Διαχείριση της ψωριασικής νόσου: Το μονοπάτι του ιατρού προς την κλινική απόφαση

Προεδρείο: *Χ. Παπαγόρας*

- **Υπάρχει τυπικός ασθενής με ΨΑ;**
  Χ. Παπαγόρας

- **Πώς τα κλινικά χαρακτηριστικά οδηγούν τη θεραπευτική απόφαση;**
  Ε. Καμπυλαυκά

Χαράλαμπος Παπαγόρας
Αν. Καθηγητής Ρευματολογίας Δ.Π.Θ.,
Α΄ Πανεπιστημιακή Παθολογική Κλινική, Π.Γ.Ν. Αλεξανδρούπολης

Ελένη Καμπυλαυκά
Ρευματολόγος, Επιστημονική Συνεργάτης Ομίλου Ιατρικού Αθηνών

Disclosures

Prof. Papagoras has received consultant and/or speaker fees from: Abbvie, Amgen, Genesis, Lilly, Pfizer, DEMO, Janssen, UCB, Boehringer-Ingelheim, Sobi

Dr. Kampylafka has received honoraria and/or speaker fees from: Abbvie, Sandoz, Janssen, Lilly

Johnson&Johnson
Innovative Medicine

5ο Πανελλήνιο Θερινό Συμπόσιο Μυοσκελετικής Υγείας
8-11 Μαίου 2025, AKS Porto Heli Conference Center, Πορτο Χελι

ΔΟΡΥΦΟΡΙΚΗ ΔΙΑΛΕΞΗ

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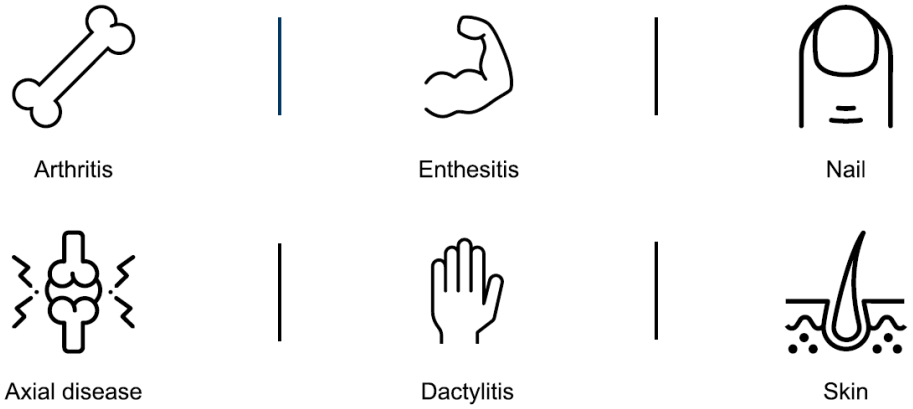
Παρασκευή 9 Μαΐου 2025
19:30-20:00

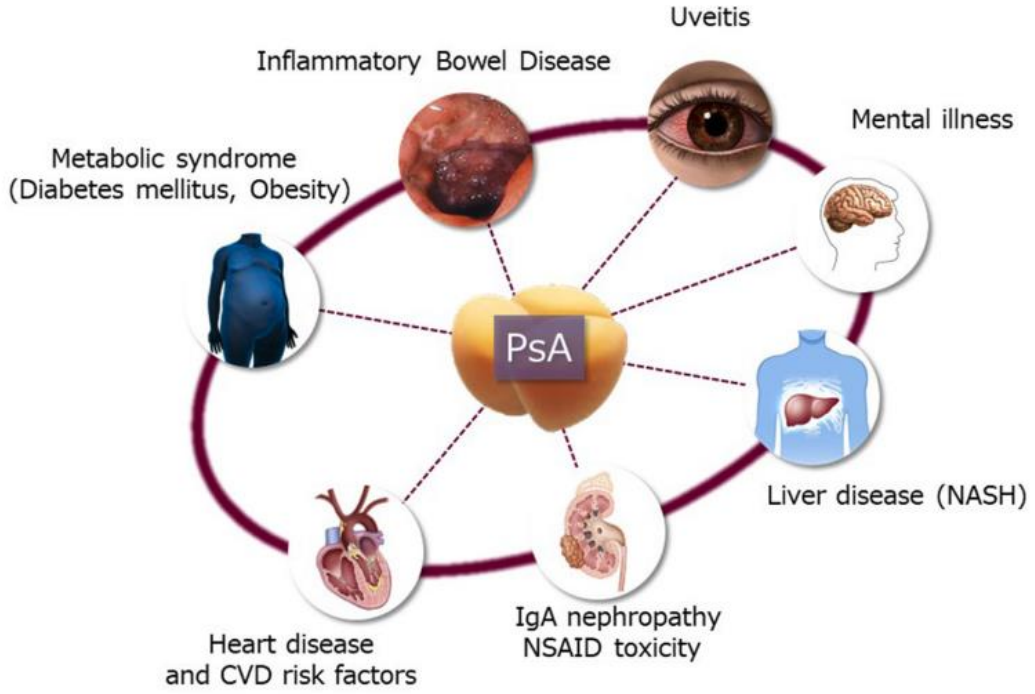
AKS Porto Heli Conference Center, Πορτο Χελι

Αξιολογήστε τη δορυφορική διάλεξη σκανάροντας το QR code

Psoriatic disease spectrum

a clinically heterogenous disease with a range of disease domains and related comorbidities

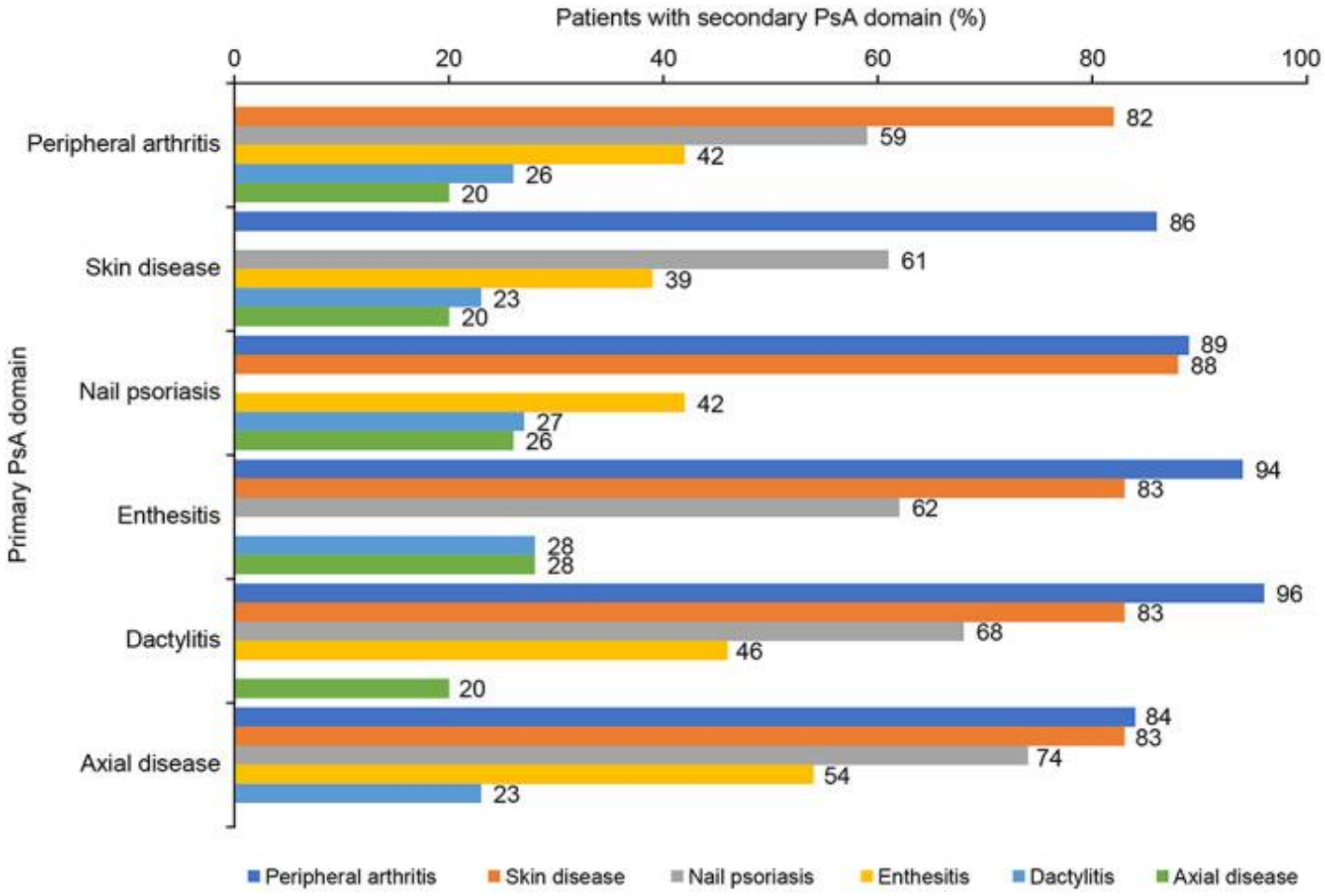




Musculoskeletal Care. 2022;20(S1):S22–S31.

Best Practice & Research Clinical Rheumatology 35 (2021) 101670

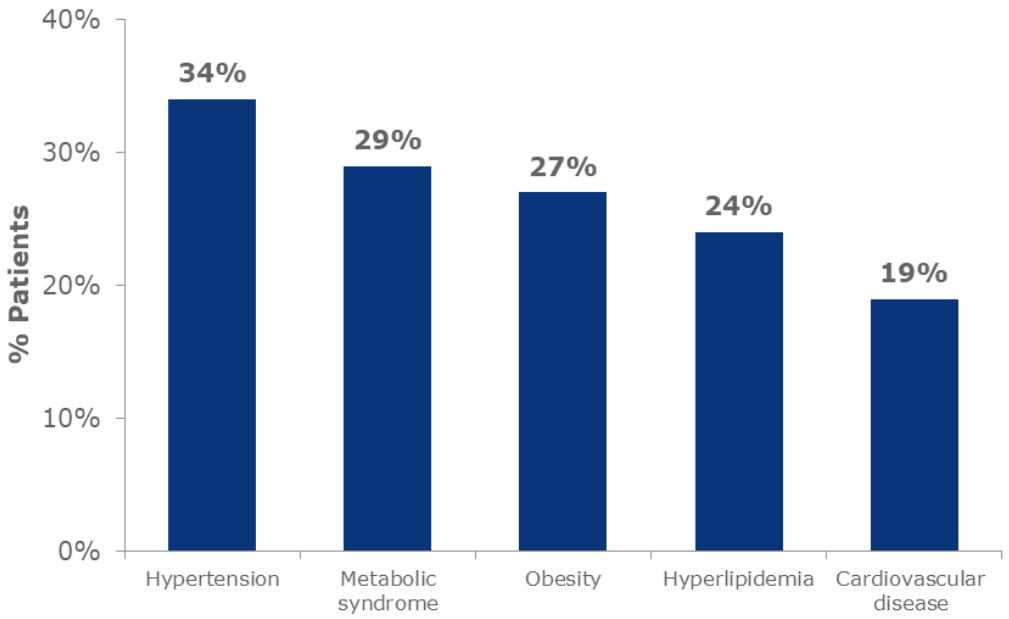
Concomitant disease domains and rates of occurrence



ACR Open Rheumatology Vol. 5, No. 8, August 2023, pp 388–398 DOI 10.1002/acr2.11556

