EADV 2025: Data reflow deck

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iMR, iMedical Review; MAF, Medical Affairs.

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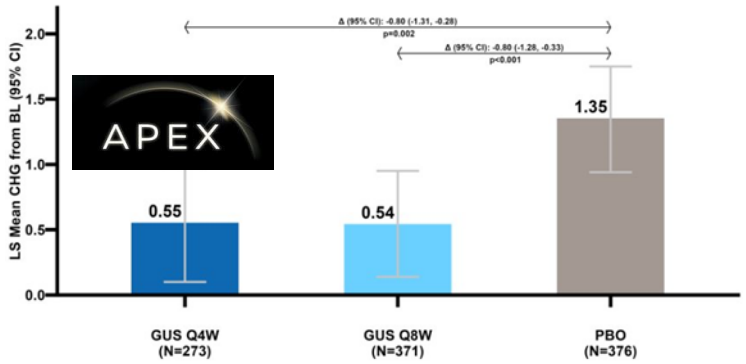
TREMFYA® (guselkumab) psoriatic disease* Core Asset Themes

Raising the bar

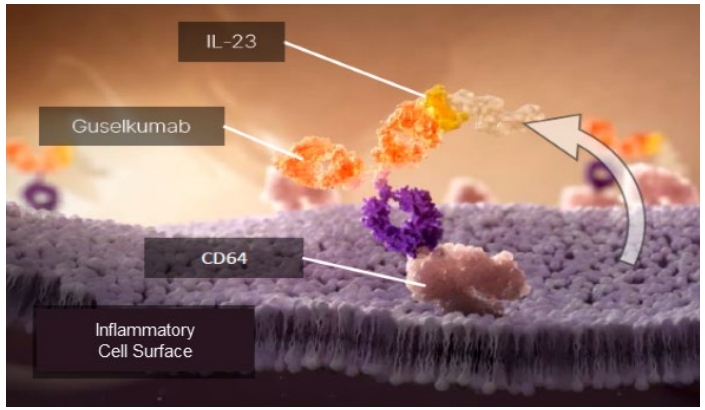


First and only IL-23i with **significant inhibition** of structural damage

Complete skin clearance for broad appropriate patient types: all skin tones, low BSA/moderate PsO and high impact sites, recent onset** and paediatric†

Treatment of PsD without evidence of new-onset ulcerative colitis or Crohn's disease

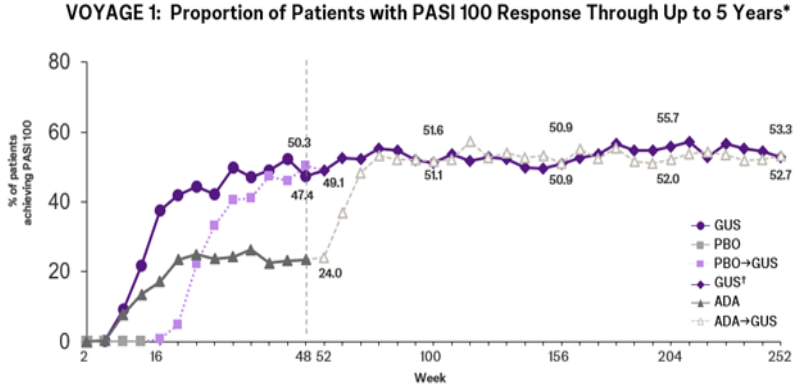
Dual-acting



GUS is structurally and functionally different from other IL-23i's

GUS targets IL-23 by binding to both CD64+ cells and the IL-23 produced by those cells in inflamed tissues

Durability and persistence



Durable **complete skin clearance** through 5 years

Significantly higher real-world **persistence** vs TNF and IL-17A inhibitors in PsO and PsA‡

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*Psoriatic disease is defined as moderate-to-severe plaque psoriasis and active psoriatic arthritis; **Pertains to recent onset of moderate-to-severe plaque psoriasis; †Paediatric approval pending; ‡Real-world evidence from electronic health records.

Contents

PsO, psoriasis; RCT, randomised controlled trial.

Contents

BSA, body surface area; IL, interleukin; PsA, psoriatic arthritis; PsO, psoriasis.

Contents

LB, late-breaker.

Guselkumab in PsO

FC01.1B

Exploring super responders who remained treatment-free for more than 3 years after guselkumab withdrawal: Insights from the Phase 3b GUIDE trial in psoriasis

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J&J Innovative Medicine

Immunology

Background

PsO

- Chronic, immune-driven, relapsing-remitting inflammatory skin disease[1,2]
- Primarily driven by dysregulation of the IL-23/ IL-17 axis[1,3]

GUS

- Fully human mAb that selectively inhibits the IL-23p19 subunit[1]
- Proven efficacy in patients with moderate-to-severe plaque PsO[1,4–7]
- Approved to treat moderate-to-severe PsO, active PsA and moderately-to-severely active ulcerative colitis and Crohn's disease[1,8]

GUIDE study

- Prospective Phase IIIb RCT investigating early intervention with GUS for disease modification in patients with PsO[1]

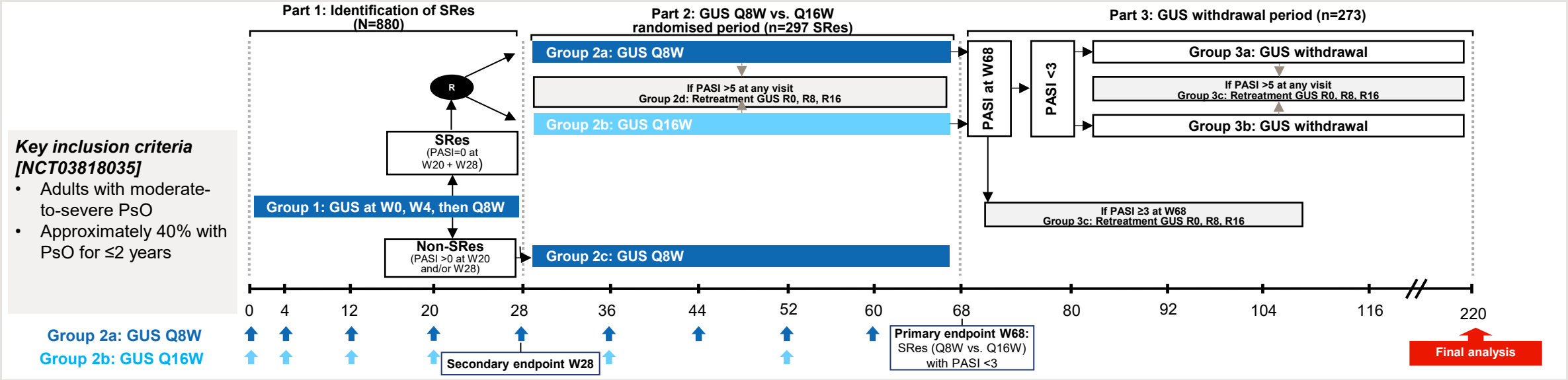
GUS, guselkumab, IL, interleukin; mAb, monoclonal antibody; MOA, mode of action; PsA, psoriatic arthritis; PsO, psoriasis; RCT, randomised controlled trial; SDD, short disease duration.

1. Schäkel K, et al. Presented at EADV, Paris, France, 17–20th September 2025. Oral presentation FC01.1B; 2. Siemińska I, et al. *Clin Rev Allergy Immunol* 2024;66:164–191; 3. Menter A, et al. *Dermatol Ther (Heidelb)* 2021;11:385–400; 4. Blauvelt A, et al. *J Am Acad Dermatol* 2017;76:405–417; 5. Reich K, et al. *J Am Acad Dermatol* 2017;76:418–431; 6. Langley RG, et al. *Br J Dermatol* 2018;178:114–23; 7. Reich K, et al. *Lancet* 2019;394:831–839; 8. Tremfya® (guselkumab). SmPC May 2025.

Guselkumab dosage q16w is not approved by Swissmedic

GUIDE study design – Parts 1, 2 and 3

GUIDE study design[1]



Phase IIIb randomised, placebo-controlled, double-blind, parallel-group, multicentre study of adults with moderate-to-severe plaque PsO[1]

GUIDE part 1: Identification of SRes[2]

- Early treatment with GUS (≤2 years from symptom onset) increased the likelihood of becoming an SRe[3]

GUIDE part 2: Disease control with an extended dosing interval for SRes[2]

- Primary endpoint was met:
  - Non-inferiority of GUS dosed Q16W vs. Q8W in SRes for maintenance of disease control (PASI <3) at W68 was demonstrated[4]

Objectives of GUIDE Part 3 W220 analysis

- To determine how long patients can sustain disease control after GUS withdrawal
- To identify SRes who maintained response for >3 years after the last GUS dose
- To assess if disease duration has an impact on remaining treatment-free

GUS, guselkumab; IL, interleukin; ITT, intention-to-treat; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; Q8W, every 8 weeks; Q16W, every 16 weeks; R, randomisation; RCT, randomised controlled trial; SRe, super responder; W, week. 1. Schäkel K, et al. Presented at EADV, Paris, France, 17–20th September 2025. Oral presentation FC01.1B; 2. Eyerich K *et al. BMJ Open* 2021;11:e049822; 3. Schäkel K *et al. J Eur Acad Dermatol Venereol* 2023;37:2016–2027; 4. Eyerich K *et al. JAMA Dermatol* 2024;e242463.

SRes remaining treatment-free through 3 years tended to have a shorter disease duration and had not received prior systemic therapies

Baseline characteristics of SRes entering GUS withdrawal in GUIDE Part 3

Baseline characteristics		SRes remaining treatment-free until W220 (n=13)	SRes initiating re-treatment prior to W220 (n=260)
Demographics			
	Mean age, yrs (SD)	42.4 (12.4)	39.6 (14.1)
	Male, n (%)	9 (69.2)	178 (68.5)
	Female, n (%)	4 (30.8)	82 (31.5)
	Mean BMI, kg/m^2 (SD)	26.1 (4.7)	27.0 (5.2)
Disease characteristics			
	Mean PsO duration, years (SD)	2.0 (4.7)	10.6 (12.8)
	LDD (>2 yrs), n (%)	1 (7.7)	134 (51.5)
	SDD (≤2 yrs), n (%)	12 (92.3)	126 (48.5)
	USDD (<15 mo), n (%)	11 (84.6)	56 (21.5)
	ISDD (≥15–≤24 mo), n (%)	1 (7.7)	70 (26.9)
	Mean BSA with PsO, % (SD)	19.1 (11.6)	25.2 (15.4)
	Mean PASI (0–72) (SD)	14.6 (3.6)	18.9 (7.5)
Hierarchical prior PsO medication*			
	Topical therapy, n (%)	9 (69.2)	85 (32.7)
	Phototherapy†, n (%)	2 (15.4)	50 (19.2)
	Non-biologic systemic therapy‡ , n (%)	0 (0)	100 (38.5)
	Biologic therapy,** n (%)	0 (0)	21 (8.1)
GUS dosing in part 2: Q8W/Q16W, %		53.8/46.2	48.9/51.2

Counts per most advanced therapy regimen; †PUVA, UVB, UVA or photosol; ‡Methotrexate, cyclosporine, fumaric acid esters, acitretin, apremilast, tofacitinib, oral steroids and other; **Infliximab, etanercept, adalimumab, efalizumab, ustekinumab, secukinumab, ixekizumab, brodalumab, certolizumab and other.

BMI, body mass index; BSA, body surface area; GUS, guselkumab; IL, interleukin; ISDD, intermediate-short disease duration; LDD, long disease duration; mo, months; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; PUVA, psoralen + ultraviolet A; Q8W, every 8 weeks; Q16W, every 16 weeks; RCT, randomised controlled trial; SD, standard deviation; SDD, short disease duration; SRe, super responder; USDD, ultra-short disease duration; UV, ultraviolet; W, week; yrs, years. Schäkel K, et al. Presented at EADV, Paris, France, 17–20th September 2025. Oral presentation FC01.1B.

Following GUS withdrawal, 11 out of 13 SRes remaining treatment-free through 3 years had <15 months PsO duration (USDD)

Baseline characteristics of SRes who remained treatment-free in GUIDE Part 3

		Patient												
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**
Demographics														
	**Age,** yrs	37	19	50	51	26	55	41	34	43	58	58	31	48
	Sex	Male	Male	Female	Male	Male	Female	Male	Male	Male	Male	Male	Female	Female
	BMI, kg/m^2	29.1	20.5	26.5	30.3	22.2	22.6	22.6	30	24.8	36.2	30.1	20.9	24.1
Disease characteristics														
	**PsO duration**, yrs	17.6	1.4	1.2	0.3	0.8	1.2	1.1	0.4	0.8	0.2	0.4	0.5	0.7
	PsO duration category	LDD	ISDD	USDD										
	PASI (0–72)	12.8	13.8	13	18.6	11.8	16.2	13.8	22.4	12.6	12.8	19.6	11.5	10.6
	DLQI (0–30)	22	21	28	21	15	12	27	24	13	24	23	11	12
Prior PsO medication use														
	**PsO therapy**	Topical + PUVA	Topical + UVB	Only topical										No therapy
	Biologic therapy	Biologic naïve												
GUS dosing in part 2		Q16W	Q8W							Q16W				

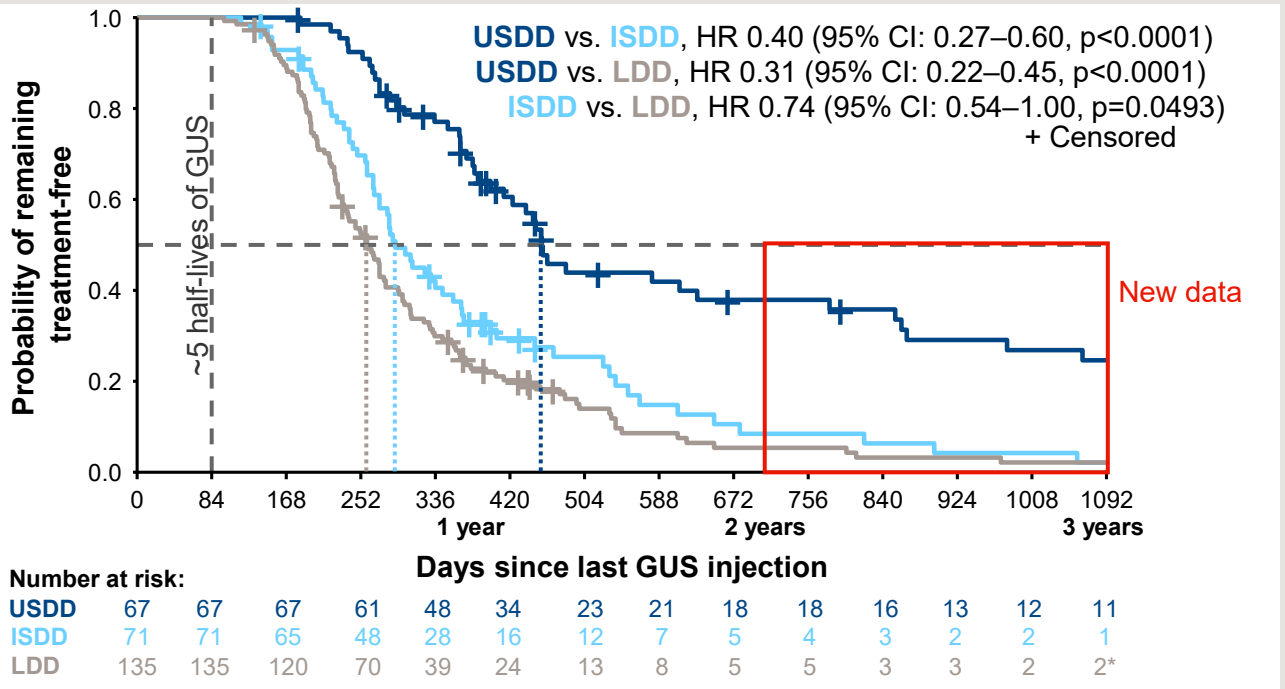
BMI, body mass index; DLQI, Dermatology Life Quality Index; GUS, guselkumab; IL, interleukin; ISDD, intermediate-short disease duration; LDD, long disease duration; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; PUVA, psoralen + ultraviolet A; Q8W, every 8 weeks; Q16W, every 16 weeks; RCT, randomised controlled trial; SRe, super responder; USDD, ultra-short disease duration; UV, ultraviolet; W, week; yrs, years.

Schäkel K, et al. Presented at EADV, Paris, France, 17–20th September 2025. Oral presentation FC01.1B.

Guselkumab dosage q16w is not approved by Swissmedic

SRes with USDD (<15 months) had the highest likelihood of remaining treatment-free through 3 years following GUS withdrawal

Probability of SRes with USDD, ISDD and LDD remaining treatment-free after GUS withdrawal



Treatment-free duration by PsO disease duration category

PsO disease duration category	Months
USDD	<15
ISDD	≥15–≤24
LDD	>24

Median treatment-free duration

Overall population: **302** days

Patients with **USDD**: **456** days

Patients with **ISDD**: **291** days

Patients with **LDD**: **259** days

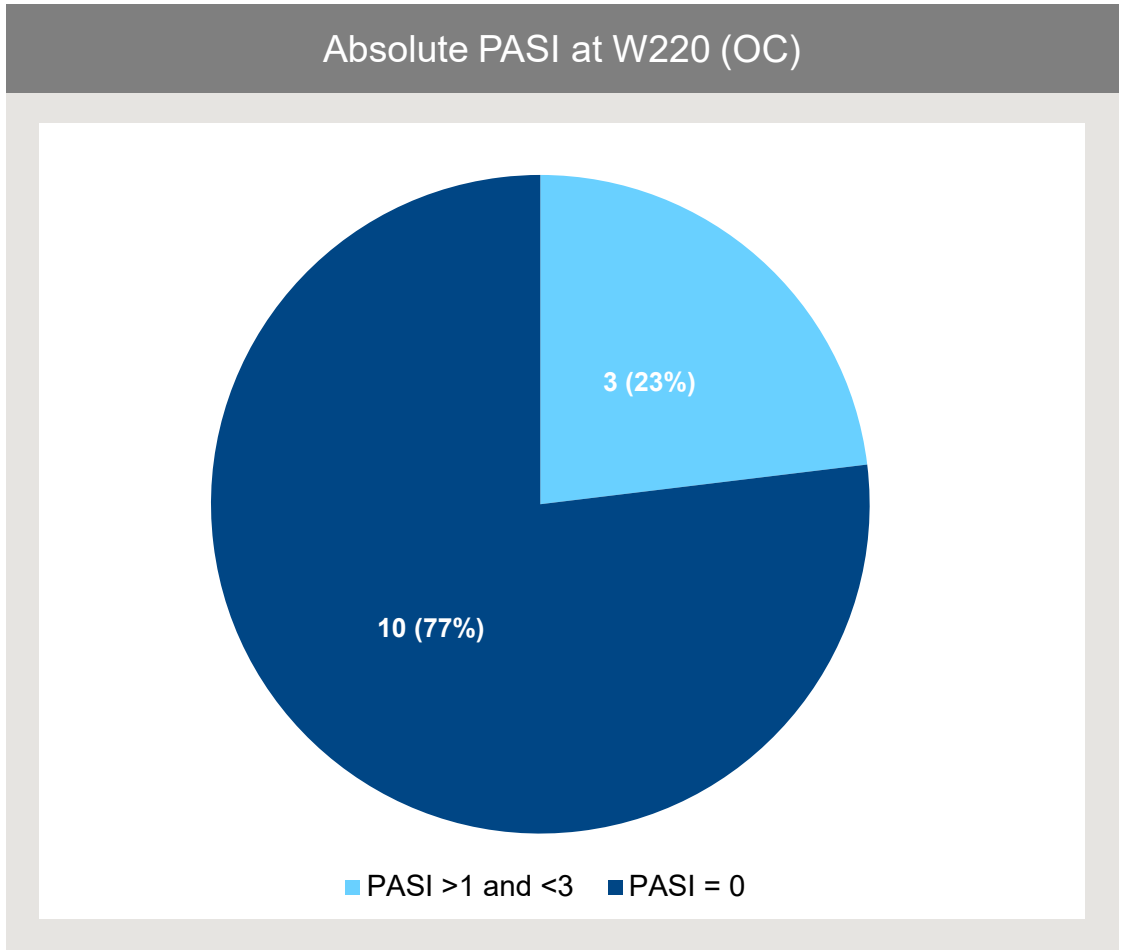
USDD vs. **ISDD**: **↑ 165 days (+57%)**

USDD vs. **LDD**: **↑ 197 days (+76%)**

Overall, 13 SRes remained treatment-free for >3 years following GUS withdrawal

p-values are nominal. Loss of maintenance of response was defined as PASI >5, at which point treatment was re-initiated. *One patient with maintenance of disease control for >3 years experienced loss of disease control at W212 prior to W220.
CI, confidence interval; GUS, guselkumab; HR, hazard ratio; IL, interleukin; ISDD, intermediate-short disease duration; LDD, long disease duration; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; RCT, randomised controlled trial; SRe, super responder; USDD, ultra-short disease duration; W, week.
Schäkel K, et al. Presented at EADV, Paris, France, 17–20th September 2025. Oral presentation FC01.1B.

Following withdrawal from GUS, 13 SRes who remained treatment-free for >3 years had high PASI response rates at W220*



At W220:

- All SRes reached disease control (defined as PASI <3)
- Complete skin clearance (defined as PASI=0) was attained by 10 of 13 SRes

*W220 corresponds to >3 years without GUS treatment, with the last injection at W52 or 60, for patients who received GUS Q16W and Q8W, respectively, during part 2 of GUIDE.
GUS, guselkumab; IL, interleukin; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; Q8W, every 8 weeks; Q16W, every 16 weeks; RCT, randomised controlled trial; SRe, super responder; W, week.
Schäkel K, et al. Presented at EADV, Paris, France, 17–20th September 2025. Oral presentation FC01.1B.

The 13 SRes who remained treatment-free for >3 years maintained overall low PASI scores following GUS withdrawal

Absolute PASI scores over time

Patient	PsO disease duration	Part 1: GUS Q8W						Part 2: GUS Q8W vs. Q16W					Part 3: GUS withdrawal											
		W0	W4	W12	W16	W20	W28	W36	W44	W52	W60	W68	W80	W92	W104	W116	W128	W140	W152	W164	W176	W188	W200	W212	W220
1	LDD	12.8	2.4	0.1	0.1	0	0	0	0	1.2	0	0.6	0	0.6	2.4	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.8	2.6	2.7
8	USDD	22.4	10.4	2.9	1.6	0	0	0	0	0	0	0	0.3	1.8	0	0.8	2	0.6	0.4	0	0.8	2.4	-*	1.6	1.6
13	USDD	10.6	4.6	0	0	0	0	0	0	0	0	0	0	0	0	0	3.3	0.8	0.3	0.1	0.1	0.1	0.1	0.1	1.2
2	ISDD	13.8	7.8	0	0	0	0	0	0	0	0	0	0	0	0.2	0	0	0	0	0	0	0	0	0	0
5	USDD	11.8	9.8	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.6	0	0	0	0	0
6	USDD	16.2	4.7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.2	0	0	0	0
7	USDD	13.8	13.4	7.7	1.7	0	0	0	0	0	0	0	0	1.2	0	0.8	0	0	0	0	0.8	0.4	0	0	0
9	USDD	12.6	3.9	1	0.3	0	0	0	0	0	0	0	1.6	0	0	0.4	0	0	0	0	0	0	0	0	0
10	USDD	12.8	12.8	2	0	0	0	0	0.2	0.1	0.2	0.2	0	0.1	0	0.8	0.1	0	0	0	-*	0	0	0	0
11	USDD	19.6	1.2	1.2	0	0	0	0	0.6	0.6	0	0	4.8	0.6	0	0	0	0	0	0	0	0.6	0	0	0
12	USDD	11.5	0	0	0	0	0	0	0	0	0	0	0	0	1.6	0	0	0	0	0	0	0.6	0.2	0	0
3	USDD	13	10	3.6	2.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	USDD	18.6	2.4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Complete skin clearance was observed in 71% of all PASI assessments

*Visit was remote. Red: PASI ≥10, yellow: PASI ≥3–<10, light green: PASI >0–<3, dark green: PASI=0.
GUS, guselkumab; IL, interleukin; ISDD, intermediate-short disease duration; LDD, long disease duration; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; Q16W, every 16 weeks; Q8W, every 8 weeks; RCT, randomised controlled trial; SRe, super responder; USDD, ultra-short disease duration; W, week.
Schäkel K, et al. Presented at EADV, Paris, France, 17–20th September 2025. Oral presentation FC01.1B.

