50.5%)	40 (38.8%)	47 (44.8%)	46 (44.2%)	254 (44.6%)

44.6% were refractory to 2 or more systemic therapy mechanisms

History of inadequate response or intolerance by system therapy mechanism in the overall population:

- Anti-TNF: 74%
- Anti-integrin: 44%
- JAK inhibitor: 26%
- Ustekinumab: 19%
- S1PR modulator: 4%
- Anti-IL-23: 1%

60% of participants with disease refractory to 1 systemic therapy had inadequate response to an anti-TNF only

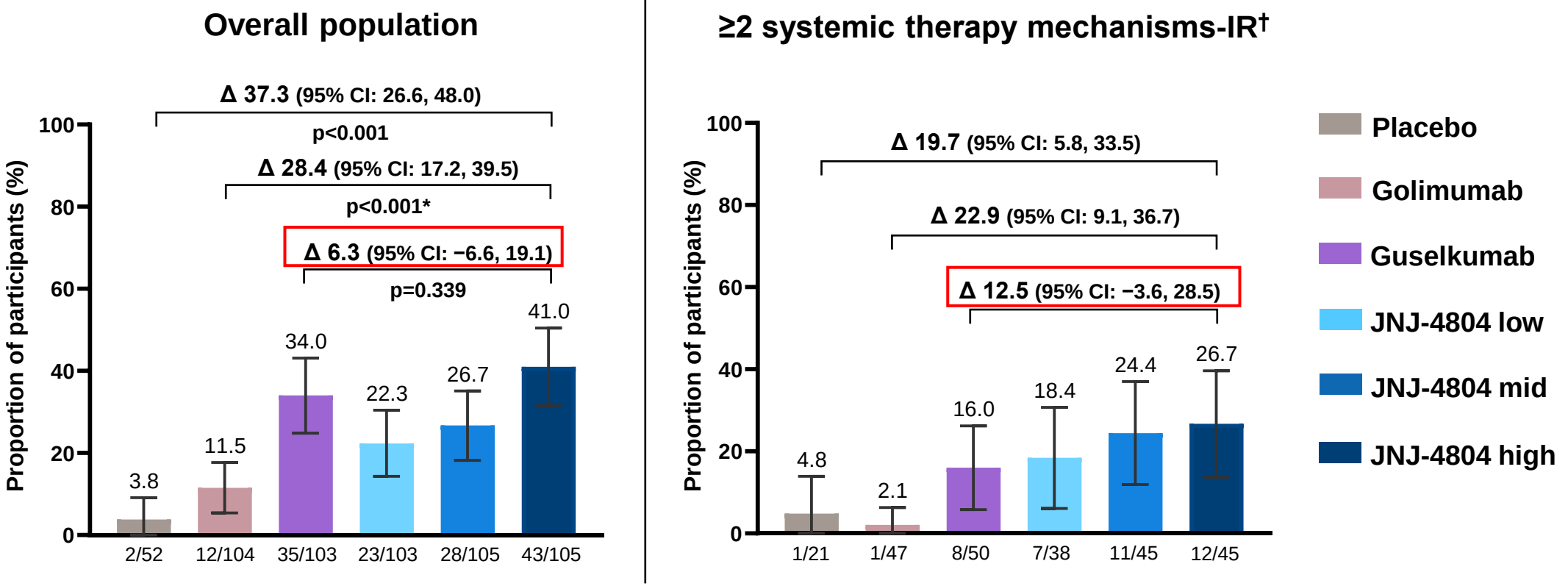
*Anti-TNF, anti-IL-12/23, anti-IL-23p19, anti-integrin, JAK inhibitor and S1PR modulator; †Denominators are the numbers of participants with inadequate response to 1 or more systemic therapy mechanisms.
GOL, golimumab; GUS, guselkumab; IL, interleukin; JAK, Janus kinase; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; S1PR, sphingosine-1-phosphate receptor; TNF, tumour necrosis factor; UC, ulcerative colitis.
Abreu MT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 1058d. Full prescribing information for guselkumab and golimumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 is not approved by Swissmedic.

Treatment disposition through Week 48: Lowest discontinuation rates observed in JNJ-4804 high-dose group

	Placebo	Golimumab	Guselkumab	JNJ-4804 low dose	JNJ-4804 mid dose	JNJ-4804 high dose	Total
Full Analysis Set	52	104	103	103	105	105	572
Number of participants who:							
Discontinued study treatment before Week 48	17 (32.7%)	32 (30.8%)	23 (22.3%)	24 (23.3%)	23 (21.9%)	14 (13.3%)	133 (23.3%)
Most common reasons for discontinuation							
Lack of efficacy	3 (5.8%)	6 (5.8%)	13 (12.6%)	5 (4.9%)	7 (6.7%)	5 (4.8%)	39 (6.8%)
Withdrawal by participant	5 (9.6%)	11 (10.6%)	4 (3.9%)	6 (5.8%)	6 (5.7%)	2 (1.9%)	34 (5.9%)
AE – worsening of UC	7 (13.5%)	11 (10.6%)	3 (2.9%)	5 (4.9%)	3 (2.9%)	5 (4.8%)	34 (5.9%)
AE – other	0	2 (1.9%)	1 (1.0%)	4 (3.9%)	3 (2.9%)	0	10 (1.7%)
Initiated prohibited medication	1 (1.9%)	0	2 (1.9%)	1 (1.0%)	0	0	4 (0.7%)

Note: Final dosing for the main treatment period was received 4 weeks prior to Week 48. Participants are presented in the treatment group assigned at Week 0.
AE, adverse event; GOL, golimumab; GUS, guselkumab; IL, interleukin; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor; UC, ulcerative colitis.
Abreu MT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 1058d. Full prescribing information for guselkumab and golimumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 is not approved by Swissmedic..

Primary endpoint: Clinical remission at Week 48

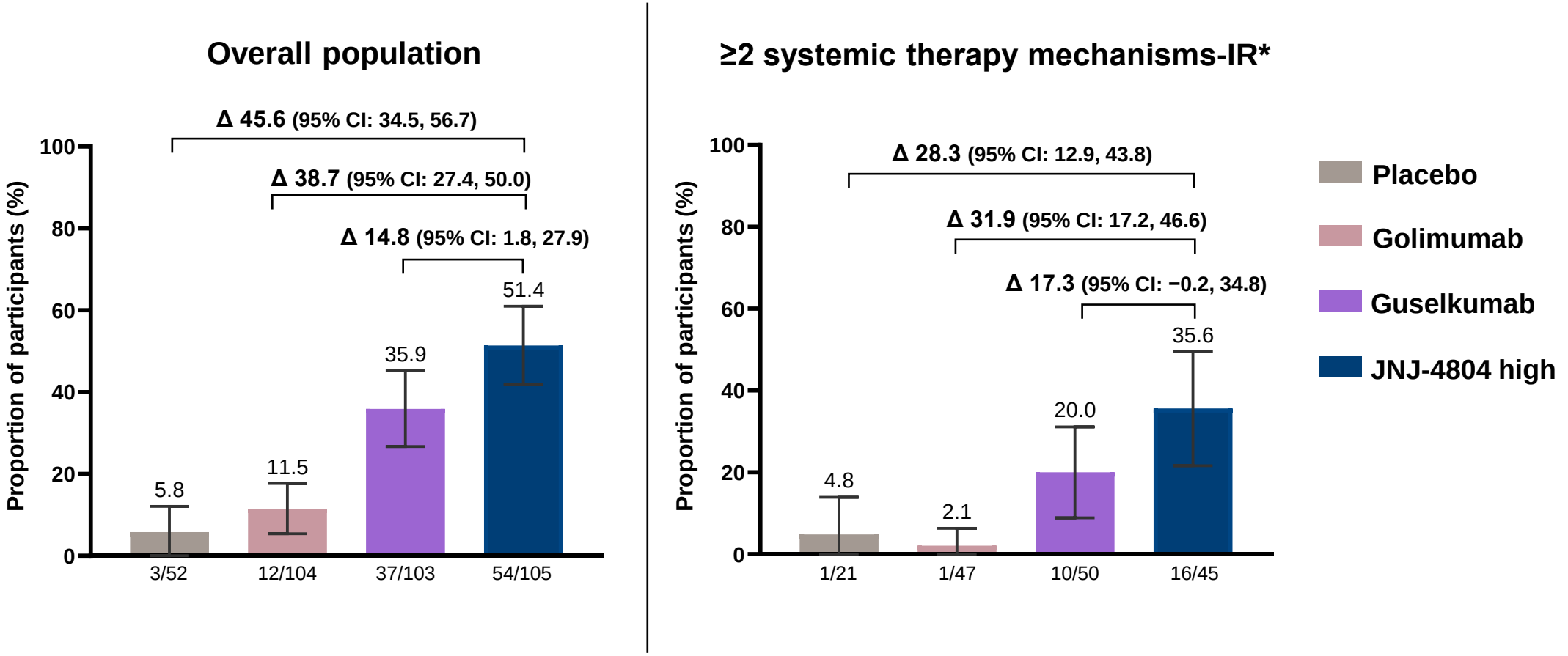


Clinical remission: Stool frequency subscore of 0 or 1, rectal bleeding subscore of 0 and endoscopy subscore of 0 or 1 per central review of the video endoscopy

*Statistically significant. All other p-values are nominal; †Patients who were inadequate responders to two or more mechanisms of systemic therapies. Modified Full Analysis Set (Full Analysis Set excluding participants with a modified Mayo <5 or missing at baseline).
CI, confidence interval; GOL, golimumab; GUS, guselkumab; IL, interleukin; IR, inadequate responder; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor; UC, ulcerative colitis.
Abreu MT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 1058d. Full prescribing information for guselkumab and golimumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 is not approved by Swissmedic..

CH_CP-581164 05/26

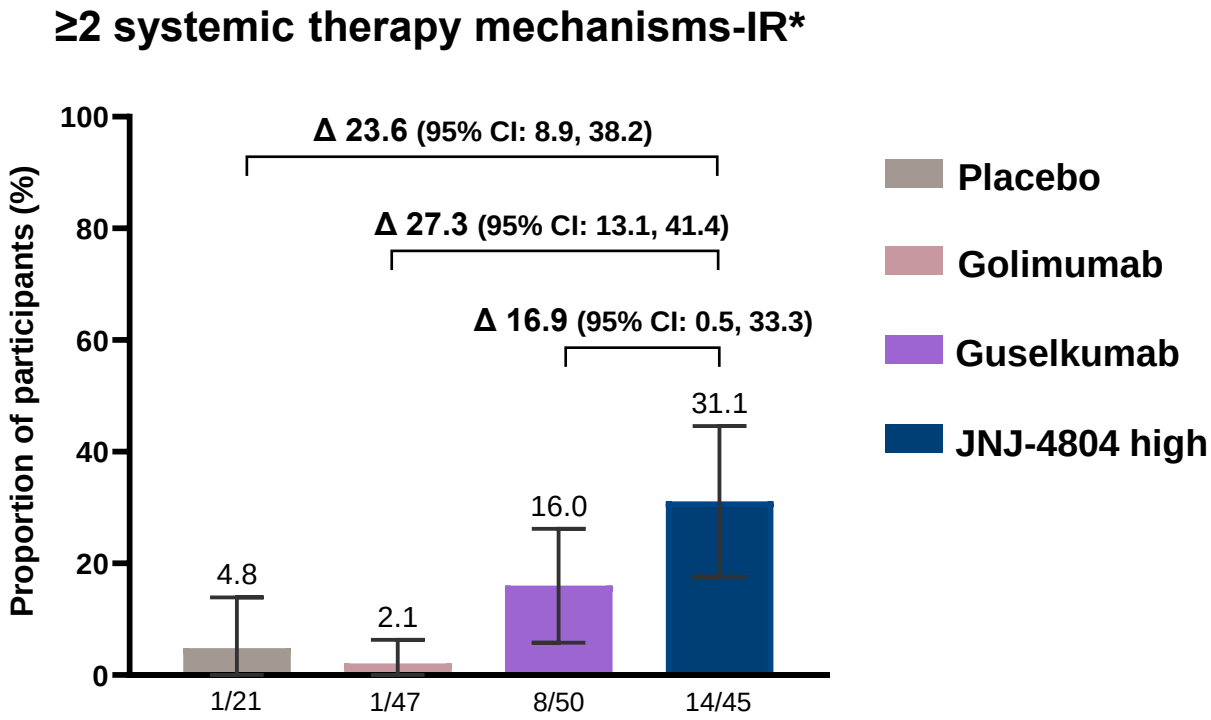
Key secondary endpoint: Endoscopic improvement at Week 48



Endoscopic improvement: Endoscopy subscore of 0 or 1 per central review of the video endoscopy

*Patients who were inadequate responders to two or more mechanisms of systemic therapies. Modified Full Analysis Set (Full Analysis Set excluding participants with a modified Mayo <5 or missing at baseline).
CI, confidence interval; GOL, golimumab; GUS, guselkumab; IL, interleukin; IR, inadequate responder; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor; UC, ulcerative colitis.
Abreu MT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 1058d. Full prescribing information for guselkumab and golimumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 is not approved by Swissmedic..

Key secondary endpoint: Histologic remission AND endoscopic improvement at Week 48 (≥2 systemic therapy mechanisms-IR population)



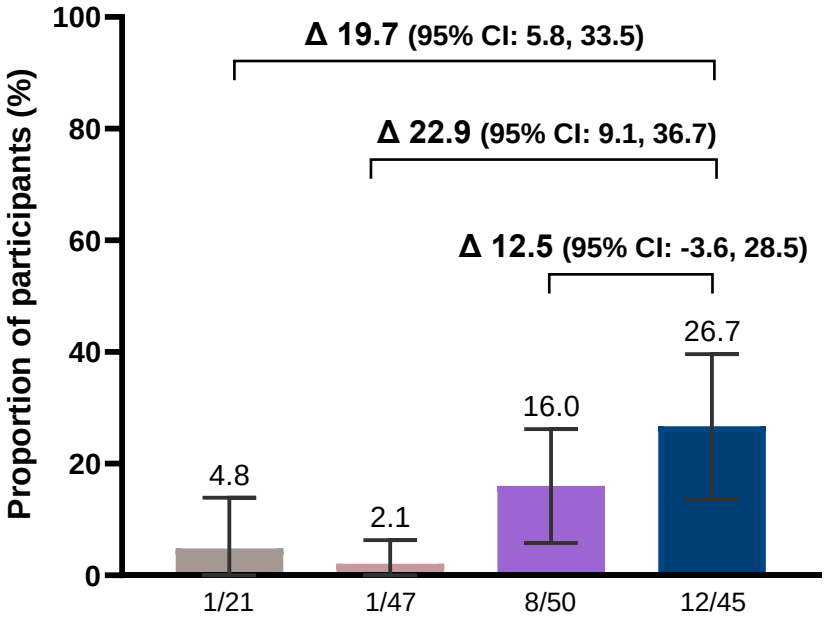
Histologic remission AND endoscopic improvement: Absence of neutrophils from the mucosa (both lamina propria and epithelium), no crypt destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system, and an endoscopy subscore of 0 or 1 per central review of the video endoscopy

*Patients who were inadequate responders to two or more mechanisms of systemic therapies. Modified Full Analysis Set (Full Analysis Set excluding participants with a modified Mayo <5 or missing at baseline).
CI, confidence interval; GOL, golimumab; GUS, guselkumab; IL, interleukin; IR, inadequate responder; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor; UC, ulcerative colitis.
Abreu MT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 1058d. Full prescribing information for guselkumab and golimumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 is not approved by Swissmedic..

Key secondary endpoint: Corticosteroid-free clinical remission at Week 48 (≥2 systemic therapy mechanisms-IR population)

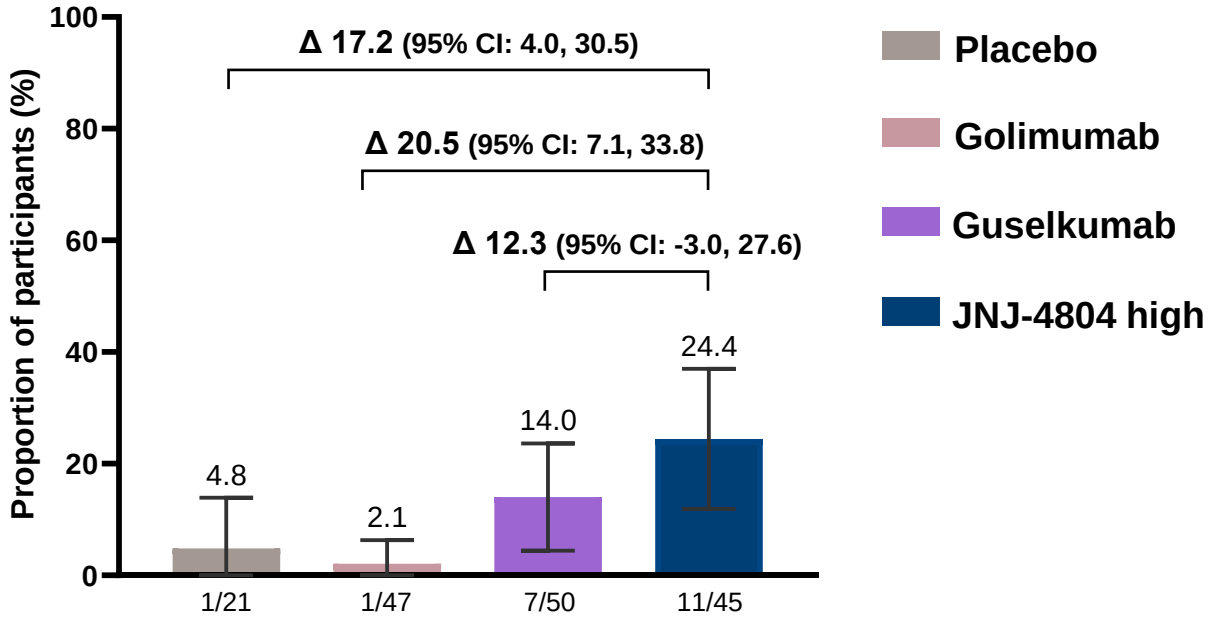
Clinical remission

≥2 systemic therapy mechanisms-IR*



Corticosteroid-free clinical remission

≥2 systemic therapy mechanisms-IR*



Corticosteroid-free clinical remission: A stool frequency subscore of 0 or 1, a rectal bleeding subscore of 0 and an endoscopy subscore of 0 or 1 per central review of the video endoscopy, with no corticosteroids received for at least 60 days

Of the participants in clinical remission at Week 48 in the JNJ-4804 high-dose group, **11/12 (91.7%) were corticosteroid-free**

*Patients who were inadequate responders to two or more mechanisms of systemic therapies. Modified Full Analysis Set (Full Analysis Set excluding participants with a modified Mayo <5 or missing at baseline).
CI, confidence interval; GOL, golimumab; GUS, guselkumab; IL, interleukin; IR, inadequate responder; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor; UC, ulcerative colitis.
Abreu MT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 1058d. Full prescribing information for guselkumab and golimumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 is not approved by Swissmedic..