Psoriatic disease spectrum

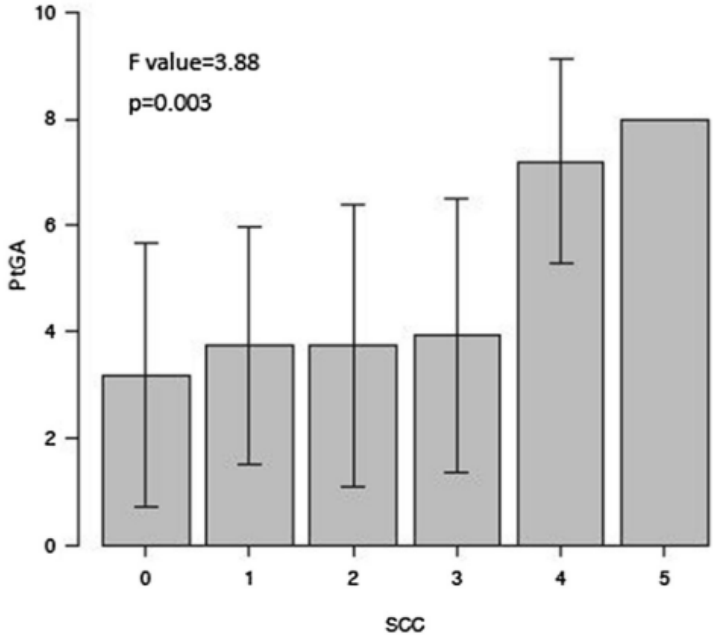
Most prevalent comorbidities amongst PsA patients



SYSTEMATIC REVIEW AND META-ANALYSIS

Gupta et al. (2021). Rheumatol Intl. 41, 275-284

Impact of Comorbidities on Disease Activity, Patient Global Assessment, and Function in PsA



A Cross-Sectional Study

One-way ANOVA analysis of PtGA and SCC. The median PtGA value was different among patients with different numbers of comorbidities, and was statistically significant. Bar graph, PtGA value in PsA patient divided in six group, considering the comorbidities number. PtGA patient's global assessment, SSC simple comorbidities count

Rheumatol Ther (2020) 7:825–836 https://doi.org/10.1007/s40744-020-00229-0

Ο κ. Γιώργος, ένας τυπικός ασθενής

52 ετών

Καπνιστής
Κοινωνική χρήση αλκοόλ

103 kg (BMI 31,8)

Από μηνός

- Δακτυλίτιδα μέσου δακτύλου ΑΡ
- Αρθρίτιδα 2ης και 3ης ΜΤΦ ΔΕ
- Χωρίς ιδιαίτερη βελτίωση με ΜΣΑΦ

.
Information based on speaker’s clinical experience.

Ο κ. Γιώργος, ένας τυπικός ασθενής

52 ετών

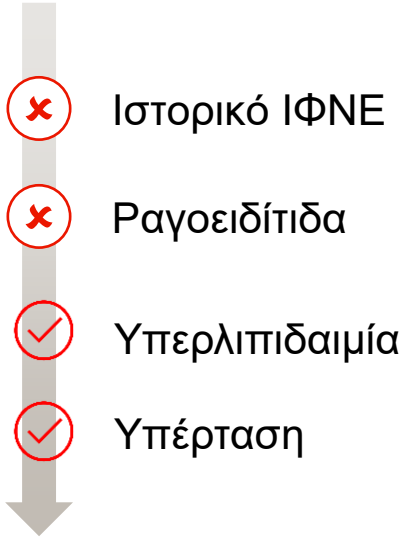
Καπνιστής
Κοινωνική χρήση αλκοόλ

103 kg (BMI 31,8)

Ψωρίαση

35 ετών

- Τριχωτό κεφαλής και μεσογλουτιαία πτυχή
- BSA 2
- τοπική αγωγή με GCs

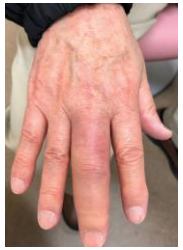


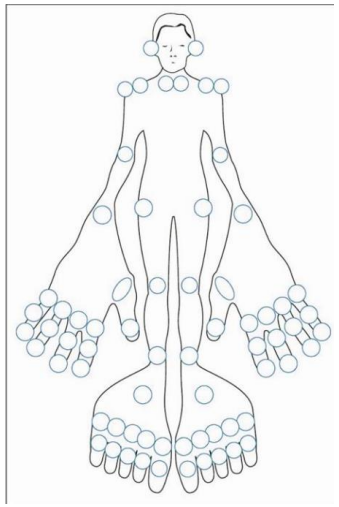
- ✗ Ιστορικό ΙΦΝΕ
- ✗ Ραγοειδίτιδα
- ✓ Υπερλιπιδαιμία
- ✓ Υπέρταση

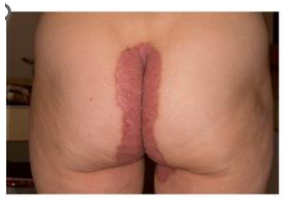
- **MTX (15 mg s.c.)**
- Εξάλειψη δακτυλίτιδας/αρθρίτιδας και σχεδόν πλήρης κάθαρση δέρματος
- διακοπή MTX ένα χρόνο μετά λόγω αύξησης ηπατικών

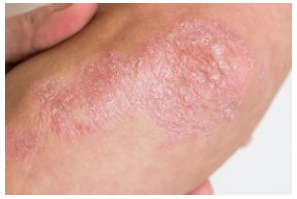
.
Information based on speaker's clinical experience.

Ο κ. Γιώργος, ένας τυπικός ασθενής









PsA FLARE

Δακτυλίτιδα μέσου ΔΕ

Αρθρίτιδα

- 3ης και 4ης ΜΤΦ ΔΕ
- 2ης και 3ης ΑΦΦ ΑΡ

Ψωρίαση

- τριχωτο κεφαλής
- μεσογλουτιαία χώρα
- αγκώνων

Assessment

BSA: 4 %

DAPSA: 33.6

TJC: 10

SJC: 7

PtGA 8

CRP: 5.6 mg/l

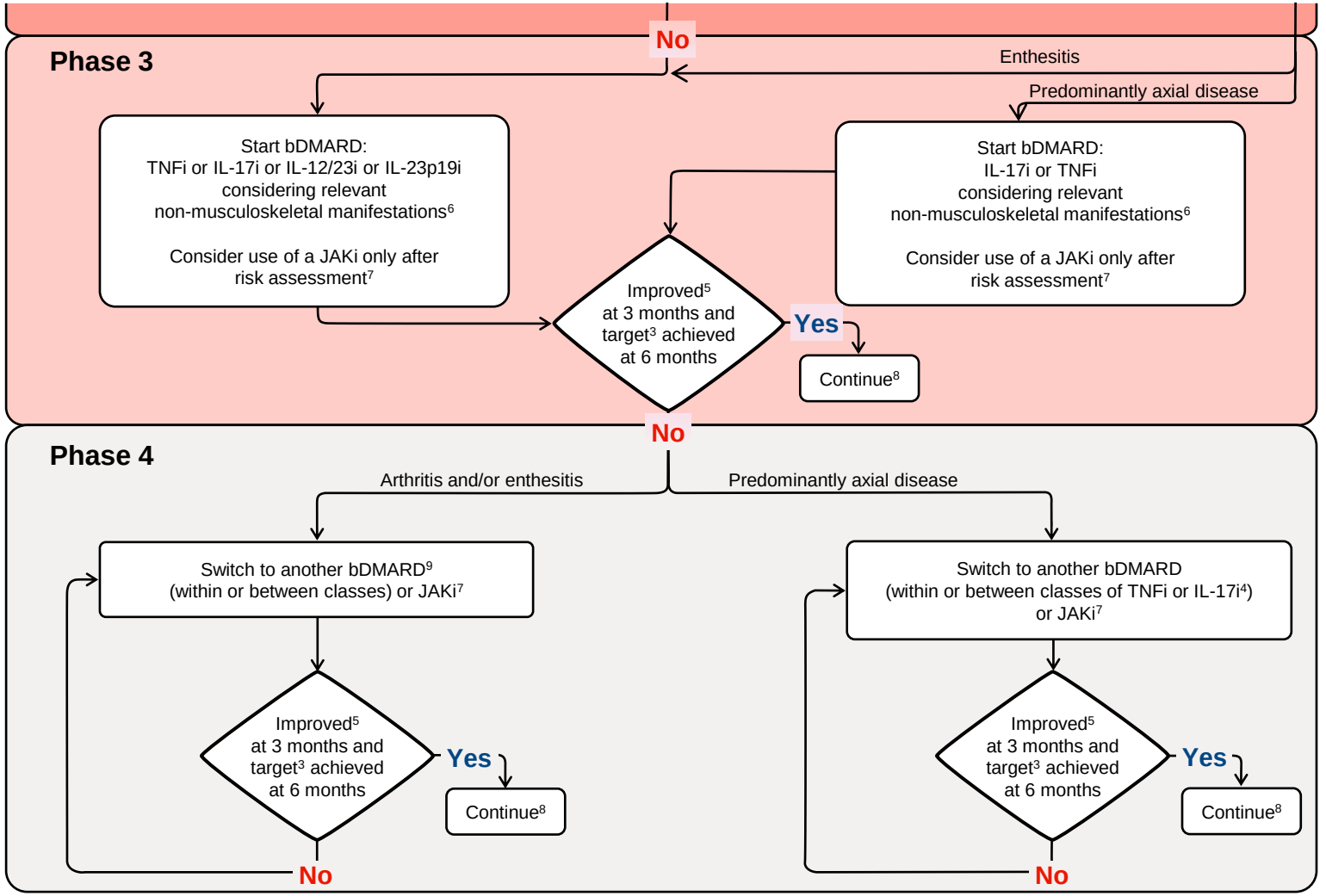
Απουσία σπονδυλικού πόνου

Απουσία διαβρώσεων

BSA, body surface area; CRP, C-reactive protein; DAPSA, Disease Activity Index for Psoriatic Arthritis;; PtGA, Patient's Global Assessment; SJC, swollen joint count; TJC, tender joint count.
Information based on speakers clinical experience.

Ποιά θεραπεία θα ταίριαζε στον ασθενή ?

EULAR 2023 recommendations for PsA treatment: When do we move beyond csDMARDs in PsA?



1. Some studies suggest that enthesitis may respond to MTX, but the level of evidence is low. 2. No glucocorticoids for axial disease. 3. The target is remission or low disease activity (especially with long-standing disease) in accordance with the treat-to-target recommendations. 4. Preferred in the presence of relevant skin involvement; however, in case of concomitant IBD or uveitis, a TNF monoclonal antibody or (for IBD) IL-23i or IL-12/23i or JAKi is recommended. 5. Improvement means at least 50% reduction in disease activity. 8. Consider tapering in sustained remission. Gossec L, et al. Ann Rheum Dis. 2024;83:706-19.