Following GUS withdrawal, three SRes maintained low PASI scores with minor fluctuations, showing no consistent increase over time

Absolute PASI scores over time

Patient	PsO disease duration	Part 1: GUS Q8W						Part 2: GUS Q8W vs. Q16W					Part 3: GUS withdrawal											
		W0	W4	W12	W16	W20	W28	W36	W44	W52	W60	W68	W80	W92	W104	W116	W128	W140	W152	W164	W176	W188	W200	W212	W220
1	LDD	12.8	2.4	0.1	0.1	0	0	0	0	1.2	0	0.6	0	0.6	2.4	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.8	2.6	2.7
8	USDD	22.4	10.4	2.9	1.6	0	0	0	0	0	0	0	0.3	1.8	0	0.8	2	0.6	0.4	0	0.8	2.4	-*	1.6	1.6
13	USDD	10.6	4.6	0	0	0	0	0	0	0	0	0	0	0	0	0	3.3	0.8	0.3	0.1	0.1	0.1	0.1	0.1	1.2
2	ISDD	13.8	7.8	0	0	0	0	0	0	0	0	0	0	0	0.2	0	0	0	0	0	0	0	0	0	0
5	USDD	11.8	9.8	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.6	0	0	0	0	0
6	USDD	16.2	4.7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.2	0	0	0	0
7	USDD	13.8	13.4	7.7	1.7	0	0	0	0	0	0	0	0	1.2	0	0.8	0	0	0	0	0.8	0.4	0	0	0
9	USDD	12.6	3.9	1	0.3	0	0	0	0	0	0	0	1.6	0	0	0.4	0	0	0	0	0	0	0	0	0
10	USDD	12.8	12.8	2	0	0	0	0	0.2	0.1	0.2	0.2	0	0.1	0	0.8	0.1	0	0	0	-*	0	0	0	0
11	USDD	19.6	1.2	1.2	0	0	0	0	0.6	0.6	0	0	4.8	0.6	0	0	0	0	0	0	0	0.6	0	0	0
12	USDD	11.5	0	0	0	0	0	0	0	0	0	0	0	0	1.6	0	0	0	0	0	0	0.6	0.2	0	0
3	USDD	13	10	3.6	2.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	USDD	18.6	2.4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

*Visit was remote. Red: PASI ≥10, yellow: PASI ≥3–<10, light green: PASI >0–<3, dark green: PASI=0.
GUS, guselkumab; IL, interleukin; ISDD, intermediate-short disease duration; LDD, long disease duration; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; Q16W, every 16 weeks; Q8W, every 8 weeks; RCT, randomised controlled trial; SRe, super responder; USDD, ultra-short disease duration; W, week.
Schäkel K, et al. Presented at EADV, Paris, France, 17–20th September 2025. Oral presentation FC01.1B.

A total of eight SRes experienced isolated increases in PASI scores, re-achieving PASI=0 at follow-up visits without the need for re-treatment

Absolute PASI scores over time

Patient	PsO disease duration	Part 1: GUS Q8W						Part 2: GUS Q8W vs. Q16W					Part 3: GUS withdrawal											
		W0	W4	W12	W16	W20	W28	W36	W44	W52	W60	W68	W80	W92	W104	W116	W128	W140	W152	W164	W176	W188	W200	W212	W220
1	LDD	12.8	2.4	0.1	0.1	0	0	0	0	1.2	0	0.6	0	0.6	2.4	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.8	2.6	2.7
8	USDD	22.4	10.4	2.9	1.6	0	0	0	0	0	0	0	0.3	1.8	0	0.8	2	0.6	0.4	0	0.8	2.4	-*	1.6	1.6
13	USDD	10.6	4.6	0	0	0	0	0	0	0	0	0	0	0	0	0	3.3	0.8	0.3	0.1	0.1	0.1	0.1	0.1	1.2
2	ISDD	13.8	7.8	0	0	0	0	0	0	0	0	0	0	0	0.2	0	0	0	0	0	0	0	0	0	0
5	USDD	11.8	9.8	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.6	0	0	0	0	0
6	USDD	16.2	4.7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.2	0	0	0	0
7	USDD	13.8	13.4	7.7	1.7	0	0	0	0	0	0	0	0	1.2	0	0.8	0	0	0	0	0.8	0.4	0	0	0
9	USDD	12.6	3.9	1	0.3	0	0	0	0	0	0	0	1.6	0	0	0.4	0	0	0	0	0	0	0	0	0
10	USDD	12.8	12.8	2	0	0	0	0	0.2	0.1	0.2	0.2	0	0.1	0	0.8	0.1	0	0	0	-*	0	0	0	0
11	USDD	19.6	1.2	1.2	0	0	0	0	0.6	0.6	0	0	4.8	0.6	0	0	0	0	0	0	0	0.6	0	0	0
12	USDD	11.5	0	0	0	0	0	0	0	0	0	0	0	0	1.6	0	0	0	0	0	0	0.6	0.2	0	0
3	USDD	13	10	3.6	2.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	USDD	18.6	2.4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

*Visit was remote. Red: PASI ≥10, yellow: PASI ≥3–<10, light green: PASI >0–<3, dark green: PASI=0.
GUS, guselkumab; IL, interleukin; ISDD, intermediate-short disease duration; LDD, long disease duration; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; Q16W, every 16 weeks; Q8W, every 8 weeks; RCT, randomised controlled trial; SRe, super responder; USDD, ultra-short disease duration; W, week.
Schäkel K, et al. Presented at EADV, Paris, France, 17–20th September 2025. Oral presentation FC01.1B.

Following GUS withdrawal, two SRes, both with USDD (<15 months), reached complete skin clearance at all visits for >3 years

Absolute PASI scores over time

Patient	PsO disease duration	Part 1: GUS Q8W						Part 2: GUS Q8W vs. Q16W					Part 3: GUS withdrawal											
		W0	W4	W12	W16	W20	W28	W36	W44	W52	W60	W68	W80	W92	W104	W116	W128	W140	W152	W164	W176	W188	W200	W212	W220
1	LDD	12.8	2.4	0.1	0.1	0	0	0	0	1.2	0	0.6	0	0.6	2.4	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.8	2.6	2.7
8	USDD	22.4	10.4	2.9	1.6	0	0	0	0	0	0	0	0.3	1.8	0	0.8	2	0.6	0.4	0	0.8	2.4	-*	1.6	1.6
13	USDD	10.6	4.6	0	0	0	0	0	0	0	0	0	0	0	0	0	3.3	0.8	0.3	0.1	0.1	0.1	0.1	0.1	1.2
2	ISDD	13.8	7.8	0	0	0	0	0	0	0	0	0	0	0	0.2	0	0	0	0	0	0	0	0	0	0
5	USDD	11.8	9.8	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.6	0	0	0	0	0
6	USDD	16.2	4.7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.2	0	0	0	0
7	USDD	13.8	13.4	7.7	1.7	0	0	0	0	0	0	0	0	1.2	0	0.8	0	0	0	0	0.8	0.4	0	0	0
9	USDD	12.6	3.9	1	0.3	0	0	0	0	0	0	0	1.6	0	0	0.4	0	0	0	0	0	0	0	0	0
10	USDD	12.8	12.8	2	0	0	0	0	0.2	0.1	0.2	0.2	0	0.1	0	0.8	0.1	0	0	0	-*	0	0	0	0
11	USDD	19.6	1.2	1.2	0	0	0	0	0.6	0.6	0	0	4.8	0.6	0	0	0	0	0	0	0	0.6	0	0	0
12	USDD	11.5	0	0	0	0	0	0	0	0	0	0	0	0	1.6	0	0	0	0	0	0	0.6	0.2	0	0
3	USDD	**13**	**10**	**3.6**	**2.6**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
4	USDD	**18.6**	**2.4**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

Both patients achieved complete skin clearance as of W20 with GUS Q8W in part 1 of the study

Red: PASI ≥10, yellow: PASI ≥3–<10, light green: PASI >0–<3, dark green: PASI=0.
GUS, guselkumab; IL, interleukin; ISDD, intermediate-short disease duration; LDD, long disease duration; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; Q16W, every 16 weeks; Q8W, every 8 weeks; RCT, randomised controlled trial; SRe, super responder; USDD, ultra-short disease duration; W, week.
Schäkel K, et al. Presented at EADV, Paris, France, 17–20th September 2025. Oral presentation FC01.1B.

Conclusions

GUIDE is the **first prospective large scale RCT to identify and characterize** patients with moderate-to-severe PsO who **maintained disease control for >3 years** after PsO treatment withdrawal[1]

- Overall, **13 SRes maintained disease control for >3 years after GUS withdrawal**, with substantially lower disease activity throughout the withdrawal period than before GUS treatment was initiated[1]

- SRes initiating **GUS within 15 months of disease onset** had a significantly **higher likelihood of remaining treatment-free** compared to those with longer disease duration[1]
  - 11 of 13 SRes who maintained treatment-free status had USDD[1]
  - 2 SRes both with USDD achieved complete skin clearance at all visits for >3 years[1]
  - ~1 in 6 SRes with USDD who initiated withdrawal, maintained treatment-free status for >3 years[1]

- Overall, PASI scores remained low during withdrawal, with a **majority of all assessments showing complete skin clearance**[1]

Together with previous biomarker data[2–4], these findings suggest that **GUS may have disease-modifying properties in a subset of patients**, particularly those initiating treatment early in the disease course
The potential for disease modification with GUS treatment should be further explored[1]

GUS, guselkumab; IL, interleukin; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; RCT, randomised controlled trial; SRe, super responder; USDD, ultra-short disease duration.

1. Schäkel K, et al. Presented at EADV, Paris, France, 17–20th September 2025. Oral presentation FC01.1B; 2. Eyerich K, *et al. JAMA Dermatol* 2024;e242463;
3. Chen Y, *et al.* Poster presentation at: ISDS Congress; 15–18 November 2023; Vienna, Austria. Presentation 186; 4. Angsana J, *et al.* Oral presentation at: ISID Congress; 10–13 May 2023; Tokyo, Japan. Presentation 587.

FC02.1F

Early intervention with guselkumab is associated with greater efficacy and higher rates of complete skin clearance independent of super responder status: The Phase 3b GUIDE trial in psoriasis

A. Pinter[1], K. Eyerich[2], K. Schäkel[3], B. Schwarz[4], R. von Kiedrowski[5], F. Lauffer[6], P. Weisenseel[7], C. Paul[8], J. Makuc[9], K. Henry[10], F. Kreimendahl[9], N. Krüger[9], N. Spindler[9], K. Asadullah[11,12]

[1]University Hospital Frankfurt am Main, Frankfurt, Germany; [2]Department of Dermatology and Venereology, Medical Center, University of Freiburg, Freiburg, Germany; [3]Department of Dermatology, and Interdisciplinary Center for Inflammatory Diseases, Heidelberg University Hospital, Heidelberg, Germany; [4]Practice for Dermatology/Allergology/Study Center Dr. med. Beate Schwarz, Langenau, Germany; [5]Dermatological Practice Selters; Company for Medical Study & Service Selters GmbH, Selters, Germany; [6]Department of Dermatology, Ludwig-Maximilians University Hospital, Munich, Germany; [7]Dermatologikum Hamburg, Hamburg, Germany; [8]Toulouse University, Toulouse, France; [9]Janssen-Cilag GmbH, A Johnson & Johnson Company, Neuss, Germany; [10]Johnson & Johnson Innovative Medicine, Cambridge, MA, United States; [11]Department of Dermatology, Venereology and Allergology, Charité – Universitätsmedizin, Berlin, Germany; [12]Dermatology Potsdam MVZ, Potsdam, Germany.

J&J Innovative Medicine

Immunology

Background

PsO

- Chronic, immune-driven, relapsing-remitting inflammatory skin disease[1,2]
- Primarily driven by dysregulation of the IL-23/ IL-17 axis[1,3]
- Despite effective therapy options, patients with PsO often start appropriate treatment later in their disease course[1,4]

GUS

- Fully human mAb that selectively inhibits the IL-23p19 subunit[1]
- Proven efficacy in patients with moderate-to-severe plaque PsO[1,5–8]
- Approved to treat moderate-to-severe PsO, active PsA and moderately-to-severely active ulcerative colitis and Crohn's disease[1,9]

GUIDE study

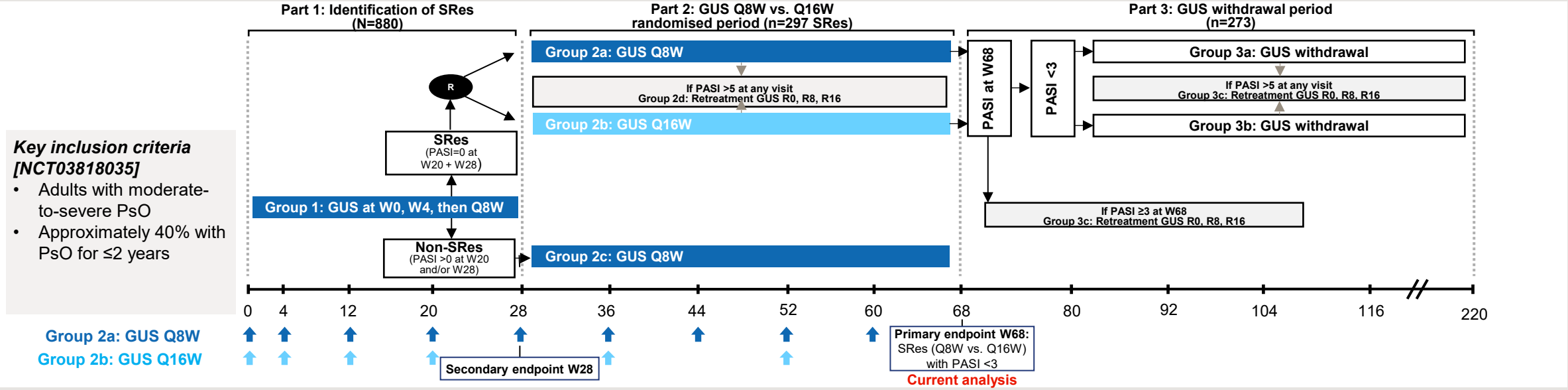
- Prospective, Phase IIIb RCT investigating early intervention with GUS in patients with moderate-to-severe PsO[1]
- Among the 880 enrolled patients, 40.6% had short disease duration (SDD, defined as ≤24 months)[1]

GUS, guselkumab, IL, interleukin; mAb, monoclonal antibody; MOA, mode of action; PsA, psoriatic arthritis; PsO, psoriasis; RCT, randomised controlled trial; SDD, short disease duration.

1. Pinter A, et al. Presented at EADV, Paris, France, 17–20th September 2025. FC02.1F; 2. Siemińska I, et al. *Clin Rev Allergy Immunol* 2024;66:164–191; 3. Menter A, et al. *Dermatol Ther (Heidelb)* 2021;11:385–400; 4. Heidbrede T, et al. *J Dtsch Dermatol Ges* 2023;21:611–619; 5. Blauvelt A, et al. *J Am Acad Dermatol* 2017;76:405–417; 6. Reich K, et al. *J Am Acad Dermatol* 2017;76:418–431; 7. Langley RG, et al. *Br J Dermatol* 2018;178:114–23; 8. Reich K, et al. *Lancet* 2019;394:831–839; 9. Tremfya® (guselkumab). SmPC May 2025.

GUIDE study design – parts 1, 2 and 3

GUIDE study design[1]



GUIDE part 1: Identification of SRes[2]

- Early treatment with GUS (≤2 years from symptom onset) increased the likelihood of becoming an SRe[3]

GUIDE part 2: Disease control with an extended dosing interval for SRes[2]

- Primary endpoint was met:
  - Non-inferiority of GUS dosed Q16W vs. Q8W in SRes for maintenance of disease control (PASI <3) at W68 was demonstrated[4]

Objectives of this analysis:

- To assess the impact of PsO disease duration (≤2 vs. >2 years) on GUS efficacy and safety through W68
- Analysis was performed using observed cases and the intention-to-treat (ITT) set (all p values are nominal)

GUS, guselkumab; IL, interleukin; ITT, intention-to-treat; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; Q8W, every 8 weeks; Q16W, every 16 weeks; R, randomisation; RCT, randomised controlled trial; SRe, super responder; W, week.

1. Pinter A, et al. Presented at EADV, Paris, France, 17–20th September 2025. FC02.1F; 2. Eyerich K *et al. BMJ Open* 2021;11:e049822; 3. Schäkel K *et al. J Eur Acad Dermatol Venereol* 2023;37:2016–2027; 4. Eyerich K *et al. JAMA Dermatol* 2024;e242463.

Disease severity at baseline was similar for patients with SDD (≤2 years) vs. LDD (>2 years)

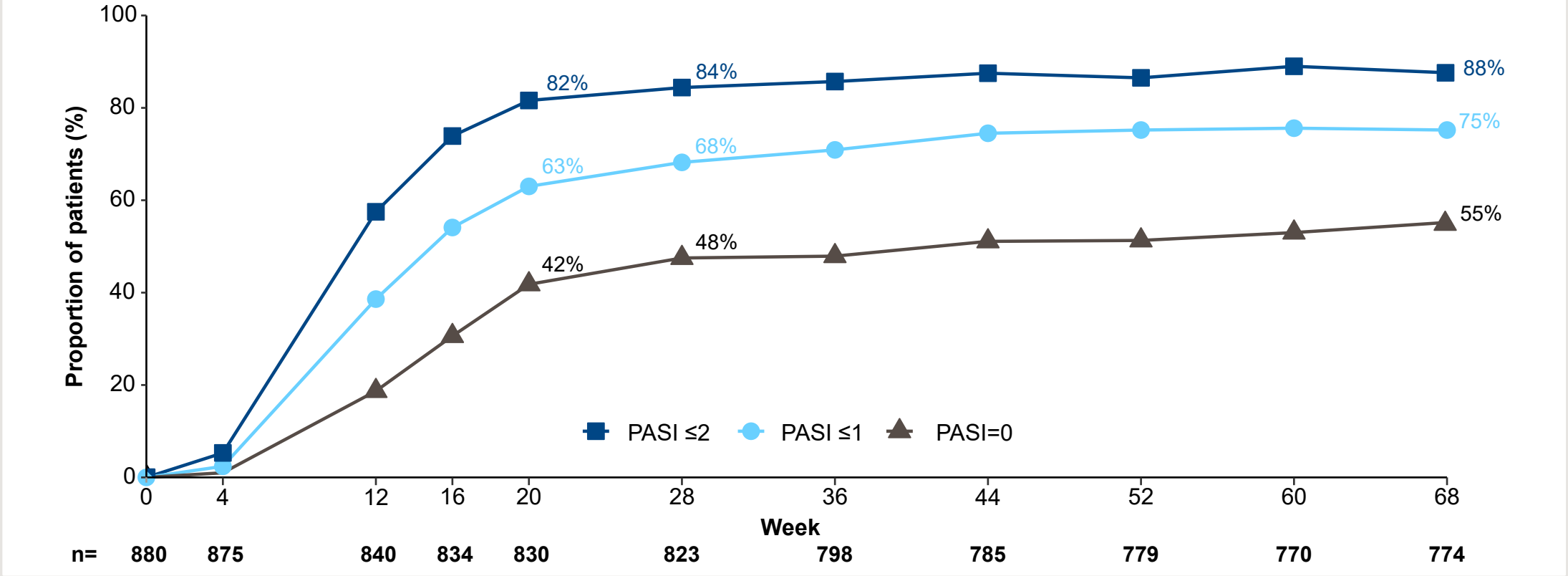
Baseline characteristics of patients enrolled in GUIDE with SDD and LDD

Baseline characteristics	SDD (n=357)	LDD (n=523)	Overall (N=880)
Demographics			
Mean age, yrs (SD)	40.3 (16.0)	44.1 (13.5)	42.5 (14.7)
Female, n (%)	114 (31.9)	146 (27.9)	260 (29.5)
Mean BMI, kg/m^2 (SD)	27.8 (6.0)	28.7 (6.0)	28.3 (6.0)
Disease characteristics			
Mean PsO duration, years (SD)	1.2 (0.6)	20.2 (13.1)	12.5 (13.8)
Mean BSA with PsO, % (SD)	25.8 (15.3)	26.8 (15.0)	26.4 (15.1)
Mean PASI (0–72) (SD)	18.7 (8.1)	19.4 (7.8)	19.1 (7.9)
PsO medication use			
Any prior PsO therapy, n (%)	341 (95.5)	523 (100)	864 (98.2)
Systemic therapy/biologic-naïve, n (%)	269 (75.4)	166 (31.8)	435 (49.4)
Prior systemic/biologic therapy, n (%)	88 (24.6)	357 (68.2)	445 (50.6)
≥1 biologic therapy, n (%)	5 (1.4)	118 (22.6)	123 (14.0)
Proportion of SRes,* n (%)	156 (43.7)	147 (28.1)	303 (34.4)
GUS dosing in part 2			
Q8W, n	75	73	148
Q16W, n	76	73	149

*SRes were randomised to Q8W and Q16W stratified by disease duration.
BMI, body mass index; BSA, body surface area; GUS, guselkumab; IL, interleukin; LDD, long disease duration; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; Q8W, every 8 weeks; Q16W, every 16 weeks; RCT, randomised controlled trial; SD, standard deviation; SDD, short disease duration; SRe, super responder.
Pinter A, et al. Presented at EADV, Paris, France, 17–20th September 2025. FC02.1F.