Summary of exposure-adjusted AEs through Week 48* (Overall population)

	Placebo	Golimumab	Guselkumab	JNJ-4804 low dose	JNJ-4804 mid dose	JNJ-4804 high dose	JNJ-4804 combined
Safety analysis set	52	104	103	103	105	105	313
Total patient-years of follow-up	25.5	65.0	73.0	72.2	76.1	85.1	233.4
Events per hundred patient-years [number of events]							
AEs	490.2 [125]	449.2 [292]	419.0 [306]	405.7 [293]	385.1 [293]	490.1 [417]	429.7 [1003]
SAEs	27.5 [7]	21.5 [14]	9.6 [7]	19.4 [14]	11.8 [9]	10.6 [9]	13.7 [32]
AEs leading to discontinuation of study treatment	27.5 [7]	18.5 [12]	5.5 [4]	12.5 [9]	6.6 [5]	3.5 [3]	7.3 [17]
Infections	109.8 [28]	100.0 [65]	98.6 [72]	98.3 [71]	93.3 [71]	82.3 [70]	90.8 [212]
Serious infections	3.9 [1]	7.7 [5]	0.0 [0]	1.4 [1]	3.9 [3]	3.5 [3]	3.0 [7]
Deaths	0.0 [0]	0.0 [0]	0.0 [0]	0.0 [0]	0.0 [0]	0.0 [0]	0.0 [0]

Most infections were **mild or moderate** and **did not result in treatment discontinuation**

The most frequently reported treatment-emergent AEs (reported in ≥5% of participants for all groups) were UC and nasopharyngitis

CH_CP-581164 05/26

*Excludes inadequate responder events after treatment escalation at Week 24.
AE, adverse event; GOL, golimumab; GUS, guselkumab; IL, interleukin; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; SAE, serious adverse event; TNF, tumour necrosis factor; UC, ulcerative colitis.
Abreu MT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 1058d. Full prescribing information for guselkumab and golimumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 is not approved by Swissmedic..

Treatment-emergent AEs of interest through Week 48*

	Placebo	Golimumab	Guselkumab	JNJ-4804 low dose	JNJ-4804 mid dose	JNJ-4804 high dose
Safety analysis set	52	104	103	103	105	105
Major adverse cardiovascular events	0	1 (1.0%)	0	1 (1.0%)	0	0
Venous thromboembolism	0	3 (2.9%)	0	0	0	1 (1.0%)
Clinically important hepatic disorders	0	0	0	0	0	0
Opportunistic infection	0	0	1 (1.0%)	0	1 (1.0%)	0
Participants with ≥1 AE of special interest						
Invasive fungal infection	0	0	0	0	0	0
Hepatitis B reactivation	0	0	0	0	0	0
Tuberculosis	0	0	0	0	1 (1.0%)	0
Malignancy	0	0	1 (1.0%)	1 (1.0%)	1 (1.0%)	0
Hypersensitivity reaction	0	0	0	1 (1.0%)	0	0
Congestive heart failure	0	0	0	1 (1.0%)	0	0
Demyelinating disorders	0	0	0	0	0	0
Lupus-like syndrome	0	0	0	0	0	0

1 case of active tuberculosis (JNJ-4804 mid dose), and 1 other opportunistic infection of oesophageal candidiasis (GUS) were reported

3 malignancies, all basal cell carcinomas, were reported in participants with no prior history; all participants continued in study after excision

*Excludes inadequate responder events after treatment escalation at Week 24.

AE, adverse event; GOL, golimumab; GUS, guselkumab; IL, interleukin; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor; UC, ulcerative colitis.

Abreu MT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 1058d. Full prescribing information for guselkumab and golimumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 is not approved by Swissmedic...

Conclusions

- JNJ-4804, the first co-antibody therapy in development for IBD, demonstrated clinically meaningful efficacy exceeding that of the monotherapies in patients with treatment-refractory disease
- In the overall population, efficacy of high-dose JNJ-4804 was superior to golimumab and numerically greater than guselkumab
- In patients with disease refractory to two or more systemic therapy mechanisms, high-dose JNJ-4804 exceeded the additive benefits of golimumab and guselkumab across all key clinical, endoscopic and histologic-endoscopic endpoints
- The safety profile of JNJ-4804 through 48 weeks was consistent with the well-established safety profiles of the component monotherapies
- Building on the molecular synergy seen in VEGA, the DUET-UC results support advancement to Phase 3 in patients with disease refractory to systemic therapies; a population with high unmet need

CH_CP-581164 05/26

GOL, golimumab; GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; JNJ-4804, guselkumab and golimumab fixed-dose combination; MOA, mechanism of action; RDBAPC, randomised, double-blind, active- and placebo-controlled; TNF, tumour necrosis factor; UC, ulcerative colitis.
Abreu MT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. 1058d. Full prescribing information for guselkumab and golimumab is available at: www.swissmedicinfo-pro.ch/. JNJ-4804 is not approved by Swissmedic..

QUASAR: Guselkumab in UC

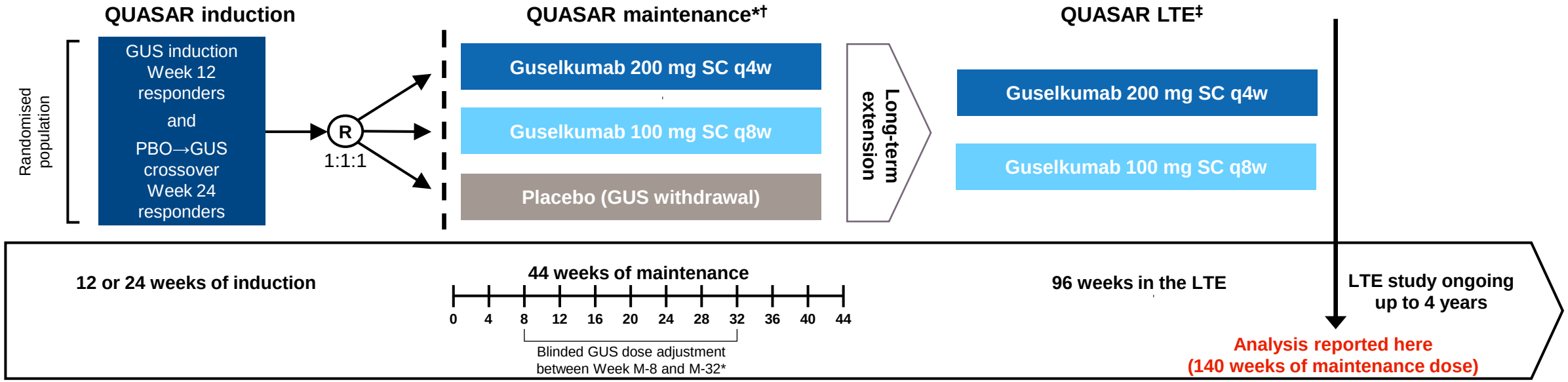
Mayo Endoscopic Subscore changes in participants with moderately to severely active ulcerative colitis treated with guselkumab in the QUASAR long-term extension

David T Rubin,[1] Jessica R Allegretti,[2] Yelina Alvarez,[3] Thomas Baker,[3] Shashi Adsul,[4] Darren Piscitelli,[4] Ye Miao,[3] Laurent Peyrin-Biroulet[5]

[1]University of Chicago Medicine Inflammatory Bowel Disease Center, Chicago, IL, USA; [2]Division of Gastroenterology, Hepatology and Endoscopy, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA; [3]Johnson & Johnson, Spring House, PA, USA; [4]Johnson & Johnson, Horsham, PA, USA; [5]Northwestern Medicine Digestive Health Institute, Chicago, IL, USA

QUASAR study design

Aim: Report Mayo Endoscopic Subscore (MES) changes over 3 years in participants with moderately to severely active UC treated with GUS in the QUASAR LTE study



- QUASAR assessed IV GUS induction (200 mg or 400 mg q4w) and SC maintenance therapy (100 mg q8w or 200 mg q4w); at induction baseline, participants had a modified Mayo (mMayo) score of 5–9, a rectal bleeding subscore ≥1 and an MES of 2 or 3
- Participants in clinical response at Week 12 post-induction could enter the randomised withdrawal maintenance study; participants on GUS 100 mg who lost clinical response between M-8 to M-32 received blinded dose adjustment to GUS 200 mg q4w
- Endoscopies were locally read (without friability assessment) and centrally read (with friability assessment), with adjudication, at induction baseline, maintenance baseline (M-0) and M-44 and were locally read at M-92 and M-140; analyses used centrally read endoscopies when available
- MES changes were analysed in participants who were randomised to GUS in the maintenance study, continued in the LTE and had endoscopic evaluations at all time points through M-140 (100 mg: N=152; 200 mg: N=141)

200 mg SC q4w; GUS 100 mg SC q8w → GUS 200 mg SC q4w; GUS 200 mg SC q4w → GUS 200 mg SC q4w (sham adjustment); †Participants who completed the safety and efficacy evaluations (including the required endoscopy procedure) at maintenance Week M-44 and who may benefit from continued study intervention, in the opinion of the investigator, had the opportunity to participate in the LTE of the Maintenance Study; ‡The study blinding was maintained during the LTE until the last participant in the Maintenance Study completed the M-44 visit. After the Maintenance Study was unblinded, participants had their study visits scheduled to coincide with their dose regimen (either q4w or q8w) and participants receiving placebo were terminated from study participation.

GUS, guselkumab; IL, interleukin; IV, intravenous; LTE, long-term extension; M, maintenance; MES, Mayo Endoscopic Subscore; mMayo, modified Mayo; MOA, mechanism of action; PBO, placebo; q4w, every 4 weeks; q8w, every 8 weeks; R, randomised; RDBPC, randomised, double-blind, placebo-controlled; SC, subcutaneous; UC, ulcerative colitis.

Rubin DT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. Mo1516. Full prescribing information: www.swissmedicinfo-pro.ch/.

CH_CP-581164 05/26

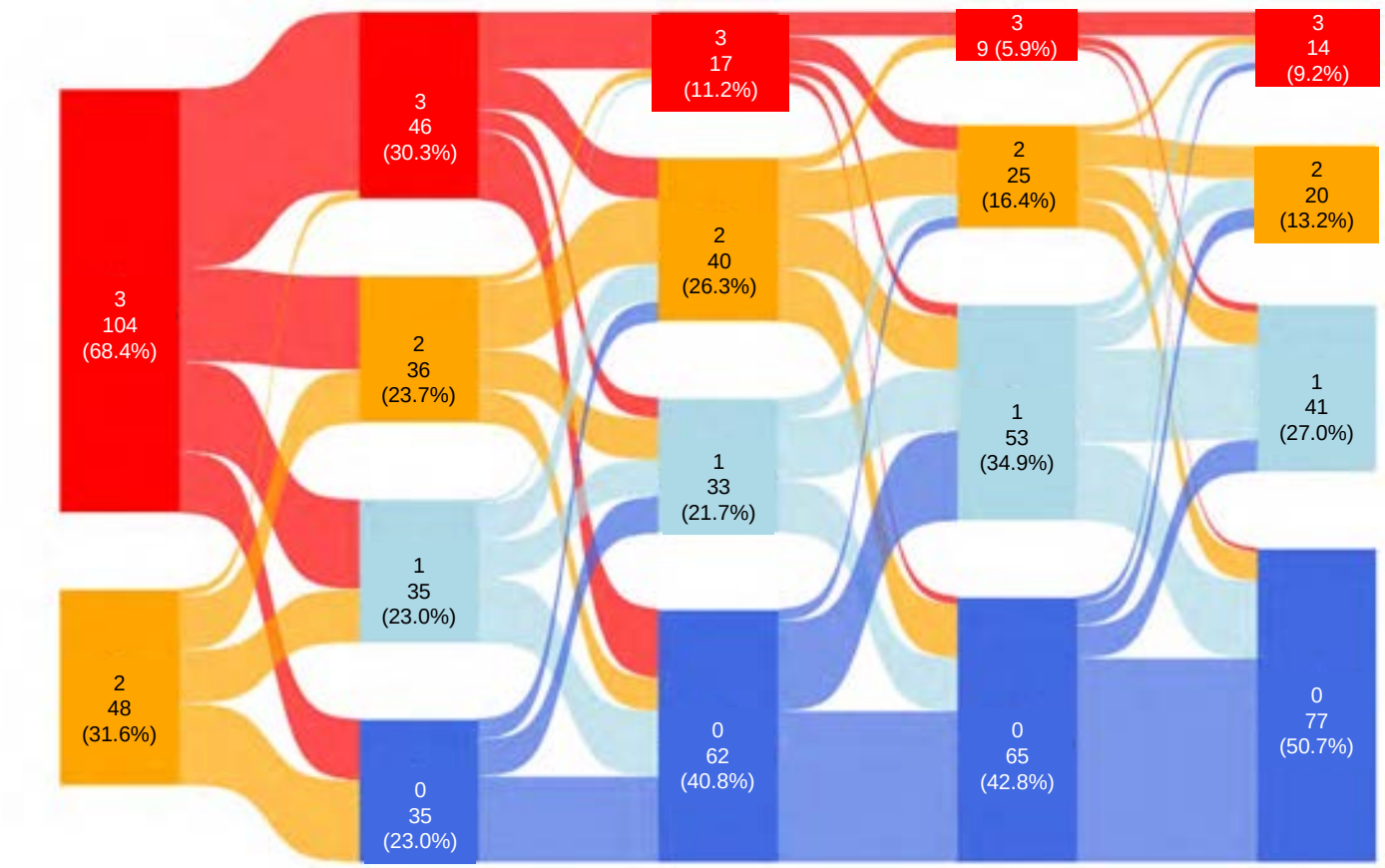
Baseline demographics, disease characteristics, biomarkers, concomitant medications and advanced therapy history

	GUS 100 mg q8w	GUS 200 mg q4w
Demographics		
Analysis set: LTE randomised full, N	155	148
Age, y, mean (SD)	40.2 (12.79)	40.6 (15.08)
Male, n (%)	83 (53.5)	75 (50.7)
Disease characteristics		
UC disease duration, y, mean (SD)	8.15 (8.980)	8.16 (8.497)
Modified Mayo score (0–9), mean (SD)	6.8 (1.16)	6.9 (1.06)
Modified Mayo score of 7–9 (severe), n (%)	94 (60.6)	97 (65.5)
Endoscopic subscore of 3 (severe), n (%)	103 (66.5)	95 (64.2)
Extensive UC, n (%)	66 (42.6)	69 (46.6)
Biomarkers		
C-reactive protein, mg/L, median (IQR)*	4.0 (1.4–10.4)	3.9 (1.5–9.5)
Faecal calprotectin, mg/kg, median (IQR)†	1709.0 (815.0–3607.0)	1605.5 (596.0–3253.0)
Concomitant UC medications		
Oral corticosteroid use at baseline, n (%)	56 (36.1)	54 (36.5)
Use of immunomodulatory drugs (6-MP, AZA, MTX), n (%)	39 (25.2)	36 (24.3)
Advanced therapy history		
Participants with prior inadequate response or intolerance to advanced therapy, n (%)	60 (38.7)	62 (41.9)
Advanced therapy naïve, n (%)	90 (58.1)	81 (54.7)

*n=150 for GUS 100 mg q8w; n=145 for GUS 200 mg q4w; †n=133 for GUS 100 mg q8w; n=134 for GUS 200 mg q4w.
6-MP, 6-mercaptopurine; AZA, azathioprine; GUS, guselkumab; IL, interleukin; IQR, interquartile range; LTE, long-term extension; MOA, mechanism of action; MTX, methotrexate; q4w, every 4 weeks; q8w, every 8 weeks; RDBPC, randomised, double-blind, placebo-controlled; SD, standard deviation; UC, ulcerative colitis; y, years.
Rubin DT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. Mo1516. Full prescribing information: www.swissmedicinfo-pro.ch/.

Mayo Endoscopic Subscores through 3 years: GUS 100 mg SC q8w, or 200 mg SC q4w after dose adjustment (M-8 to M-32) (N=152)

- At induction baseline, all participants had an MES of 2 or 3
- After induction (at Week M-0), 46.0% had an MES of 0 or 1
- Following maintenance treatment, the percentage of participants with an MES of 0 or 1 increased through Week M-92: 77.6%; and was maintained at Week M-140: 77.7%
- The percentage of participants with an MES of 3 decreased from induction baseline to Week M-0 (100 mg: 68.4% to 30.3%), and continued to decrease until Week M-92: 5.9%
- By Week M-44 and through Week M-140, most participants with an MES of 0 or 1 were also in endoscopic remission (MES=0)



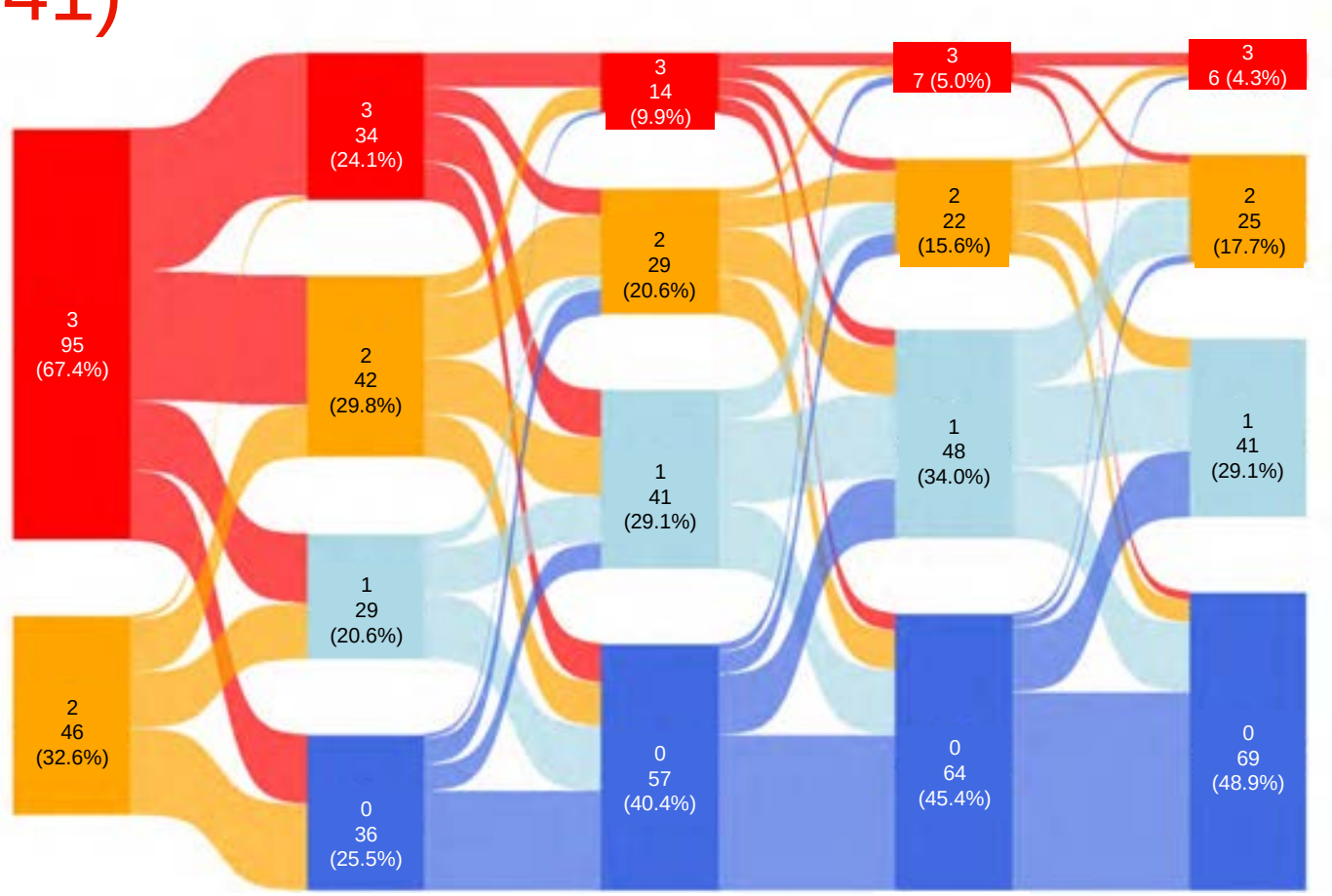
Sankey diagrams showing MES at induction baseline, maintenance baseline, Week M-44, Week M-92 and Week M-140. Participants in the 100 mg cohort (clinical response between maintenance Weeks M-8 to 32 had blinded dose adjustment to 200 mg. The top number in each box is the MES; the bottom numbers are participant numbers and percentages, respectively. Participants who had an ostomy or colectomy, or discontinued study agent due to lack of efficacy or an AE of worsening UC prior to the designated time point had their induction baseline value carried forward from the time of the event onward. For participants who discontinued study agent for any other reason prior to the designated time point, their observed values (if available) were used. After accounting for these events, participants who were missing the MES at any visit were excluded from the analysis.