GRAPPA recommendations 2021

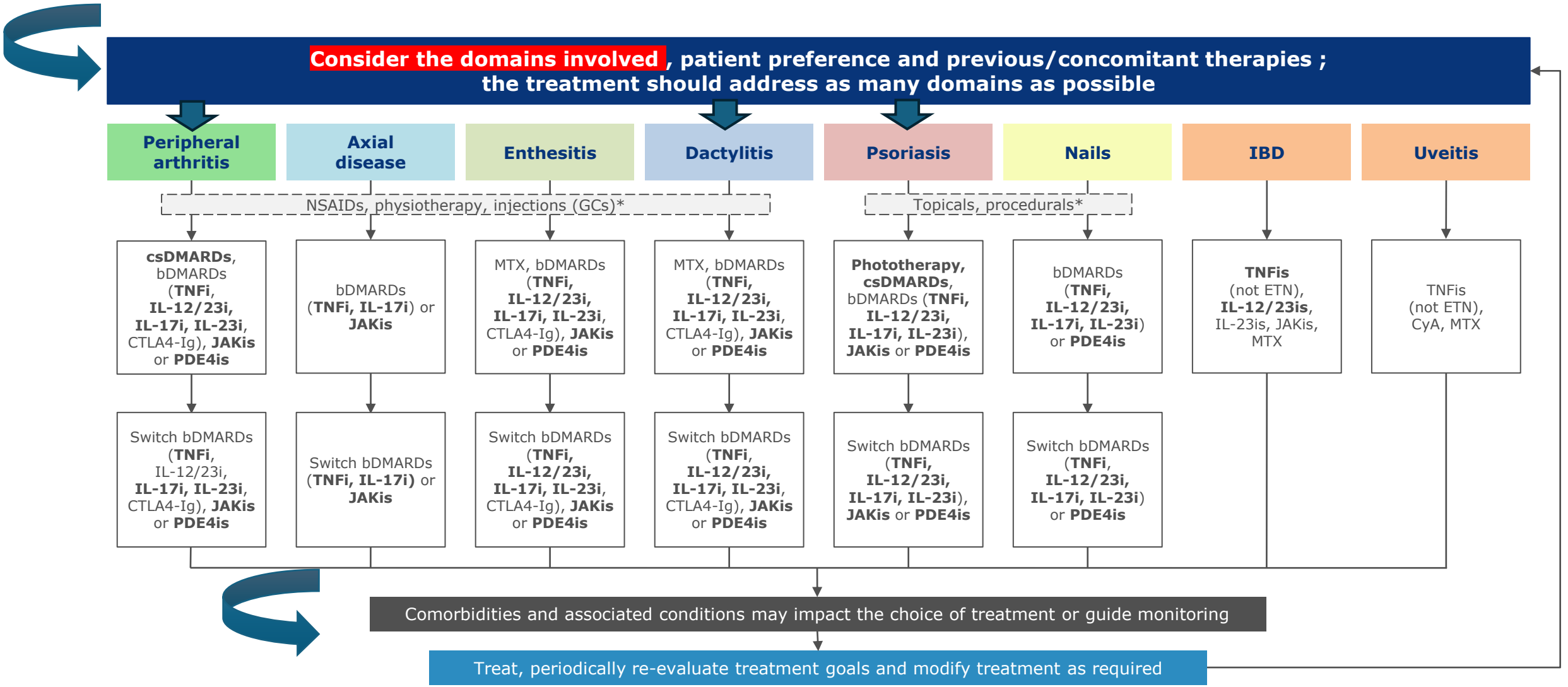


Figure adapted from Coates LC, et al. 2022. The order of the products in the boxes is sorted by mechanism of action and does not reflect guidance on relative efficacy or suggested usage.

Bold text indicates a strong recommendation, standard text a conditional recommendation. The asterisks indicate a conditional recommendation based on data from abstracts only.

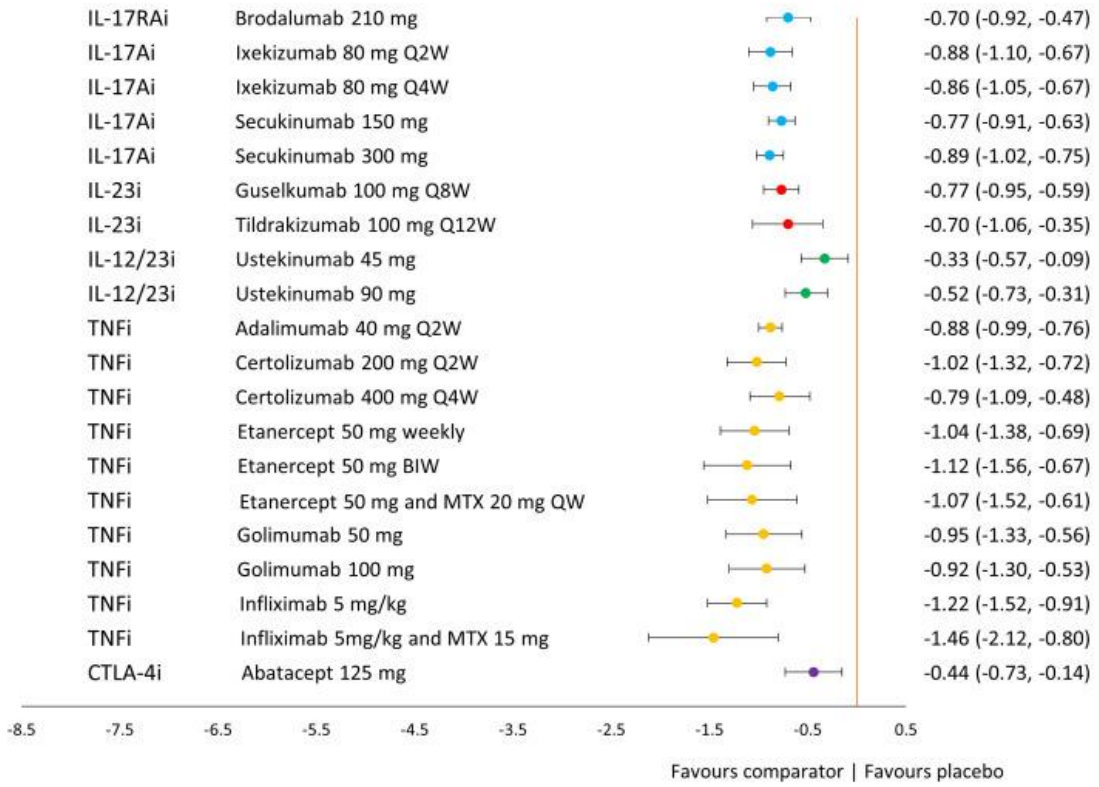
Coates LC, et al. *Nat Rev Rheumatol* 2022;18:465–479.

Targeted systemic therapies for psoriatic arthritis: a systematic review and comparative synthesis

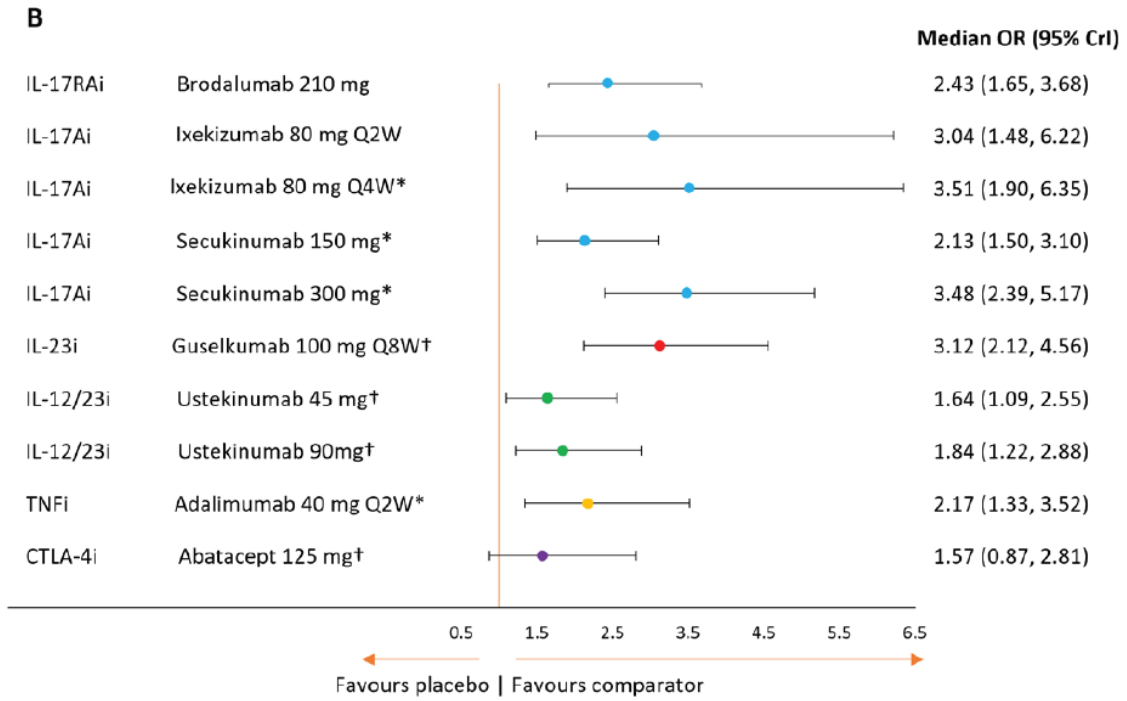
Arthritis & Dactylitis Data

Forest plot of treatment effects for key comparators versus placebo

on ACR response



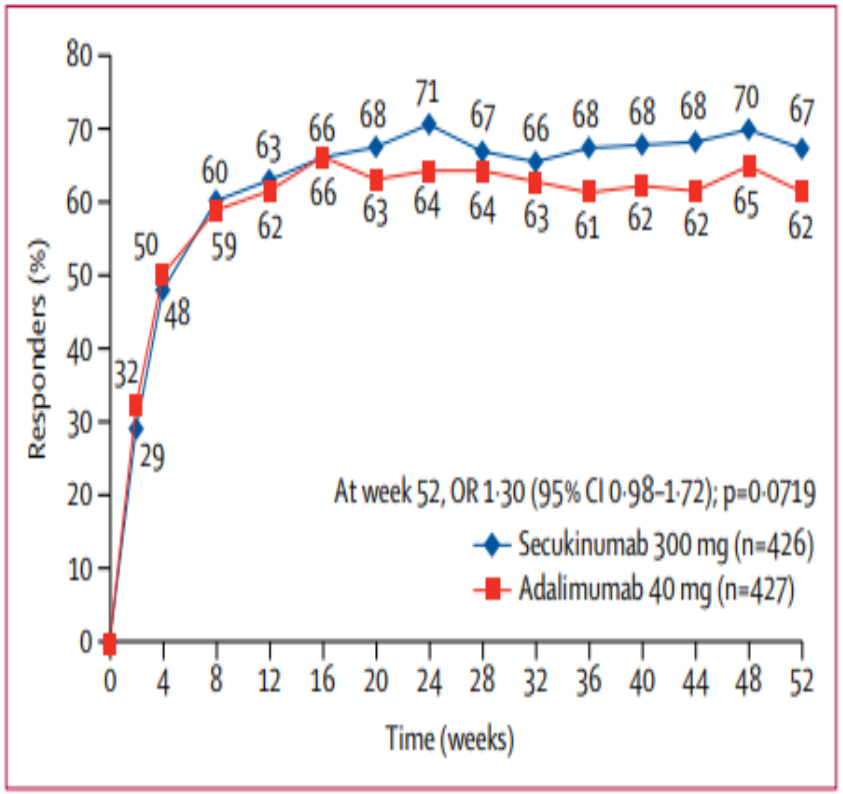
on dactylitis response



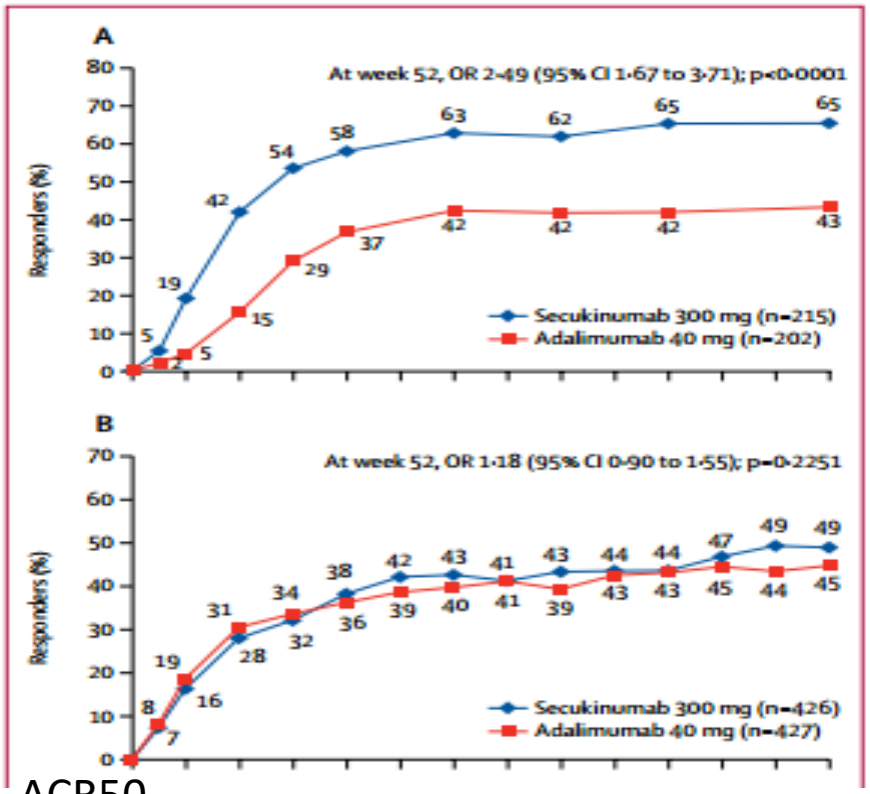
McInnes IB et al. RMD Open 2022;8:e002074