GUS led to complete skin clearance in >50% of the overall study population at W68

PASI responses in patients receiving GUS through W68

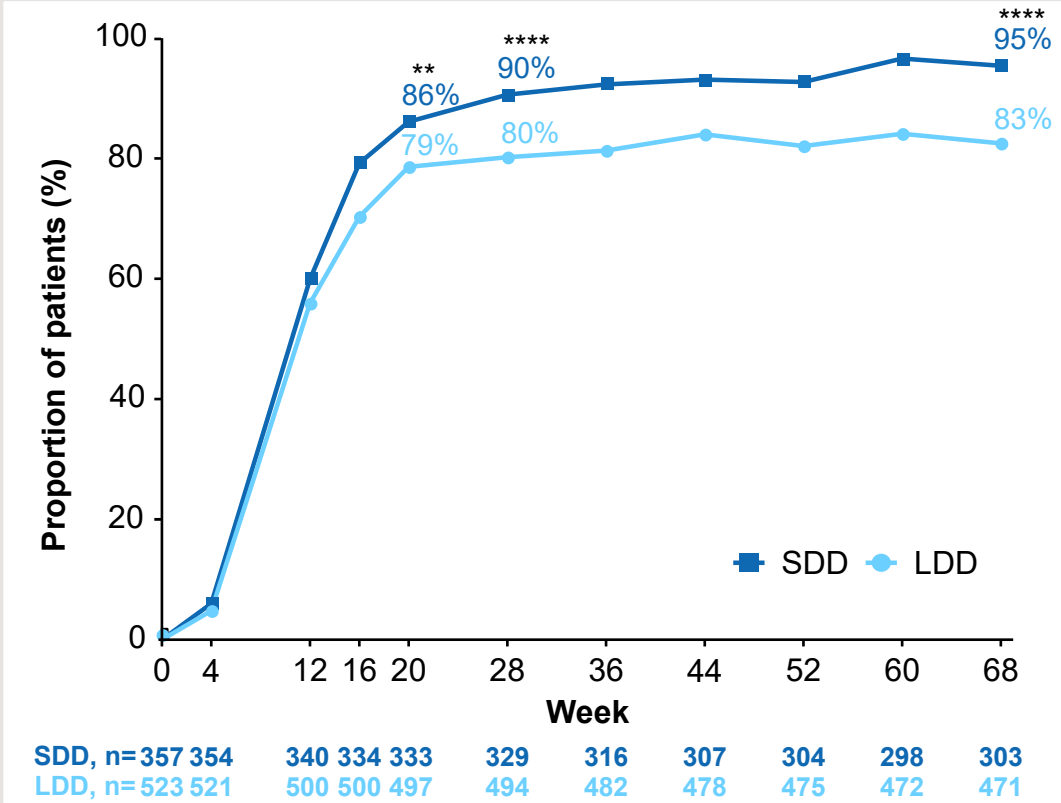


GUS, guselkumab; IL, interleukin; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; RCT, randomised controlled trial; W, week.
Pinter A, et al. Presented at EADV, Paris, France, 17–20th September 2025. FC02.1F.

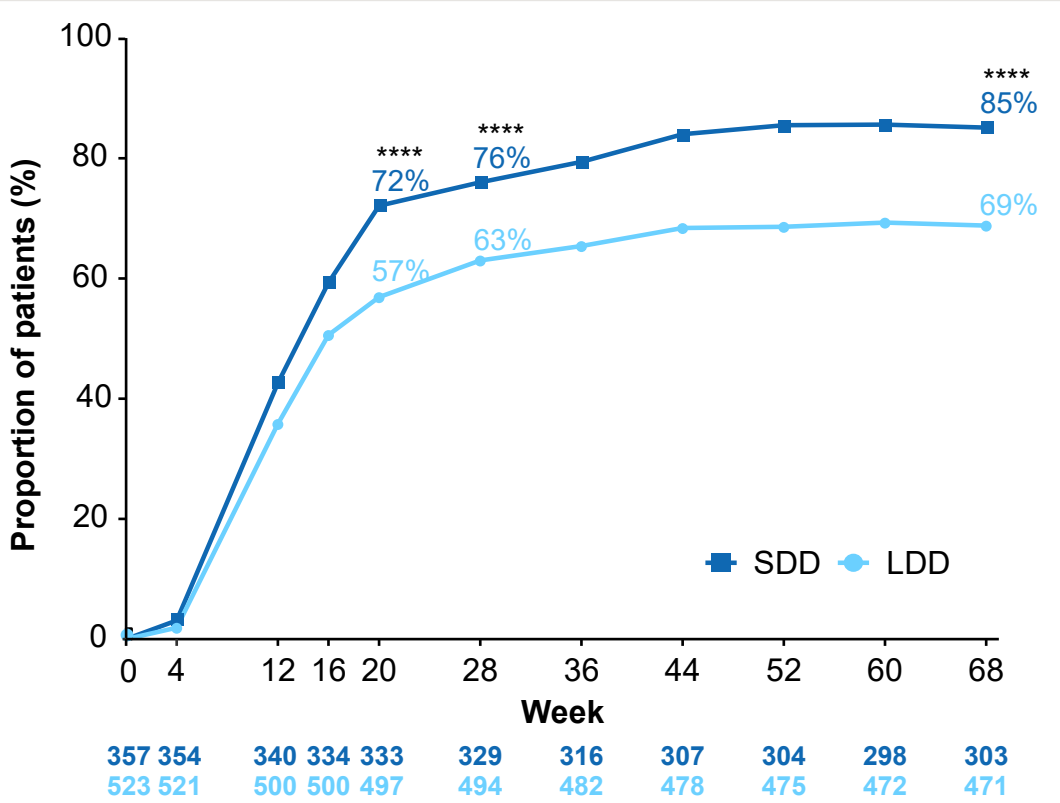
Guselkumab dosage q16w is not approved by Swissmedic

GUS demonstrated higher PASI ≤2 and PASI ≤1 response rates in patients with SDD (≤2 years) vs. LDD (>2 years) through W68

PASI ≤2 response in patients receiving GUS



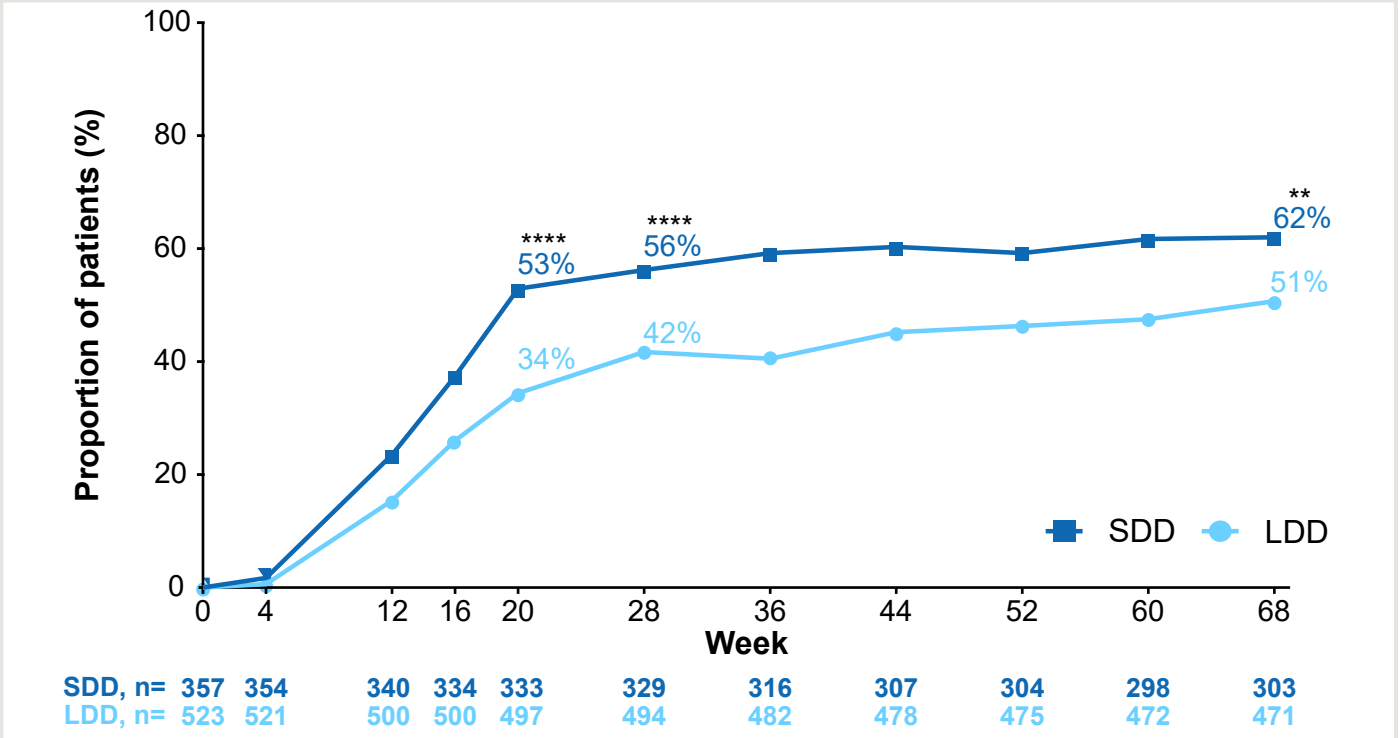
PASI ≤1 response in patients receiving GUS



Nominal **p<0.01, ****p<0.0001 vs. LDD;† †Two-sided, two-group, normal approximation, unadjusted Wald Z test (SDD vs. LDD).
GUS, guselkumab; IL, interleukin; LDD, long disease duration; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; RCT, randomised controlled trial; SDD, short disease duration; W, week.
Pinter A, et al. Presented at EADV, Paris, France, 17–20th September 2025. FC02.1F.

Patients with SDD who received GUS had complete skin clearance earlier and at substantially higher rates vs. patients with LDD through W68

PASI=0 response in patients receiving GUS



- Patients with SDD demonstrated higher rates of complete skin clearance (PASI=0) vs. patients with LDD
- This trend was consistent among both SRes and Non-SRes:

	SRes		Non-SRes	
W68 PASI=0	**SDD**	**LDD**	**SDD**	**LDD**
	83.6%	**75.7%**	**43.6%**	**40.2%**

Patients with SDD were more likely to maintain PASI=0 between W36 and W68 vs. LDD (OR: 1.43 [95% CI: 1.05–1.94])

Nominal **p<0.01, ****p<0.0001 vs. LDD; ††Two-sided, two-group, normal approximation, unadjusted Wald Z test (SDD vs. LDD).
CI, confidence interval; GUS, guselkumab; IL, interleukin; LDD, long disease duration; MOA, mode of action; OR, odds ratio; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; RCT, randomised controlled trial; SDD, short disease duration; W, week.
Pinter A, et al. Presented at EADV, Paris, France, 17–20th September 2025. FC02.1F.

No new safety signals were identified for GUS through Week 68 among patients with SDD (≤2 years) and LDD (>2 years)

Safety profile of GUS through Week 68

Safety through Week 68, n (%)	SDD (n=357)	LDD (n=523)	Overall (N=880)
Patients with TEAEs	310 (86.8)	453 (86.6)	763 (86.7)
Common TEAEs			
Nasopharyngitis	104 (29.1)	188 (35.9)	292 (33.2)
Headache	46 (12.9)	63 (12.0)	109 (12.4)
Hypertension	27 (7.6)	56 (10.7)	83 (9.4)
Arthralgia	20 (5.6)	49 (9.4)	69 (7.8)
Back pain	22 (6.2)	27 (5.2)	49 (5.6)
Death	1 (0.3)*	1 (0.2)†	2 (0.2)
MACE	4 (1.1)‡	2 (0.4)‡	6 (0.7)‡
TEAE of interest	4 (1.1)	2 (0.4)	6 (0.7)
Acute TB or reactivation	0	0	0
Non-melanoma skin cancer**	4 (1.1)	0	4 (0.5)
Transitional cell carcinoma	1 (0.3)	1 (0.2)	2 (0.2)
IBD	0	0	0

*Unknown; †Accidental asphyxiation; ‡Only myocardial infarction was reported; **Includes basal cell carcinoma and squamous cell carcinoma.
GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; LDD, long disease duration; MACE, major adverse cardiac event; MOA, mode of action; PsO, psoriasis; RCT, randomised controlled trial; SDD, short disease duration; TB, tuberculosis; TEAE, treatment-emergent adverse event; W, week.
Pinter A, et al. Presented at EADV, Paris, France, 17–20th September 2025. FC02.1F.

Conclusions

- This *post hoc* analysis of data from the GUIDE study in PsO demonstrated **sustained GUS efficacy in the overall population through W68**
- **Patients with SDD treated with GUS achieved earlier and substantially higher rates of complete skin clearance** compared with those with LDD through W68
- The advantage of SDD was evident for all patients in both the SRe and non-SRe populations, **reinforcing the benefits of early treatment with GUS**

GUS, guselkumab, IL, interleukin; LDD, long disease duration; MOA, mode of action; non-SRe, non-super responder; PsO, psoriasis; RCT, randomised controlled trial; SDD, short disease duration; SRe, super responder; W, week.

Pinter A, et al. Presented at EADV, Paris, France, 17–20th September 2025. FC02.1F.

P2070

Guselkumab shows strong long-term effectiveness and high drug survival in patients with moderate-to-severe psoriasis across different treatment lines – first interim results of the non-interventional German G-REAL study

M. Hoffmann[1], K. Schäkel[2], D. Mortazawi[3], B. Korge[4], D. Greiner-Krüger[5], M-L. Schaarschmidt[6], F. Taut[7], L. Scharfenberger[8], B. Sepanski[8], N. Krüger[8], J. Behrens[8], N. Spindler[8], R. von Kiedrowski[9]*

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*Presenting author.

J&J Innovative Medicine

Immunology

Background

PsO is a chronic, immune-mediated disease characterised by red, scaly plaques and is driven by the IL-23/IL-17 inflammatory pathway[1]

GUS, a selective, p19 subunit-targeted **IL-23 inhibitor**, **has demonstrated significant* and durable efficacy in patients with moderate-to-severe PsO**[2,3]

Previously, **ECLIPSE**, a Phase III, double-blind trial in PsO, **showed that GUS is superior to SEC (an IL-17A inhibitor)** in terms of PASI90 response after 1 year[4]

G-REAL is a prospective, non-interventional, multicentre study **assessing long-term effectiveness and impact of GUS and SEC on health-related quality of life** in patients with PsO across different treatment lines in routine clinical care in Germany

*GUS vs. ADA for IGA 0/1 and PASI 90 at Weeks 16, 24 and 48 ($p<0.001$);[2] GUS vs. ADA for IGA 0/1, PASI 75 and PASI 90 at Week 16, and IGA 0/1, IGA 0, PASI 90 and PASI 100 at Week 24 ($p<0.001$).[3]
GUS, guselkumab, IGA, Investigator Global Assessment; IL, interleukin; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; SEC, secukinumab.
1. Menter A, et al. *Dermatol Ther (Heidelb).* 2021;11:385–400; 2. Blauvelt A, et al. *J Am Acad Dermatol.* 2017;76:405–417; 3. Reich K, et al. *J Am Acad Dermatol.* 2017;76:418–431; 4. Reich K, et al. *Lancet.* 2019;394:831–839.
Hoffmann M, et al. Presented at EADV, Paris, France, 17–20th September 2025. P2070.

Objectives and study design

This **first interim analysis** from the G-REAL study:

- Assessed **GUS effectiveness**, **PROs** and **drug survival** across treatment lines, over 84 weeks
- Evaluated effectiveness and **safety** of **GUS** and **SEC** over 84 weeks

Study design:

- Adult patients with **moderate-to-severe PsO**, defined as **PASI score >5** at baseline
- Patients treated per routine clinical care: **GUS Q8W** or **SEC Q4W**
- Data were collected at W0, W4, W12, W20, W28, W52 and W84

Primary outcomes:

- PASI 90 at W84 with GUS across treatment lines
- DLQI 0/1 at W84 with GUS across treatment lines

GUS, guselkumab; IL, interleukin; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PRO, patient-reported outcome; PsO, psoriasis; Q4W, every 4 weeks; Q8W, every 8 weeks; SEC, secukinumab; W, week.
Hoffmann M, et al. Presented at EADV, Paris, France, 17–20th September 2025. P2070.

Current interim analysis

- Phase I of enrolment included 332 patients, out of a total of 650 planned patients
- Enrolment phases were pre-defined to allow for timely, balanced enrolment in the treatment groups (GUS and SEC) and lines*
- Analysable clinical data were available for 239 and 87 patients receiving GUS and SEC, respectively

Statistics:

- Impact of GUS
  - Clinical effectiveness and PRO data were analysed
  - Drug survival was analysed using Kaplan–Meier estimates†
- Impact of GUS vs. SEC
  - Effectiveness data were analysed using non-responder imputation after applying treatment failure rules‡
  - Nominal p-values were reported

*Treatment lines based on previous biological treatment received by the individual patient (GUS: bio-naïve, one prior biologic, and ≥2 prior biologics; SEC: bio-naïve and ≥1 prior biologic); †In the absence of confirmation of treatment discontinuation (including patients lost to follow-up), the time to event was censored on the last documented study date; ‡Treatment was considered to have failed when (1) GUS or SEC was discontinued due to lack of effectiveness, loss of effectiveness or an AE of psoriasis worsening, or (2) a new therapy other than the therapy at baseline was started.
AE, adverse event; GUS, guselkumab; IL, interleukin; MOA, mode of action; PRO, patient-reported outcome; PsO, psoriasis; SEC, secukinumab.
Hoffmann M, et al. Presented at EADV, Paris, France, 17–20th September 2025. P2070.

Baseline patient and disease characteristics were generally well balanced between treatment cohorts

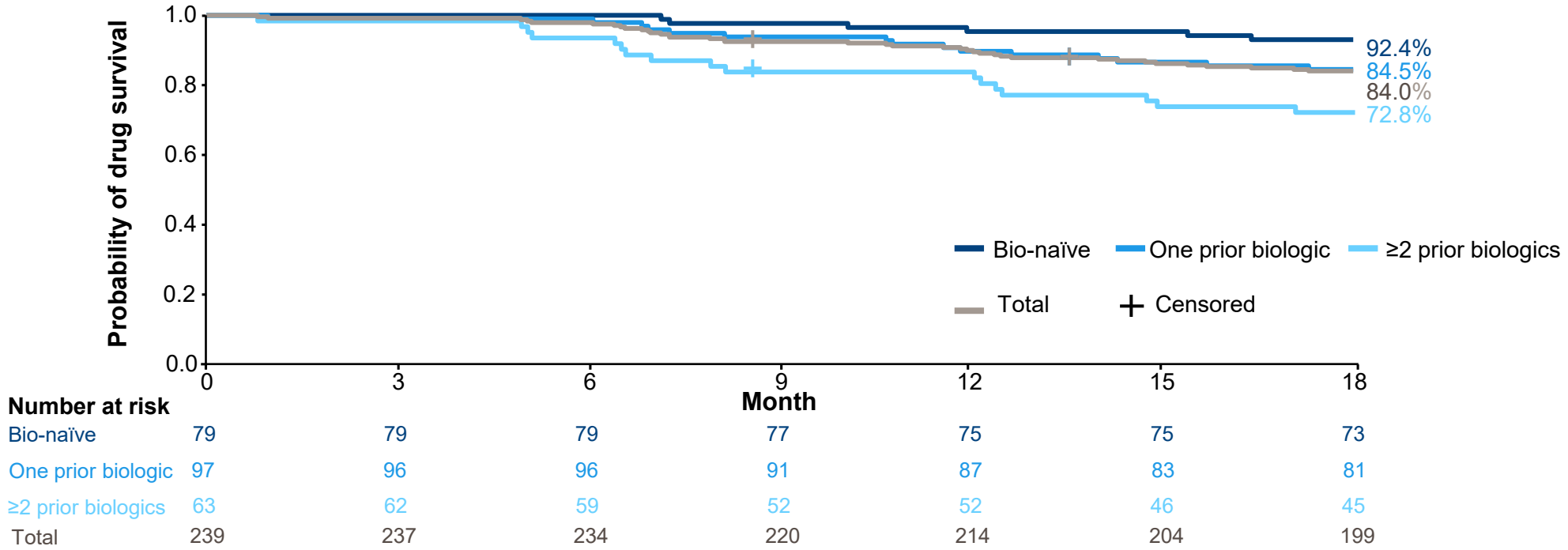
Baseline characteristics of patients enrolled in G-REAL

Baseline characteristics		GUS (n=239)*	SEC (n=87)*
Demographics			
	Mean age, yrs (SD)	48.5 (13.6)	47.3 (13.6)
	Female, n (%)	94 (39.3)	33 (37.9)
	Mean BMI, kg/m^2 (SD)	29.0 (5.7)	29.5 (6.8)
Disease characteristics			
	Mean PsO disease duration, yrs (SD)	17.6 (11.9)	13.4 (13.7)
	Mean PASI (0–72) (SD)	14.6 (8.5)	15.2 (7.4)
	Mean DLQI (0–30) (SD)	14.0 (7.8)	14.9 (7.7)
Concomitant diseases†, n (%)			
	Arterial hypertension	65 (27.2)	23 (26.4)
	Psoriatic arthritis	61 (25.5)	23 (26.4)
	Hyperlipidaemia	27 (11.3)	6 (6.9)
	Diabetes	15 (6.3)	11 (12.6)
	Obesity	17 (7.1)	7 (8.0)
Prior csDMARD use, n (%)			
	Methotrexate	112 (46.9)	37 (42.5)
	Cyclosporine	22 (9.2)	5 (5.7)

*Ns are presented for the Full Analysis Set; †Top five most frequent concomitant diseases shown.
BMI, body mass index; csDMARD, conventional synthetic disease-modifying anti-rheumatic drug; DLQI, Dermatology Life Quality Index; GUS, guselkumab; IL, interleukin; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; SD, standard deviation; SEC, secukinumab; yrs, years.
Hoffmann M, et al. Presented at EADV, Paris, France, 17–20th September 2025. P2070.