AE, adverse event; GUS, guselkumab; IL, interleukin; LTE, long-term extension; M, maintenance; MES, Mayo Endoscopic Subscore; MOA, mechanism of action; q4w, every 4 weeks; q8w, every 8 weeks; RDBPC, randomised, double-blind, placebo-controlled; SC, subcutaneous; UC, ulcerative colitis.

Rubin DT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. Mo1516. Full prescribing information: www.swissmedicinfo-pro.ch/.

Mayo Endoscopic Subscores through 3 years: GUS 200 mg SC q4w (N=141)

- At induction baseline, all participants had an MES of 2 or 3
- After induction (at Week M-0), 46.1% had an MES of 0 or 1
- Following maintenance treatment, the percentage of participants with an MES of 0 or 1 increased through Week M-92: 79.4%; and was maintained at Week M-140: 78.0%
- The percentage of participants with an MES of 3 decreased from induction baseline to Week M-0: 67.4% to 24.1%, continued to decrease until Week M-92: 5.0%, and was maintained (4.3%) at Week M-140
- By Week M-44 and through Week M-140, most participants with an MES of 0 or 1 were also in endoscopic remission (MES=0)



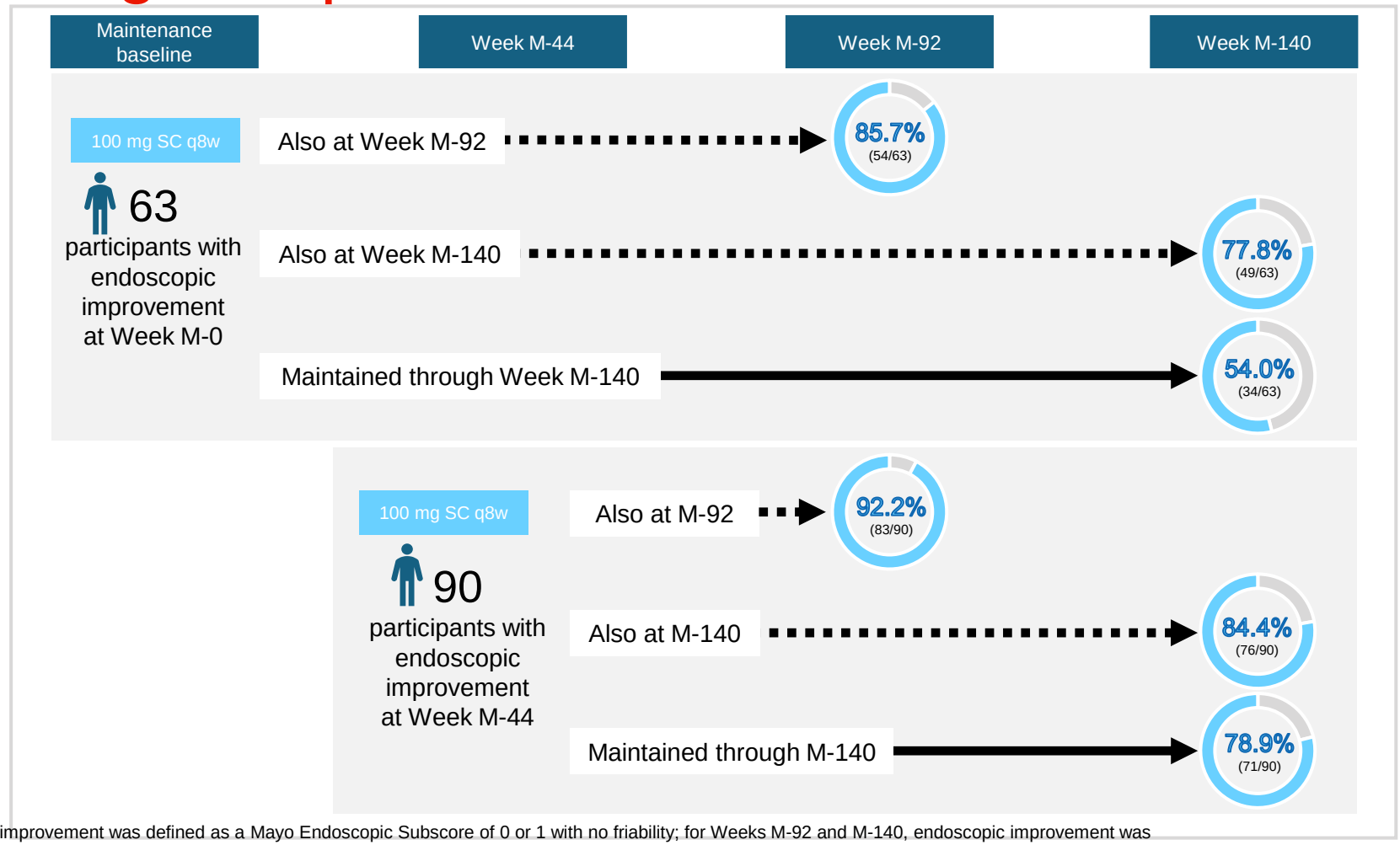
Sankey diagrams showing MES at induction baseline, maintenance baseline, Week M-44, Week M-92 a[illegible] had blinded dose adjustment to 200 mg. The top number in each box is the MES; the bottom numbers a[illegible] percentages, respectively. Participants who had an ostomy or colectomy, or discontinued study agent due to lack of efficacy or an AE of worsening UC prior to the designated time point had their induction baseline value carried forward from the time of the event onward. For participants who discontinued study agent for any other reason prior to the designated time point, their observed values (if available) were used. After accounting for these events, participants who were missing the MES at any visit were excluded from the analysis.

AE, adverse event; GUS, guselkumab; IL, interleukin; LTE, long-term extension; M, maintenance; MES, Mayo Endoscopic Subscore; MOA, mechanism of action; q4w, every 4 weeks; RDBPC, randomised, double-blind, placebo-controlled; SC, subcutaneous; UC, ulcerative colitis.

Rubin DT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. Mo1516. Full prescribing information: www.swissmedicinfo-pro.ch/.

Participants maintaining endoscopic improvement by study time point: GUS 100 mg SC q8w

61.5% of participants with endoscopic improvement* at maintenance baseline maintained endoscopic improvement at all subsequent time points



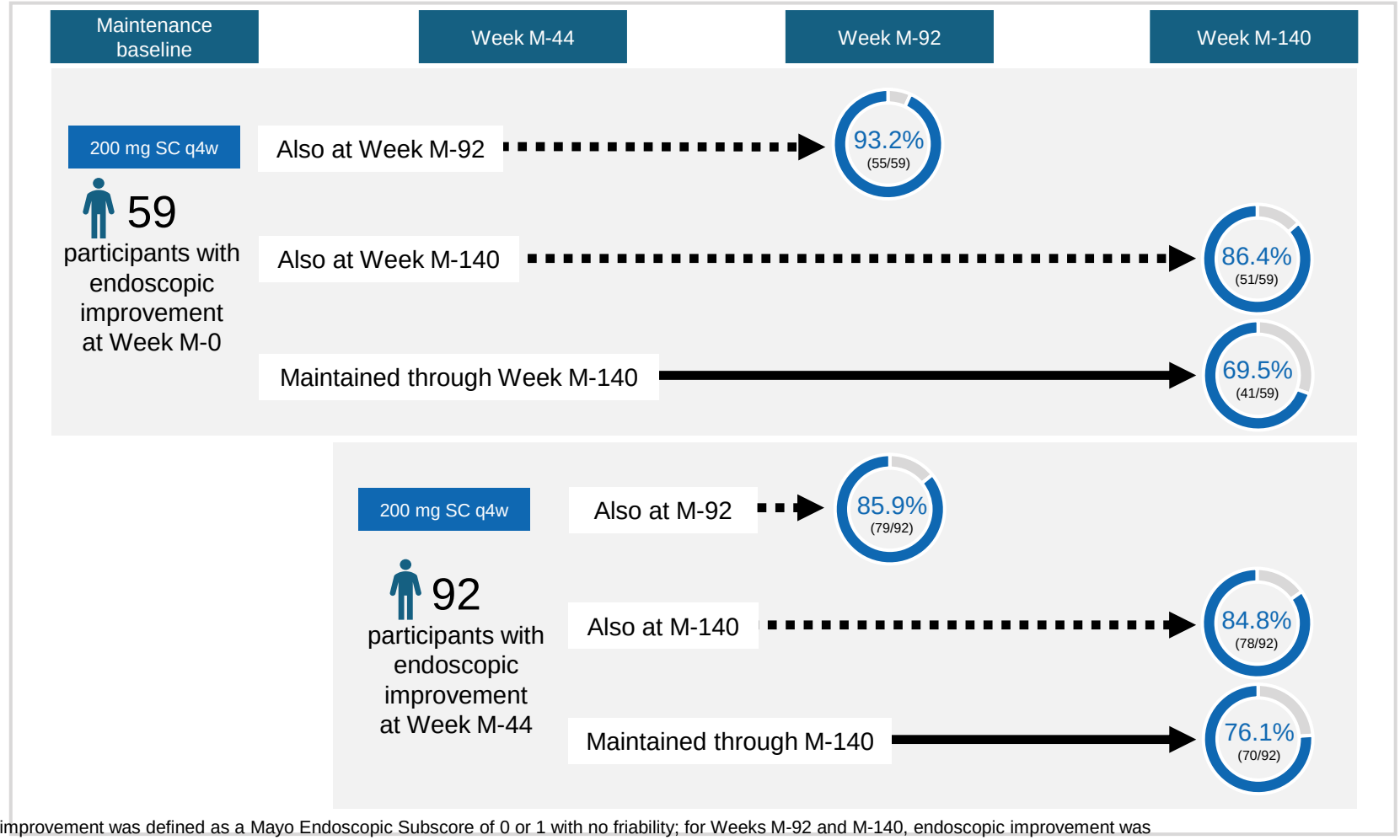
*For induction baseline, maintenance baseline and Week M-44, endoscopic improvement was defined as a Mayo Endoscopic Subscore of 0 or 1 with no friability; for Weeks M-92 and M-140, endoscopic improvement was defined as a Mayo Endoscopic Subscore of 0 or 1.

GUS, guselkumab; IL, interleukin; LTE, long-term extension; M, maintenance; MOA, mechanism of action; q8w, every 8 weeks; RDBPC, randomised, double-blind, placebo-controlled; SC, subcutaneous; UC, ulcerative colitis.

Rubin DT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. Mo1516. Full prescribing information: www.swissmedicinfo-pro.ch/.

Participants maintaining endoscopic improvement by study time point: GUS 200 mg SC q4w

61.5% of participants with endoscopic improvement* at maintenance baseline maintained endoscopic improvement at all subsequent time points



*For induction baseline, maintenance baseline and Week M-44, endoscopic improvement was defined as a Mayo Endoscopic Subscore of 0 or 1 with no friability; for Weeks M-92 and M-140, endoscopic improvement was defined as a Mayo Endoscopic Subscore of 0 or 1.

GUS, guselkumab; IL, interleukin; LTE, long-term extension; M, maintenance; MOA, mechanism of action; q4w, every 4 weeks; RDBPC, randomised, double-blind, placebo-controlled; SC, subcutaneous; UC, ulcerative colitis.

Rubin DT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. Mo1516. Full prescribing information: www.swissmedicinfo-pro.ch/.

Conclusions

- Both guselkumab maintenance doses were associated with similar trends in continued endoscopic improvements over 3 years
- While approximately half of induction clinical responders still had moderate to severe endoscopic disease activity (MES of 2 or 3) at the beginning of maintenance, continued endoscopic improvement was observed following treatment, with most patients maintaining an MES of 0 or 1 and endoscopic remission through Week M-140

GUS, guselkumab; IL, interleukin; LTE, long-term extension; M, maintenance; MES, Mayo Endoscopic Subscore; MOA, mechanism of action; RDBPC, randomised, double-blind, placebo-controlled; UC, ulcerative colitis.
Rubin DT, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. Mo1516.

Guselkumab in IBD

Safety of guselkumab in patients aged ≥60 years with immune-mediated inflammatory diseases: a pooled analysis of registrational trials in UC, CD, PsA and PsO

Adam S. Faye, Shaji Sebastian, Victoria McCaffrey, Ivana Bravatà, Maciej Nazar, Darren Piscitelli, Soumya D. Chakravarty, Sharaf Adsul, Jacqueline Yee, Thomas Baker, Bruce E. Sands

Objective and methods

Objective

Evaluate the safety of GUS up to 1 year in participants aged ≥60 years pooled from 14 Phase 2/3 RCTs

Methods

Analysis cohort

- Data were pooled from 14 Phase 2/3 RCTs of GUS in PsA, PsO, UC and CD
- Adults who received ≥1 dose of study treatment were included

Outcomes and analyses

- Pooled safety data from RCTs were analysed through up to 1 year
  - **By age:**
    - ≥60 years of age
    - Overall population
  - **By indication:**
    - IBD: UC and CD
    - All indications: PsA, PsO, UC, CD
- Exposure-adjusted incidence rates of TEAEs were reported per 100 patient-years with 95% confidence intervals

Pooled data from 14 Phase 2/3 RCTs of GUS in PsA, PsO, UC and CD

Trial ID*	Name	Indication	Data analysed
NCT03162796	DISCOVER-1	PsA	Up to W60
NCT03158285	DISCOVER-2	PsA	Up to W52
NCT02319759	PsA Phase 2	PsA	Up to W54
NCT02203032	NAVIGATE	PsO	Up to W52
NCT02207231	VOYAGE 1	PsO	Up to W52
NCT02207244	VOYAGE 2	PsO	Up to W52
NCT01483599	X-PLORE	PsO	Up to W52
NCT05528510	ASTRO	UC	Up to W24
NCT04033445	QUASAR	UC	Up to W20, W32 or W44†
NCT03662542	VEGA	UC	Up to W38‡
NCT03466411	GALAXI 1	CD	Up to W48
NCT03466411	GALAXI 2	CD	Up to W48
NCT03466411	GALAXI 3	CD	Up to W48
NCT05197049	GRAVITI	CD	Up to W48

*All trials except those highlighted in darker grey had treat-through designs; †Depending on entry or treatment status; ‡Monotherapy arm only.
CD, Crohn's disease; GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; MOA, mechanism of action; NA, not applicable; PsA, psoriatic arthritis; PsO, psoriasis; RCT, randomised controlled trial; TA, therapy area; TEAE, treatment-emergent adverse event; UC, ulcerative colitis; W, week.
Faye AS, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O98. Full prescribing information: www.swissmedicinfo-pro.ch/.

Baseline characteristics were generally balanced across treatment, age and indication groups

Baseline characteristics by age group and indication

		Patients aged ≥60 years				Overall population			
		IBD*		All indications†		IBD*		All indications†	
		GUS (N=238)	PBO (N=98)	GUS (N=618)	PBO (N=212)	GUS (N=2388)	PBO (N=1025)	GUS (N=5379)	PBO (N=1910)
Demographics									
	Age, years	66.1 (5.2)	66.1 (4.9)	65.3 (4.6)	65.3 (4.5)	39.5 (13.9)	39.0 (13.6)	42.6 (13.3)	42.0 (13.4)
	Race, Asian/Black/White	16%/1%/77%	16%/0%/76%	9%/1%/88%	9%/0%/87%	22%/2%/72%	22%/2%/71%	14%/1%/82%	15%/2%/80%
Indication									
	CD	35%	20%	14%	9%	46%	33%	20%	18%
	UC	65%	80%	25%	37%	54%	67%	24%	36%
	PsD	-	-	61%	54%	-	-	56%	46%

Data are shown as mean (standard deviation) unless otherwise indicated.
*Includes UC and CD Phase 2/3 GUS RCTs. †Includes PsA, PsO, UC, and CD phase 2/3 GUS RCTs.
CD, Crohn's disease; GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; MOA, mechanism of action; NA, not applicable; PBO, placebo; PsA, psoriatic arthritis; PsD, psoriatic disease; PsO, psoriasis; RCT, randomised controlled trial; TA, therapy area; UC, ulcerative colitis.
Faye AS, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O98. Full prescribing information: www.swissmedicinfo-pro.ch/.
.

Exposure and follow-up

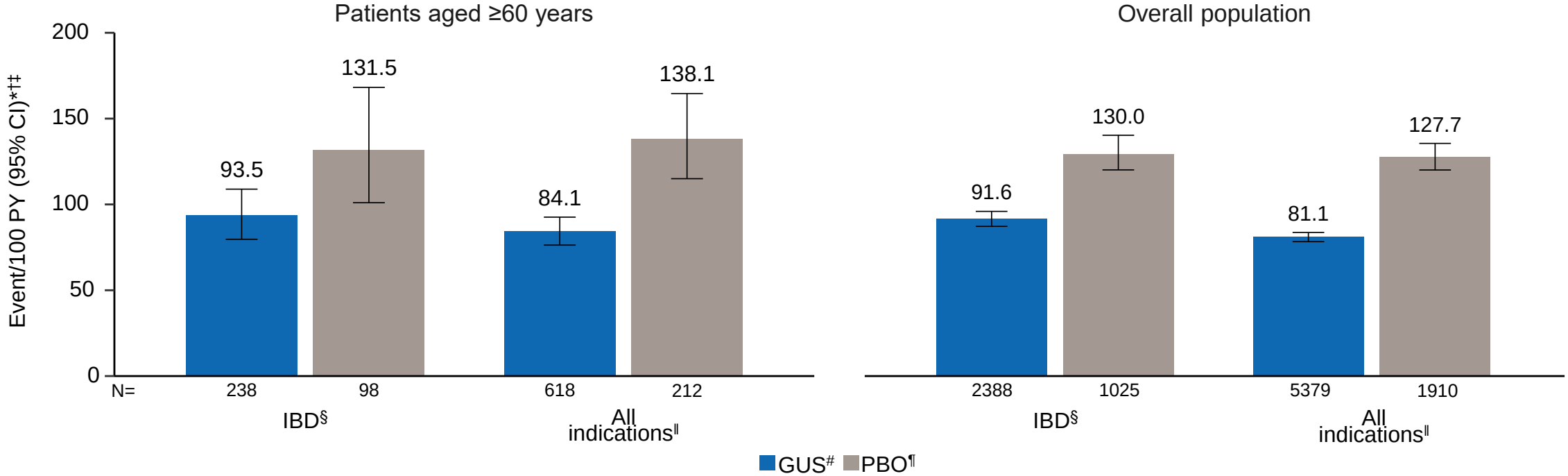
Exposure and follow-up metrics by age group and indication*

	Patients aged ≥60 years				Overall population			
	IBD†		All indications‡		IBD†		All indications‡	
	GUS§ (N=238)	PBO‖ (N=98)	GUS§ (N=618)	PBO‖ (N=212)	GUS§ (N=2388)	PBO‖ (N=1025)	GUS§ (N=5379)	PBO‖ (N=1910)
Mean follow-up, weeks#	38.5	25.5	41.9	22.3	41.3	25.6	42.8	22.9
Mean treatment, weeks	31.1	22.4	32.8	19.2	34.0	21.9	33.7	19.5
Total PY of follow-up	175.5	47.9	496.8	90.5	1889.0	502.5	4411.7	836.5

- **IBD**: 238 patients aged ≥60 years received GUS for 175.5 patient-years of follow-up
- **All indications**: 618 patients aged ≥60 years received GUS for 496.8 patient-years of follow-up

*Safety events reported throughout the reporting period to approximately 1 year; SCS all treated; †Includes UC and CD Phase 2/3 GUS RCTs; ‡Includes PsA, PsO, UC and CD Phase 2/3 GUS RCTs; §UC: All GUS data and up to 12 weeks post-induction for PBO in Maintenance Study. CD, PsO, PsA: Data from first GUS dose for early escape/crossover; ‖UC: Data to first GUS dose (PBO) or ≥12W after last induction (re-randomised to PBO), until dose adjustment. CD, PsO, PsA: Data to early escape/rescue/crossover; #Cumulative treatment duration for each study agent was calculated as the time from first to last dose across all relevant periods.
CD, Crohn's disease; GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; MOA, mechanism of action; NA, not applicable; PBO, placebo; PsA, psoriatic arthritis; PsO, psoriasis; PY, patient-years; RCT, randomised controlled trial; SCS, summary of clinical safety; TA, therapy area; UC, ulcerative colitis; W, weeks.
Faye AS, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O98. Full prescribing information: www.swissmedicinfo-pro.ch/.