Secukinumab versus adalimumab for treatment of active psoriatic arthritis (EXCEED): a double-blind, parallel-group, randomised, active-controlled, phase 3b trial

ACR20



PASI 90

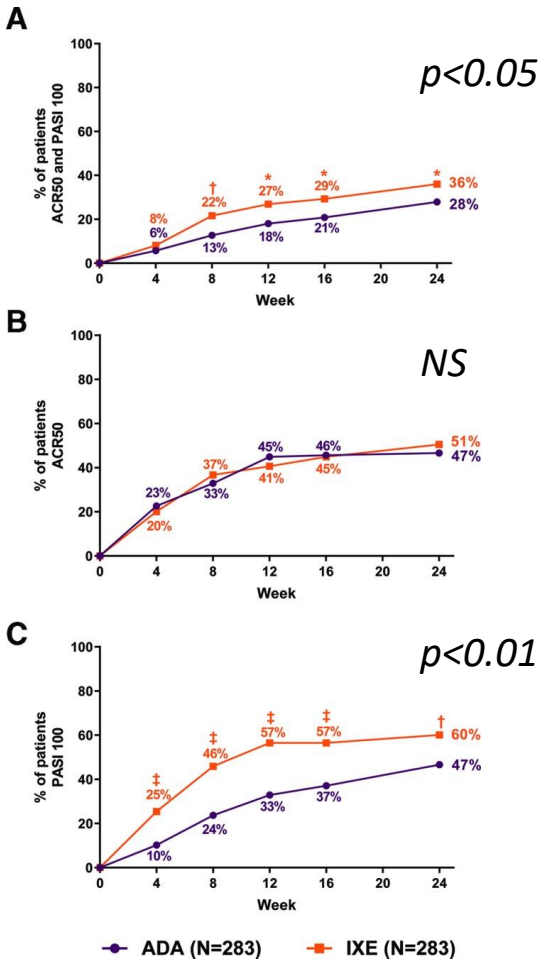


ACR50

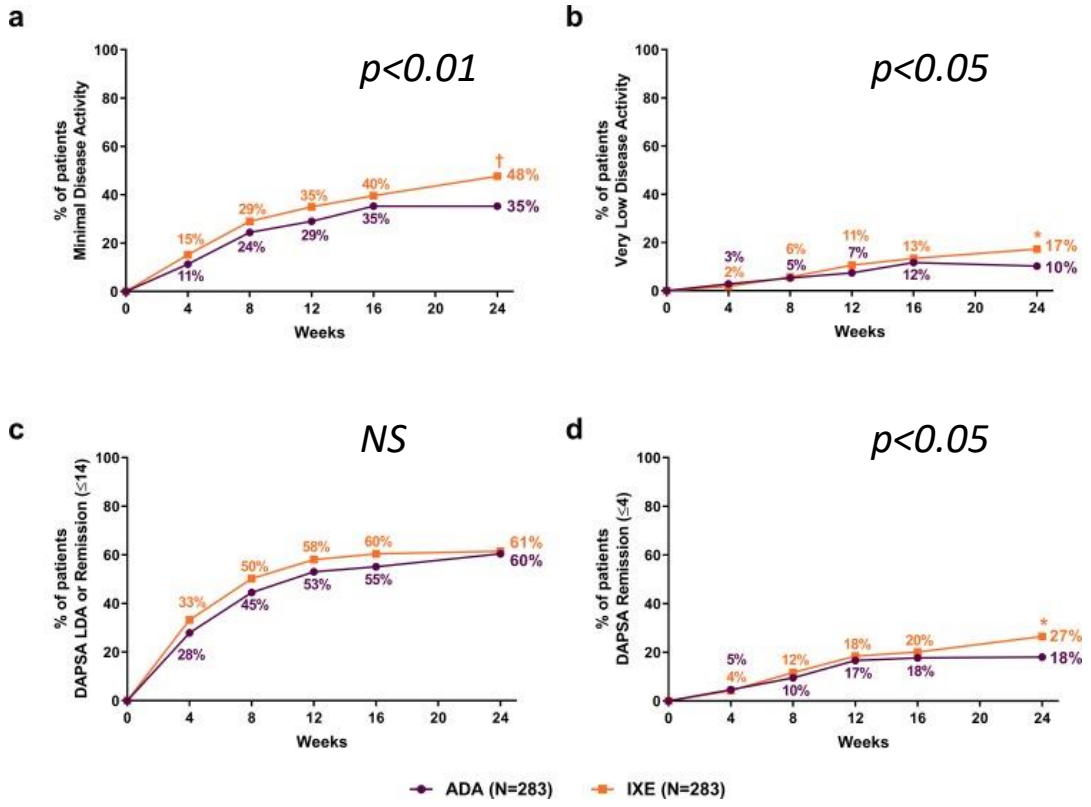
Secukinumab did not meet statistical significance for superiority versus adalimumab in the primary endpoint of ACR20 response at week 52. However, secukinumab was associated with a higher treatment retention rate than adalimumab.

Mc Innes IB et al. Lancet. 2020 May 9;395(10235):1496-1505

A head-to-head comparison of the efficacy and safety of ixekizumab and adalimumab in biological-naïve patients with active psoriatic arthritis: 24-week results of a randomised, open-label, blinded-assessor trial



combined ACR50 and PASI 100 response



IXE was superior to ADA in achievement of simultaneous improvement of joint and skin disease (ACR50 and PASI100) in patients with PsA and inadequate response to csDMARDs. Safety and tolerability for both biologicals were aligned with established safety profiles

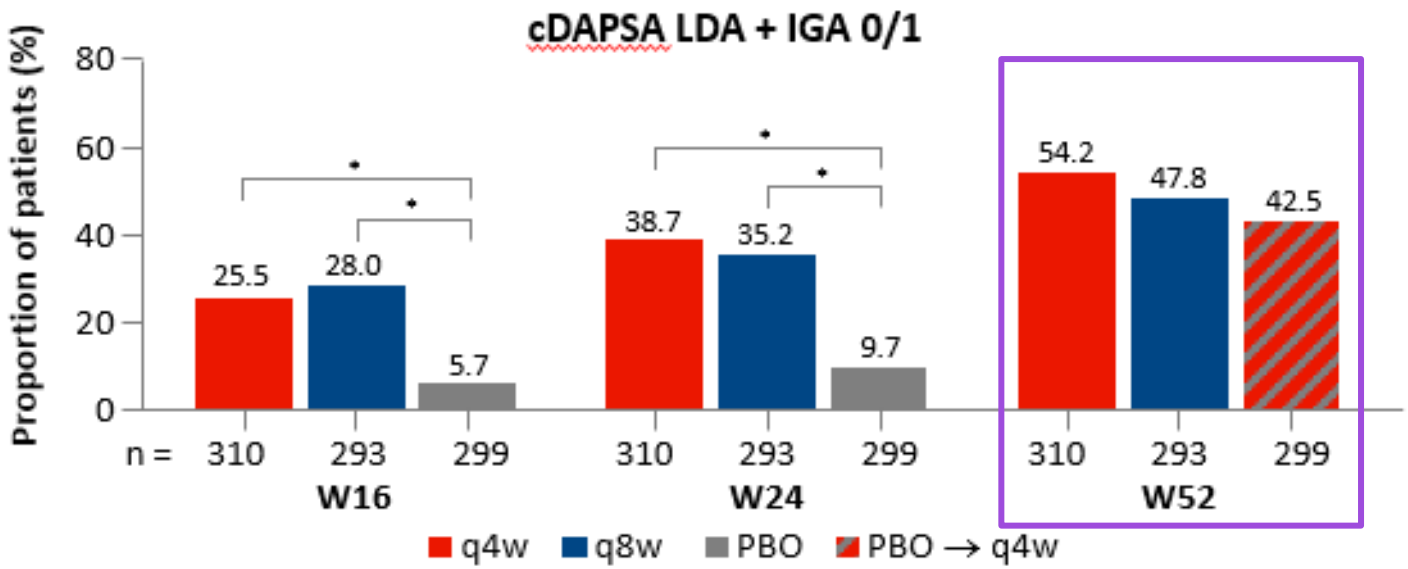
Mease PJ, et al. Ann Rheum Dis 2020;79:123–131

DISCOVER-1&2 post hoc analysis

Low peripheral joint disease activity state and clear/almost-clear skin

in patients with active psoriatic arthritis

GUS-randomized patients were significantly more likely to achieve **cDAPSA LDA + IGA 0/1 at W16** (first timepoint assessed)



*Nominal p ≤ 0.001.

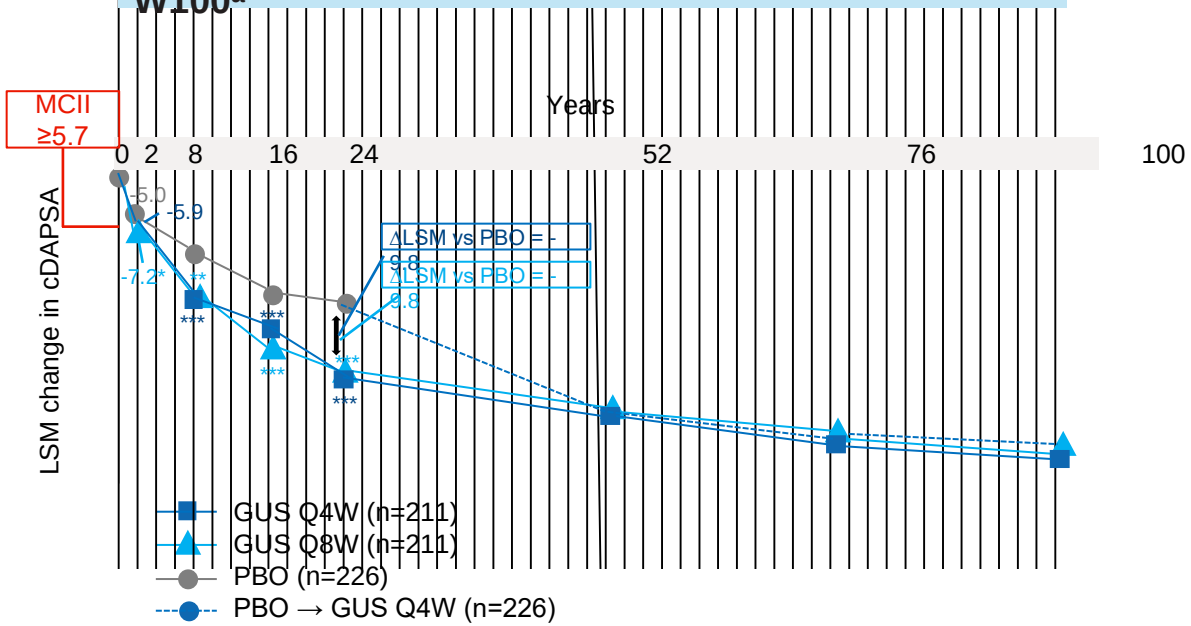
*Nominal p≤0.001 for GUS vs. PBO.
cDAPSA, clinical Disease Activity Index for Psoriatic Arthritis; GUS, guselkumab; IGA, Investigator's Global Assessment; IL, interleukin; LDA, low disease activity; PBO, placebo; PsA, psoriatic arthritis; qXw, every X weeks; RDBPC, randomised, double-blind, placebo-controlled; W, Week.
Aletaha D, et al. Presented at EULAR, Vienna, Austria, 12–15th June 2024. Poster POS0254.