High drug survival rates with GUS were sustained through 18 months across treatment lines

Drug survival rates with GUS treatment through 18 months



Number at risk							
Bio-naïve	79	79	79	77	75	75	73
One prior biologic	97	96	96	91	87	83	81
≥2 prior biologics	63	62	59	52	52	46	45
Total	239	237	234	220	214	204	199

Through W84, the highest probability of drug survival was observed among bio-naïve patients (92.4%), followed by those who had received one prior biologic (84.5%) and ≥2 prior biologics (72.8%)

GUS, guselkumab; IL, interleukin; MOA, mode of action; PsO, psoriasis; SEC, secukinumab; W, week.
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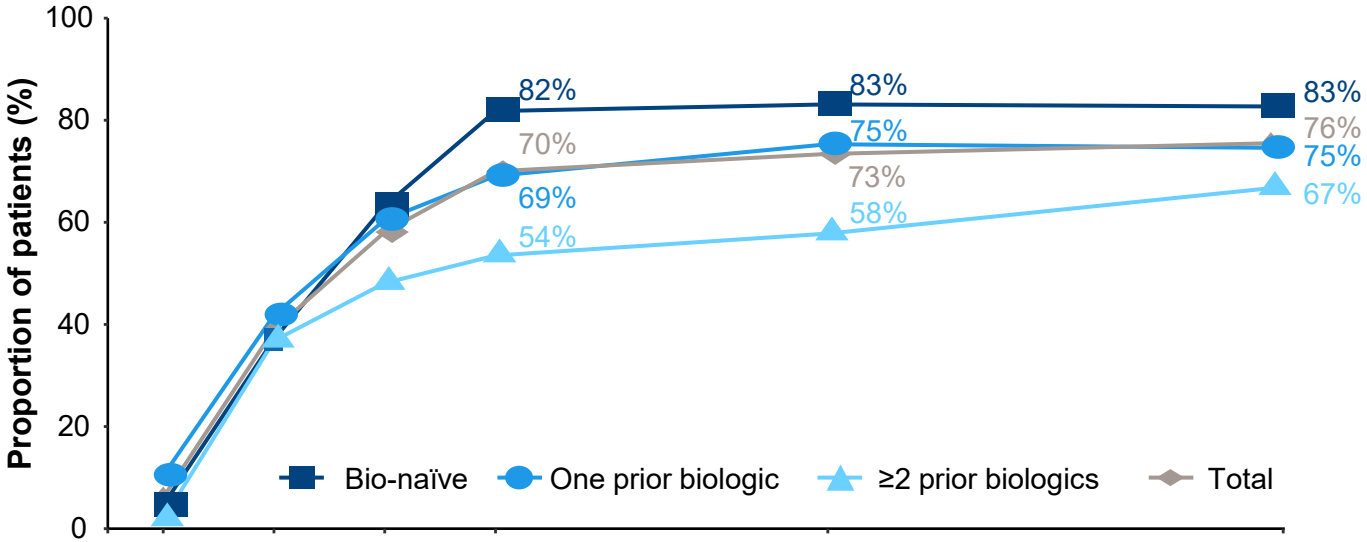
PASI90 response rates were highest among bio-naïve patients

PASI90 response in patients receiving GUS

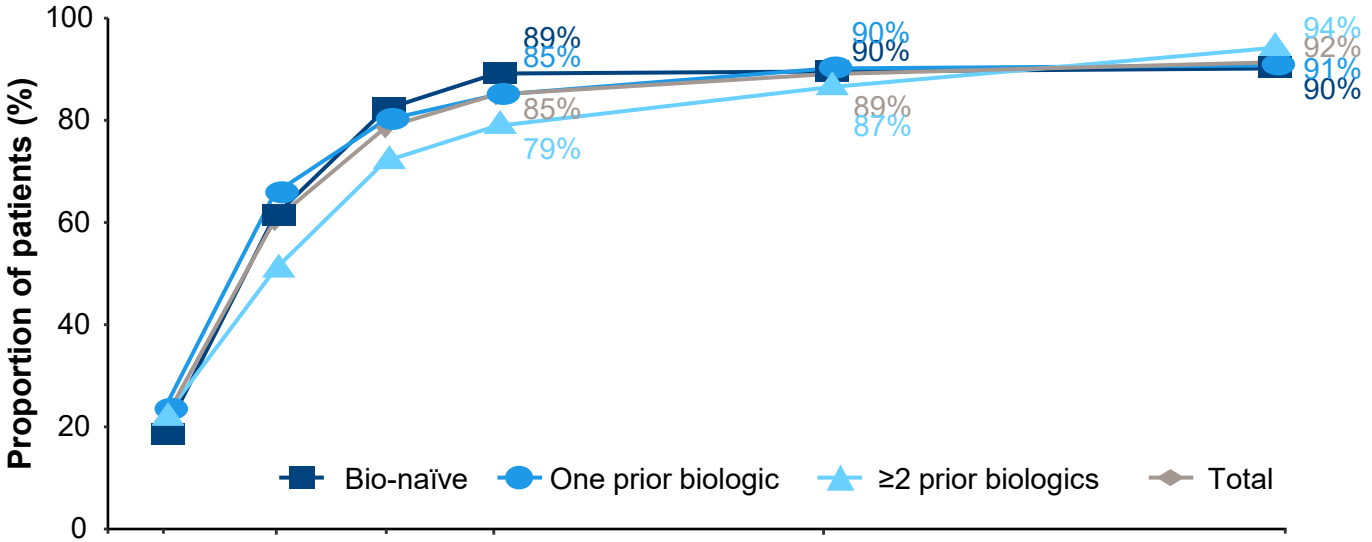


High levels of PASI 90 response were generally achieved and maintained through W84 across treatment lines

GUS, guselkumab; IL, interleukin; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; SEC, secukinumab; W, week.
Hoffmann M, et al. Presented at EADV, Paris, France, 17–20th September 2025. P2070.

High PASI ≤3 response rates were generally achieved with GUS and maintained through W84 across treatment lines

PASI ≤3 response in patients receiving GUS



	W4	W12	W20	W28	W52	W84
Bio-naïve, n=	65	70	68	66	59	52
One prior biologic, n=	77	91	76	81	73	67
≥2 prior biologics, n=	55	57	54	43	45	36
Total, n=	197	218	198	190	177	155

PASI ≤3 response rates observed with GUS were generally similar across treatment lines

GUS, guselkumab; IL, interleukin; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; SEC, secukinumab; W, week.
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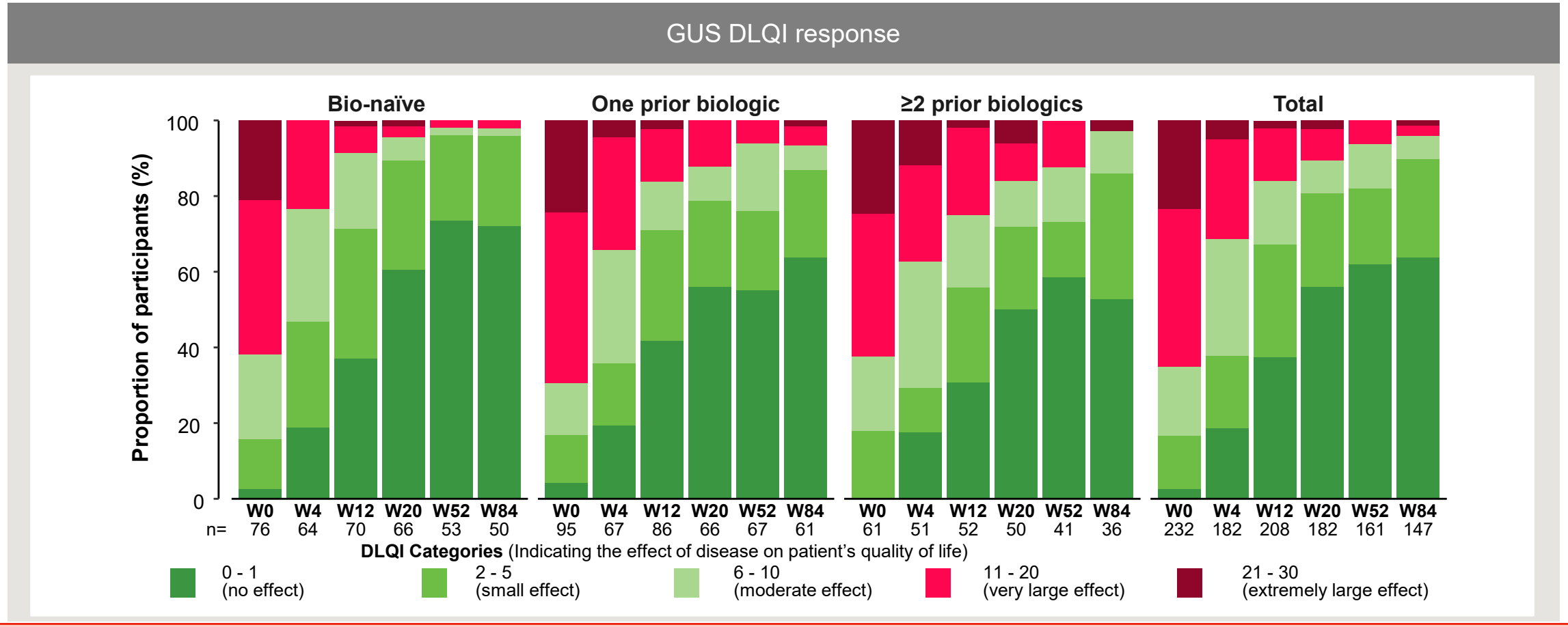
Quality of life improved rapidly and continued to improve with GUS through W84 across treatment lines



In the total population, DLQI 0/1 response rates increased from 2.6% at W0 to 63.9% at W84 in patients receiving GUS.
Through W84, highest DLQI 0/1 response rates with GUS were seen among bio-naïve patients

DLQI, Dermatology Life Quality Index; GUS, guselkumab; IL, interleukin; MOA, mode of action; PsO, psoriasis; SEC, secukinumab; W, week.

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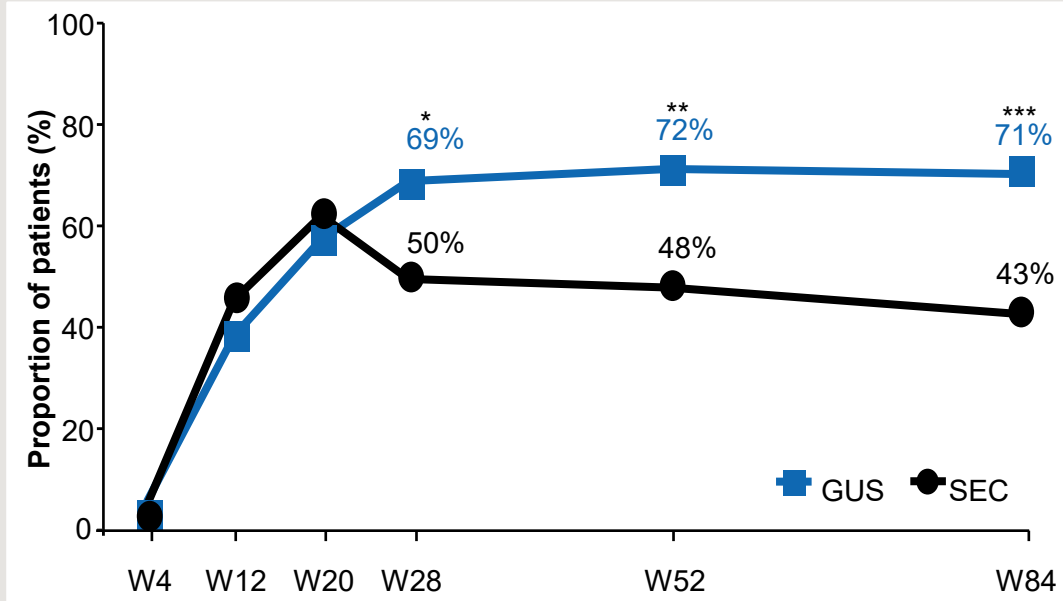
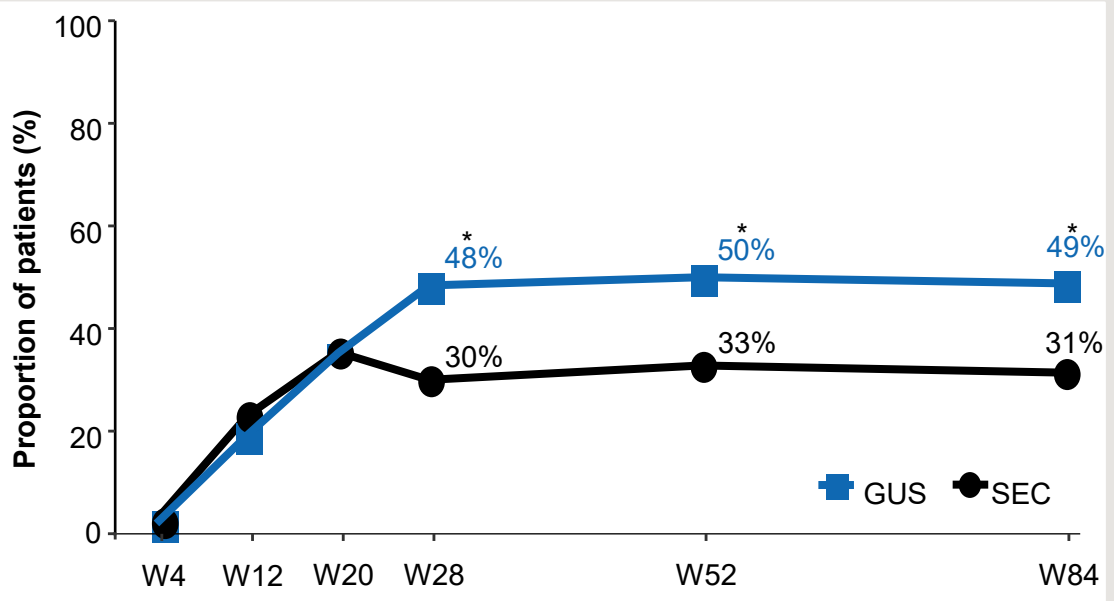
Total population: After W20, GUS demonstrated higher PASI90 and PASI=0 response rates vs. SEC through W84

PASI90 response†



	W4	W12	W20	W28	W52	W84
GUS, n=	197	219	199	192	180	164
SEC, n=	74	74	48	50	58	51

PASI=0 response†



	W4	W12	W20	W28	W52	W84
GUS, n=	197	219	199	192	180	164
SEC, n=	74	74	48	50	58	51

Treatment failure rates were 5.0% for GUS and 21.8% for SEC

Nominal *p<0.05, **p<0.01, ***p<0.001 vs. SEC; †Analysed after applying treatment failure rules.
GUS, guselkumab; IL, interleukin; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; SEC, secukinumab; W, week.
Hoffmann M, et al. Presented at EADV, Paris, France, 17–20th September 2025. P2070.

No new safety signals for GUS were identified through W84

Safety profile of GUS through W84

Safety through W84, n (%)	GUS (n=244)*	SEC (n=88)*
Any AE	140 (57.4)	46 (52.3)
ADR†‡	22 (9.0)	13 (14.8)
Infections and infestations	12 (4.9)	7 (8.0)
Skin and subcutaneous tissue disorders	5 (2.0)	0 (0.0)
Gastrointestinal disorders	3 (1.2)	2 (2.3)
General disorders and administration site conditions	0 (0.0)	2 (2.3)
Any SAE	19 (7.8)	5 (5.7)
SADR	2 (0.8)	1 (1.1)
Infections and infestations	2 (0.8)	0 (0.0)
Cardiac disorders	0 (0.0)	1 (1.1)
Deaths	0 (0.0)	0 (0.0)

*N are presented for the Safety Analysis Set, defined as all enrolled patients who received at least one dose of GUS or SEC; †Defined as an AE considered related to treatment; ‡Most frequently reported system organ classes for ADRs are shown.
AE, adverse event; ADR, adverse drug reaction; GUS, guselkumab; IL, interleukin; MOA, mode of action; PsO, psoriasis; SADR, serious adverse drug reaction; SAE, serious adverse event; SEC, secukinumab; W, week.
Hoffmann M, et al. Presented at EADV, Paris, France, 17–20th September 2025. P2070.

Conclusions

- In the G-REAL study, treatment with GUS was associated with robust long-term clinical effectiveness, marked quality of life improvements and high drug survival rates through W84 in patients with moderate-to-severe PsO, irrespective of prior biological treatment
- Bio-naïve patients had the highest response and drug survival rates, highlighting the benefits of GUS when used as a first-line biologic
- Onset of response was similar with GUS and SEC; however, higher PASI90 and complete skin clearance response rates were achieved with GUS from W28 through W84

GUS, guselkumab, IL, interleukin; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; SEC, secukinumab; W, week.
Hoffmann M, et al. Presented at EADV, Paris, France, 17–20th September 2025. P2070.

P3695

Impact of guselkumab in real-life on sleep quality measured using a wearable device in patients with moderate to severe psoriasis: Data from the CASSIOPÉE study

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Immunology

Background

Moderate-to-severe PsO is a chronic, immune-mediated inflammatory skin disease that impairs patients' QoL

Beyond its physical impact, PsO has social and psychological impacts, including sleep disturbance

GUS has demonstrated efficacy in RCTs and effectiveness in a real-world setting. However, the real-world impact of GUS across several dimensions of QoL, such as sleep quality, is not well understood

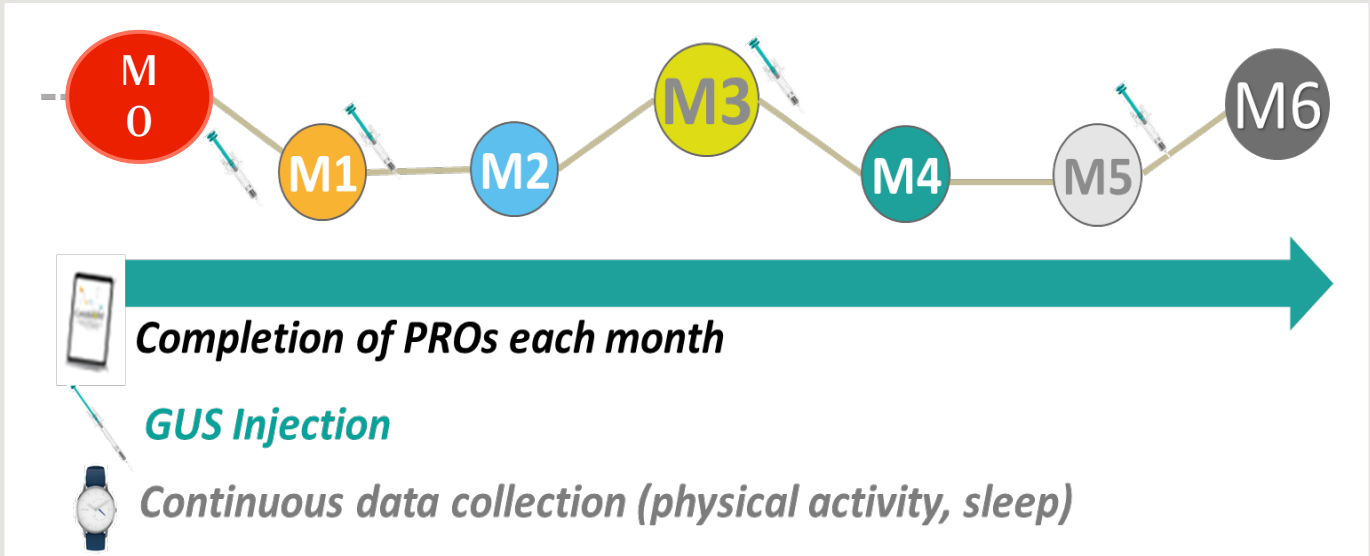
CASSIOPÉE is a prospective, non-interventional, multicentre study conducted in France evaluating effectiveness and safety of GUS over 6 months, and the impact of GUS on QoL, sexual health, sleep quality, physical activity and psychological wellbeing

GUS, guselkumab, IL, interleukin; MOA, mode of action; PsO, psoriasis; QoL, quality of life; RCT, randomised controlled trial.
Marie-Aleth R, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3695.

CASSIOPEE objectives and study design

The objective of this analysis was to assess the real-world impact of GUS treatment on patients' QoL, specifically sleep quality, using a wearable device

CASSIOPEE study design



- PsO severity was clinically evaluated at M0, M3 and M6, and QoL was assessed using self-reported questionnaires
- Sleep-related parameters were collected using a wearable device worn day and night by patients throughout the study; parameters were analysed over 7 full days within a defined interval for each visit

GUS, guselkumab, IL, interleukin; M, month; MOA, mode of action; PRO, patient-reported outcome; PsO, psoriasis; QoL, quality of life.
Marie-Aleth R, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3695.

Baseline characteristics of patients with PsO who initiated GUS

Baseline characteristics of patients initiating GUS treatment

Baseline characteristics		Effectiveness population (N=207)
Demographics		
	Age, yrs, mean (SD)	43.9 ± 12.1
	Female, %	42.0
	BMI, kg/m^2, mean (SD)	27.9 ± 6.3
Disease characteristics		
	PsO disease duration, yrs, mean (SD)	20.9 ± 13.2
	PGA score, %	
	Mild (2)	25.6
	Moderate (3)	50.7
	Severe (≥4)	23.7
Prior treatment for PsO		
	Conventional systemic treatment,* %	84.1
	Biologic therapy,† %	26.1

*Including methotrexate, ciclosporin, acitretin, UVB phototherapy and PUVA therapy; †Including adalinumab, secukinumab, ustekinumab, ixekizumab and etanercept.
BMI, body mass index; GUS, guselkumab; IL, interleukin; MOA, mode of action; PGA, Physician's Global Assessment; PsO, psoriasis; PUVA, psoralen plus ultraviolet-A radiation; SD, standard deviation; UVB, ultraviolet B; yrs, years.
Marie-Aleth R, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3695.

After GUS initiation, PsO severity decreased, and QoL, itching and pain scores improved

Mean scores (± SD) for PsO severity and QoL measures at M0, M3 and M6 among patients with available data

Area of interest	Score	Scale	M0 (N=207)		M3 (n=162)		M6 (n=144)	
			n	Mean ± SD	n	Mean ± SD	n	Mean ± SD
QoL	DLQI	0–30*	188	12.8 ± 6.7	160	3.9 ± 5.1	143	2.4 ± 4.1
PsO severity	PGA	0–4*	207	3.0 ± 0.7	141	0.9 ± 0.9	176	0.6 ± 0.8
Fatigue	FACIT-F	0–52*	190	33.7 ± 12.0	157	35.8 ± 11.6	140	36.6 ± 12.2
Pruritus	NRS – Itching	0–10*	191	6.2 ± 2.8	156	2.8 ± 2.6	137	2.1 ± 2.3
Skin pain	NRS – Skin pain	0–10*	191	5.1 ± 2.7	156	2.1 ± 2.3	137	1.7 ± 2.2

*Higher scores denote greater severity.
DLQI, Dermatology Life Quality Index; FACIT-F, Functional Assessment of Chronic Illness Therapy – Fatigue Scale; GUS, guselkumab; IL, interleukin; M, month; MOA, mode of action; NRS, Numeric Rating Scale; PGA, Physician's Global Assessment; PsO, psoriasis; QoL, quality of life; SD, standard deviation.
Marie-Aleth R, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3695.