Exposure-adjusted incidence of adverse events



Adverse events were numerically lower with GUS vs PBO

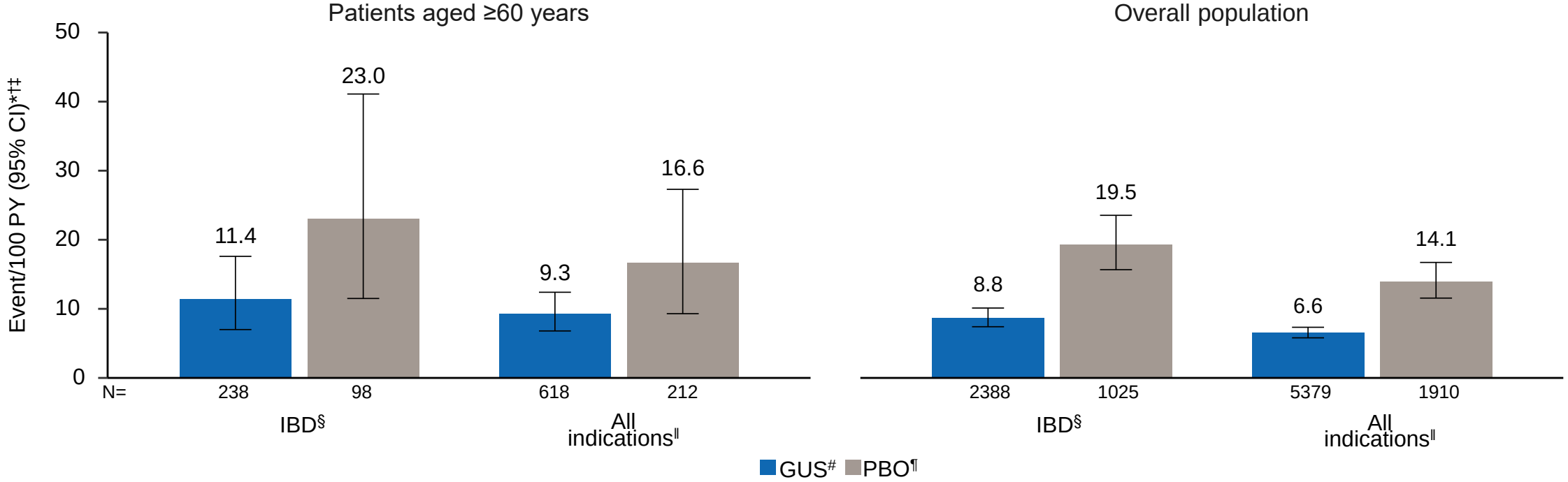
*Safety events reported throughout the reporting period to approximately 1 year; SCS all treated; †Confidence interval based on an exact method assuming that the observed number of subjects follows a Poisson distribution; ‡Cumulative treatment duration for each study agent was calculated as the time from first to last dose across all relevant periods; §Includes UC and CD Phase 2/3 GUS RCTs; ‖Includes PsA, PsO, UC and CD Phase 2/3 GUS RCTs; #UC: All GUS data and up to 12 weeks post-induction for PBO in Maintenance Study. CD, PsO, PsA: Data from first GUS dose for early escape/crossover; ¶UC: Data to first GUS dose (PBO) or ≥12W after last induction (re-randomised to PBO), until dose adjustment. CD, PsO, PsA: Data to early escape/rescue/crossover.

CD, Crohn's disease; CI, confidence interval; GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; MOA, mechanism of action; NA, not applicable; PBO, placebo; PsA, psoriatic arthritis; PsO, psoriasis; PY, patient-years; RCT, randomised controlled trial; SCS, summary of clinical safety; TA, therapy area; UC, ulcerative colitis; W, weeks.

Faye AS, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O98. Full prescribing information: www.swissmedicinfo-pro.ch/.

.

Exposure-adjusted incidence of serious adverse events



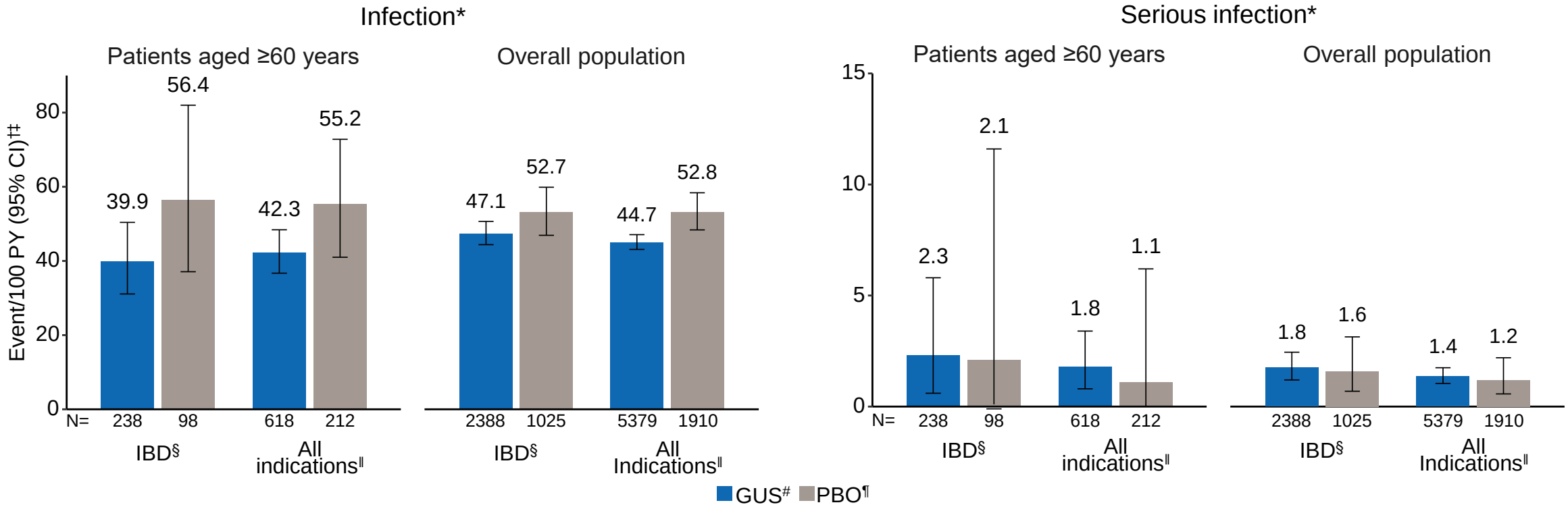
- Serious adverse events were numerically lower with GUS vs PBO
- No deaths were reported with GUS across indications among patients aged ≥60 years

*Safety events reported throughout the reporting period to approximately 1 year; SCS all treated; †Cumulative treatment duration for each study agent was calculated as the time from first to last dose across all relevant periods; ‡Confidence interval based on an exact method assuming that the observed number of subjects follows a Poisson distribution; §Includes UC and CD Phase 2/3 GUS RCTs; ‖Includes PsA, PsO, UC and CD Phase 2/3 GUS RCTs; #UC: All GUS data and up to 12 weeks post-induction for PBO in Maintenance Study. CD, PsO, PsA: Data from first GUS dose for early escape/crossover; ¶UC: Data to first GUS dose (PBO) or ≥12W after last induction (re-randomised to PBO), until dose adjustment. CD, PsO, PsA: Data to early escape/rescue/crossover.

CD, Crohn's disease; CI, confidence interval; GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; MOA, mechanism of action; NA, not applicable; PBO, placebo; PsA, psoriatic arthritis; PsO, psoriasis; PY, patient-years; RCT, randomised controlled trial; SCS, summary of clinical safety; TA, therapy area; UC, ulcerative colitis; W, weeks.

Faye AS, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O98. Full prescribing information: www.swissmedicinfo-pro.ch/.

Exposure-adjusted incidence of infections and serious infections



- Infections were numerically lower with GUS vs PBO
- Rates of serious infections were comparable across treatment groups

*Safety events reported throughout the reporting period to approximately 1 year; SCS all treated; †Cumulative treatment duration for each study agent was calculated as the time from first to last dose across all relevant periods; ‡Confidence interval based on an exact method assuming that the observed number of subjects follows a Poisson distribution; §Includes UC and CD Phase 2/3 GUS RCTs; ‖Includes PsA, PsO, UC and CD Phase 2/3 GUS RCTs; #UC: All GUS data and up to 12 weeks post-induction for PBO in Maintenance Study. CD, PsO, PsA: Data from first GUS dose for early escape/crossover; ¶UC: Data to first GUS dose (PBO) or ≥12W after last induction (re-randomised to PBO), until dose adjustment. CD, PsO, PsA: Data to early escape/rescue/crossover.
CD, Crohn's disease; CI, confidence interval; GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; MOA, mechanism of action; NA, not applicable; PBO, placebo; PsA, psoriatic arthritis; PsO, psoriasis; PY, patient-years; RCT, randomised controlled trial; SCS, summary of clinical safety; TA, therapy area; UC, ulcerative colitis; W, weeks.
Faye AS, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O98. Full prescribing information: www.swissmedicinfo-pro.ch/.

Exposure-adjusted incidence of targeted adverse events

Targeted AEs by age group and indication*

	Patients aged ≥60 years				Overall population			
	IBD†		All indications‡		IBD†		All indications‡	
	GUS§ (N=238)	PBO‖ (N=98)	GUS§ (N=618)	PBO‖ (N=212)	GUS§ (N=2388)	PBO‖ (N=1025)	GUS§ (N=5379)	PBO‖ (N=1910)
Event/100 PY (95% CI)#								
Active tuberculosis¶	0.0 (0.0, 1.7)	0.0 (0.0, 6.2)	0.0 (0.0, 0.6)	0.0 (0.0, 3.3)	0.1 (0.0, 0.3)	0.0 (0.0, 0.6)	<0.1 (0.0, 0.1)	0.0 (0.0, 0.4)
Opportunistic infection**	1.1 (0.1, 4.1)	2.1 (<0.1, 11.6)	0.6 (0.1, 1.8)	1.1 (<0.1, 6.2)	0.3 (0.1, 0.6)	0.6 (0.1, 1.8)	0.2 (0.1, 0.3)	0.4 (0.1, 1.0)
MACE††	1.1 (0.1, 4.1)	4.2 (0.5, 15.1)	1.2 (0.4, 2.6)	2.2 (0.3, 8.0)	0.3 (0.1, 0.7)	0.4 (<0.1, 1.4)	0.4 (0.2, 0.6)	0.4 (0.1, 1.0)
VTE‡‡	0.6 (<0.1, 3.2)	2.1 (0.1, 11.6)	0.4 (<0.1, 1.4)	1.1 (<0.1, 6.2)	0.4 (0.2, 0.8)	0.2 (<0.1, 1.1)	0.3 (0.2, 0.5)	0.1 (0.0, 0.7)

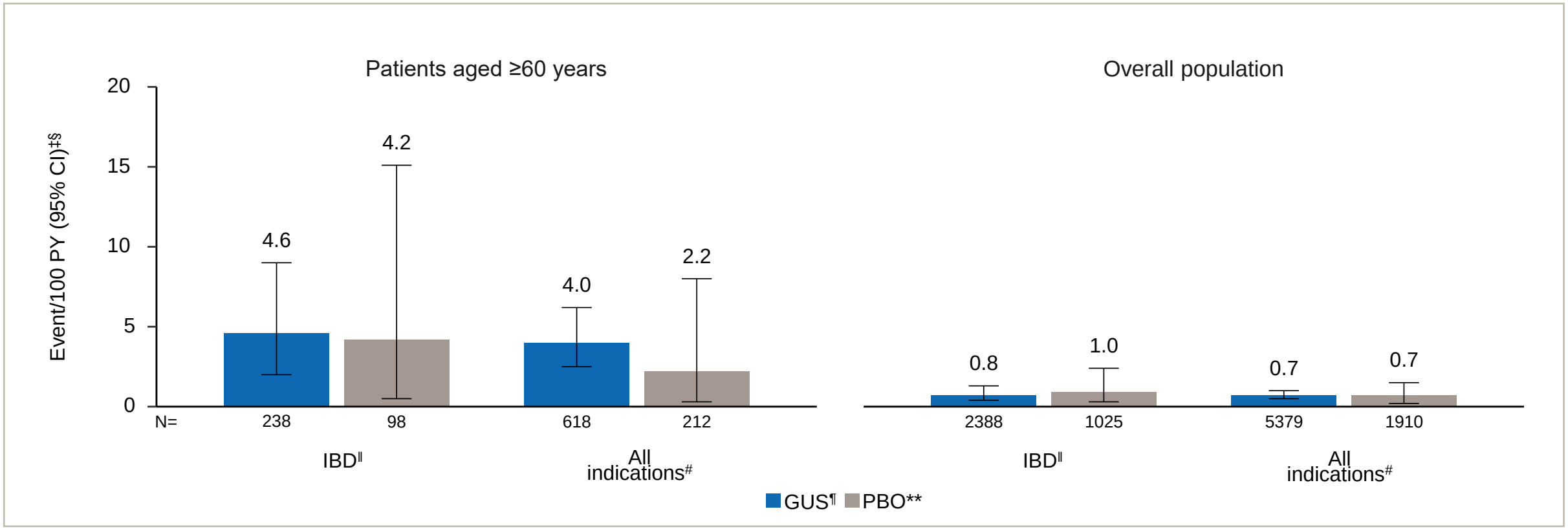
- Opportunistic infections, MACEs and VTEs were numerically lower with GUS vs PBO
- No cases of active tuberculosis were reported with GUS across indications among patients aged ≥60 years

*Safety events reported throughout the reporting period of approximately 1 year, SCS updated; Includes UC and CD Phase 2/3 SCS RCTs; †Includes HA, PsO, UC and CD Phase 2/3 SCS data; §eCOA GUS data and up to 12 weeks post-induction for PBO in Maintenance Study. CD, PsO, PsA: Data from first GUS dose for early escape/crossover; ‖UC: Data to first GUS dose (PBO) or ≥12W after last induction (re-randomised to PBO), until dose adjustment. CD, PsO, PsA: Data to early escape/rescue/crossover; #Cumulative treatment duration for each study agent was calculated as the time from first to last dose across all relevant periods; ¶Active tuberculosis events are identified by the MedDRA HLT of 'Tuberculous infections' excluding the preferred term of 'Latent tuberculosis'; **Opportunistic infections are defined as the narrow terms in the MedDRA SMQ of 'Opportunistic Infections'; ††MACEs were identified by clinical review; ‡‡VTE terms are based on customised MedDRA query.

AE, adverse event; CD, Crohn's disease; CI, confidence interval; GUS, guselkumab; HLT, High Level Term; IBD, inflammatory bowel disease; IL, interleukin; MACE, major adverse cardiovascular event; MedDRA, Medical Dictionary for Regulatory Activities; MOA, mechanism of action; NA, not applicable; PBO, placebo; PsA, psoriatic arthritis; PsO, psoriasis; PY, patient-years; RCT, randomised controlled trial; SCS, summary of clinical safety; SMQ, standardised MedDRA queries; TA, therapy area; UC, ulcerative colitis; VTE, venous thromboembolism; W, weeks.

Faye AS, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O98. Full prescribing information: www.swissmedicinfo-pro.ch/.

Exposure-adjusted incidence of malignancies*†



CH_CP-581164 05/26

Malignancy (including non-melanoma skin cancer) rates were comparable with GUS and PBO

*Malignancies are defined as the narrow terms in the MedDRA SMQ of 'Malignant Tumours'; †The majority of malignancies reported in patients aged ≥60 years were non-melanoma skin cancers, primarily basal cell carcinoma and squamous cell carcinoma; ‡Safety events reported throughout the reporting period to approximately 1 year; SCS all treated; §Cumulative treatment duration for each study agent was calculated as the time from first to last dose across all relevant periods; ‖Includes UC and CD Phase 2/3 GUS RCTs; #Includes PsA, PsO, UC and CD Phase 2/3 GUS RCTs; ¶UC: All GUS data and up to 12 weeks post-induction for PBO in Maintenance Study. CD, PsO, PsA: Data from first GUS dose for early escape/crossover; **UC: Data to first GUS dose (PBO) or ≥12W after last induction (re-randomised to PBO), until dose adjustment. CD, PsO, PsA: Data to early escape/rescue/crossover.

CD, Crohn's disease; CI, confidence interval; GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; MedDRA, Medical Dictionary for Regulatory Activities; MOA, mechanism of action; NA, not applicable; PBO, placebo; PsA, psoriatic arthritis; PsO, psoriasis; PY, patient-years; RCT, randomised controlled trial; SCS, summary of clinical safety; SMQ, standardised MedDRA queries; TA, therapy area; UC, ulcerative colitis; W, weeks.

Faye AS, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O98. Full prescribing information: www.swissmedicinfo-pro.ch/.

Conclusions

- Among adults aged ≥60 years with CD, UC, PsO or PsA pooled from 14 RCTs, exposure-adjusted adverse event rates were similar to or lower than those observed with PBO through up to 1 year of follow-up

- This result was observed for adverse events, serious adverse events, infections, MACEs and VTEs in both the IBD and all indications groups
- No deaths or active tuberculosis cases were reported with GUS
- Findings in adults aged ≥60 years were generally consistent with those observed in the overall study population

- Overall, GUS showed a favourable safety profile in adults aged ≥60 years

CD, Crohn's disease; GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; MACE, major adverse cardiovascular event; MOA, mechanism of action; NA, not applicable; PBO, placebo; PsA, psoriatic arthritis; PsO, psoriasis; RCT, randomised controlled trial; TA, therapy area; UC, ulcerative colitis; VTE, venous thromboembolism.

Faye AS, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. O98. Full prescribing information: www.swissmedicinfo-pro.ch/.