Efficacy of Guselkumab in bio-naive psoriatic arthritis patients with **severe disease activity**:
Post-hoc analysis of a Phase 3, randomized, double-blind, placebo-controlled study

Patient demographics and clinical characteristics

		cDAPSA >27 (n=648)
Demographics		
	Age, years	45.4 (11.5)
	Male, %	52
	BMI, kg/m^2	28.9 (6.1)
Characteristics		
	Duration, years	5.4 (5.7)
	SJC (0–66)	13.1 (7.3)
	TJC (0–68)	23.1 (12.7)
	CRP, mg/dL	2.0 (2.4)
	cDAPSA (0–154)	49.5 (18.8)
	PASDAS (0–10)	6.8 (1.0)[a]
	PtGA-Arthritis (0–100 VAS)	70.5 (17.5)[c]
	% BSA with PsO	18.2 (21.1)[d]
	PASI score (0–72)	10.3 (11.4)[c]
	Pain (0–100 VAS)	65.5 (17.3)
	FACIT-Fatigue (0–52)	28.7 (9.4)[c]
Medication use at baseline		
	csDMARDs, %	70
	Methotrexate, %	61
	Corticosteroids, %	19
	NSAIDs, %	69

GUS-treated patients had ~72–74% improvement at W100[a]



cDAPSA improvement over time in patients with baseline score >27

*p<0.05; **p<0.001; ***p<0.0001 for GUS vs. PBO.

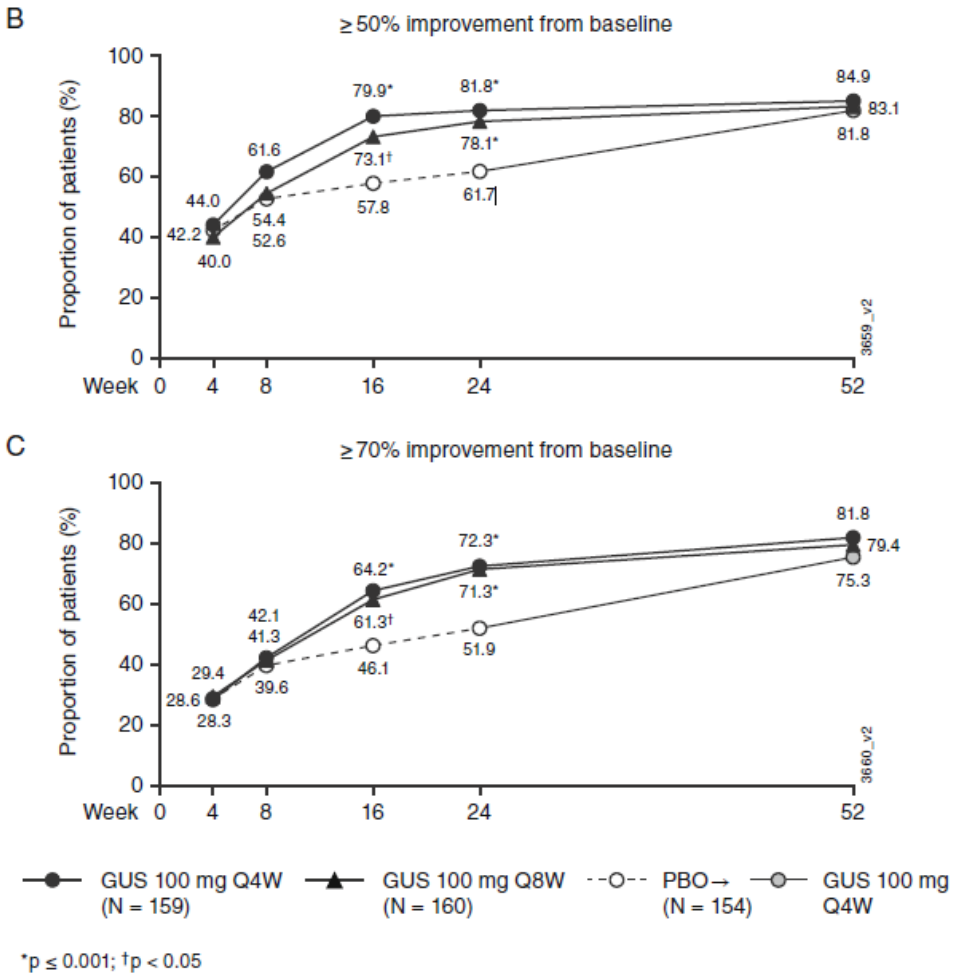
[a]Estimated from mean scores at baseline.

cDAPSA, Clinical Disease Activity Index for PsA; GUS, guselkumab; IL-23, interleukin-23; LDA/REM, low disease activity or remission; LSM, least squares mean; MCII, minimal clinically important improvement; MOA, mechanism of action; NRI, non-responder imputation; PASDAS, PsA Disease Activity Score; PBO, placebo; PsA, psoriatic arthritis; Q4W, at Week 0, Week 4 and every 4 weeks; Q8W, at Week 0, Week 8 and every 8 weeks; RCT, randomised controlled trial; W, Week.

Ritchlin CT, et al. Presented at ACR, Washington DC, USA, 14–19th November 2024. Poster P1474.

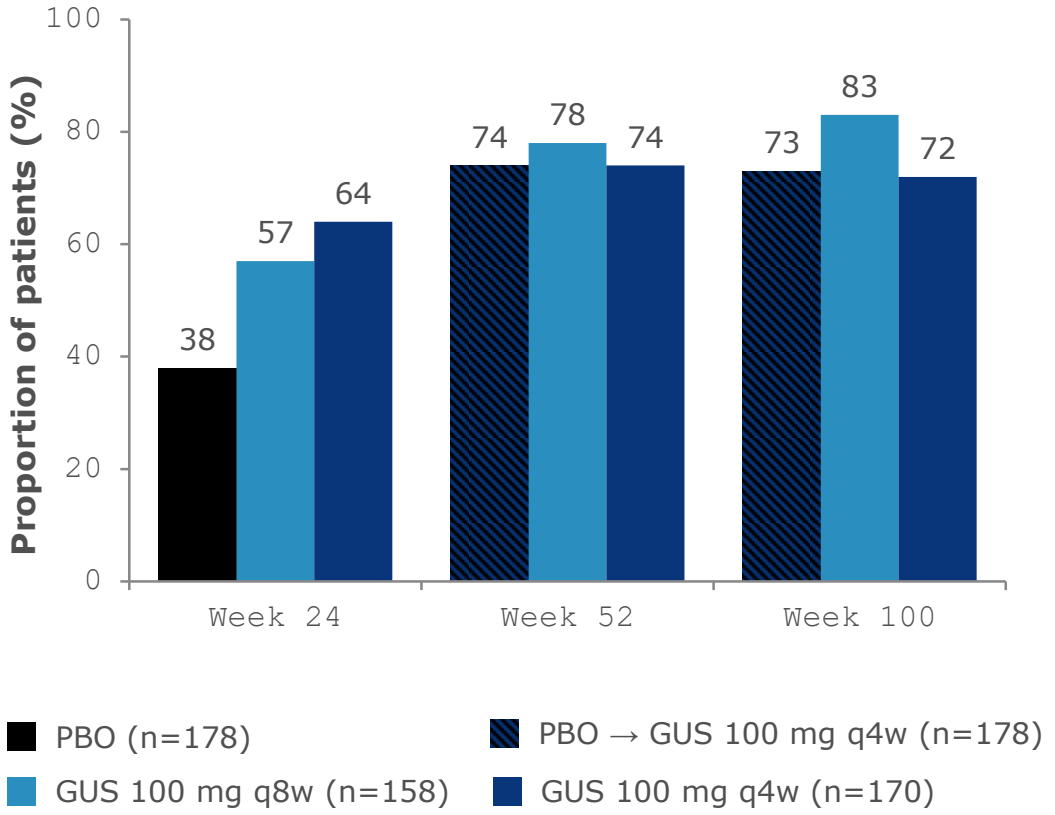
Dactylitis resolution in bio naïve patients through Week 100

% improvement in DSS from baseline for patients with DSS 1 or higher at baseline



ACR Open Rheumatology Vol. 5, No. 4, April 2023, pp 227–240 DOI 10.1002/acr2.11537

Dactylitis resolution through Week 100 (NRI)



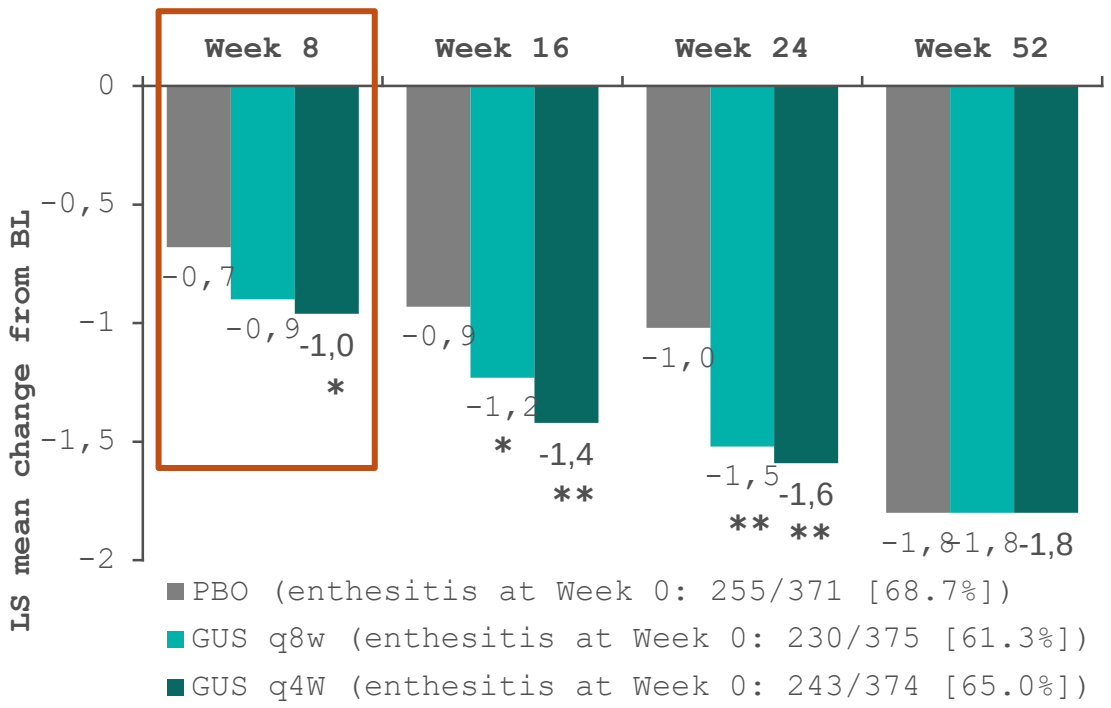
GUS, guselkumab; NRI, non-responder imputation; PBO, placebo; q4w, every 4 weeks; q8w, every 8 weeks.