Patients receiving GUS showed rapid improvement in sleep duration and quality

Sleep quality at M0, M3 and M6 in the cohort with data collected via a connected watch (N=215)

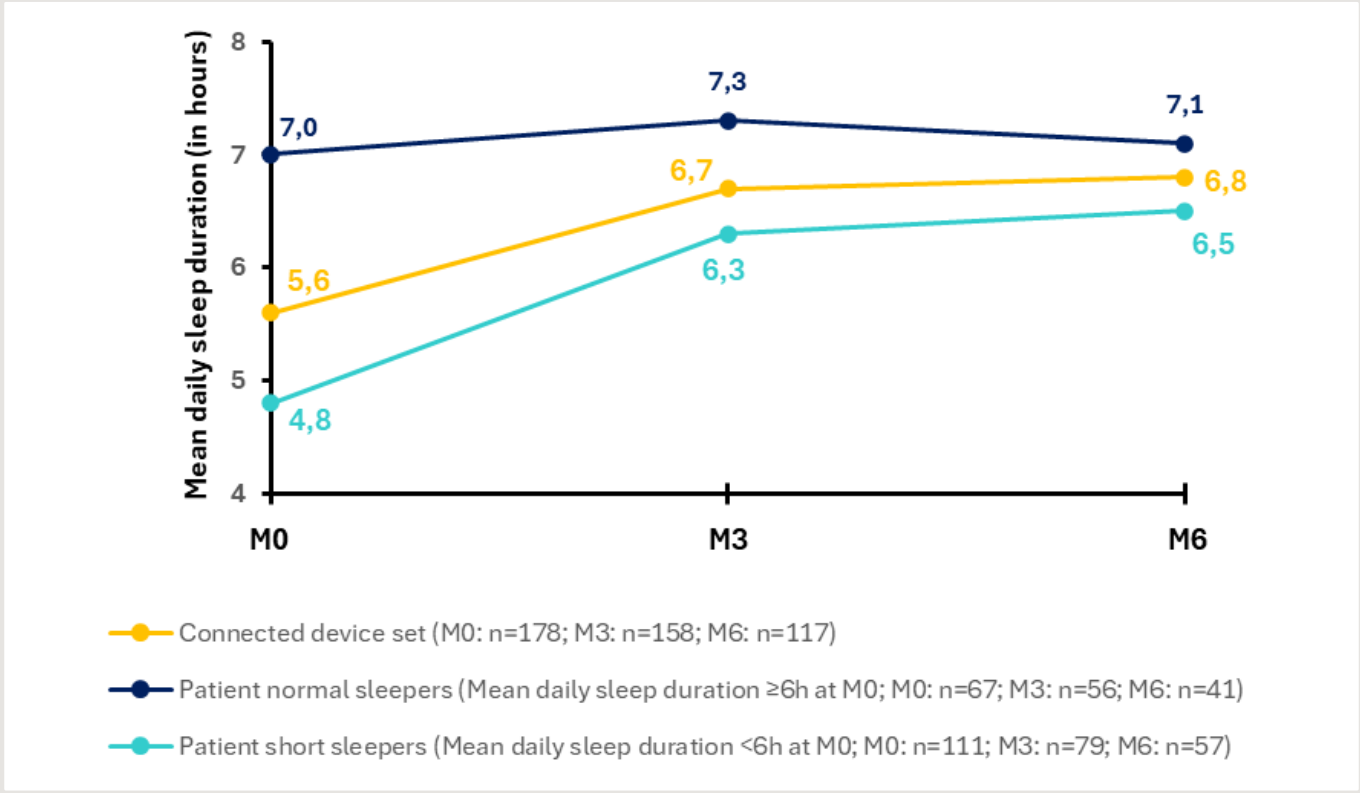
	M0 (N=215)		M3 (N=215)		M6 (N=215)	
	n	Mean ± SD	n	Mean ± SD	n	Mean ± SD
Daily sleep in hours*	178	5.6 ± 1.3	158	6.7 ± 1.6	117	6.8 ± 1.5
Weekly sleep in hours*	178	39.3 ± 9.2	158	47 ± 11.1	117	47.6 ± 10.2
Weekly light sleep in hours*	178	23.2 ± 6.7	158	28.3 ± 9	117	27.7 ± 7.8
Weekly deep sleep in hours*	178	16 ± 5.9	158	18.7 ± 7	117	19.9 ± 7.6
Median weekly sleep gain in minutes†	-	-	135	55.3	98	60.7
Daily QS score*	192	47.6 ± 15.4	172	55.2 ± 19.7	130	56 ± 18.5
High sleep quality (score QS ≥70), %	192	4.2%	172	29.1%	130	23.8%
QS score evolution†‡ **(95% CI)**	- -	- -	156	6.9 ± 19.5 (3.8–10)	115	5 ± 20.5 (1.2–8.8)
Number of nighttime awakenings	192	2 ± 1.5	172	2.1 ± 1.4	130	2.1 ± 1.2

A clinically relevant increase in sleep duration (>15 minutes/night) was observed in 69.6% of patients at M3 and 74.5% of patients at M6 vs M0

*Mean ± SD; †Compared with M0; ‡The QS score is a composite score out of 100, specific to the connected device evaluating sleep quality and calculated based on total sleep duration, proportion of deep sleep, interruption (duration of nightly awakenings) and regularity of bedtime and waking times. A score of 70 or higher indicates high sleep quality (<50: low; 50–70: moderate).
CI, confidence level; GUS, guselkumab; IL, interleukin; M, month; MOA, mode of action; PsO, psoriasis; QS, quality sleep; SD, standard deviation.
Marie-Aleth R, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3695.

Short sleepers (<6 hours/night)* had greater gains in sleep duration than patients initially sleeping ≥6 hours/night

Improvements in average daily sleep duration (in hours) through 6 months



- Patients with initially short sleep patterns had greater gains in sleep duration than patients initially sleeping ≥6 hours/night (+104.4 minutes vs. +23 minutes, respectively, at M6)
  - They also experienced more severe itching than long sleepers (NRS ≥9 vs. ≤3, respectively (OR: 5.2 [1.5–17.6]; p=0.0077))

*In total, 62.4% of patients were classified as 'short sleepers'.
GUS, guselkumab; h, hour; IL, interleukin; M, month; MOA, mode of action; NRS, Numeric Rating Scale; OR, odds ratio; PsO, psoriasis.
Marie-Aleth R, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3695.

Conclusions

- After GUS initiation, PsO severity decreased, and QoL, itching and pain scores improved
- Patients receiving GUS showed rapid improvements in sleep duration and quality
- Patients with an initially poor sleep pattern experienced more ‘normal’ sleep duration (6–7 hours/night) with GUS treatment

GUS, guselkumab; IL, interleukin; MOA, mode of action; PsO, psoriasis; QoL, quality of life.
Marie-Aleth R, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3695.

Guselkumab in PsA

P2542/EPS04.10

Patient reported impact and satisfaction with guselkumab and IL-17 inhibitors in psoriatic arthritis: 12-month results of the PsABIOnd observational study

L. Gossec[1], M. Sharaf[2], X. Baraliakos[3], M. Kishimoto[4], R. Queiro-Silva[5], E. Lubrano[6], E. Rampakakis[7, 8], L. Köleséri[9], K. Lozenski[10], C. Roux[11], E. R. Soriano[12], P. Rahman[13], F. Behrens[14], S. Siebert[15]

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Objectives

This analysis of a partial population (1015 out of 1313 patients) from the ongoing PsABIOnd study assessed PsA PROs and patient satisfaction with GUS and IL-17i treatment at the 12-month visit in a real-world setting

GUS, guselkumab, i, inhibitor; IL, interleukin; MOA, mode of action; PRO, patient-reported outcome; PsA, psoriatic arthritis; RWE, real-world evidence.
Gossec L, et al. Presented at EADV, Paris, France, 17–20th September 2025. P2542/EPS04.10.

Baseline characteristics of patients in PsABIOnd

Baseline characteristics of patients in PsABIOnd

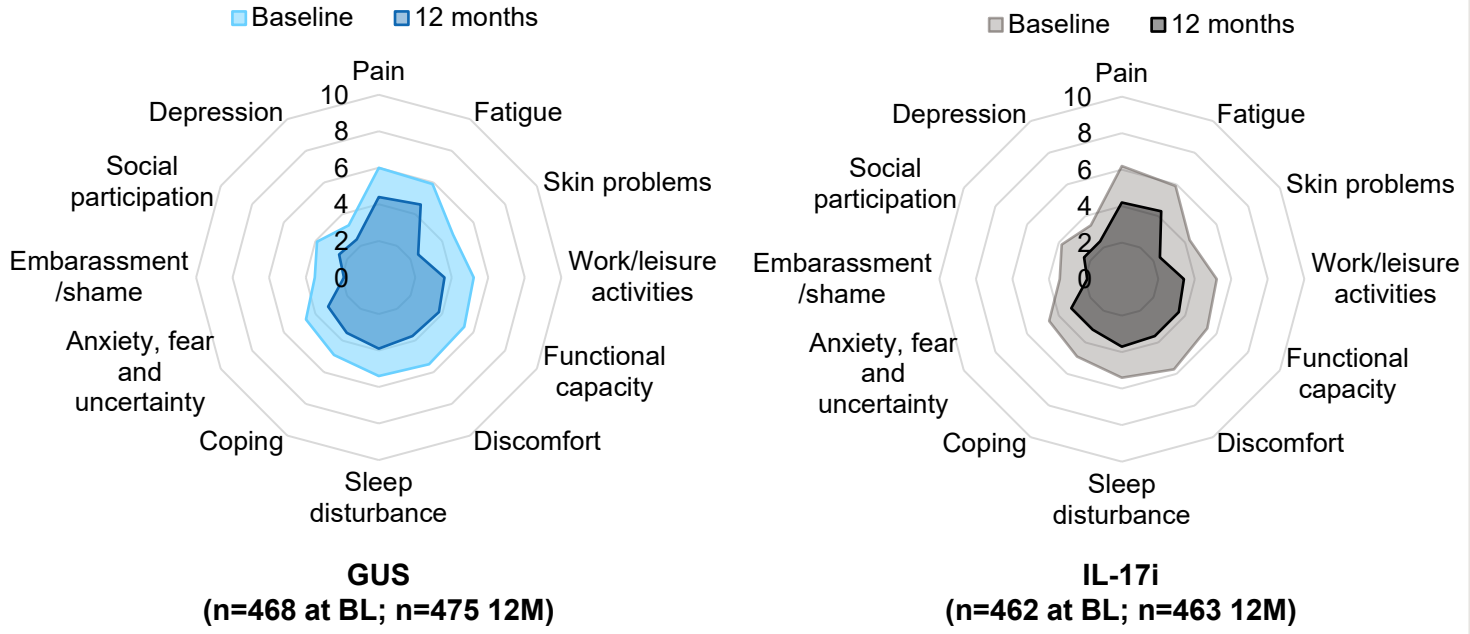
Baseline characteristics		GUS (n=511)	IL-17i (n=504)
Demographics			
	Age, years	53.0 (12.9)	53.7 (11.9)
	Female, %	61	60
	BMI, kg/m^2	30.0 (6.4)[a]	29.5 (6.3)[b]
Characteristics			
	PsA disease duration, years	7.9 (8.2)[c]	7.4 (8.5)[d]
	cDAPSA (0–154)	24.9 (14.6)[e]	27.2 (16.8)[f]
	Enthesitis, %	48[g]	48[h]
	Dactylitis, %	16[g]	20[h]
	BSA with PsO		
	3–10%	36[i]	32[j]
	>10%	12[i]	9[j]
	PsAID-12 total score (0–10)	5.1 (2.2)[k]	5.1 (2.2)[l]
	PtGA (0–100)	59.4 (22.1)[a]	60.7 (23.3)[m]
Initial bDMARD treatment line, %			
	1st	37	37
	2nd	27	36
	3rd	20	19
	4th	16	8

- PsA disease burden was high across cohorts at baseline
- A higher proportion of patients in the GUS cohort were initiating their 4th treatment line

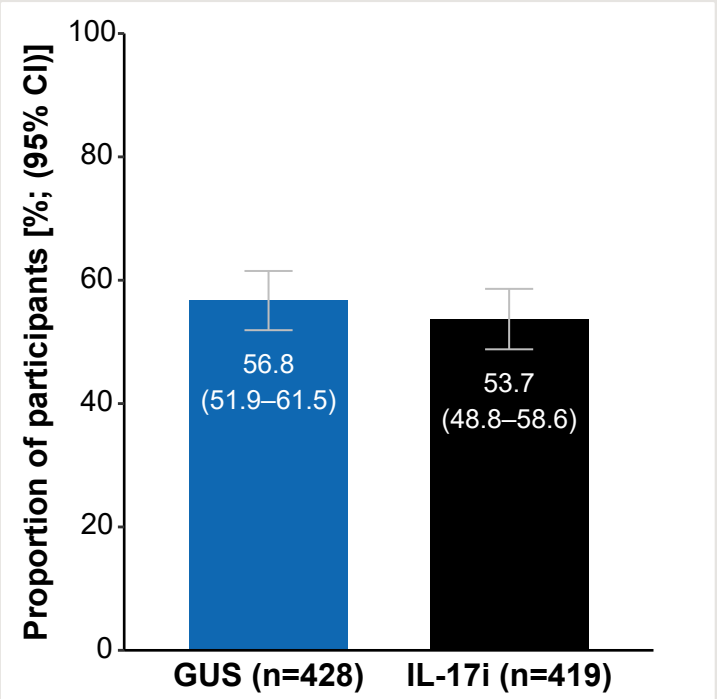
Data shown are mean (SD) unless otherwise noted. [a]n=479; [b]n=453; [c]n=502; [d]n=503; [e]n=439; [f]n=432; [g]n=489; [h]n=476; [i]n=459; [j]n=449; [k]n=468; [l]n=462; [m]n=464. bDMARD, biologic disease-modifying anti-rheumatic drug; BMI, body mass index; BSA, body surface area; cDAPSA, Clinical Disease Activity Index for PsA; GUS, guselkumab; i, inhibitor; IL, interleukin; MOA, mode of action; PsA, psoriatic arthritis; PsAID, Psoriatic Arthritis Impact of Disease; PtGA, Patient's Global Assessment; RWE, real-world evidence; SD, standard deviation. Gossec L, et al. Presented at EADV, Paris, France, 17–20th September 2025. P2542/EPS04.10.

Improvements across PsAID-12 items were similar in patients treated with GUS and IL-17i at 12 months

PsAID-12 item scores at baseline and 12 months



Attainment of MCII (decrease ≥1.4) in PsAID-12 total score at 12 months*

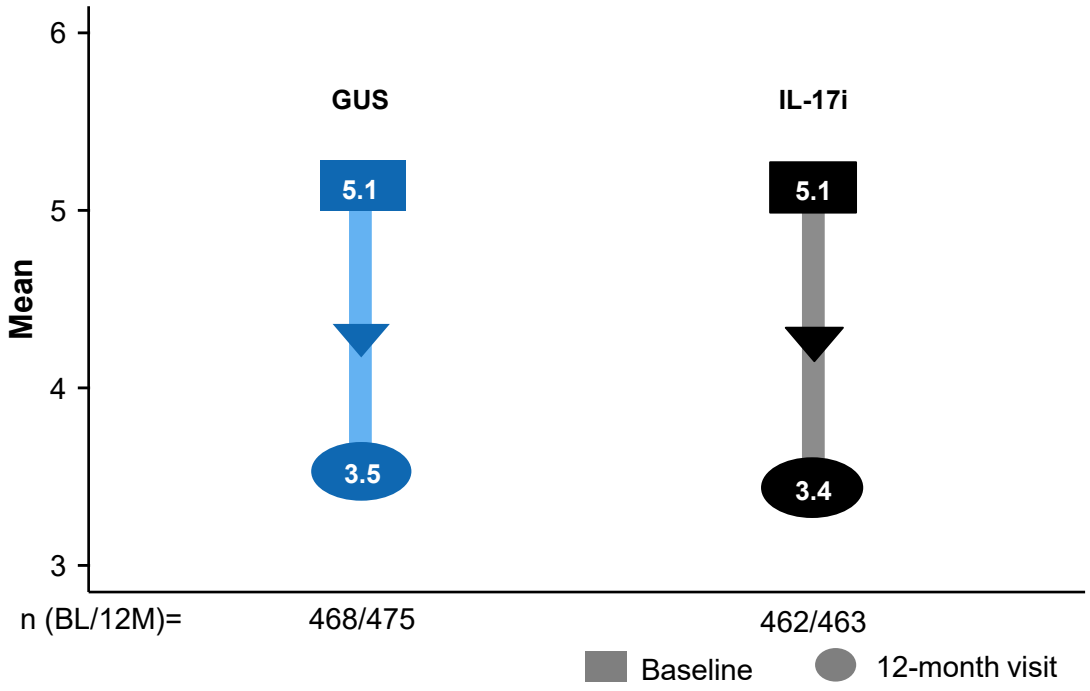


Clinically meaningful improvements in PsAID-12 total score at 12 months were observed by 50% of patients treated with GUS and IL-17i
Mean changes from baseline in PsAID-12 total score (−1.6, −1.7) were similar with GUS and IL-17i at 12 months

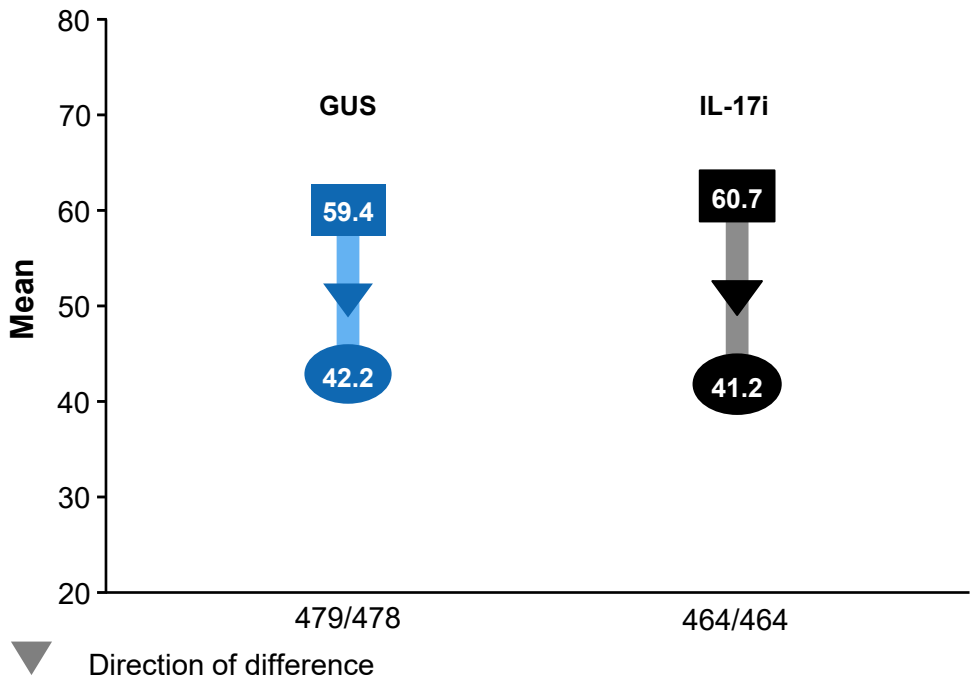
*Among participants with baseline PsAID-12 score of ≥1.4.
BL, baseline; CI, confidence level; GUS, guselkumab; i, inhibitor; IL, interleukin; M, month; MCII, minimal clinically important improvement; MOA, mode of action; PsA, psoriatic arthritis; PsAID-12, Psoriatic Arthritis Impact of Disease-12; RWE, real-world evidence.
Gossec L, et al. Presented at EADV, Paris, France, 17–20th September 2025. P2542/EPS04.10.

Improvement in disease burden and patient-rated overall disease activity was similar with GUS and IL-17i at the 12-month visit

Change from baseline in PsAID-12 total score at 12 months



Change from baseline in PtGA VAS at 12 months



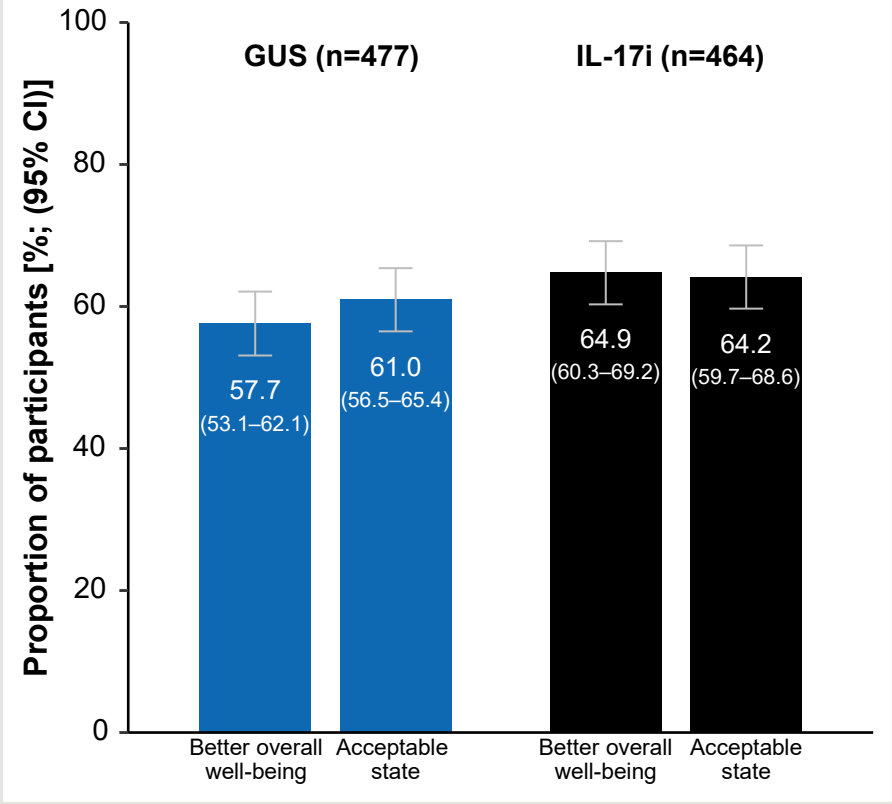
Mean (95% CI) changes from baseline in PsAID-12 total score were −1.6 (−1.8, −1.4) with GUS and −1.7 (−1.9, −1.5) with IL-17i
Mean (95% CI) changes from baseline in PtGA VAS were −17.0 (−19.7, −14.4) with GUS and −19.1 (−22.0, −16.3) with IL-17i

BL, baseline; CI, confidence level; GUS, guselkumab; i, inhibitor; IL, interleukin; M, month; MOA, mode of action; PsA, psoriatic arthritis; PsAID-12, Psoriatic Arthritis Impact of Disease-12; PtGA, Patient's Global Assessment; RWE, real-world evidence; VAS, visual analogue scale.

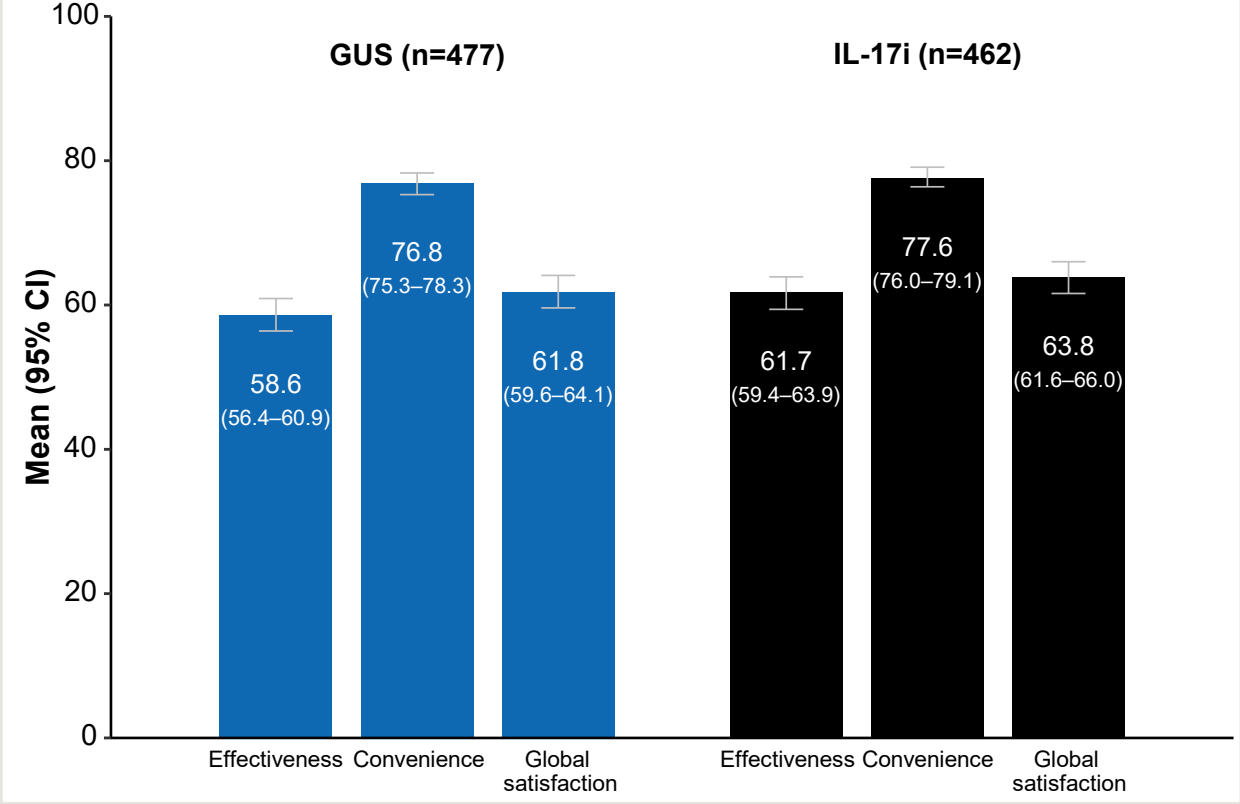
Gossec L, et al. Presented at EADV, Paris, France, 17–20th September 2025. P2542/EPS04.10.