OP95

Pregnancy outcomes in maternal exposure to guselkumab: Review of cases reported to the company's global safety database

Uma Mahadevan,[1] Millie Long,[2] Mette Julsgaard,[3] Connie Lin,[4] Anja Geldhof,[5] Mauricio Rosas Ballina,[6] Hewei Li,[7] Javier P. Gisbert,[8] María Chaparro[8]

[1]University of California, San Francisco, CA, USA; [2]University of North Carolina, Chapel Hill, NC, USA; [3]Department of Hepatology and Gastroenterology, Aarhus University Hospital, Aarhus, Denmark; [4]Johnson & Johnson, Horsham, PA, USA; [5]Johnson & Johnson, Diegem, Belgium; [6]Actelion Research & Development, Basel, Switzerland; [7]Johnson & Johnson, Titusville, NJ, USA; [8]Hospital Universitario de La Princesa, Instituto de Investigación Sanitaria Princesa (IIS-Princesa), Universidad Autónoma de Madrid (UAM), and Centro de Investigación Biomédica en Red de Enfermedades Hepáticas y Digestivas (CIBEREHD), Madrid, Spain.

Objective and methods

Objective

This analysis reported data on pregnancy cases with known outcomes in women exposed to GUS during pregnancy from the Company Global Safety Database

Methods

Pregnancy cases reported to the Company Global Safety Database through 12 July 2025 were analysed

Reporting sources:

Interventional

- Data reported from clinical trials

Non-interventional

- Data reported from registries (e.g., observational studies)

Spontaneous reporting

- Physician or self-reported (e.g., unsolicited)

Timing of reporting:

Prospective data

- Collected from pregnancies with GUS exposure reported before outcomes were known

Retrospective data

- Included simultaneous reports of pregnancies and outcomes

GUS, guselkumab; IL, interleukin; MOA, mechanism of action; NA, not applicable; TA, therapy area.
Mahadevan U, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP95. Guselkumab is not approved in pregnant patients in IBD by Swissmedic.

Objective and methods

Objective

This analysis reported data on pregnancy cases with known outcomes in women exposed to GUS during pregnancy from the Company Global Safety Database

Methods

Pregnancy cases reported to the Company Global Safety Database through 12 July 2025 were analysed

Therapeutic indications were categorised as:

- Psoriatic disease
- CD
- UC
- Other/not reported

Maternal GUS exposure occurred:

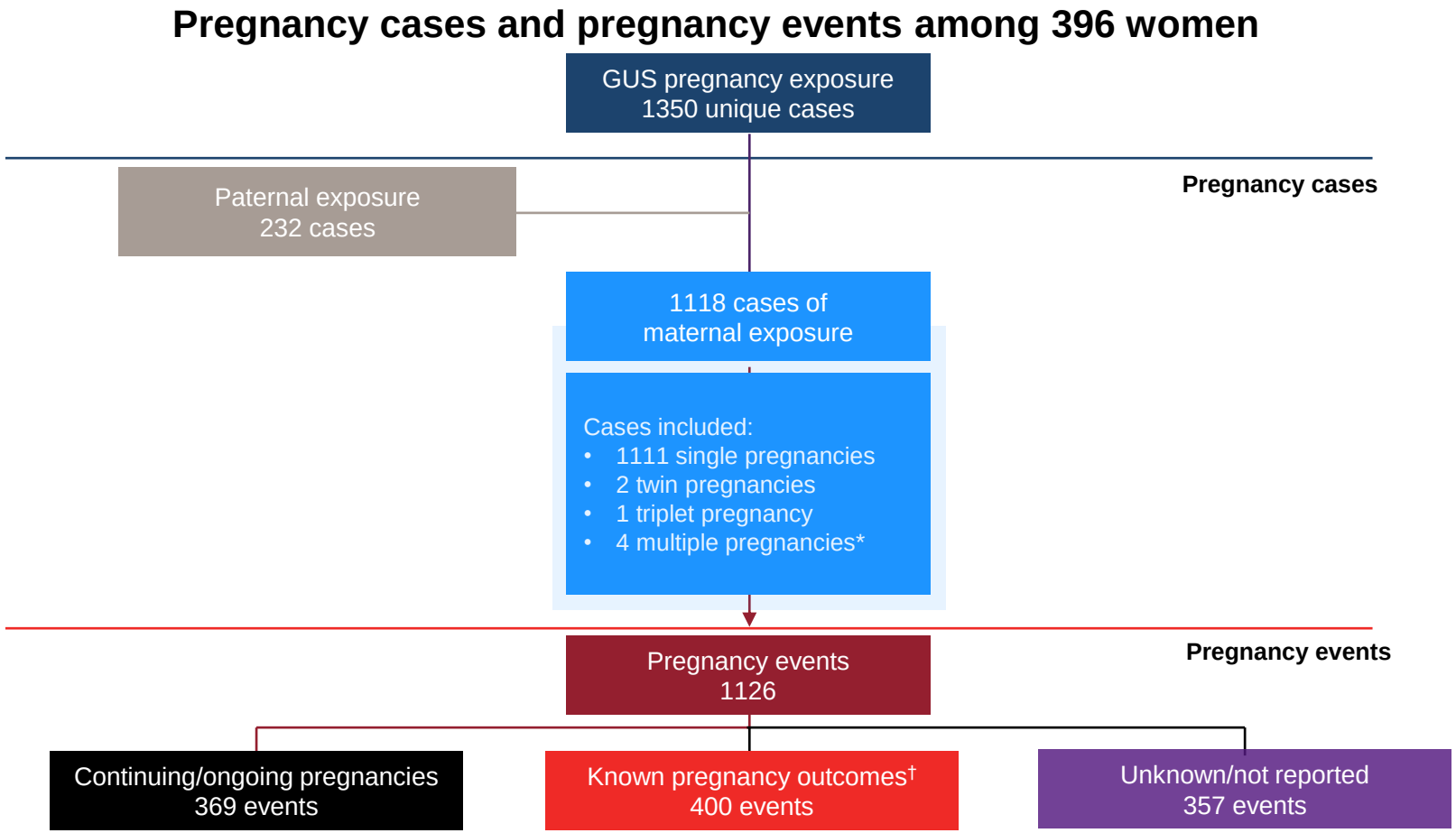
- Preconception only
- Any T1: during the 1st trimester with possible T2 or T3 exposure (excluding T1+T2+T3)
- T2+T3: after 1st trimester
- T3 only: 3rd trimester only
- T1+T2+T3: exposure during all 3 trimesters
- NR: not reported

Pregnancy outcomes were classified as:

- Live births
- Spontaneous abortions
- Elective terminations
- Ectopic pregnancies
- Stillbirths

CD, Crohn's disease; GUS, guselkumab; IL, interleukin; MOA, mechanism of action; NA, not applicable; NR, not reported; T1, first trimester; T2, second trimester; T3, third trimester; TA, therapy area; UC, ulcerative colitis.
Mahadevan U, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP95. Guselkumab is not approved in pregnant patients in IBD by Swissmedic.

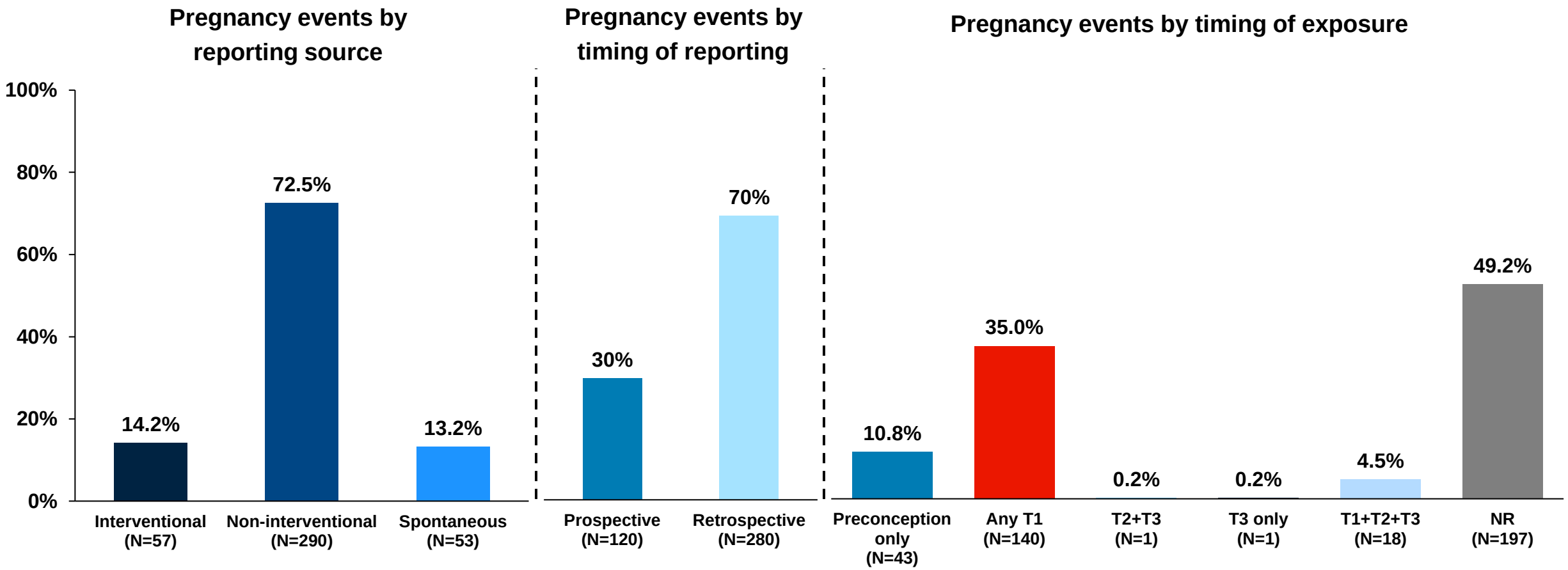
Among 396 women, 400 pregnancy events with known outcomes occurred



- Maternal age was reported for 264/396 women (67%); mean maternal age was **32 years**

*Four women had two single pregnancies each; †These 400 events were from 287 medically confirmed pregnancies and 109 medically unconfirmed pregnancies.
CD, Crohn's disease; GUS, guselkumab; IL, interleukin; MOA, mechanism of action; NA, not applicable; TA, therapy area.
Mahadevan U, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP95. Guselkumab is not approved in pregnant patients in IBD by Swissmedic.

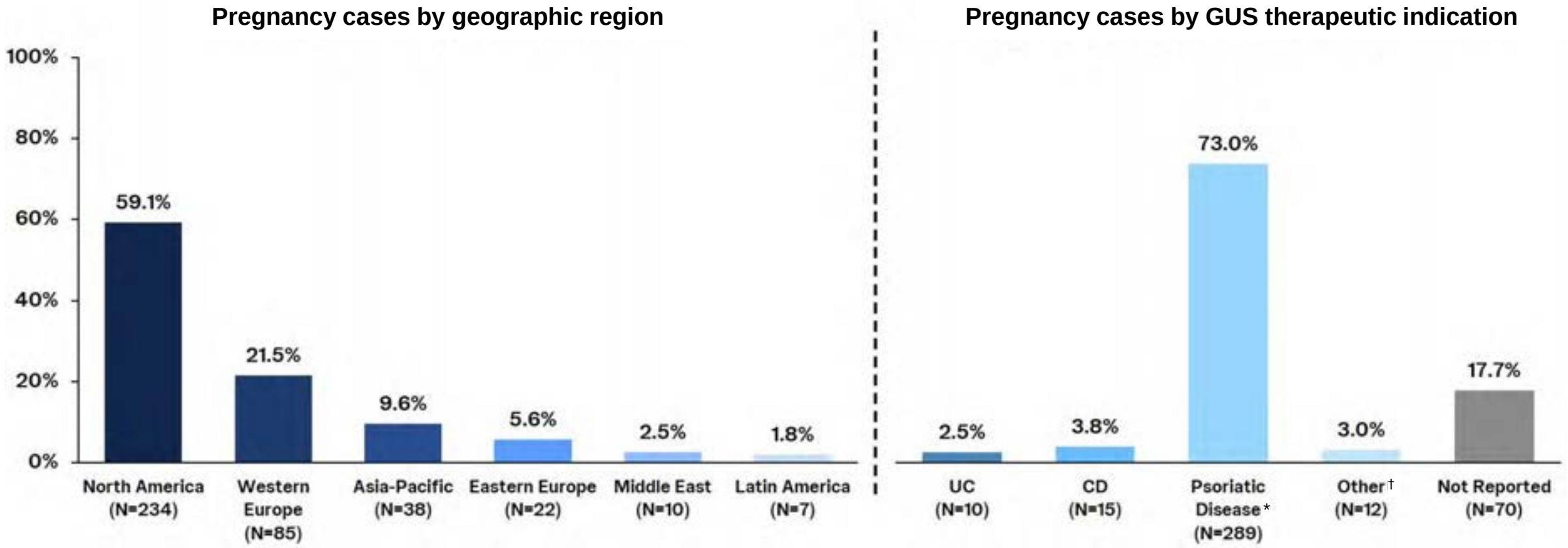
Most pregnancy events were from retrospective reports and non-interventional settings



Among cases with data reported, GUS exposure during the 1st trimester was most common

Preconception only: Within 3 months prior to conception. Any T1 includes 105 events with exposure only during T1, 8 events with T1+T2 exposure, and 27 events with T1 and possible T2 or T3 exposure (excluding T1+T2+T3). T2+T3: exposure after the 1st trimester. T3 only: exposure during the 3rd trimester only. T1+T2+T3: exposure during all 3 trimesters. NR: timing of exposure was not reported.
GUS, guselkumab; IL, interleukin; MOA, mechanism of action; NA, not applicable; NR, not reported; T1, first trimester; T2, second trimester; T3, third trimester; TA, therapy area.
Mahadevan U, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP95. Guselkumab is not approved in pregnant patients in IBD by Swissmedic.

Women living in North America and Western Europe comprised the majority of pregnancy cases



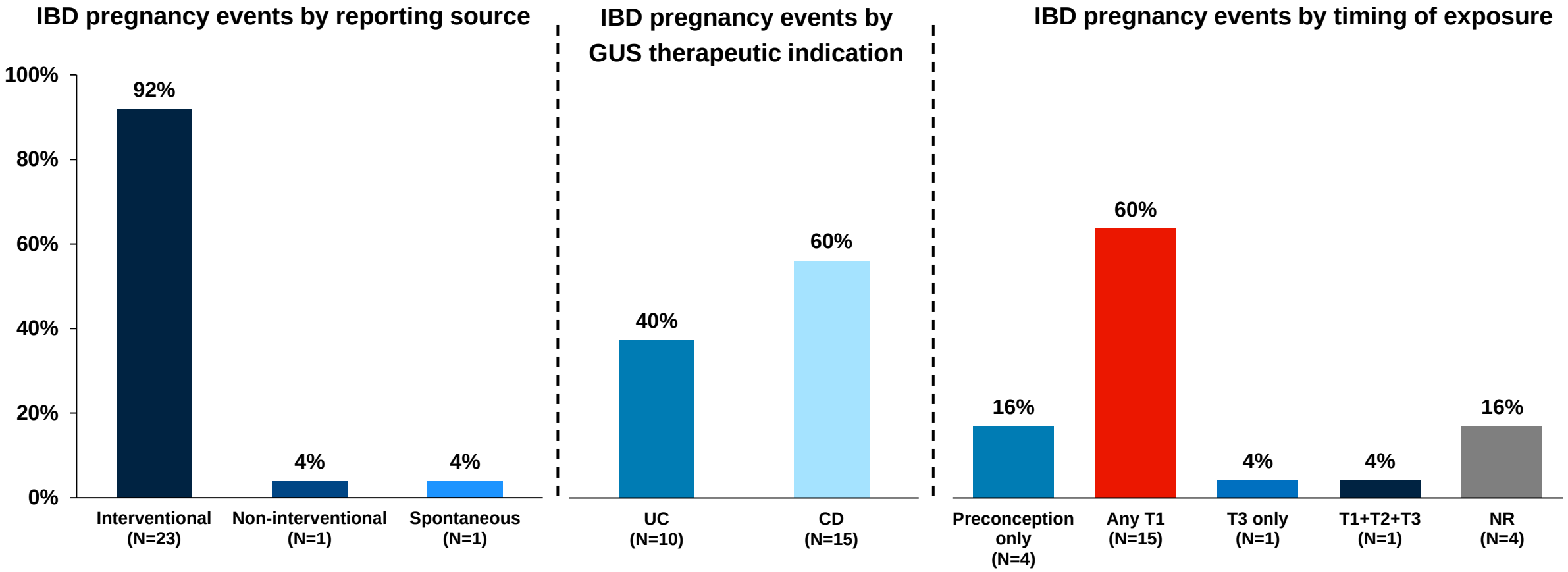
Among cases with reported therapeutic indication, GUS was mostly used to treat psoriatic disease

*Includes cases reporting indications as PsO, PsA, and PsO + PsA; †Other indications included hidradenitis suppurativa, palmoplantar pustulosis, guttate PsO, pityriasis rubra pilaris, rheumatoid arthritis and healthy individuals from Phase 1 studies.

CD, Crohn's disease; GUS, guselkumab; IL, interleukin; MOA, mechanism of action; NA, not applicable; PsA, psoriatic arthritis; PsO, psoriasis; T1, first trimester; T2, second trimester; T3, third trimester; TA, therapy area; UC, ulcerative colitis.

Mahadevan U, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP95. Guselkumab is not approved in pregnant patients in IBD by Swissmedic.

Most pregnancy events reporting IBD indication were for CD treatment and from interventional studies



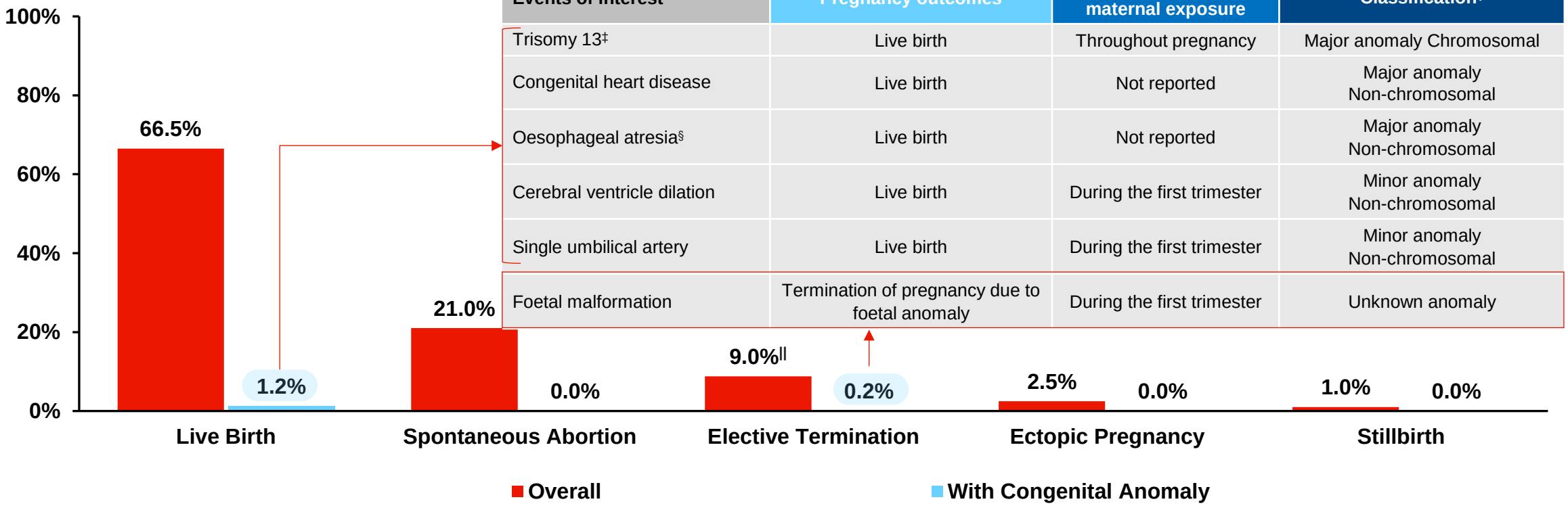
The first trimester was the most common time period for GUS exposure

Preconception only: Within 3 months prior to conception. Any T1 includes 14 events with exposure only during T1 and 1 event with T1 and possible T2 or T3 exposure (excluding T1+T2+T3). T3 only: exposure during the 3rd trimester only. T1+T2+T3: exposure during all 3 trimesters. NR: timing of exposure was not reported.