McInnes IB et al. Arthritis Rheumatol 2022;74:475-485

Enthesitis resolution through Week 100

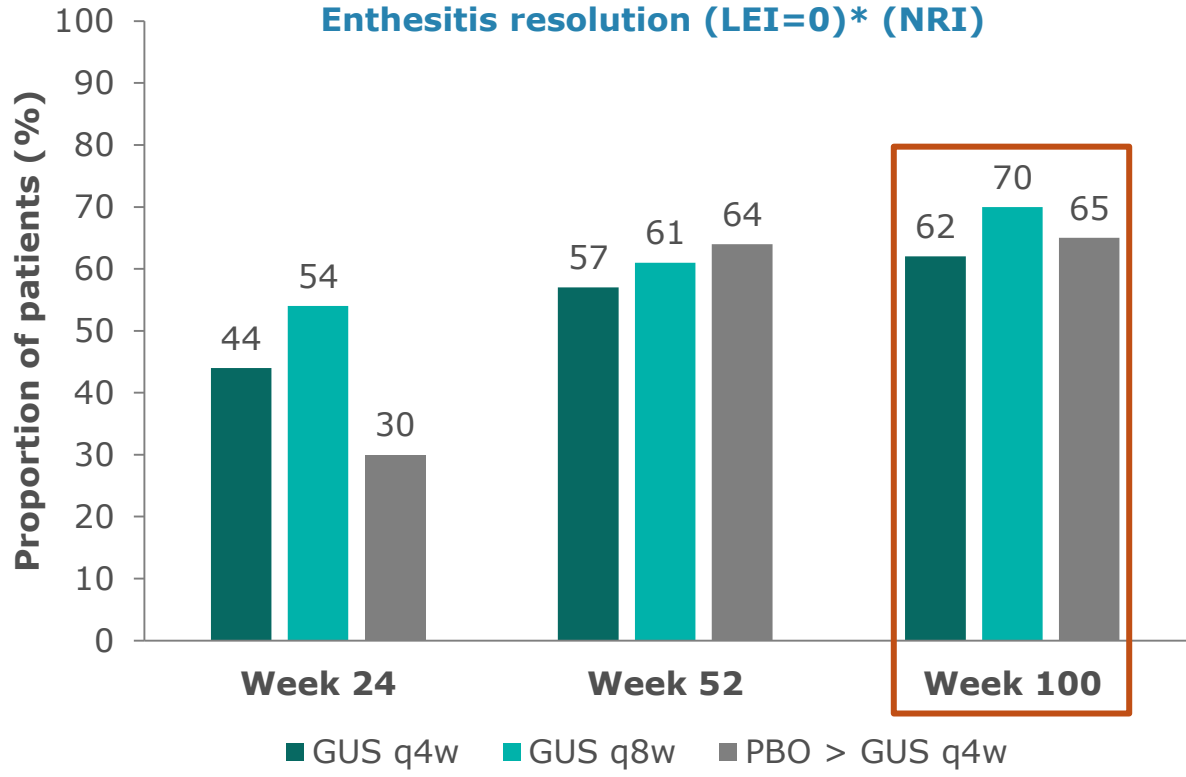
728 patients with enthesitis at BL_mean LEI score 2.8

Mean change from BL in LEI score



*p<0.05 vs. PBO; **p<0.001 vs. PBO. Unadjusted (nominal), not controlled for multiplicity; interpret only as supportive.

Enthesitis resolution (LEI=0)* (NRI)



*Data are based on patients with enthesitis at BL (n=170 with GUS q4w, n=158 with GUS q8w, n=178 with PBO > GUS q4w) and include the application of missing data handling rules (imputed as no response/no change from baseline if missing)..

McGonagle D et al. Presented at EULAR 2020. #AB0801;

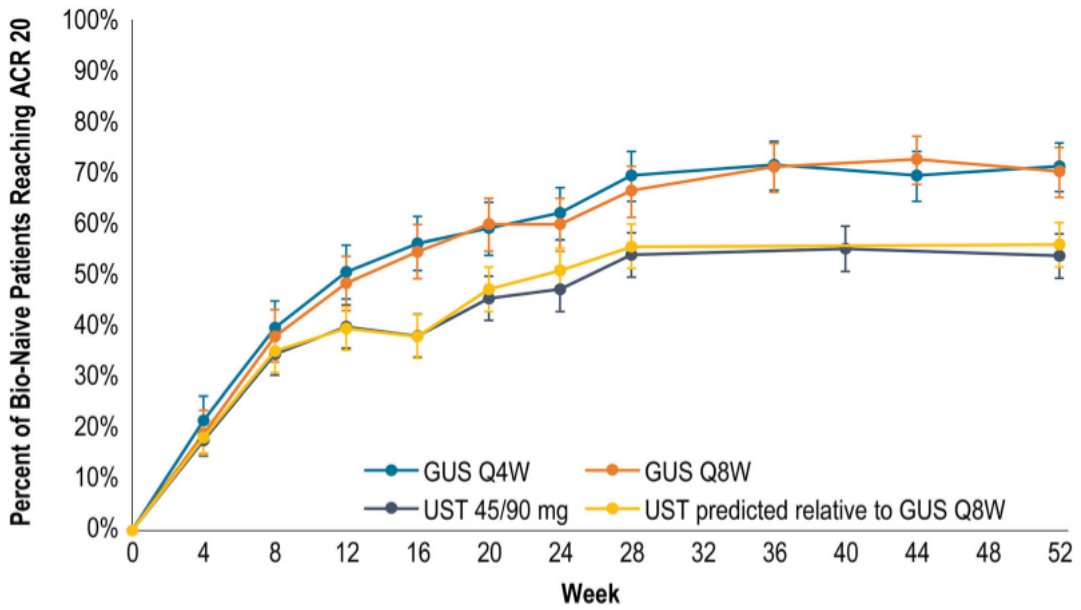
McInnes IB et al. *Arthritis Rheumatol* 2022;74(3):475–485

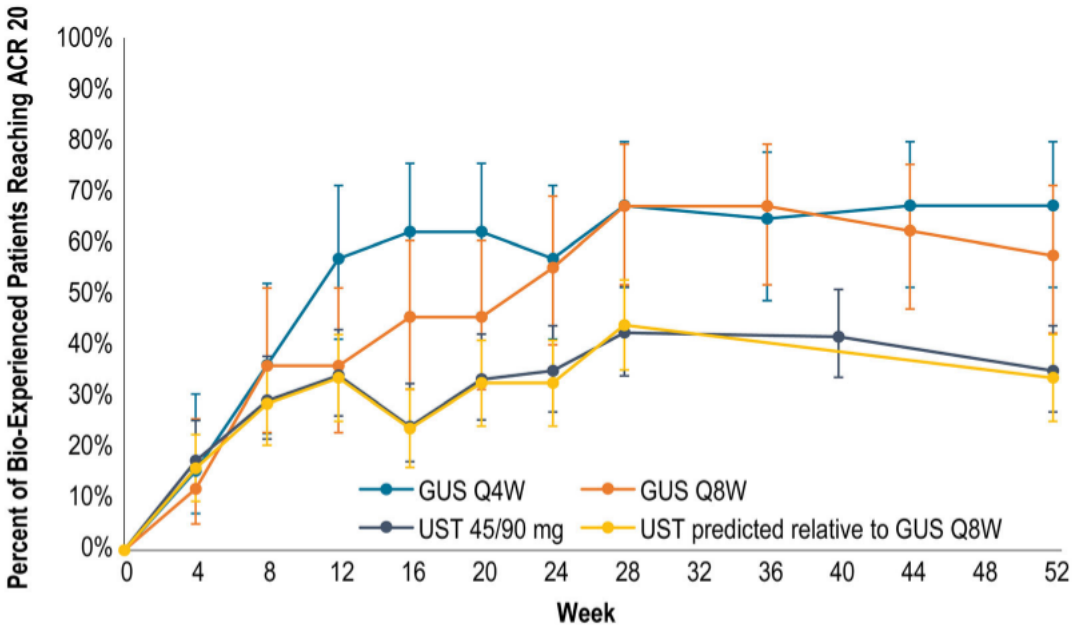
Rheumatol Ther (2024) 11:457–474
https://doi.org/10.1007/s40744-024-00644-7

ORIGINAL RESEARCH

Comparing Efficacy of Guselkumab versus Ustekinumab in Patients with Psoriatic Arthritis: An Adjusted Comparison Using Individual Patient Data from the DISCOVER and PSUMMIT Trials

Pushpike Thilakarathne · Agata Schubert · Steve Peterson · Wim Noel · Barkha P. Patel · Fareen Hassan

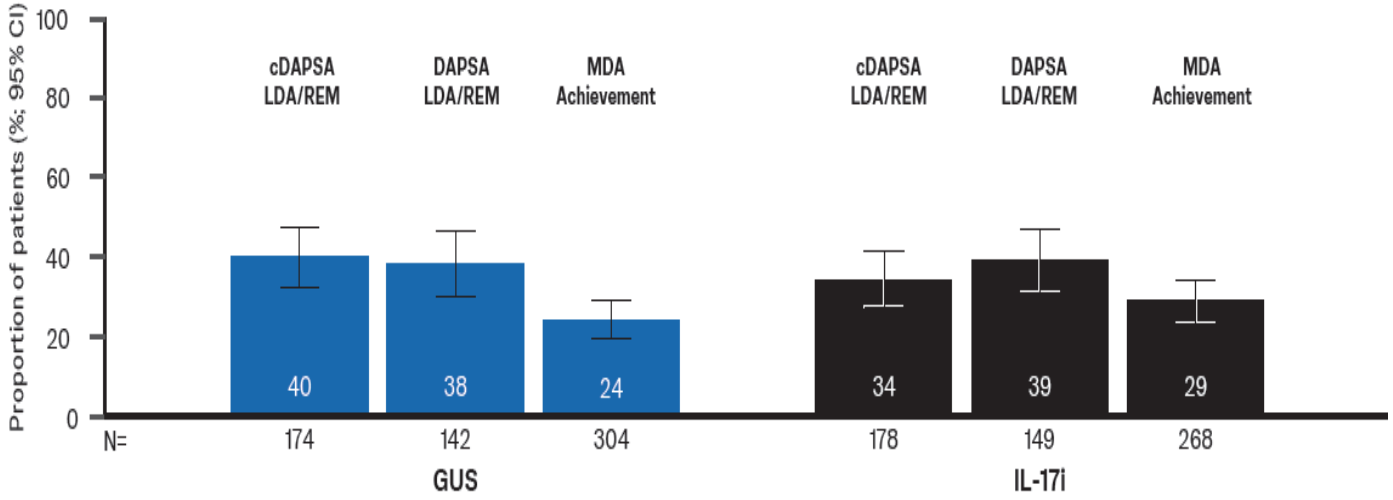




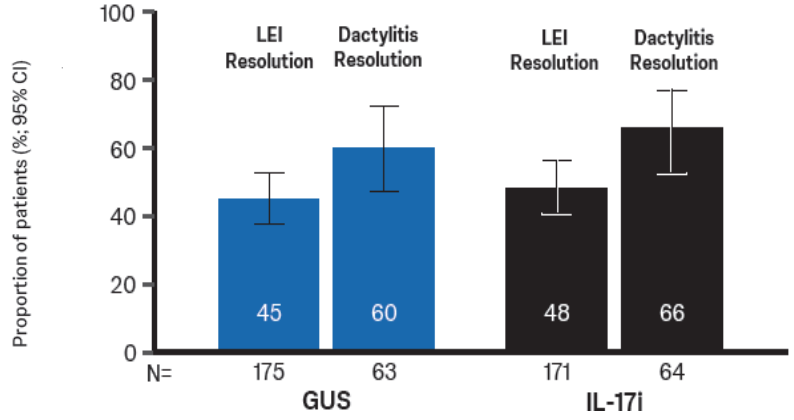
Guselkumab and IL-17 Inhibitors show comparable treatment persistence and effectiveness in psoriatic arthritis: 6-month interim results of the PsABIOnd observational cohort study