Patient satisfaction was high with GUS and IL-17i at 12 months

Attainment of PASS at 12 months



TSQM-9 scores at 12 months



CI, confidence level; GUS, guselkumab; i, inhibitor; IL, interleukin; MOA, mode of action; PASS, Patient Acceptable Symptom State; PsA, psoriatic arthritis; RWE, real-world evidence; TSQM-9, Treatment Satisfaction Questionnaire for Medication–9 items.

Gossec L, et al. Presented at EADV, Paris, France, 17–20th September 2025. P2542/EPS04.10.

Conclusions

- Interim 1-year findings from the real-world, global, prospective PsABIOnd study of patients with PsA showed that with both GUS or IL-17i treatment:
  - ✓ More than half of patients reached clinically meaningful improvements in multidomain PROs
  - ✓ Majority (>60%) of patients reported reaching acceptable disease state
  - ✓ High levels of satisfaction with treatment were reported
- Results suggest that both mechanisms of action appear to be effective in PsA over 1 year of treatment

GUS, guselkumab, i, inhibitor; IL, interleukin; MOA, mode of action; PRO, patient-reported outcome; PsA, psoriatic arthritis; RWE, real world evidence.
Gossec L, et al. Presented at EADV, Paris, France, 17–20th September 2025. P2542/EPS04.10.

P3828

Guselkumab and IL-17 inhibitors show comparable treatment persistence and effectiveness in psoriatic arthritis: 12-month results of the PsABIOnd observational study

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PsABIOnd: A real-world study evaluating treatment persistence, PROs, effectiveness and safety of GUS and IL-17is[1–3]

Treatment

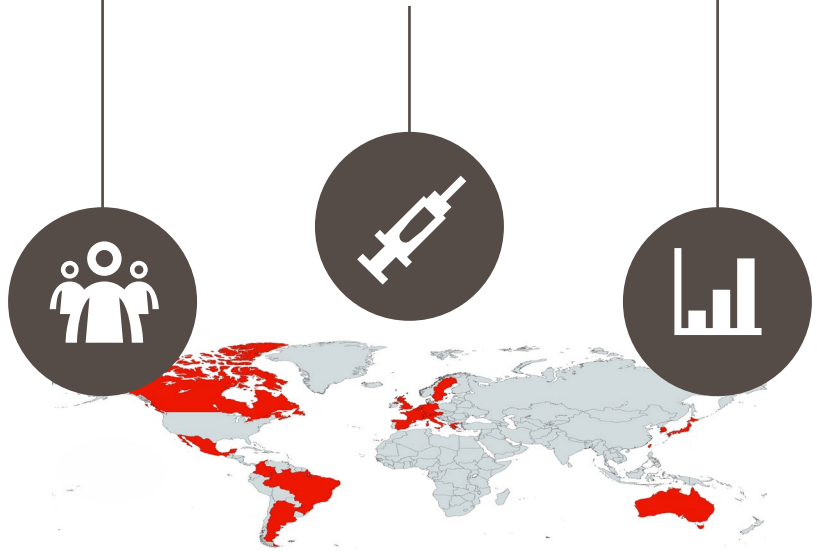
- GUS vs. approved IL-17i

Study population

- Overall, 1313 patients across 155 sites and 20 countries
- Confirmed diagnosis per CASPAR
- Treatment lines: 1st, 2nd, 3rd or 4th line bDMARD

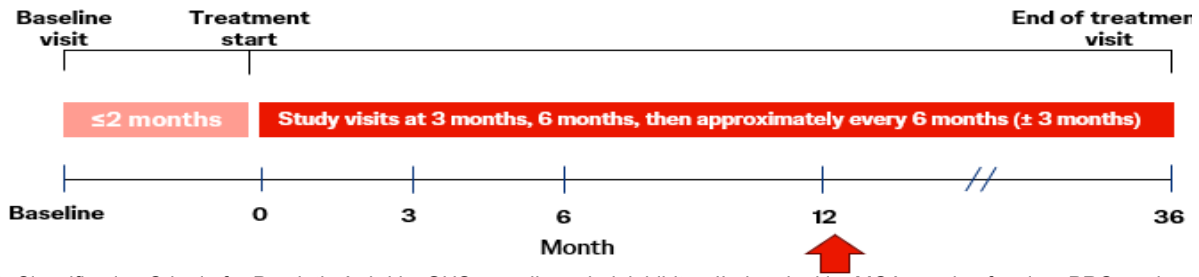
Data collection

- At baseline, 3 months and every 6 (± 3) months for 3 years
- Stopped if the patient switched to a non-index drug or after 2nd treatment change



Aim

- To assess the use of GUS and approved IL-17i therapies in routine clinical practice in patients with PsA



Study design

- Estimated completion date is August 2027
- As of 14 June 2024, 1015 out of 1313 participants had available and analysable 12-month visit data

bDMARD, biologic disease-modifying anti-rheumatic drug; CASPAR, Classification Criteria for Psoriatic Arthritis; GUS, guselkumab; i, inhibitor; IL, interleukin; MOA, mode of action; PRO, patient-reported outcome; PsA, psoriatic arthritis; RWE, real-world evidence.

1. Siebert S, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3828; 2. Siebert S, et al. *Rheumatol Ther* 2023;10:489–505;
3. ClinicalTrials.gov. NCT05049798. Available at: https://clinicaltrials.gov/study/NCT05049798 (accessed September 2025).

Objectives

This analysis of a partial population (1015 out of 1313) from the ongoing PsABIOnd study assessed treatment persistence and effectiveness at the 12-month visit in patients initiating either GUS or an IL-17i in a real-world setting

GUS, guselkumab; i, inhibitor; IL, interleukin; MOA, mode of action; PsA, psoriatic arthritis; RWE, real-world evidence.
Siebert S, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3828.

Baseline participant and disease characteristics were generally well balanced between cohorts

Baseline characteristics of PsABIOnd patients

Baseline characteristics		GUS (n=511)	IL-17i (n=504)
Demographics			
	Age, yrs	53.0 (12.9)	53.7 (11.9)
	Females	61%	60%
	BMI, kg/m^2	30.0 (6.4)[a]	29.5 (6.3)[b]
Characteristics			
	PsA disease duration, yrs	7.9 (8.2)[c]	7.4 (8.5)[d]
	cDAPSA (0-154)	24.9 (14.6)[e]	27.2 (16.8)[f]
	Enthesitis	48%[g]	48%[h]
	Dactylitis	16%[g]	20%[h]
	BSA with PsO		
	3–10%	36%[i]	32%[j]
	>10%	12%[i]	9%[j]
Patient-reported outcomes			
	DLQI (0–30)	7.5 (7.3)[k]	6.1 (6.7)[l]
	HAQ-DI (0–3)	1.1 (0.7)[a]	1.1 (0.7)[l]
	PtGA (0–100)	59.4 (22.1)[a]	60.7 (23.3)[m]
Initial bDMARD treatment line			
	1st	37%	37%
	2nd	27%	36%
	3rd	20%	19%
	4th	16%	8%

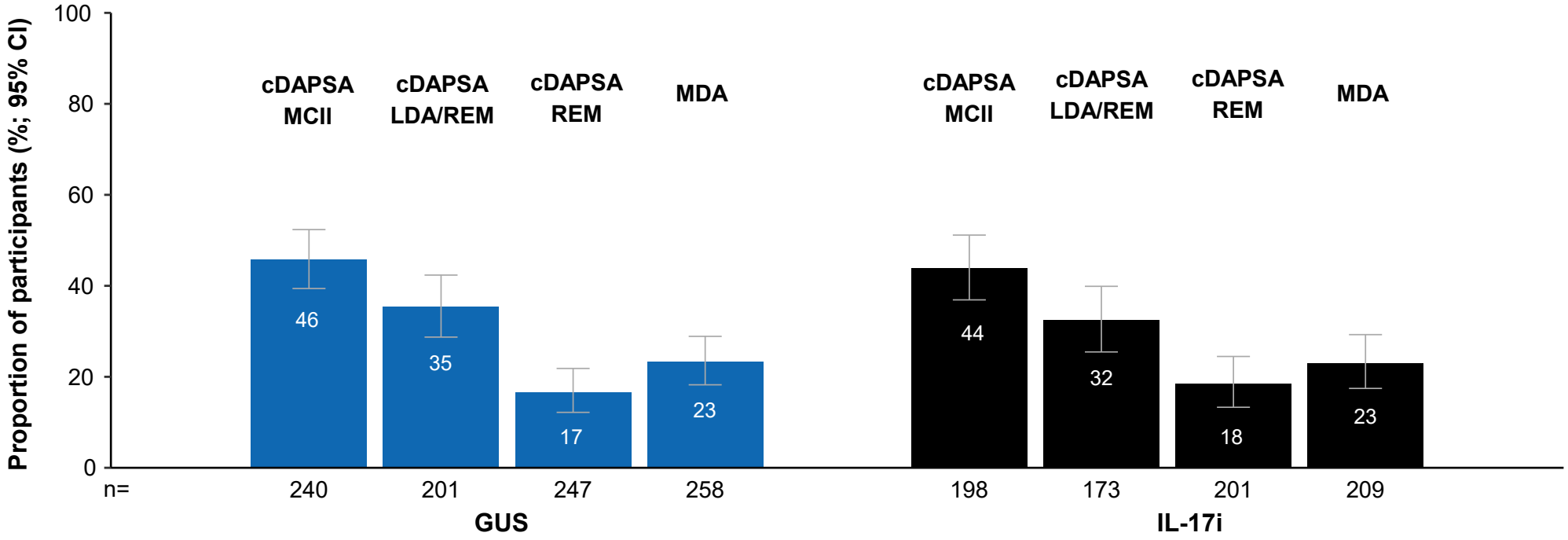
A higher proportion of patients in the GUS cohort were initiating their 4th treatment line vs. the IL-17i cohort

Data shown are mean (SD) unless otherwise noted. [a]n=479; [b]n=453; [c]n=502; [d]n=503; [e]n=439; [f]n=432; [g]n=489; [h]n=476; [i]n=459. [j]n=449; [k]n=477; [l]n=465; [m]n=464. bDMARD, biologic disease-modifying anti-rheumatic drug; BMI, body mass index; BSA, body surface area; cDAPSA, Clinical Disease Activity Index for PsA; DLQI, Dermatology Life Quality Index; GUS, guselkumab; HAQ-DI, Health Assessment Questionnaire–Disability Index; i, inhibitor; IL, interleukin; MOA, mode of action; PsA, psoriatic arthritis; PsO, psoriasis; PtGA, Patient's Global Assessment; RWE, real-world evidence; SD, standard deviation; yrs, years.

Siebert S, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3828.

Treatment effectiveness was similar with GUS and IL-17i across PsA outcomes at the 12-month visit

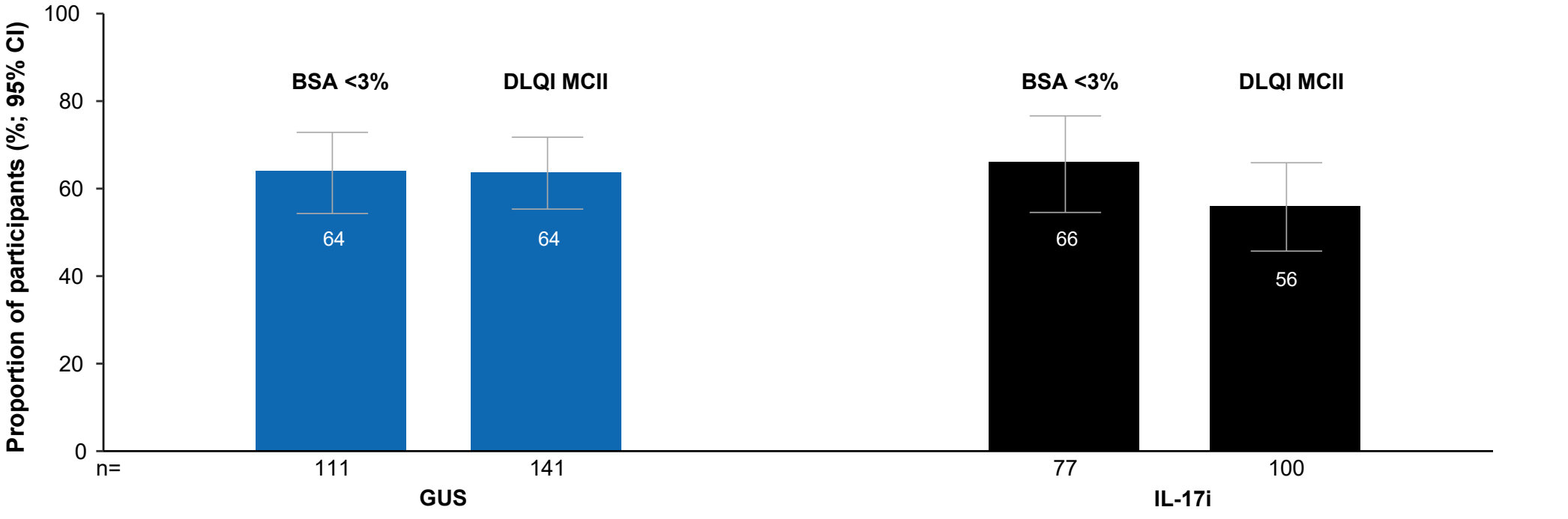
Composite clinical outcomes at 12 months



Number of patients (n) indicated under the X-axis correspond to the number of patients included in each respective analysis.
cDAPSA, Clinical Disease Activity Index for PsA; CI, confidence level; GUS, guselkumab; i, inhibitor; IL, interleukin; LDA, low disease activity; MCII, minimal clinically important improvement; MDA, minimal disease activity; MOA, mode of action; PsA, psoriatic arthritis; REM, remission; RWE, real-world evidence.
Siebert S, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3828.

Treatment effectiveness was similar with GUS and IL-17i across PsA outcomes at the 12-month visit

Skin PsO outcomes at 12 months



Number of patients (n) indicated under the X-axis correspond to the number of patients included in each respective analysis.
BSA, body surface area; CI, confidence level; DLQI, Dermatology Life Quality Index; GUS, guselkumab; i, inhibitor; IL, interleukin; MCII, minimal clinically important improvement; MOA, mode of action; PsA, psoriatic arthritis; PsO, psoriasis; RWE, real-world evidence.
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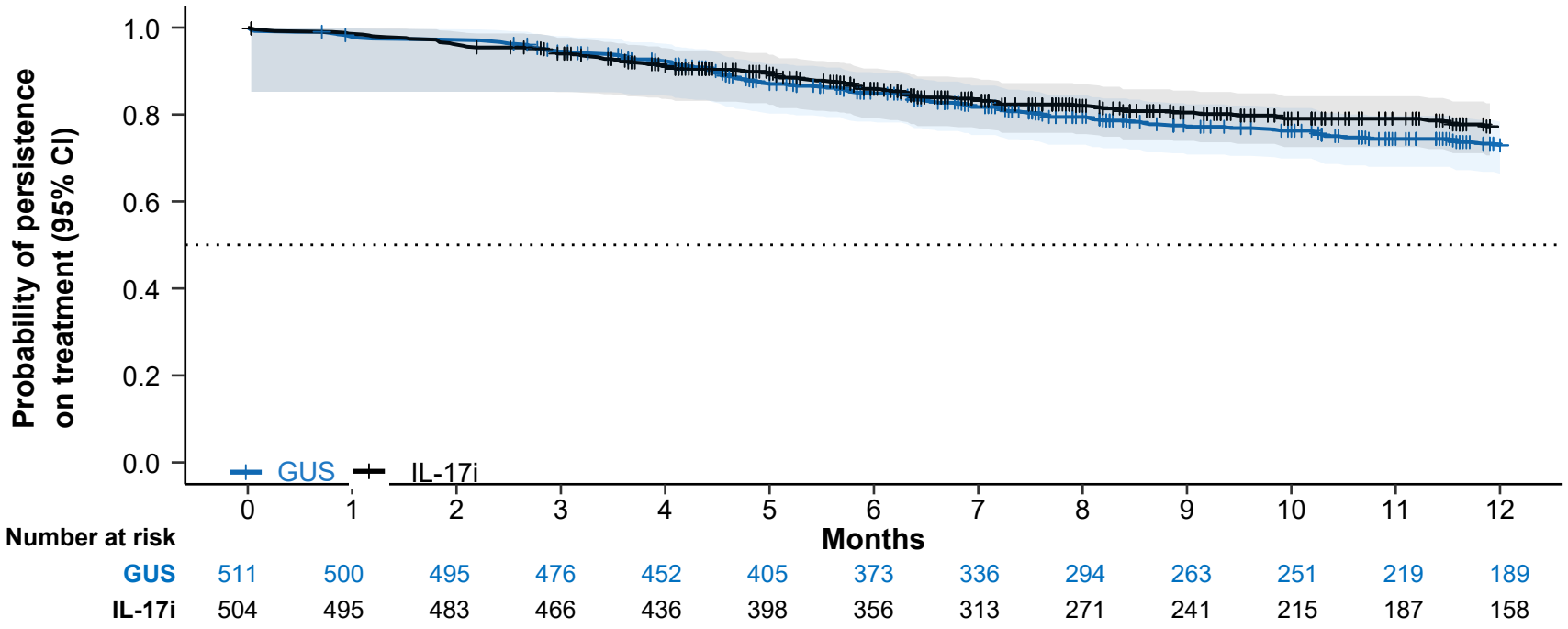
Treatment persistence rate was high with both GUS and IL-17i at the 12-month visit

- Approximately 80% and 83% of patients receiving GUS and IL-17i, respectively, remained on their initial treatment line up to the 12-month visit
- PS-adjusted* HR of GUS vs. IL-17i stop/switch was 1.11 (95% CI: 0.85–1.44)
- Reasons for initial treatment line discontinuation were consistent between cohorts

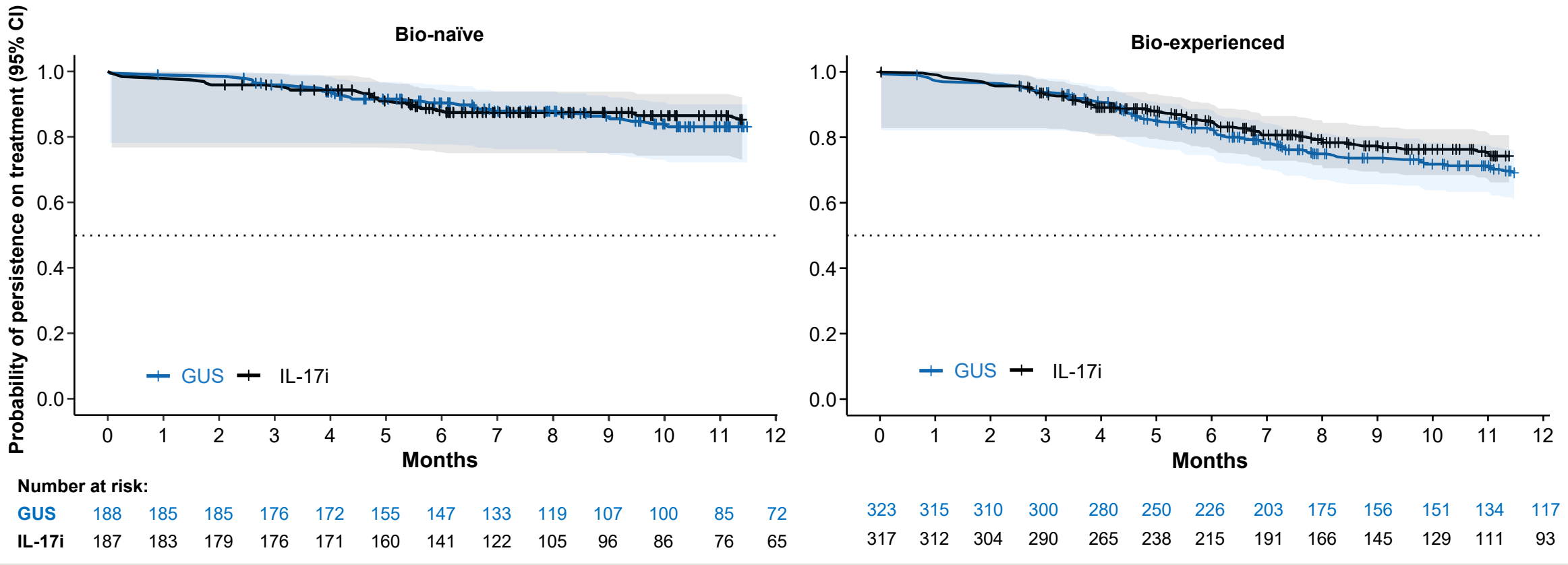
Treatment persistence through 12 months



*Adjusted for potential confounders at baseline including initial bDMARD treatment line, among others.
bDMARD, biologic disease-modifying anti-rheumatic drug; CI, confidence level; GUS, guselkumab; HR, hazard ratio; i, inhibitor; IL, interleukin; MOA, mode of action; PsA, psoriatic arthritis; PS, propensity score; RWE, real-world evidence.
Siebert S, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3828.