CD, Crohn's disease; GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; MOA, mechanism of action; NA, not applicable; NR, not reported; T1, first trimester; T2, second trimester; T3, third trimester; TA, therapy area; UC, ulcerative colitis.

Mahadevan U, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP95. Guselkumab is not approved in pregnant patients in IBD by Swissmedic.

66.5% (266/400) of pregnancy events with maternal exposure to GUS resulted in live birth

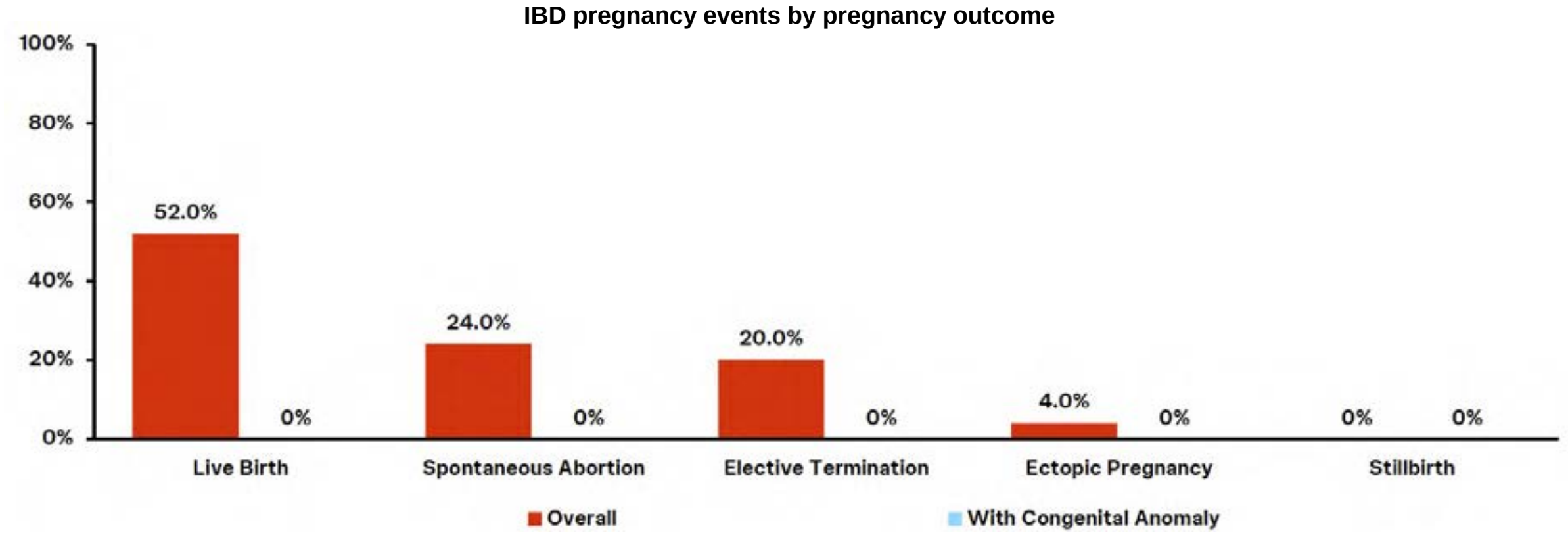


Events of interest*	Pregnancy outcomes	Timing of maternal exposure	Classification†
Trisomy 13‡	Live birth	Throughout pregnancy	Major anomaly Chromosomal
Congenital heart disease	Live birth	Not reported	Major anomaly Non-chromosomal
Oesophageal atresia§	Live birth	Not reported	Major anomaly Non-chromosomal
Cerebral ventricle dilation	Live birth	During the first trimester	Minor anomaly Non-chromosomal
Single umbilical artery	Live birth	During the first trimester	Minor anomaly Non-chromosomal
Foetal malformation	Termination of pregnancy due to foetal anomaly	During the first trimester	Unknown anomaly

Of the 400 pregnancy events with known outcomes, 6 (1.5%) pregnancies were associated with congenital anomalies. All pregnancy cases associated with congenital anomalies were reported retrospectively

*Medical Dictionary for Regulatory Activities (MedDRA, version 28.0) was used to identify adverse events based on the System Organ Class of congenital, familial or genetic disorders, which is a sub-search of the Standardized MedDRA Query of pregnancy and neonatal topics; †Major and chromosomal congenital anomalies per EUROCAT classification are reported unless otherwise specified; ‡Pre-term delivery at less than 37 weeks; baby died due to Trisomy 13; §Baby adverse event of tracheomalacia was reported; ‖One case reported baby adverse event of foetal disorder with no further information; conservatively, it was categorised as a foetal defect.
GUS, guselkumab; IL, interleukin; MOA, mechanism of action; NA, not applicable; TA, therapy area.
Mahadevan U, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP95. Guselkumab is not approved in pregnant patients in IBD by Swissmedic.

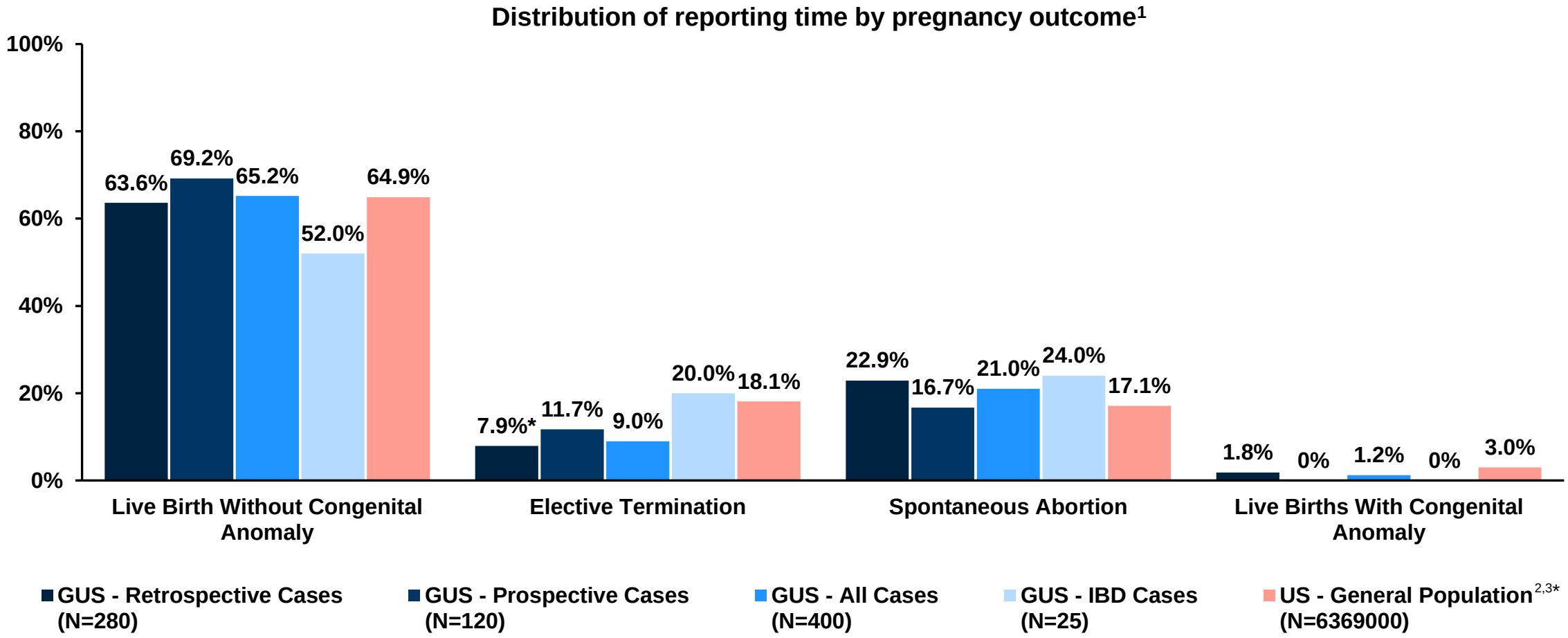
52.0% (13/25) of IBD pregnancy events with maternal exposure to GUS resulted in live birth



Of the 25 pregnancy events with IBD indication, no pregnancies were associated with congenital anomalies

GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; MOA, mechanism of action; NA, not applicable; TA, therapy area.
Mahadevan U, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP95. Guselkumab is not approved in pregnant patients in IBD by Swissmedic.

Pregnancy outcomes with maternal exposure were consistent with the US general population



CH_CP-581164 05/26

*Congenital anomalies affect 1 in every 33 babies in the United States.

GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; MOA, mechanism of action; NA, not applicable; TA, therapy area.

1. Mahadevan U, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP95; 2. Curtin SC, et al. *NCHS Data Brief*. 2013;(136):1–8; 3. About Birth Defects. U.S. Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/birth-defects/index.html. Accessed May 2026. Guselkumab is not approved in pregnant patients in IBD by Swissmedic.

Conclusions

- These findings suggest no apparent impact of GUS on pregnancy outcomes; however, they should be interpreted cautiously, given data limitations*
- Live births, elective terminations, spontaneous abortions and congenital anomalies were consistent with the US population
- Further studies are warranted to confirm these observations and to better characterise the safety profile of GUS exposure during pregnancy

*The limitations of these findings include, but are not limited to, the lack of study control, a small sample size of pregnancies with known outcomes, and reported data with varying degrees of missing information.
GUS, guselkumab; IL, interleukin; MOA, mechanism of action; NA, not applicable; TA, therapy area.
Mahadevan U, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP95. Guselkumab is not approved in pregnant patients in IBD by Swissmedic.

ANTHEM: Icotrokinra in UC

OP487

Efficacy of icotrokinra, the first targeted oral peptide that selectively blocks the IL-23 receptor, in ulcerative colitis patients with or without prior intolerance or inadequate response to advanced therapies: results from the ANTHEM-UC study

Edward V. Loftus, Jr., Vipul Jairath, Maria T. Abreu, Minhu Chen, Karen Chachu, Edouard Louis, Jimmy Limdi, Katsuyoshi Matsuoka, Lindsey Surace, Ngozi Erondu, Edmund Arthur, Nicole Houck, Bin Zou, Joyce Zhan, Mary Ellen Frustaci, Grazyna Rydzewska, Britta Siegmund

ANTHEM-UC study design

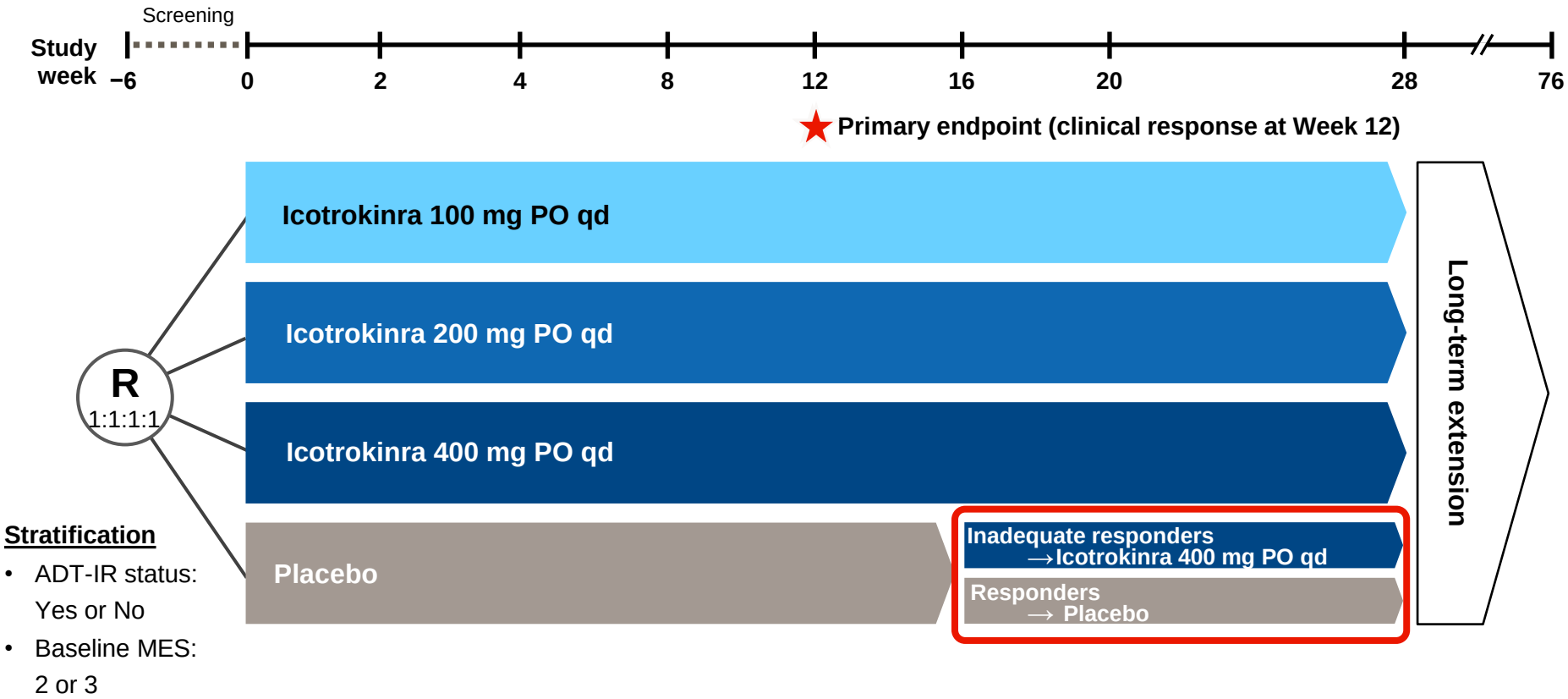
Aim: Report the efficacy of icotrokinra in ANTHEM-UC participants with and without prior inadequate response or intolerance to advanced therapies for UC

Key eligibility criteria:

- Diagnosed UC of ≥12 weeks duration and a Modified Mayo score (mMS) of 5–9, inclusive
- MES ≥2 per central review of screening video endoscopy
- **ADT-IR**: inadequate response or intolerance (IR) to TNFα blockers, IL-12/23 antagonists, integrin receptor antagonists, JAKis or S1P modulators

  OR

  Non-ADT-IR: IR to corticosteroids, 6-MP or AZA or corticosteroid dependence (exposure to ADT without IR is permitted)



CH_CP-581164 05/26

Clinical response: a decrease from baseline in the modified Mayo score by ≥30% and ≥2 points, with either a ≥1-point decrease from baseline in the rectal bleeding subscore or a rectal bleeding subscore of 0 or 1.
Analyses in subpopulations by ADT-IR history were prespecified and exploratory (not controlled for multiple comparisons). Analyses at Week 28 were prespecified and exploratory (not controlled for multiple comparisons).
5-MP, 6-mercaptopurine; ADT, advanced therapy; AZA, azathioprine; ICO, icotrokinra; IL-23R, interleukin-23 receptor; IR, inadequate response or intolerance; JAKi, Janus kinase inhibitor; MES, Mayo Endoscopic Subscore; mMS, Modified Mayo score; PO, oral; qd, once daily; R, randomisation; RDBPC, randomised, double-blind, placebo controlled; S1P, sphingosine-1 phosphate; TNF, tumour necrosis factor; UC, ulcerative colitis.
Loftus EV Jr, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP487. Icotrokinra is not approved by Swissmedic.

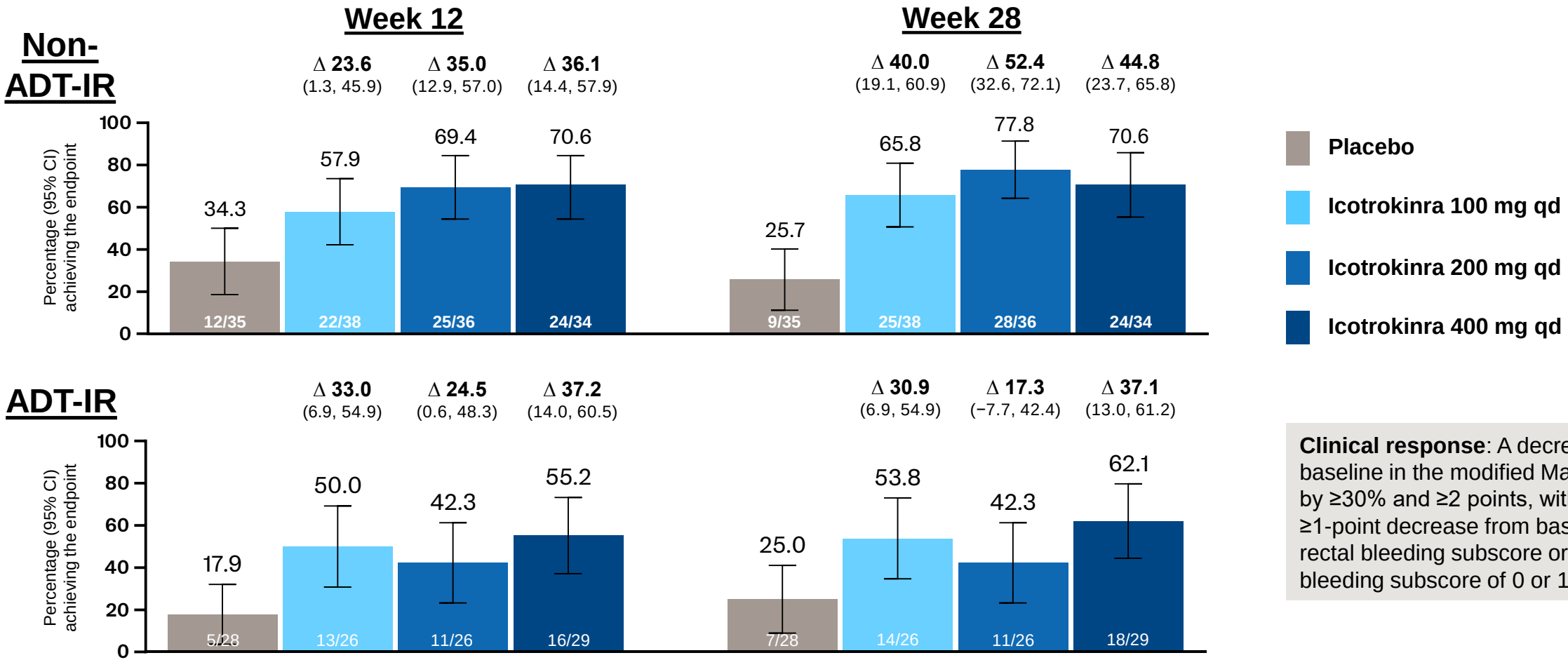
Demographics and baseline disease characteristics