Treatment effectiveness at 6 months

Composite outcome measures



LEI and dactylitis resolution

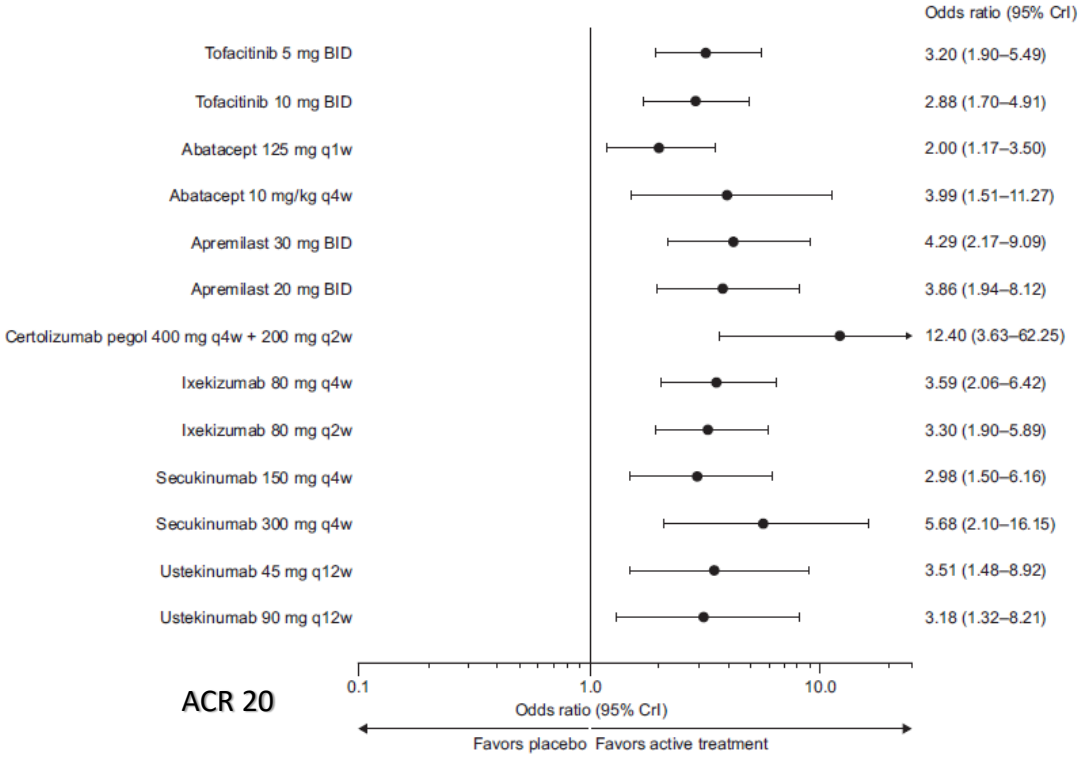


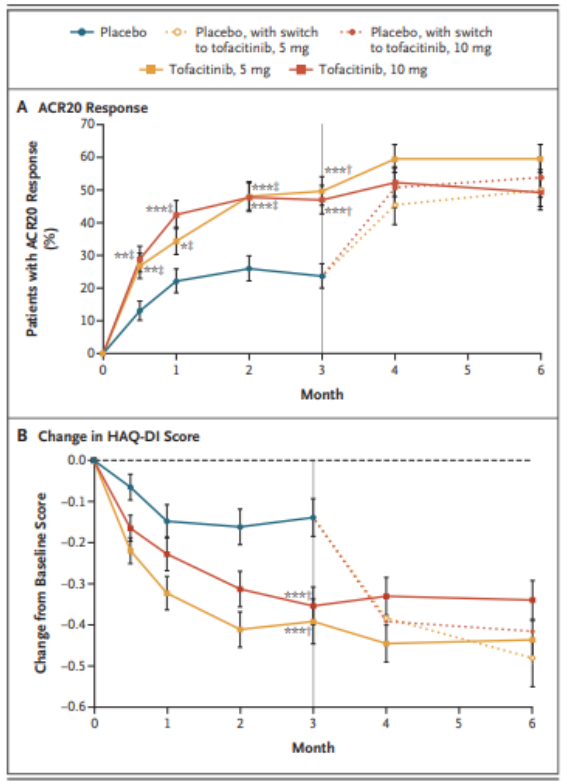
Treatment persistence at the 6M visit was high in both cohorts → 339/360 (94.2%) GUS pts and 304/326 (93.3%) IL-17i pts

Number of participants (N) indicated under the x-axis correspond to the number of participants included in each respective analysis. [a]Reported proportions were corrected after submission of the abstract.
BSA, body surface area; (c)DAPSA, (Clinical) Disease Activity Index for PsA; CI, confidence interval; DLQI, Dermatology Life Quality Index; GUS, guselkumab; IL-17i, interleukin-17 inhibitor; IL-23, interleukin-23; LDA/REM, low disease activity or remission; LEI, Leeds Enthesitis Index; MDA, minimal disease activity; MOA, mechanism of action; NA, not applicable; Obs, observational; PsA, psoriatic arthritis.
Gossec L, et al. Presented at ACR, Washington DC, USA, 14–19th November 2024. Poster P1464.

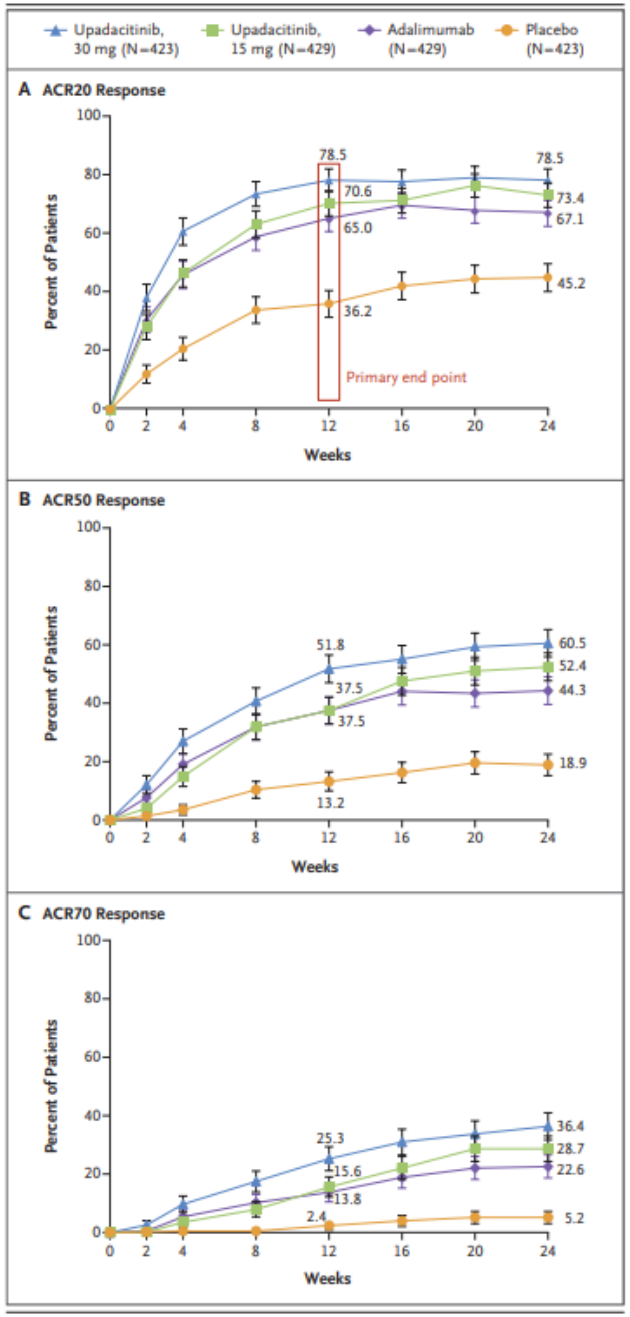
22

JAKi in PsA - Musculoskeletal





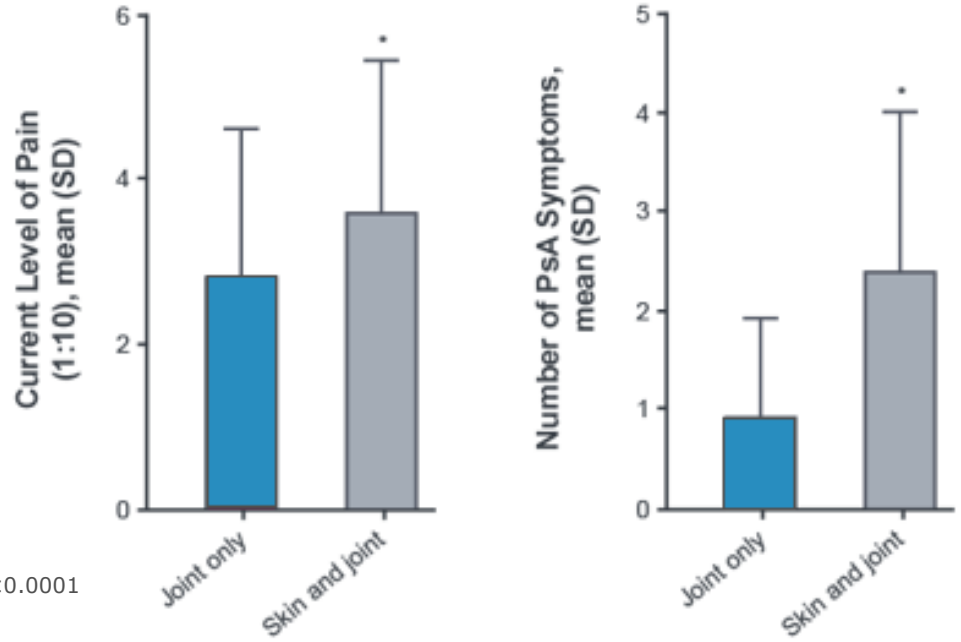
Gladman, NEJM 2017



McInnes, NEJM 2021

Skin involvement in PsA patients worsens overall disease activity, patient-reported pain and QoL

Patients experience greater pain and number of PsA symptoms with skin and joint involvement[1]

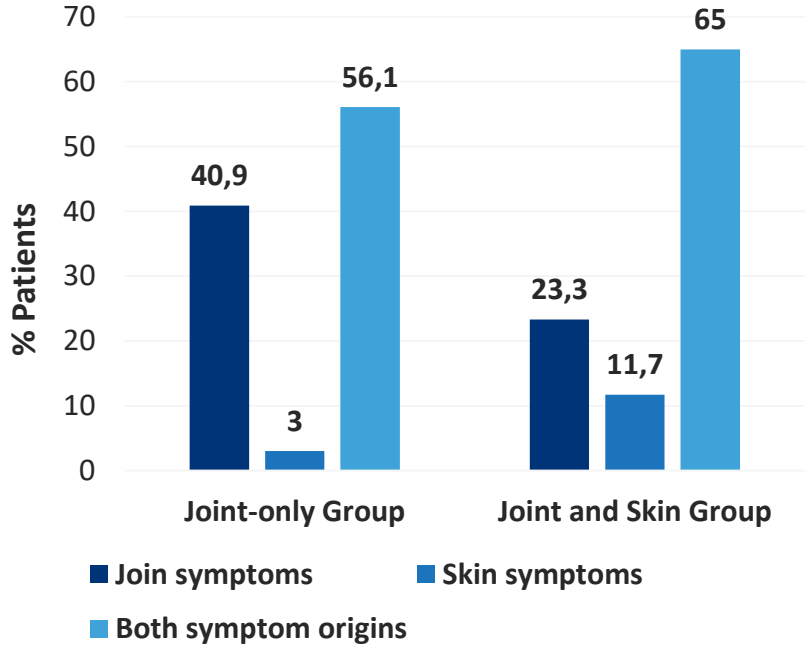


*p<0.0001

A RETROSPECTIVE ANALYSIS OF THE ADELPHI 2015 PSA DISEASE SPECIFIC PROGRAMME, A REAL-WORLD, CROSS-SECTIONAL SURVEY OF RHEUMATOLOGISTS AND THEIR CONSULTING PSA PATIENTS FROM THE USA AND EUROPE (FRANCE, GERMANY, ITALY, SPAIN, AND UK)

de Vlam et al. (2018) Rheumatol Ther. 5(2):423-436

Cause of Anxiety/Depression



Analysis of individual PsAID12 scores in patients **(N=2703)** with 'joint-only' and 'joint and skin' symptoms. Significant differences between the two groups were seen for all questions making up the PsAID12questionnaire.