Persistence on GUS and IL-17i was similar across prior treatment subgroups at the 12-month visit

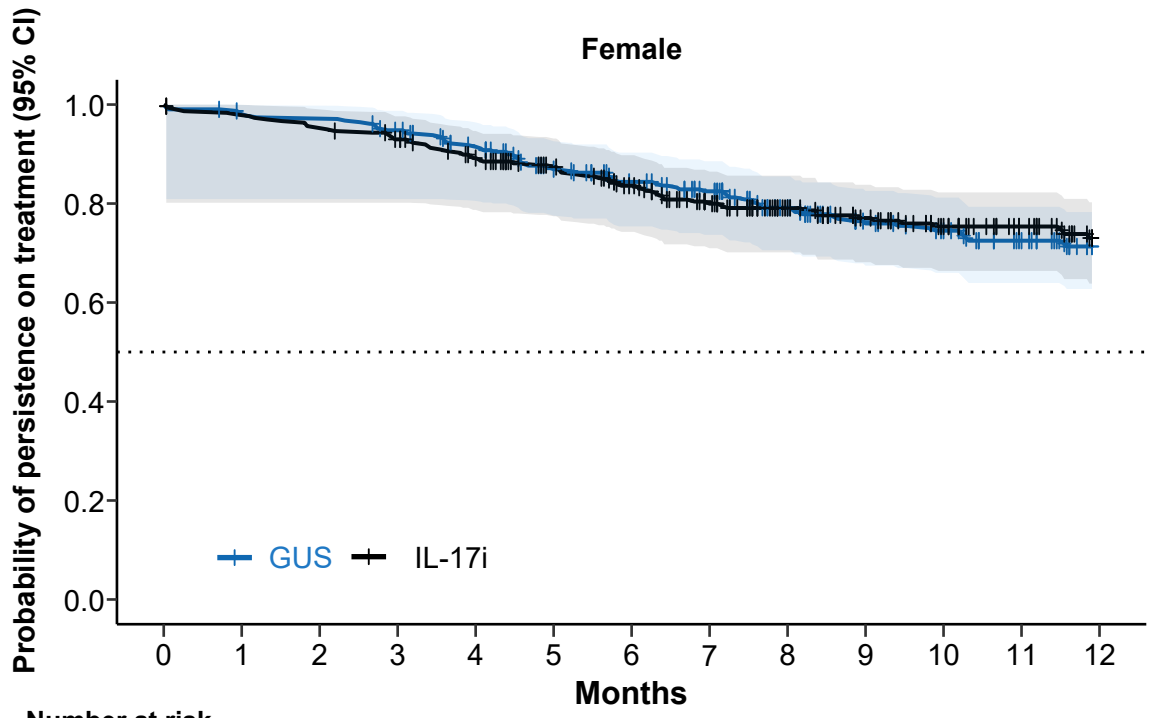
Persistence with GUS and IL-17i over 12 months in bio-naïve and bio-experienced patients with PsA

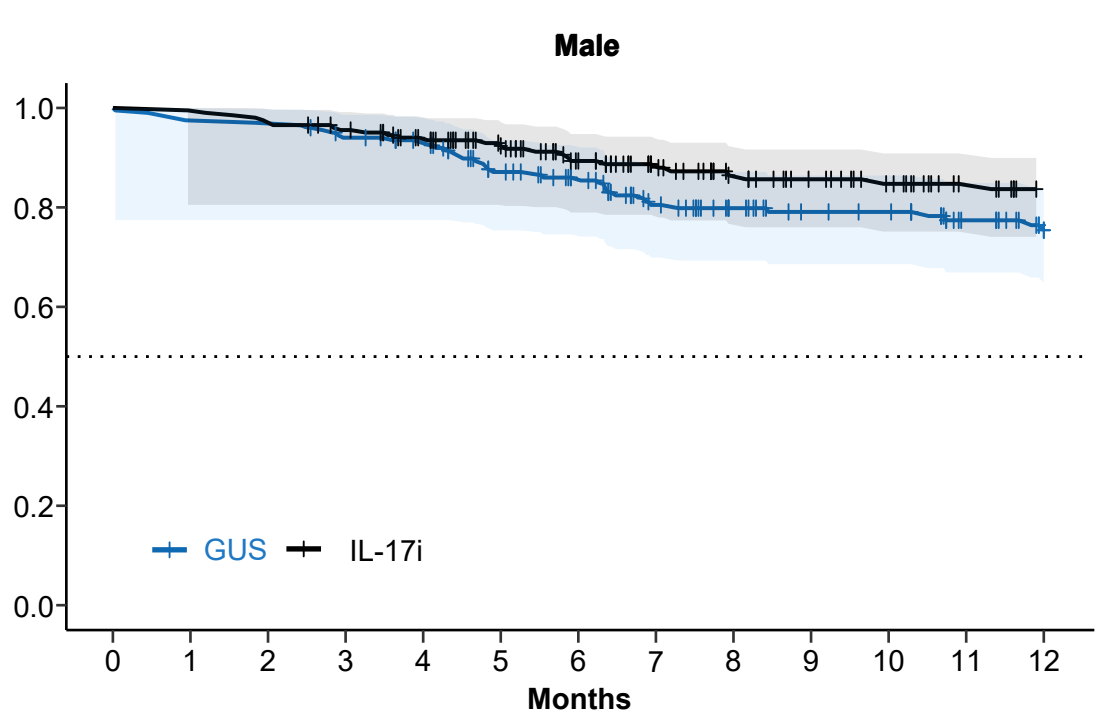


GUS, guselkumab; i, inhibitor; IL, interleukin; MOA, mode of action; PsA, psoriatic arthritis; RWE, real-world evidence.
Siebert S, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3828.

Persistence on GUS and IL-17i was similar regardless of sex at the 12-month visit

Persistence with GUS and IL-17i over 12 months in female and male patients with PsA





Number at risk

GUS	310	304	300	289	271	246	226	211	183	161	151	134	114
IL-17i	301	293	285	275	257	235	214	189	163	142	124	107	86

GUS	201	196	195	187	181	159	147	125	111	102	100	85	75
IL-17i	203	202	198	191	179	163	142	124	108	99	91	80	72

GUS, guselkumab; i, inhibitor; IL, interleukin; MOA, mode of action; PsA, psoriatic arthritis; RWE, real-world evidence.
Siebert S, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3828.

Conclusions

- Interim findings from the real-world, global, prospective PsABIOnd study showed that patients with PsA had similar 12-month treatment persistence with GUS or IL-17i over 12 months
  - ✓ Persistence was similar across biologic treatment history and sex subgroups
- GUS and IL-17i effectiveness was similar across key PsA domains at 12 months
- These results add to real-world evidence of the long-term effectiveness of GUS and IL-17i, supporting efficacy data from RCTs

GUS, guselkumab; i, inhibitor; IL, interleukin; MOA, mode of action; PsA, psoriatic arthritis; RCT, randomised controlled trial; RWE, real-world evidence.
Siebert S, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3828.

P3437

Inhibition of structural damage progression with the selective IL-23i guselkumab in participants with active PsA: Results through Week 24 of the Phase 3, randomized, double-blind, placebo-controlled APEX study

P. J. Mease[1,2], C. T. Ritchlin[3], L. C. Coates[4], A. P. Kollmeier[5], B. Zhou[6], Y. Jiang[6], K. Bensley[6], K. Im[7], R. Batra[8], S. D. Chakravarty[9,10], P. Rahman[11], D. van der Heijde[12], J. F. Merola[13]*

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*Presenting author.

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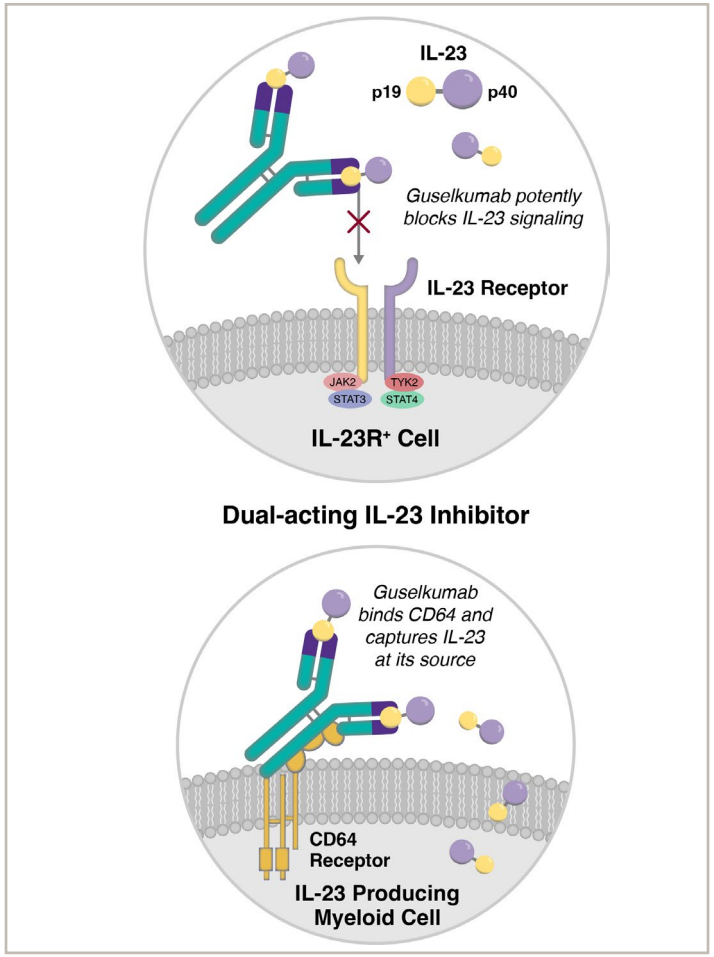
Background and objectives

GUS inhibition of structural damage progression in PsA

- PsA, a chronic, heterogeneous, inflammatory disease affecting joints and skin, can substantially impact health-related quality of life[1,2]
  - Structural damage resulting from chronic inflammation leads to reduced physical function and quality of life[3]
- GUS is a fully human, dual-acting, mAb that selectively inhibits the IL-23p19 subunit[4]
  - It is indicated to treat moderate-to-severe plaque PsO, active PsA, and moderately to severely active CD and UC[5]
- In DISCOVER-2, biologic-naïve patients with active PsA receiving GUS Q4W exhibited significantly less radiographic progression vs. PBO ($p<0.0001$); the lower rate of radiographic progression seen with GUS Q8W vs. PBO did not reach statistical significance[6]

Objective

- Report findings through W24 of the ongoing Phase 3b, randomised, double-blind, placebo-controlled APEX study (NCT04882098), intended to further evaluate GUS effects on clinical and radiographic progression outcomes in patients with active PsA



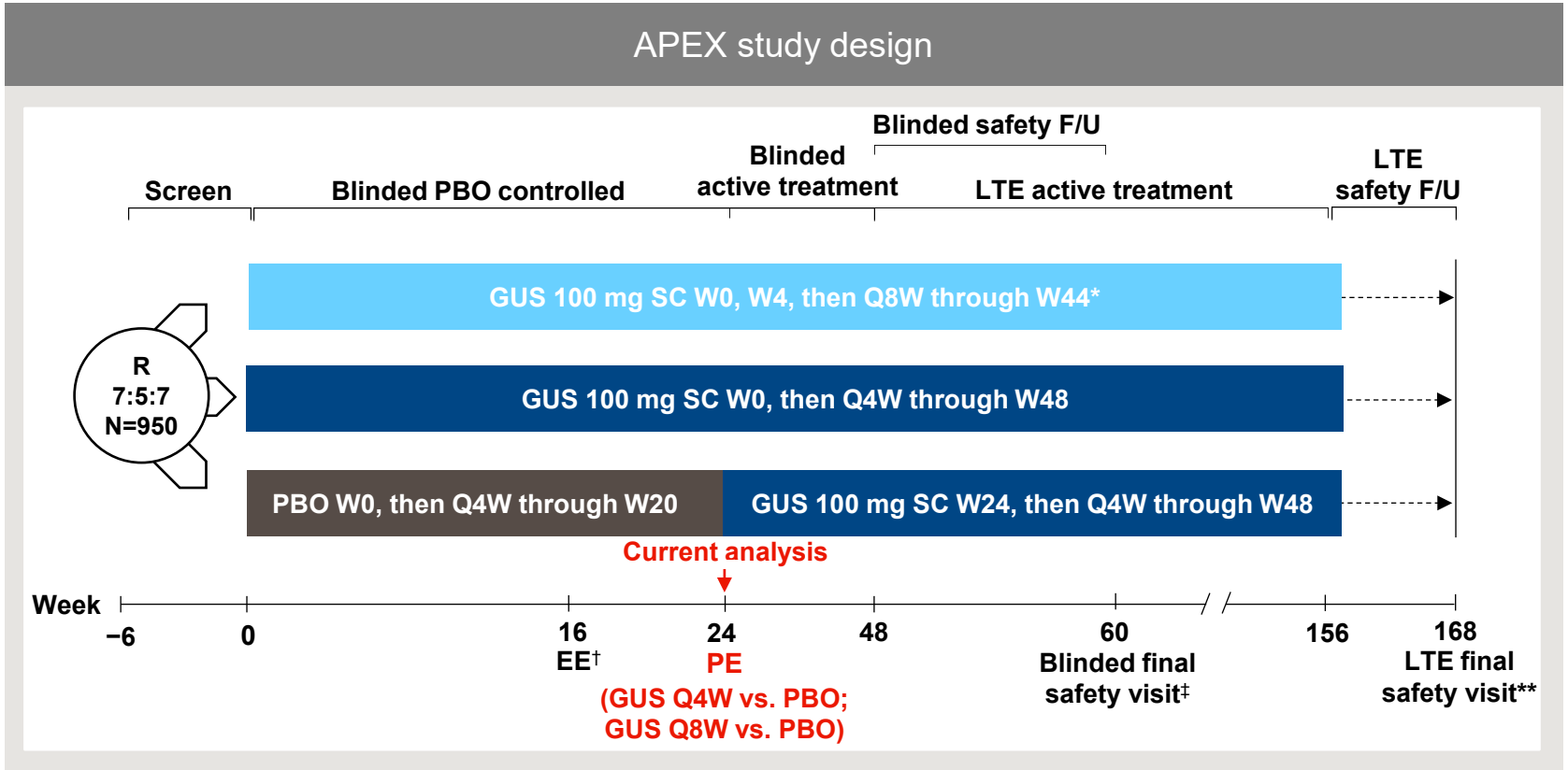
CD, Crohn's disease; GUS, guselkumab; IL-23R; interleukin-23 receptor; IL, interleukin; mAb, monoclonal antibody; MOA, mode of action; PBO, placebo; PsA, psoriatic arthritis; PsO, psoriasis; Q4W, every 4 weeks; Q8W, every 8 weeks; RDBPC, randomised, double-blind, placebo controlled; UC, ulcerative colitis. 1. Gladman DD, et al. *Q J Med* 1987;62:127–141; 2. Ritchlin CT. *J Rheumatol* 2008;35:1434–1437; 3. van der Heijde D, et al. *Arthritis Res Ther* 2020;22:18; 4. Sachen KL, et al. *Front Immunol* 2025;16:1532852; 5. Tremfya® (guselkumab). SmPC May 2025; 6. Mease PJ, et al. *Lancet* 2020;395:1126–1136.
Mease PJ, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3437.

APEX study design

Inclusion criteria
- ✓ Biologic-naïve
- ✓ Aged ≥18 years
- ✓ Active PsA for ≥6 months (despite prior csDMARD, apremilast, NSAID); meeting CASPAR criteria
- ✓ ≥3 SJC, ≥3 TJC, CRP ≥0.3 mg/dL
- ✓ ≥2 erosive joints on hand/foot radiographic imaging
- ✓ Active plaque PsO (≥1 PsO plaque ≥2 cm and/or nail PsO)

Multiplicity-controlled primary endpoints
- ACR20 response at W24

Major secondary endpoints
- Mean change in total PsA-modified vdH-S score at W24



- mFAS: All randomised patients, excluding those from Ukraine sites rendered unable to support key study operations due to major disruptions; employed as the main efficacy analysis set (N=1020)
- Safety analysis set: All patients who received ≥1 administration of any study intervention (N=1054)

*PBO SC W8 then Q8W through W48 administered to maintain blinding; †EE if <20% improvement from baseline in both TJC and SJC at W16. EE patients may initiate/increase dose permitted medication up to the maximum dose, at the investigator's discretion; ‡Final safety visit for those who do not enter LTE; **Final safety visit for those who entered LTE. ACR, American College of Rheumatology; CASPAR, Classification Criteria for Psoriatic Arthritis; CRP, C-reactive protein; csDMARD, conventional synthetic disease-modifying anti-rheumatic drug; EE, early escape; F/U, follow-up; GUS, guselkumab; IL, interleukin; LTE, long-term extension; mFAS, modified full analysis set; MOA, mode of action; NSAID, non-steroidal anti-inflammatory drug; PBO, placebo; PE, primary endpoint; PsA, psoriatic arthritis; PsO, psoriasis; Q4W, every 4 weeks; Q8W, every 8 weeks; R, randomised; RDBPC, randomised, double-blind, placebo controlled; SC, subcutaneous; SJC, swollen joint count; TJC, tender joint count; vdH-S, van der Heijde–Sharp score; W, week. Mease PJ, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3437.

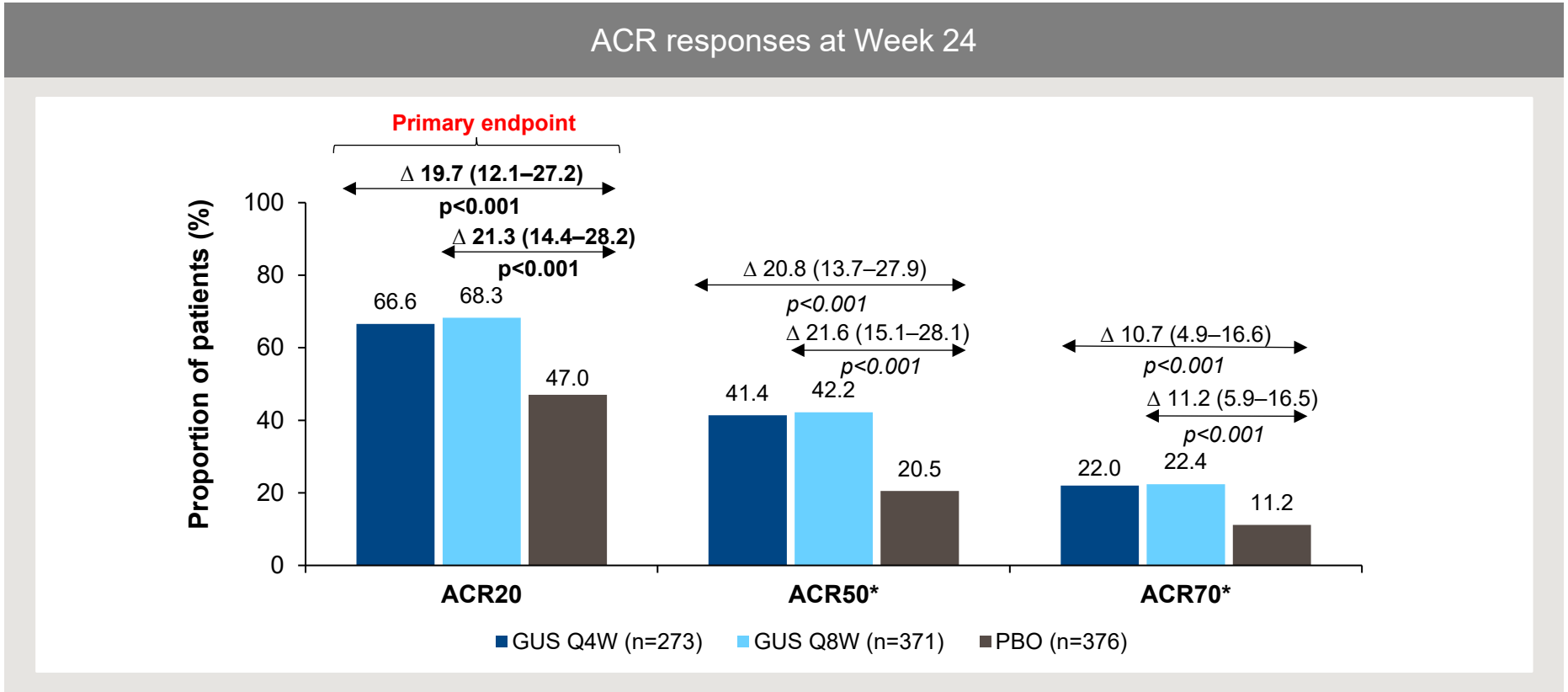
Characteristics of patients enrolled in APEX with active and erosive PsA were similar across groups

Baseline characteristics	GUS Q4W (n=273)	GUS Q8W (n=371)	PBO (n=376)	Total (N=1020)
Baseline demographics				
Age, yrs	52.2 (13.2)	53.2 (12.9)	53.5 (13.0)	53.0 (13.0)
Male	55%	54%	57%	55%
Weight, kg	85.6 (20.1)	83.2 (17.4)	83.1 (18.2)	83.8 (18.5)
BMI, kg/m^2	29.4 (6.0)	29.0 (5.6)	28.9 (5.7)	29.1 (5.7)
PsA characteristics				
PsA disease duration, yrs	7.5 (7.1)	7.2 (7.6)	7.2 (6.9)	7.3 (7.2)
SJC (0–66)	9.0 (6.0–14.0)*	10.0 (6.0–14.0)*	9.0 (6.0–15.0)*	9.0 (6.0–14.0)*
TJC (0–68)	16.0 (10.0–27.0)*	17.0 (11.0–26.0)*	16.6 (10.0–25.5)*	16.1 (10.0–26.0)*
HAQ-DI (0–3)	1.2 (0.7)	1.2 (0.6)	1.2 (0.7)	1.2 (0.7)
CRP, mg/dL	0.7 (0.4–1.5)*	0.8 (0.4–1.6)*	0.8 (0.4–1.8)*	0.8 (0.4–1.6)*
Enthesitis/dactylitis	58% / 44%	59% / 39%	59% / 45%	58% / 43%
Mean LEI (1–6) **/ DSS** (1–60)	3.2 / 10.8	3.0 / 11.0	3.0 / 10.2	3.1 / 10.6
PsO characteristics				
% BSA	15.0 (19.2)	16.5 (21.9)	16.3 (21.5)	16.0 (21.0)
PASI (0–72)	7.6 (8.3)	8.3 (10.1)	8.2 (9.5)	8.1 (9.4)
Radiographic characteristics				
PsA-modified vdH-S score (0–528)	27.7 (47.6)	26.7 (43.4)	26.8 (42.2)	27.0 (44.1)
Erosion score (0–320)	13.7 (24.3)	13.4 (21.9)	13.4 (20.7)	13.5 (22.1)
JSN score (0–208)	14.0 (24.2)	13.3 (22.8)	13.4 (22.4)	13.5 (23.0)

Background PsA medication use and treatment completion through W24 (96–97%) were consistent across treatment groups

Values are reported as mean (SD) unless otherwise noted. *Values are median (IQR). BMI, body mass index; BSA, body surface area; CRP, C-reactive protein; DSS, Dactylitis Severity Score; GUS, guselkumab; HAQ-DI, Health Assessment Questionnaire–Disability Index; IL, interleukin; IQR, interquartile range; JSN, joint space narrowing; LEI, Leeds Enthesitis Index; MOA, mode of action; PASI, Psoriasis Area and Severity Index; PBO, placebo; PsA, psoriatic arthritis; Q4W, every 4 weeks; Q8W, every 8 weeks; RDBPC, randomised, double-blind, placebo controlled; SD, standard deviation; SJC, swollen joint count; TJC, tender joint count; vdH-S, van der Heijde–Sharp; yrs, years.
Mease PJ, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3437.

GUS demonstrated significantly higher ACR20 response rates vs. PBO at W24 (primary endpoint)



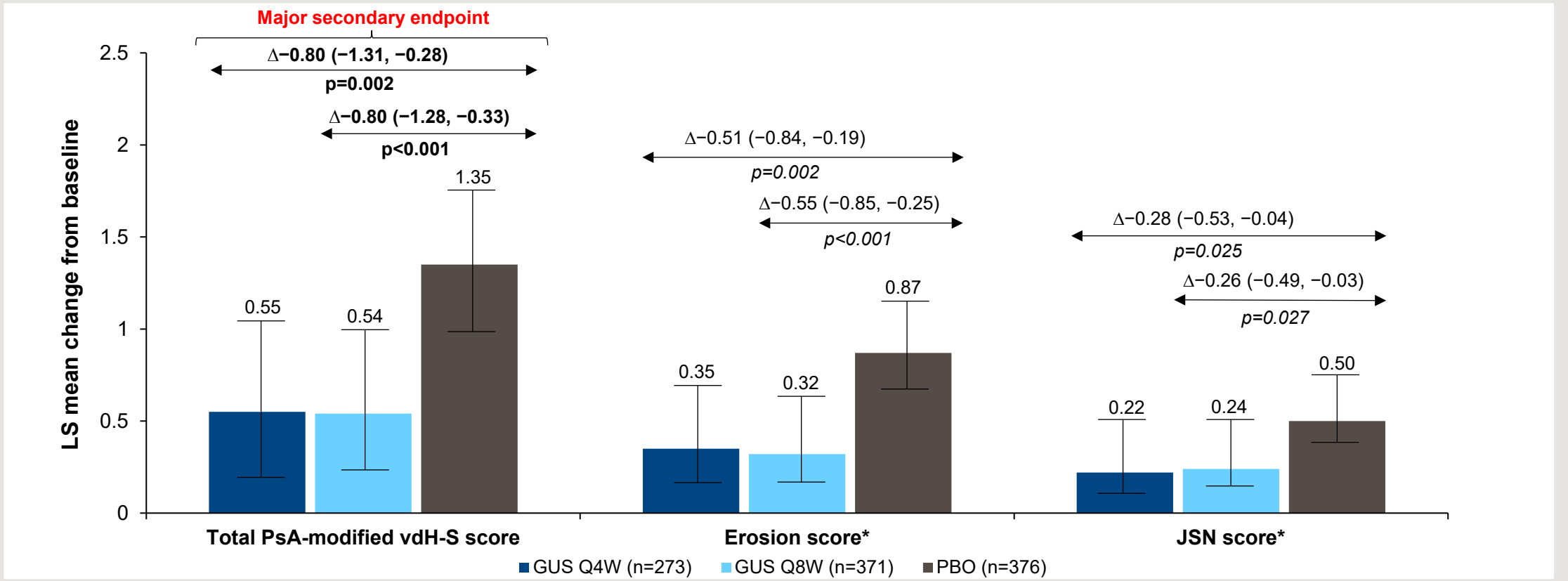
Significantly higher rates of ACR50 and ACR70 were demonstrated with GUS vs. PBO at W24

Primary endpoint p-values are multiplicity controlled using a fixed sequence testing procedure and can be used to determine statistical significance. Statistics are based on CMH across multiple imputed datasets. *Italicised p-values are nominal.
Δ, treatment difference (95% CI). ACR, American College of Rheumatology; CI, confidence interval; CMH, Cochran–Mantel–Haenszel; GUS, guselkumab; IL, interleukin; MOA, mode of action; PBO, placebo; PsA, psoriatic arthritis; Q4W, every 4 weeks; Q8W, every 8 weeks; RDBPC, randomised, double-blind, placebo controlled; W, week.
Mease PJ, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3437.