	Placebo		Icotrokinra 100 mg qd		Icotrokinra 200 mg qd		Icotrokinra 400 mg qd	
	Non-ADT-IR N=35	ADT-IR N=28	Non-ADT-IR N=38	ADT-IR N=26	Non-ADT-IR N=36	ADT-IR N=26	Non-ADT-IR N=34	ADT-IR N=29
UC disease duration (years), mean (SD)	8.7 (9.4)	7.7 (6.3)	5.8 (5.8)	9.8 (5.8)	6.9 (7.6)	9.0 (7.5)	6.6 (6.5)	8.7 (8.6)
Extensive disease on screening endoscopy, n (%)	15 (42.9%)	12 (42.9%)	13 (34.2%)	10 (38.5%)	14 (38.9%)	9 (34.6%)	16 (47.1%)	13 (44.8%)
Modified Mayo score, mean (SD)	6.66 (1.41)	6.86 (0.97)	6.32 (1.21)	6.88 (1.37)	6.83 (1.18)	6.65 (1.65)	6.44 (1.48)	6.55 (1.33)
Mayo Endoscopic Subscore = 3 [severe], n (%)	20 (57.1%)	16 (57.1%)	21 (55.3%)	17 (65.4%)	22 (61.1%)	15 (57.7%)	19 (55.9%)	18 (62.1%)
Faecal calprotectin >250 mg/kg, n/N (%)	26/29 (89.7%)	20/23 (87.0%)	28/33 (84.8%)	19/21 (90.5%)	29/31 (93.5%)	20/22 (90.9%)	27/31 (87.1%)	25/27 (92.6%)
CRP >3 mg/L, n (%)	16 (45.7%)	14 (50.0%)	18 (47.4%)	13 (52.0%)	18 (50.0%)	20 (76.9%)	17 (51.5%)	16 (55.2%)
Exposed to ADT without IR, n (%)	3 (8.6%)	-	4 (10.5%)	-	5 (13.9%)	-	3 (8.8%)	-
Prior ADT-IR, n (%)								
1 ADT class	-	22 (78.6%)	-	19 (73.1%)	-	21 (80.8%)	-	15 (51.7%)
2 ADT classes	-	6 (21.4%)	-	6 (23.1%)	-	5 (19.2%)	-	14 (48.3%)
>2 ADT classes	-	0	-	1 (3.8%)	-	0	-	0

CH_CP-581164 05/26

ADT classes include TNFα blockers (adalimumab, golimumab, infliximab), IL-12/23 antagonists (ustekinumab), integrin receptor antagonists (vedolizumab), JAK inhibitors (tofacitinib, upadacitinib, filgotinib) and S1P receptor modulators (ozanimod, etrasimod).
ADT, advanced therapy; CRP, C-reactive protein; ICO, icotrokinra; IL-23R, interleukin-23 receptor; IR, inadequate response or intolerance; JAK, Janus kinase; MOA, mechanism of action; qd, once daily; RDBPC, randomised, double-blind, placebo-controlled; S1P, sphingosine-1-phosphate; SD, standard deviation; TNFα, tumour necrosis factor alpha; UC, ulcerative colitis.
Loftus EV Jr, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP487. Icotrokinra is not approved by Swissmedic.

Clinical response (primary endpoint at Week 12)



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

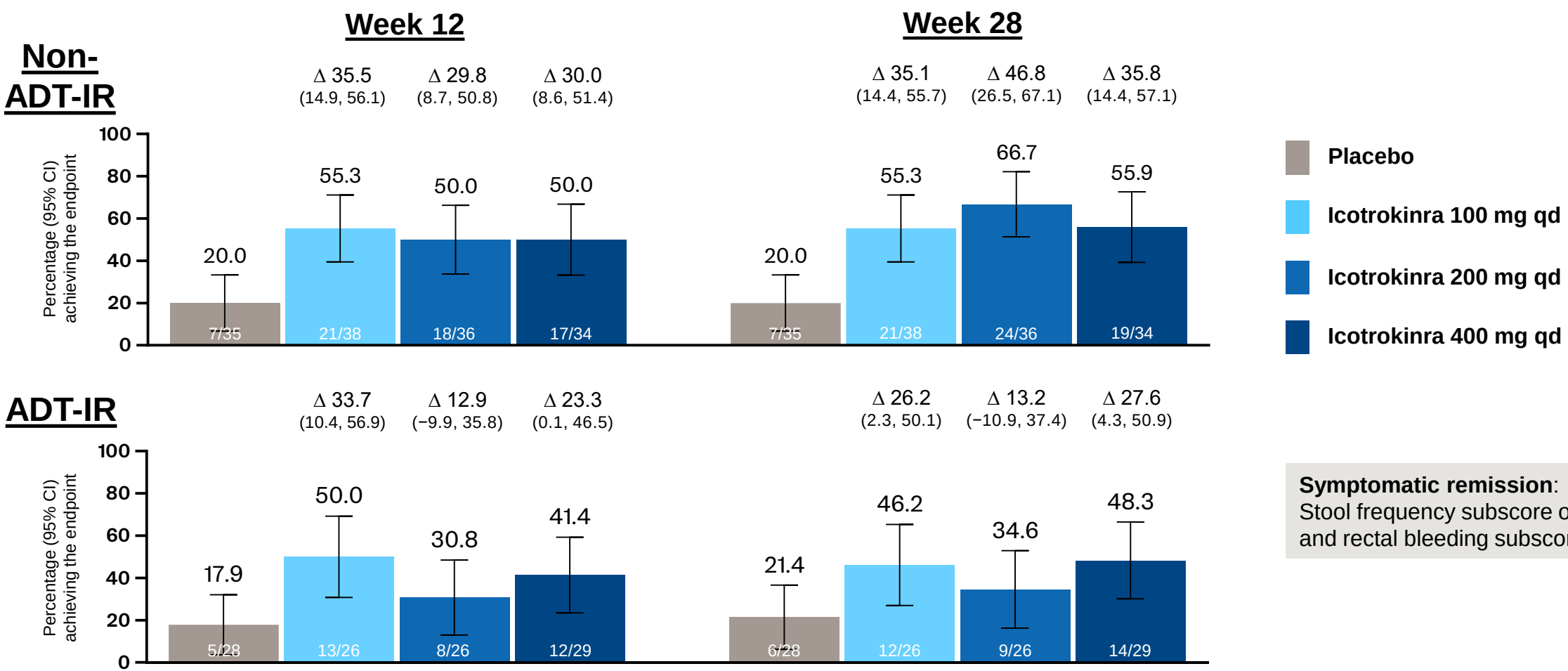
CH_CP-581164 05/26

Δ = adjusted treatment difference (95% confidence interval) vs placebo. Adjusted treatment differences and 95% CIs were based on the common risk difference by use of Mantel–Haenszel stratum weights and the Sato variance estimator, using stratification factors of ADT-IR status (Yes or No) and Mayo endoscopic subscore (moderate [2] or severe [3]). Participants with intercurrent events of ostomy or colectomy, prohibited changes in UC medication, or discontinuation of study intervention for any reason except those due to major disruptions (e.g., COVID-19-related reasons or regional crisis, excluding COVID-19 infection) were considered nonresponders. Participants who met inadequate response criteria for dose adjustment at Week 16 were also considered non-responders moving forward. For participants discontinuing study intervention due to major disruptions, their observed values, if available, were used. After accounting for these scenarios, participants who were missing data necessary for calculation of the outcome measure at the assessment time point were considered not to have achieved that endpoint.

ADT, advanced therapy; CI, confidence interval; ICO, icotrokinra; IL-23R, interleukin-23 receptor; IR, inadequate response or intolerance; MOA, mechanism of action; qd, once daily; RDBPC, randomised, double-blind, placebo-controlled; UC, ulcerative colitis.

Loftus EV Jr, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP487. Icotrokinra is not approved by Swissmedic.

Symptomatic remission



Symptomatic remission:
Stool frequency subscore of 0 or 1 and rectal bleeding subscore of 0

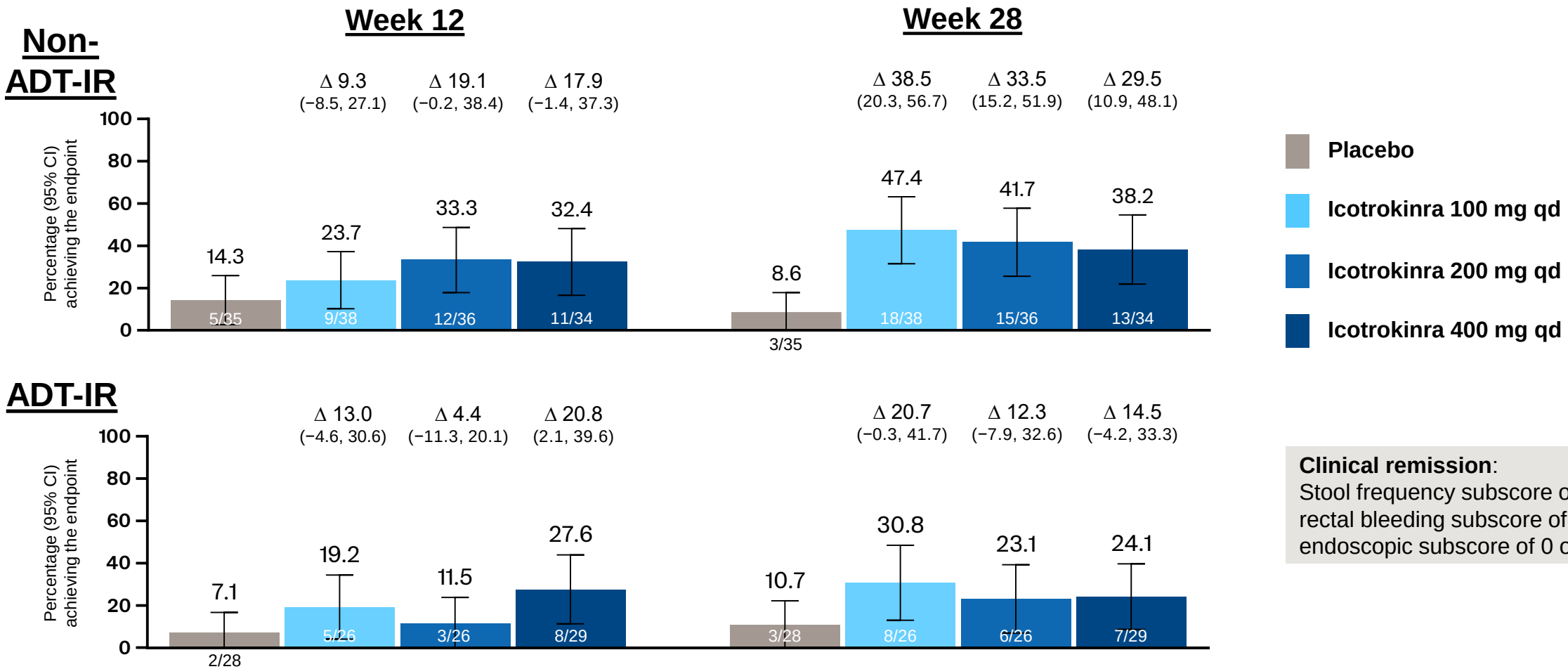
CH_CP-581164 05/26

Δ = adjusted treatment difference (95% confidence interval) vs placebo. Adjusted treatment differences and 95% CIs were based on the common risk difference by use of Mantel–Haenszel stratum weights and the Sato variance estimator, using stratification factors of ADT-IR status (Yes or No) and Mayo endoscopic subscore (moderate [2] or severe [3]). Participants with intercurrent events of ostomy or colectomy, prohibited changes in UC medication, or discontinuation of study intervention for any reason except those due to major disruptions (e.g., COVID-19-related reasons or regional crisis, excluding COVID-19 infection) were considered nonresponders. Participants who met inadequate response criteria for dose adjustment at Week 16 were also considered non-responders moving forward. For participants discontinuing study intervention due to major disruptions, their observed values, if available, were used. After accounting for these scenarios, participants who were missing data necessary for calculation of the outcome measure at the assessment time point were considered not to have achieved that endpoint.

ADT, advanced therapy; CI, confidence interval; ICO, icotrokinra; IL-23R, interleukin-23 receptor; IR, inadequate response or intolerance; MOA, mechanism of action; qd, once daily; RDBPC, randomised, double-blind, placebo-controlled; UC, ulcerative colitis.

Loftus EV Jr, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP487. Icotrokinra is not approved by Swissmedic.

Clinical remission



Clinical remission:
Stool frequency subscore of 0 or 1, rectal bleeding subscore of 0 and Mayo endoscopic subscore of 0 or 1

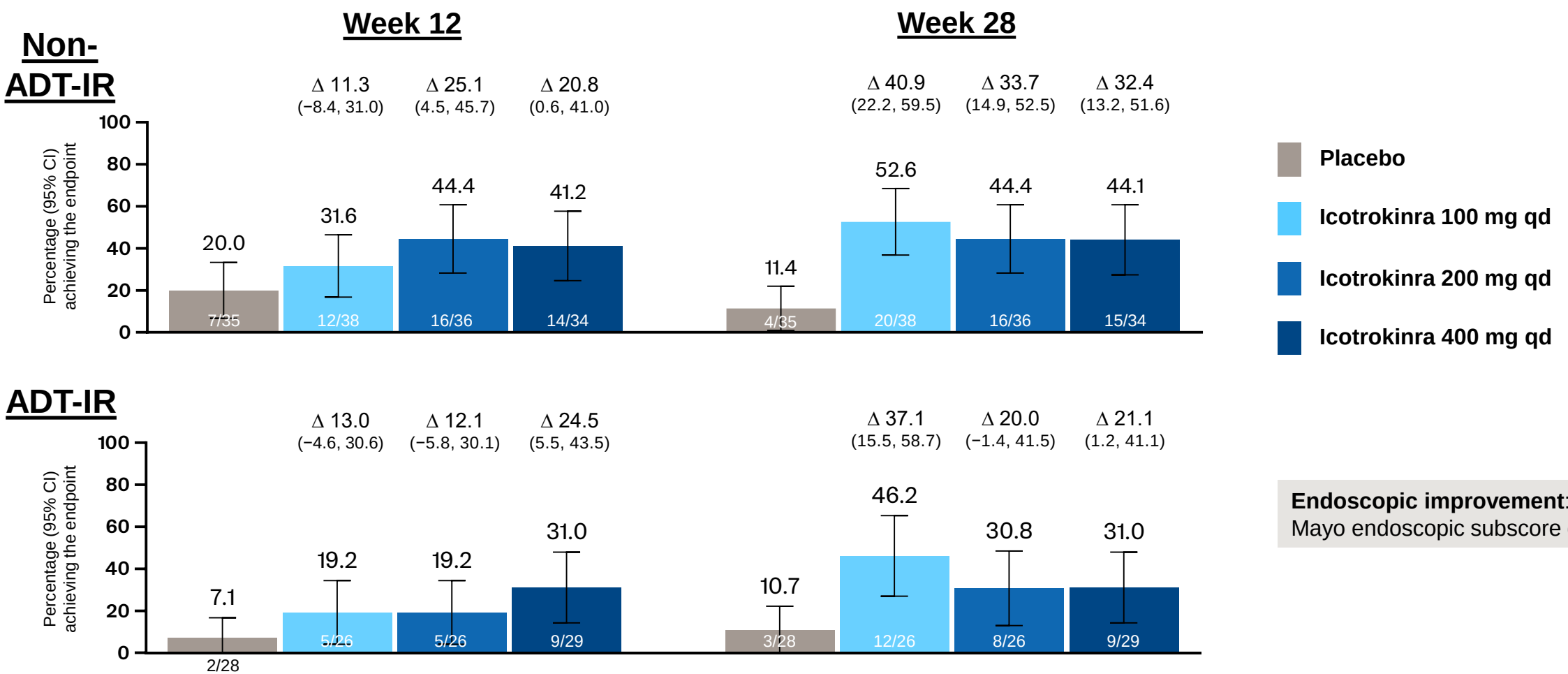
CH_CP-581164 05/26

Δ = adjusted treatment difference (95% confidence interval) vs placebo. Adjusted treatment differences and 95% CIs were based on the common risk difference by use of Mantel–Haenszel stratum weights and the Sato variance estimator, using stratification factors of ADT-IR status (Yes or No) and Mayo endoscopic subscore (moderate [2] or severe [3]). Participants with intercurrent events of ostomy or colectomy, prohibited changes in UC medication, or discontinuation of study intervention for any reason except those due to major disruptions (e.g., COVID-19-related reasons or regional crisis, excluding COVID-19 infection) were considered nonresponders. Participants who met inadequate response criteria for dose adjustment at Week 16 were also considered non-responders moving forward. For participants discontinuing study intervention due to major disruptions, their observed values, if available, were used. After accounting for these scenarios, participants who were missing data necessary for calculation of the outcome measure at the assessment time point were considered not to have achieved that endpoint.

ADT, advanced therapy; CI, confidence interval; ICO, icotrokinra; IL-23R, interleukin-23 receptor; IR, inadequate response or intolerance; MOA, mechanism of action; qd, once daily; RDBPC, randomised, double-blind, placebo-controlled; UC, ulcerative colitis.

Loftus EV Jr, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP487. Icotrokinra is not approved by Swissmedic.

Endoscopic improvement



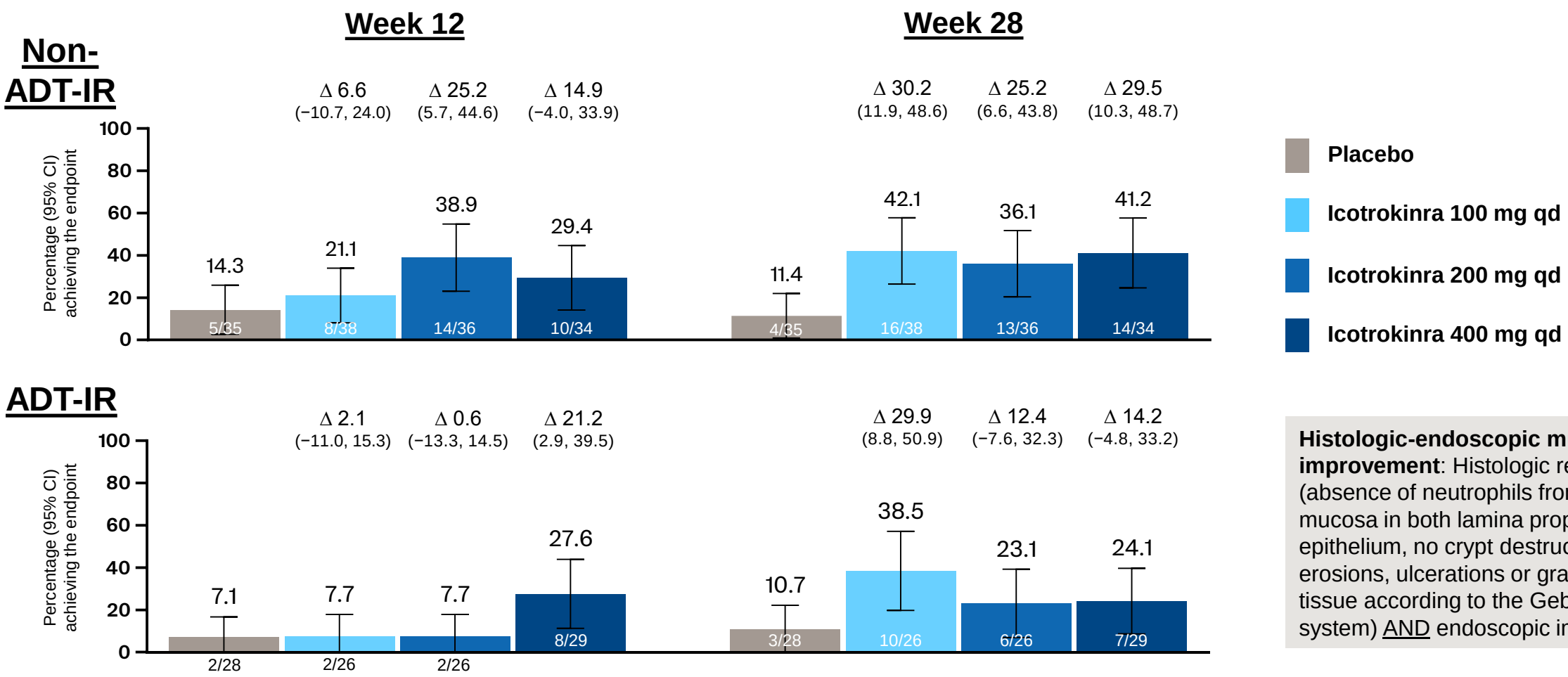
Endoscopic improvement:
Mayo endoscopic subscore of 0 or 1

Δ = adjusted treatment difference (95% confidence interval) vs placebo. Adjusted treatment differences and 95% CIs were based on the common risk difference by use of Mantel–Haenszel stratum weights and the Sato variance estimator, using stratification factors of ADT-IR status (Yes or No) and Mayo endoscopic subscore (moderate [2] or severe [3]). Participants with intercurrent events of ostomy or colectomy, prohibited changes in UC medication, or discontinuation of study intervention for any reason except those due to major disruptions (e.g., COVID-19-related reasons or regional crisis, excluding COVID-19 infection) were considered nonresponders. Participants who met inadequate response criteria for dose adjustment at Week 16 were also considered non-responders moving forward. For participants discontinuing study intervention due to major disruptions, their observed values, if available, were used. After accounting for these scenarios, participants who were missing data necessary for calculation of the outcome measure at the assessment time point were considered not to have achieved that endpoint.

ADT, advanced therapy; CI, confidence interval; ICO, icotrokinra; IL-23R, interleukin-23 receptor; IR, inadequate response or intolerance; MOA, mechanism of action; qd, once daily; RDBPC, randomised, double-blind, placebo-controlled; UC, ulcerative colitis.

Loftus EV Jr, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP487. Icotrokinra is not approved by Swissmedic.

Histologic-endoscopic mucosal improvement



Histologic-endoscopic mucosal improvement: Histologic remission (absence of neutrophils from the mucosa in both lamina propria and epithelium, no crypt destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system) AND endoscopic improvement

Δ = adjusted treatment difference (95% confidence interval) vs placebo. Adjusted treatment differences and 95% CIs were based on the common risk difference by use of Mantel–Haenszel stratum weights and the Sato variance estimator, using stratification factors of ADT-IR status (Yes or No) and Mayo endoscopic subscore (moderate [2] or severe [3]). Participants with intercurrent events of ostomy or colectomy, prohibited changes in UC medication, or discontinuation of study intervention for any reason except those due to major disruptions (e.g., COVID-19-related reasons or regional crisis, excluding COVID-19 infection) were considered nonresponders. Participants who met inadequate response criteria for dose adjustment at Week 16 were also considered non-responders moving forward. For participants discontinuing study intervention due to major disruptions, their observed values, if available, were used. After accounting for these scenarios, participants who were missing data necessary for calculation of the outcome measure at the assessment time point were considered not to have achieved that endpoint.

ADT, advanced therapy; CI, confidence interval; HEMI, histologic-endoscopic mucosal improvement; ICO, icotrokinra; IL-23R, interleukin-23 receptor; IR, inadequate response or intolerance; MOA, mechanism of action; qd, once daily; RDBPC, randomised, double-blind, placebo-controlled; UC, ulcerative colitis.

Loftus EV Jr, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP487. Icotrokinra is not approved by Swissmedic.

Conclusions

- Once-daily icotrokinra demonstrated efficacy in participants with moderately to severely active ulcerative colitis at Week 12 and Week 28, irrespective of prior ADT history
- Within the active treatment groups, clinical and endoscopic outcomes (clinical response, symptomatic remission, clinical remission, endoscopic improvement and HEMI) were generally maintained or improved in both subpopulations from Week 12 to Week 28
- Proportions of participants who met these endpoints were greater in the non-ADT-IR subpopulation compared with the ADT-IR subpopulation

ADT, advanced therapy; HEMI, histologic-endoscopic mucosal improvement; ICO, icotrokinra; IL-23R, interleukin-23 receptor; IR, inadequate response or intolerance; MOA, mechanism of action; RDBPC, randomised, double-blind, placebo-controlled; UC, ulcerative colitis.

Loftus EV Jr, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. OP487. Icotrokinra is not approved by Swissmedic.

Key data only

UC and CD: Retrospective analyses of the Crohn's & Colitis Foundation Database

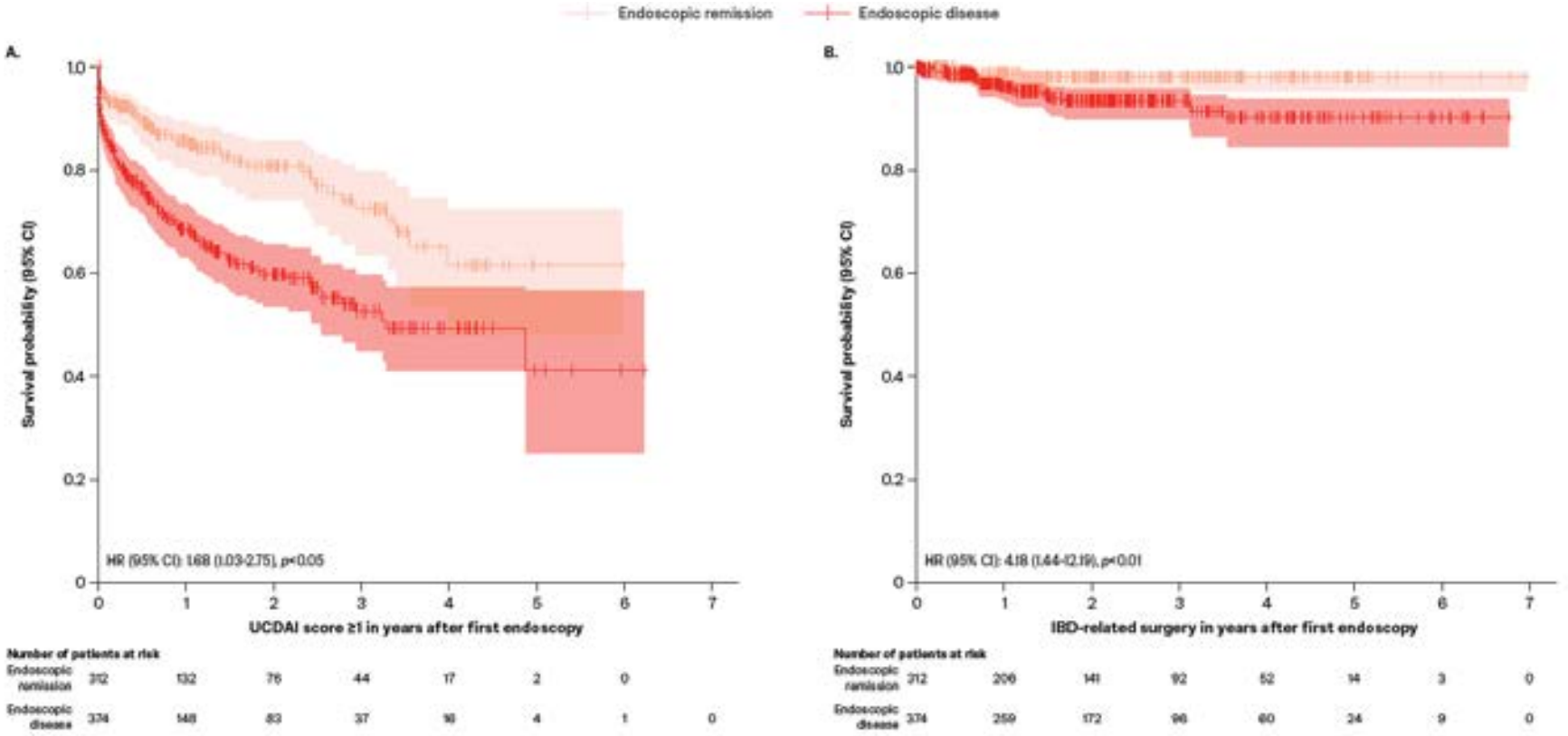
Impact of endoscopic remission on long-term outcomes and IBD-related surgery in patients with ulcerative colitis: a retrospective cohort analysis from the Crohn's & Colitis Foundation database

Carla Truyers,[1] Dominik Naessens,[1] Myrlene Sanon,[2] Elise Wu,[2] Jackie Kwong,[3] Shashi Adsul[2]

[1]Johnson & Johnson, Beerse, Belgium; [2]Johnson & Johnson, Horsham, PA, USA; [3]Johnson & Johnson, Raritan, NJ, USA

Aim: To assess the association between endoscopic remission and subsequent outcomes in patients with UC, including clinical worsening and IBD-related surgery

Time to first (A) UCDAI score ≥1* and (B) IBD-related surgery†



- At index, not achieving endoscopic remission was associated with earlier clinical worsening ($p<0.05$) and a higher likelihood of undergoing IBD-related surgery during follow-up ($p<0.01$)
- Repeated-measures analysis confirmed that patients with endoscopic remission had independently associated lower UCDAI scores over time vs those without remission (0.61-point difference; $p<0.0001$)

Conclusions

- In this retrospective cohort study, endoscopic remission in UC was associated with less subsequent clinical worsening and fewer IBD-related surgeries, as well as lower subsequent UCDAI scores compared with no endoscopic remission
- These findings show that endoscopic remission in UC is associated with improved long-term outcomes, including lower subsequent clinical activity and fewer patient-relevant events, even after adjusting for baseline UCDAI score, which supports endoscopic remission as an important therapeutic target in UC

Endoscopic remission: MES score = 0. **Endoscopic disease:** MES score >0.
Retrospective cohort study using the Crohn's & Colitis Foundation IBD Plexus database (data collected between November 2016 and June 2024). Data were primarily pooled from the electronic health records of patients diagnosed with IBD across
17 academic medical centres in the United States. Adults (≥18 years of age) with UC, ≥1 endoscopic assessment (MES) and biologic use on or before the index date were included.
*Multivariate analysis of clinical worsening; †Univariate analysis due to limited events.
CI, confidence interval; HR, hazard ratio; IBD, inflammatory bowel disease; MES, Mayo Endoscopic Subscore; MOA, mechanism of action; NA, not applicable; UC, ulcerative colitis; UCDAI, Ulcerative Colitis Disease Activity Index.
Truyers C, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. Sa1520. Full prescribing information: www.swissmedicinfo-pro.ch/.

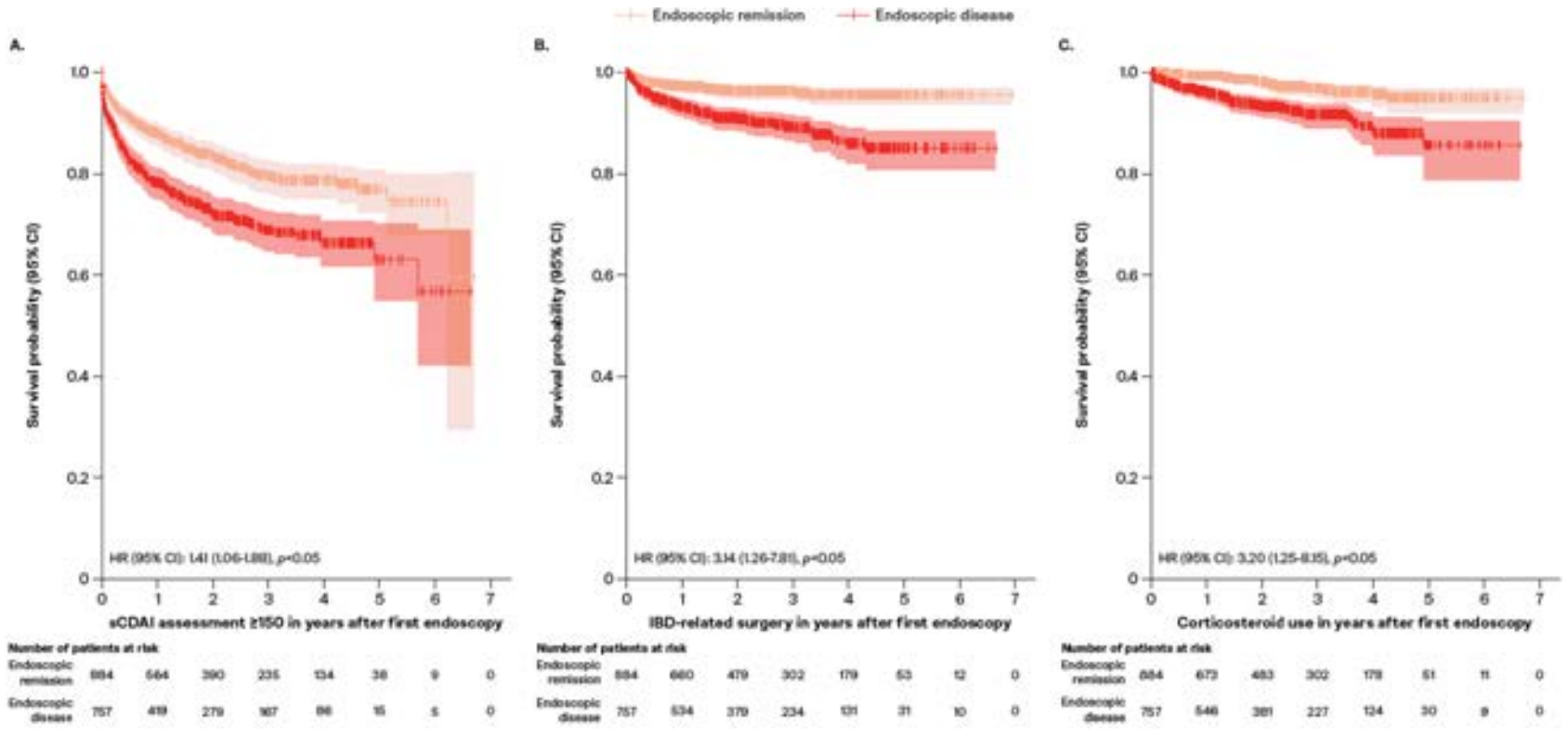
Long-term clinical outcomes, IBD-related surgery, and corticosteroid use in patients with Crohn's disease in endoscopic remission: a retrospective cohort analysis from the Crohn's & Colitis Foundation database

Carla Truyers,[1] Dominik Naessens,[1] Myrlene Sanon,[2] Elise Wu,[2] Jackie Kwong,[3] Shashi Adsul[2]

[1]Johnson & Johnson, Beerse, Belgium; [2]Johnson & Johnson, Horsham, PA, USA; [3]Johnson & Johnson, Raritan, NJ, USA

Aim: To evaluate whether achieving endoscopic remission is associated with future clinical disease activity, as measured by the short CDAI (sCDAI), IBD-related surgery and corticosteroid use in patients with CD

Time to (A) first sCDAI score ≥150, (B) first IBD-related surgery and (C) corticosteroid use (multivariate analysis)



- Compared with patients in endoscopic remission, those without endoscopic remission experienced earlier and more frequent events during follow-up, including clinically active disease (sCDAI ≥150; p<0.05), IBD-related surgery (p<0.05) and corticosteroid use after adjustment for prior corticosteroid use (p<0.05)
- After controlling for pre-index sCDAI scores, repeated-measures analysis confirmed that patients with endoscopic remission had significantly lower sCDAI scores over time compared with those without endoscopic remission (13.3-point difference; p<0.01)

Conclusions

- In this retrospective cohort study, endoscopic remission in CD was associated with a lower likelihood of clinically active disease, IBD-related surgery, and corticosteroid use, as well as lower subsequent sCDAI scores compared with no endoscopic remission
- These findings show a statistically significant association between endoscopic remission and improved long-term outcomes, including subsequent clinical disease activity and fewer patient-relevant events, which supports endoscopic remission as an important therapeutic target in CD

Endoscopic remission: SES-CD ≤2. **Endoscopic disease:** SES-CD >2.
Retrospective cohort study using the Crohn's & Colitis Foundation IBD Plexus database (data collected between November 2016 and June 2024). Data were primarily pooled from the electronic health records of patients diagnosed with IBD across
17 academic medical centres in the United States. Adults (≥18 years of age) with CD, ≥1 SES-CD assessment and biologic use on or before the index SES-CD assessment were included.
CD, Crohn's disease; CI, confidence interval; HR, hazard ratio; IBD, inflammatory bowel disease; MOA, mechanism of action; NA, not applicable; sCDAI, short Crohn's Disease Activity Index; SES-CD, Simple Endoscopic Score for Crohn's Disease.
Truyers C, et al. Presented at DDW, Chicago, IL, USA, 2–5 May 2026. Sa1521. Full prescribing information: www.swissmedicinfo-pro.ch/.

Tremfya® Abbreviated Information for Professionals

TREMFYA® (Guselkumab, human IgG1λ mAb) solution for injection for subcutaneous or intravenous use.
I: Indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis (PsO) who are candidates for systemic therapy, active psoriatic arthritis (PsA) alone or in combination with methotrexate, who have an inadequate response or have been intolerant to prior disease-modifying antirheumatic drug (DMARD) therapy, and for the treatment of moderate to severe active ulcerative colitis (UC) or Crohn's disease (CD) who have an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic treatment. **D:** Administration under the supervision and guidance of a physician experienced in the treatment of these diseases. Self-injection is possible after training. For psoriasis and psoriatic arthritis, the recommended dose is 100 mg as a s.c. injection at week 0 and 4, followed by every 8 weeks (q8w). For ulcerative colitis or Crohn's disease, the induction dose is 200 mg i.v. or alternatively 400 mg s.c. at week 0, 4 and 8, followed by a maintenance dose of 100 mg s.c. from week 16 onwards q8w. Alternatively, a maintenance dose of 200 mg as a s.c. injection every 4 weeks (q4w) may be considered at the physician's discretion from week 12. If there is no response after 12 weeks (UC and CD), 16 weeks (PsO) or 24 weeks (PsA), consider discontinuation of therapy. **CI:** Severe hypersensitivity to active substance/ excipients. Clinically relevant active infections (e.g. active tuberculosis). **VM:** In case of severe infections: monitor the patient closely and discontinue treatment until the infection resolves. No live vaccines during therapy. TB screening before therapy, if necessary, prophylactic treatment for latent TB. Discontinue therapy in case of severe hypersensitivity reactions. **AEs:** Very common: respiratory tract infections; common: herpes simplex infections, tinea infections, gastroenteritis, headache, diarrhea, increased transaminases, arthralgia, injection site reactions, hypersensitivity, urticaria, rashes. See product information for further AEs. **IA:** No clinically relevant interactions observed to date. **Packaging:** solution for injection in pre-filled syringe, pen, or pen - PushPen (100 mg/ 1 ml or 200 mg/ 2 ml); concentrate for solution for infusion in vial (200 mg/ 20 ml). **Tariff category:** B.

Detailed information: www.swissmedic.ch or www.swissmedicinfo-pro.ch/

Marketing Authorization Holder: Janssen-Cilag AG, Gubelstrasse 34, 6300 Zug (CP-564852 02/26)

Ulcerative colitis at 40x magnification