Guselkumab dosage q4w is not approved by Swissmedic

Significantly lower rates of radiographic progression were observed with GUS vs. PBO at W24 (major secondary endpoint)

LS mean change from baseline in radiographic progression scores at W24

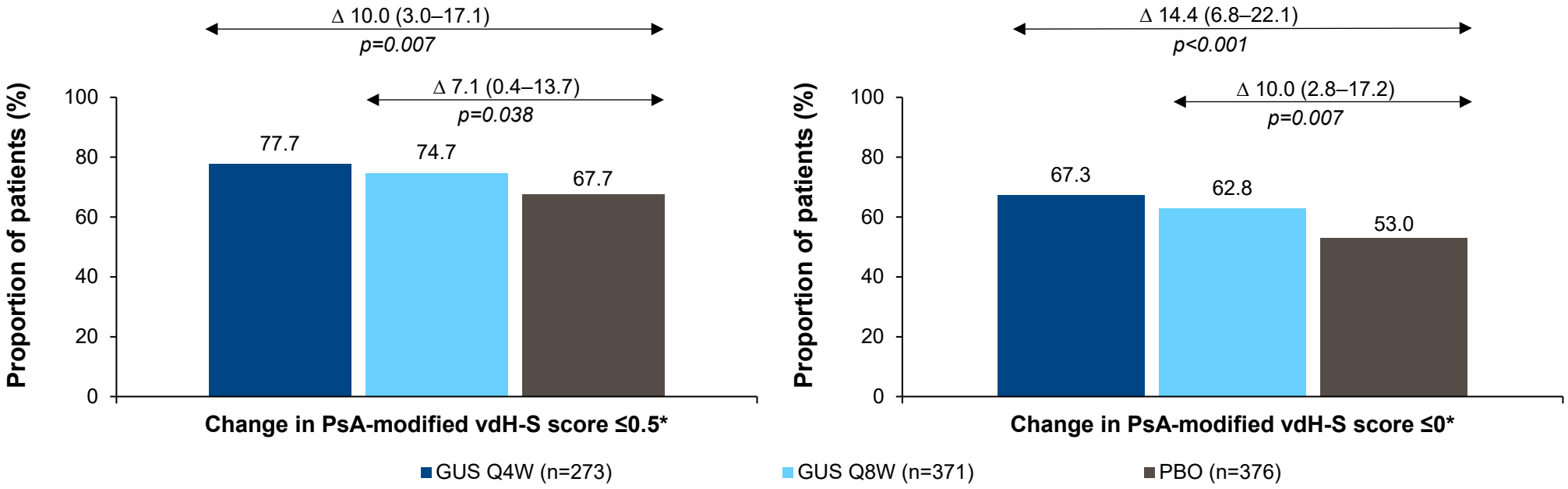


GUS exhibited consistent treatment effects for both erosion and JSN scores

Major secondary endpoint (PsA-modified vdH-S score) p-values are multiplicity controlled using a fixed sequence testing procedure and can be used to determine statistical significance. Statistics are based on ANCOVA across multiply imputed datasets. Δ, treatment difference (95% CI). *Italicised p-values are nominal. ANCOVA, analysis of covariance; BL, baseline; CI, confidence interval; GUS, guselkumab; IL, interleukin; JSN, joint space narrowing; LS, least squares; MOA, mode of action; PBO, placebo; PsA, psoriatic arthritis; Q4W, every 4 weeks; Q8W, every 8 weeks; RDBPC, randomised, double-blind, placebo controlled; vdH-S, van der Heijde–Sharp; W, week. Mease PJ, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3437.

Higher proportions of patients who received GUS showed no radiographic progression at W24 vs. PBO

Patients with no radiographic progression at Week 24



Δ, treatment difference (95% CI); *Italicised p-values are nominal.
CI, confidence interval; GUS, guselkumab; IL, interleukin; MOA, mode of action; PBO, placebo; PsA, psoriatic arthritis; Q4W, every 4 weeks; Q8W, every 8 weeks; RDBPC, randomised, double-blind, placebo controlled; vdH-S, van der Heijde-Sharp; W, week.
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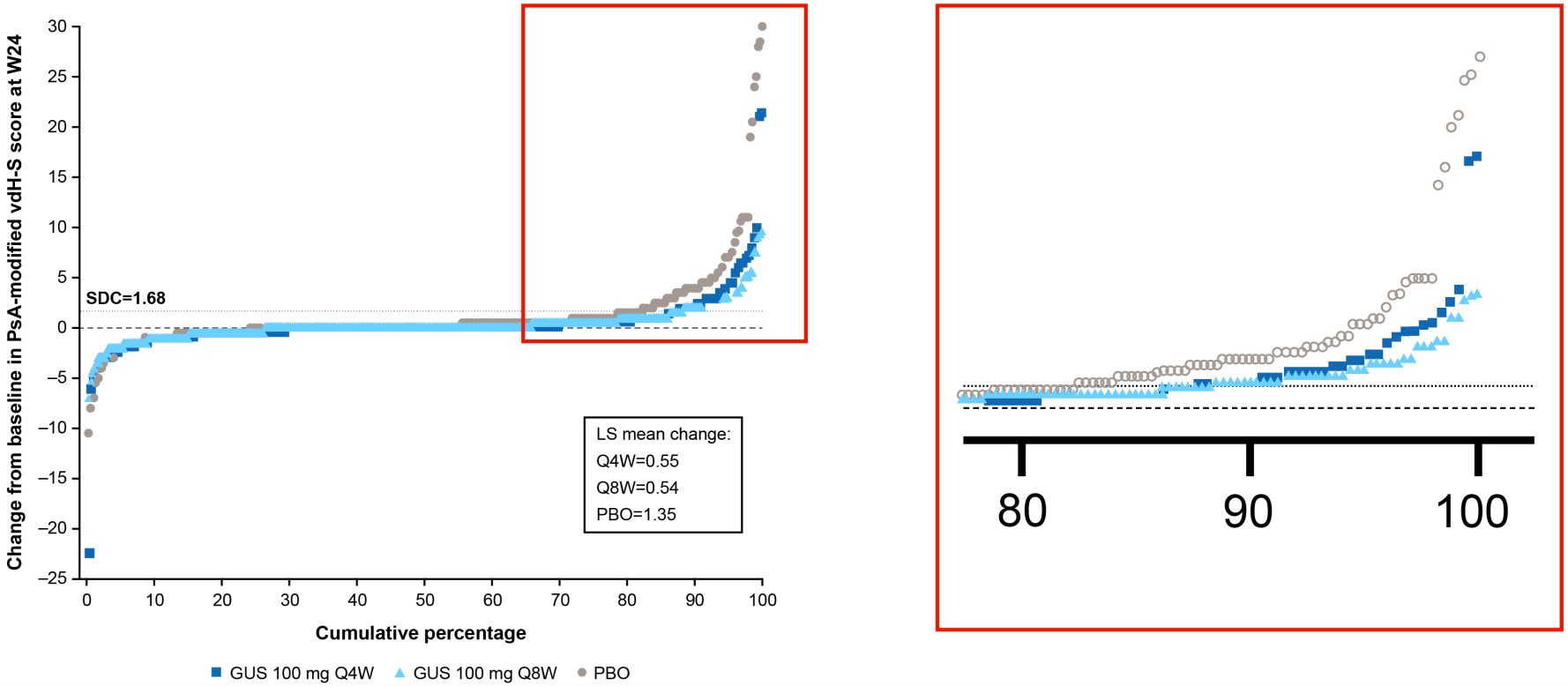
Patient-level data showed clear separation between GUS and PBO

Change from baseline in PsA-modified vdH-S score at Week 24



GUS, guselkumab; IL, interleukin; LS, least squares; MOA, mode of action; PBO, placebo; PsA, psoriatic arthritis; Q4W, every 4 weeks; Q8W, every 8 weeks; RDBPC, randomised, double-blind, placebo controlled; SDC, smallest detectable change; vdH-S, van der Heijde–Sharp; W, week.

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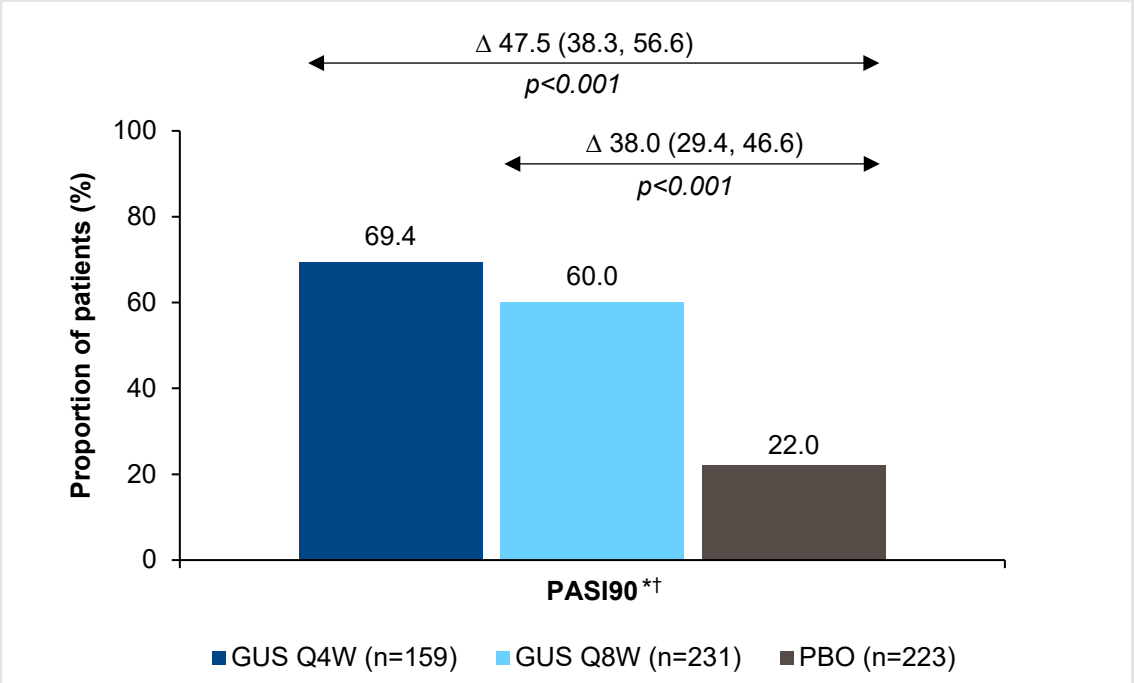
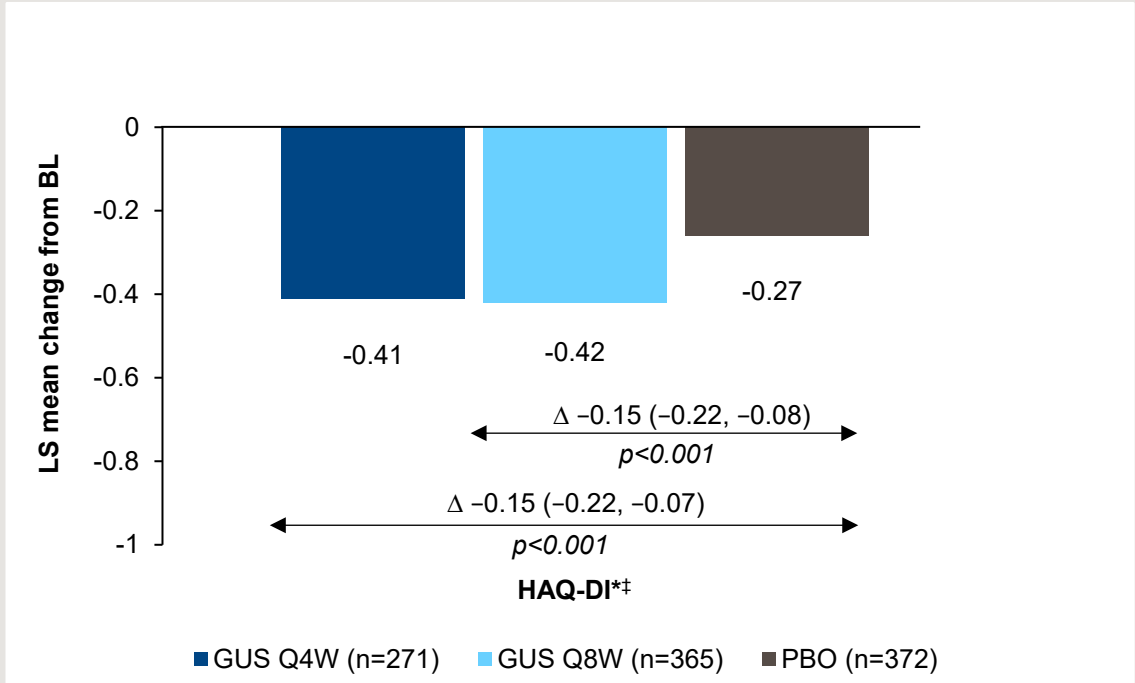
GUS demonstrated higher rates of skin clearance and greater improvement in physical function vs. PBO at W24

PASI90 response at Week 24



HAQ-DI response at Week 24



Δ, treatment difference (95% CI).
*Italicised p-values are nominal; †Among patients who had ≥3% BSA psoriatic involvement and an IGA score of ≥2 (mild) at baseline; ‡HAQ-DI score is the average of the computed categories scores (dressing, arising, eating, walking, hygiene, gripping and daily living). Lower scores indicate better functioning.
BL, baseline; BSA, body surface area; CI, confidence interval; GUS, guselkumab; HAQ-DI, Health Assessment Questionnaire–Disability Index; IGA, Investigator's Global Assessment; IL, interleukin; MOA, mode of action; PASI, Psoriasis Area Severity Index; PBO, placebo; PsA, psoriatic arthritis; Q4W, every 4 weeks; Q8W, every 8 weeks; RDBPC, randomised, double-blind, placebo controlled; W, week.
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GUS AE profile through W24 was similar to PBO

GUS safety profile through Week 24 vs. PBO			
Safety through Week 24	**GUS Q4W (n=280)**	**GUS Q8W (n=388)**	**PBO (n=386)**
Mean weeks of follow-up	24.0	23.9	23.8
Patients with ≥1:			
AE, n (%)	107 (38.2)	165 (42.5)	144 (37.3)
SAE, n (%)	5 (1.8)	12 (3.1)	10 (2.6)
AE leading to study agent discontinuation, n (%)	2 (0.7)	6 (1.5)	1 (0.3)
Infection, n (%)	52 (18.6)	91 (23.5)	81 (21.0)
Serious infection, n (%)	2 (0.7)	5 (1.3)	1 (0.3)
Active tuberculosis	0	0	0
Opportunistic infection	0	0	0
Venous thromboembolism event, n (%)	1 (0.4)	1 (0.3)	1 (0.3)
Anaphylactic or serum sickness reaction	0	0	0
Clinically important hepatic disorder*	0	0	0

- Study remains blinded through W48
- Two patients experienced malignancy (prostate, renal), one MACE was reported and one COVID-19-related death occurred in an unvaccinated, elderly patient
- No new-onset IBD

Safety analysis set. AEs are coded using MedDRA Version 27.0. Data are n (%) unless otherwise noted.
*Clinically important hepatic disorders were prespecified as AE terms within the MedDRA category of Drug-Related Hepatic Disorders that met the criteria for an SAE or led to study agent discontinuation.
AE, adverse event; GUS, guselkumab; IBD, inflammatory bowel disease; IL, interleukin; MACE, myocardial infarction; MedDRA, Medical Dictionary for Regulatory Activities; MOA, mode of action; PBO, placebo; PsA, psoriatic arthritis; Q4W, every 4 weeks; Q8W, every 8 weeks RDBPC, randomised, double-blind, placebo controlled; SAE, serious adverse event; W, week.
Mease PJ, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3437.

Conclusions

At W24 of the ongoing Phase IIIb APEX study of GUS, a dual-acting selective IL-23i for PsA, the following were demonstrated with the Q4W and Q8W regimens:

- ✓ Significantly higher ACR20 response rates vs. PBO
- ✓ Significantly lower rates of radiographic progression (Δ GUS vs. PBO = –0.80)

- ✓ Consistent effects on erosion and JSN scores
- ✓ Higher proportion of patients with no progression of structural damage vs. PBO
- ✓ Higher rates of ACR50, ACR70 and PASI90, and greater improvement in physical function vs. PBO

- ✓ Similar AE profile for GUS and PBO
- ✓ No new GUS safety signal

GUS is the only selective IL-23i to demonstrate significant inhibition of structural damage progression

Δ, treatment difference (95% CI).
ACR, American College of Rheumatology; AE, adverse event; GUS, guselkumab; i, inhibitor; IL, interleukin; JSN, joint space narrowing; MOA, mode of action; PASI, Psoriasis Area Severity Index; PBO, placebo; PsA, psoriatic arthritis; Q4W, every 4 weeks; Q8W, every 8 weeks; RDBPC, randomised double-blind placebo-controlled; W, Week.
Mease PJ, et al. Presented at EADV, Paris, France, 17–20th September 2025. P3437.

Low priority abstracts

Guselkumab

GUIDE	GUIDE Phase 3b trial results: Early intervention with guselkumab results in higher rates of fingernail psoriasis clearance and maintenance of nail response following treatment withdrawal	Knut Schäkel, Kilian Eyerich, Andreas Pinter, Peter Weisenseel, Carle Paul, Julian Wilke, Nina Trenkler, Yanqing Chen, Nikolas Spindler, Nenja Krüger, Khusru Asadullah		P2645
China Ph4	Maintenance of response after guselkumab withdrawal: Findings from an observational study in Chinese patients with moderate-to-severe plaque psoriasis	Songmei Geng, Aijun Chen, Liangdan Sun, Andrea Chen, Bin Yang		P2163
	Predictors of psoriasis relapse after guselkumab withdrawal: An observational analysis of Chinese patients	Aijun Chen, Songmei Geng, Liangdan Sun, Andrea Chen, Bin Yang		P2164
	Super-response to guselkumab treatment in Chinese patients with moderate-to-severe psoriasis: A *post hoc* analysis from a Phase 4 RCT	Min Zheng, Kun Huang, Songmei Geng, Xiaohua Tao, Liangdan Sun, Chao Ji, Bin Yang, Yan Lu, Xiaoxue Di, Weilong Zhao, Rui Wang		P2219
	Efficacy of guselkumab through 48 weeks in Chinese psoriasis patients with and without metabolic comorbidities: A *post hoc* analysis of a Phase 4 RCT	Min Zheng, Rong Xiao, Chunlei Zhang, Furen Zhang, Qianjin Lu, Xia Li, Huiping Wang, Yuling Shi, Xiaoxue Di, Weilong Zhao, Rui Wang		P2165
RECAP	Real-world characteristics of patients initiating advanced therapy for plaque psoriasis in the US specialty dermatology networks	Lawrence Rasouliyan, Amanda Althoff, David Wu, Nan Li, Timothy Fitzgerald, Jing Zhao		P2137
SPECTREM	SPECTREM: Guselkumab demonstrates consistent significant clearance across the full range of low body surface area, moderate psoriasis with special sites involvement	Linda Stein Gold, Bruce Strober, April W. Armstrong, Theodore Alkousakis, Kim A. Papp, Richard Langley, Olivia Choi, Daphne Chan, Jenny Jeyarajah, Vlada Groysman, Mark G. Lebwohl	Encore	P3886
	SPECTREM: Guselkumab efficacy across multiple high-impact sites in participants with low BSA moderate plaque psoriasis	Stephen K. Tyring, Angela Y. Moore, Harrison Nguyen, Nicole Seminara, Henry Yu, Theodore Alkousakis, Olivia Choi, Katelyn Rowland, Daphne Chan, Jenny Jeyarajah, Lorne Albrecht	Encore	P3388
PROTOSTAR	Guselkumab pharmacokinetics and immunogenicity in pediatric psoriasis: Phase 3 PROTOSTAR study	V. Sinha, H. Crauwels, M. Zimmermann, O.N. Obianom, B. van Hartingsveldt, M. Jett, G. Jiang, A. Vermeulen	Encore	P1867

BSA, body surface area; RCT, randomised controlled trial.

Low priority abstracts

Guselkumab

VISIBLE	VISIBLE: Guselkumab impact on psoriatic arthritis through Week 48 in participants with moderate-to-severe psoriasis across all skin tones	Alice B. Gottlieb, Amy McMichael, Tina Bhutani, Olivia Choi, Katelyn Rowland, Theodore Alkousakis, Jessica Vasquez, Tony Ma, Soumya D. Chakravarty, Daphne Chan, Andrea Nguyen, Seemal R. Desai, Andrew Alexis, Joseph F. Merola*	Encore	FC01.1G
	VISIBLE Cohort A: Guselkumab demonstrated skin clearance and improved health-related quality of life through Week 48 in participants with moderate-to-severe plaque psoriasis across all skin tones	Andrew Alexis, Adrian O. Rodriguez, Geeta Yadav, Stephen K. Tyring, Olivia Choi, Theodore Alkousakis, Daphne Chan, Tony Ma, Maxwell Sauder, Javier Alonso-Llamazares, Seemal R. Desai	Encore	P3364
	VISIBLE Cohort B: Guselkumab demonstrated scalp clearance and improved health-related quality of life through Week 48 in participants with moderate-to-severe scalp psoriasis across all skin tones	Amy McMichael, Tina Bhutani, Stacy Smith, Theodore Alkousakis, Olivia Choi, Daphne Chan, Tony Ma, Ross Radusky, Jensen Yeung, George Han, Susan C. Taylor	Encore	P2199
CERES	Baseline characteristics of patients with moderate-to-severe plaque psoriasis treated with guselkumab self-administered using the one-press injector in Portugal: A study on treatment satisfaction	Fernando Mota, Joao Teles Sousa, Joana Antunes, Pedro Mendes-Bastos, Ana Brasileiro, Vitor Neto, Martinha Henrique, Rita Pimenta, Sofia Magina, Tiago Torres	Encore	P2175
GAIA	Persistence of guselkumab in psoriatic disease over 3 years in real life conditions, a nationwide claims database analysis	Laure Gossec, Claudepierre Pascal, Constantin Arnaud, Denis Jullien, Samira		P3146

LB, late-breaker.