Tillett W et al. Rheumatol Ther. 2020;7:617–637

2023 EULAR Recommendations for the Management of PsA

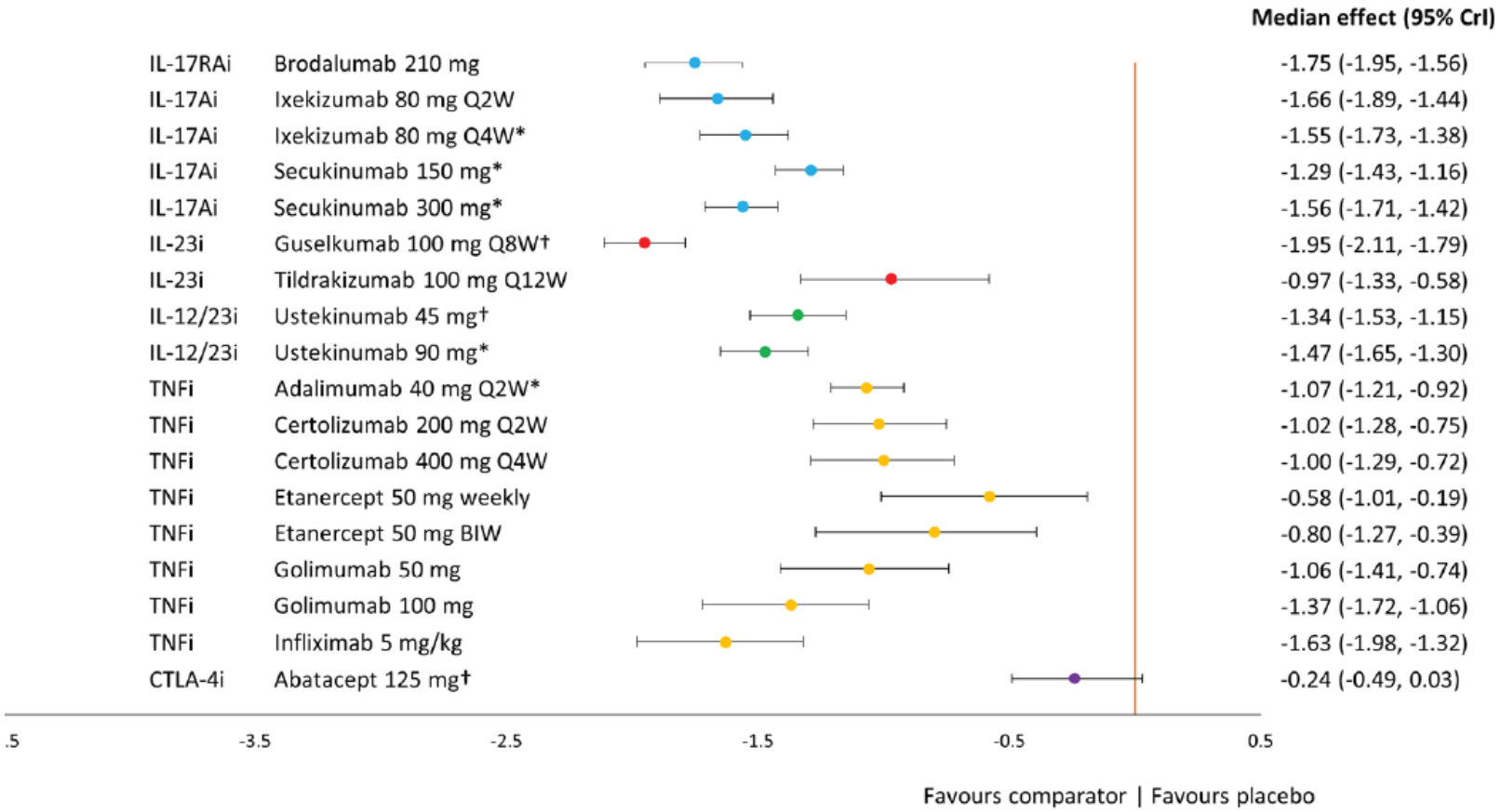
	Recommendations	LoE	GoR	LoA (mean)
8.	In patients clinically relevant axial disease with insufficient response to NSAIDs, therapy with an IL-17A inhibitor, a TNFi, an IL-17 A/F inhibitor or a JAKi* should be considered.	1b	B	9.4
9.	The choice of the mode of action should reflect non-musculoskeletal manifestations related to PsA; • **with clinically relevant skin involvement**, preference should be given to an IL-17A or IL-17A/F or IL-23 or IL-12/23 inhibitor; • **with uveitis** to an anti-TNF monoclonal antibody; and • **with IBD** to an anti-TNF monoclonal antibody or an IL-12-23i or IL-23i or a JAKi*.	1b	B	9.6
10.	In patients with an inadequate response or intolerance to a bDMARD or a JAKi, switching to another bDMARD or JAKi* should be considered, including one switch within a class.	1b/4	C	9.5
11.	In patients in sustained remission, cautious tapering of DMARDs may be considered.	2b	B	9.4

*For JAKis, caution is needed for patients aged 65 years or above, those who are current or past long-time smokers, with a history of atherosclerotic cardiovascular disease or other cardiovascular risk factors or with other malignancy risk factors, and with known risk factors for venous thromboembolism

Gossec L, et al. Ann Rheum Dis 2024;**0**:1–14. doi:10.1136/ard-2024-225531

Targeted systemic therapies for psoriatic arthritis: a systematic review and comparative synthesis

On PASI response

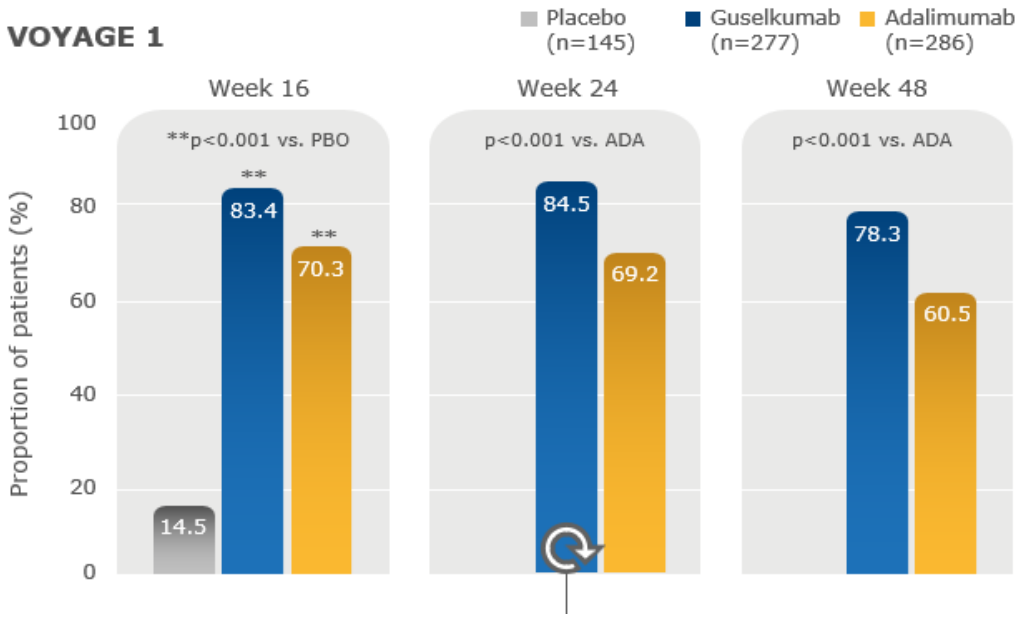


McInnes IB et al. RMD Open 2022;8:e002074

Υψηλά επίπεδα κάθαρσης δέρματος τριχωτού κεφαλής και βελτιώσεις στην ποιότητα ζωής

GUS showed superior scalp responses compared with ADA[1–3]

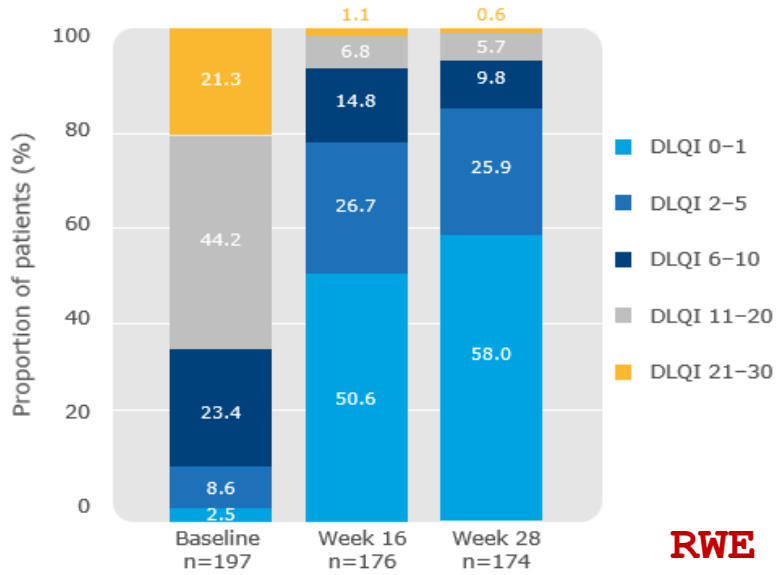
ss-IGA score of 0/1 and an improvement of ≥2 points from baseline[1,2]*



VOYAGE 1/2: Scalp PsO

*Patients with a baseline ss-IGA score of ≥2. ss-IGA score: 0=clear complexion, 1=minimal lesions.[1–4]
ADA, adalimumab; GUS, guselkumab; PASI100, 100% improvement in Psoriasis Area and Severity Index score; PBO, placebo; PsO, psoriasis; ss-IGA, scalp-specific Investigator's Global Assessment.
1. Blauvelt A, et al. *J Am Acad Dermatol* 2017;76:405–417; 2. Blauvelt A, et al. Presented at AAD, Orlando, FL, US, 3–7 March 2017. P4768; 3. Reich K, et al. *J Am Acad Dermatol* 2017;76:418–431;

DLQI scores in patients with scalp PsO treated with GUS



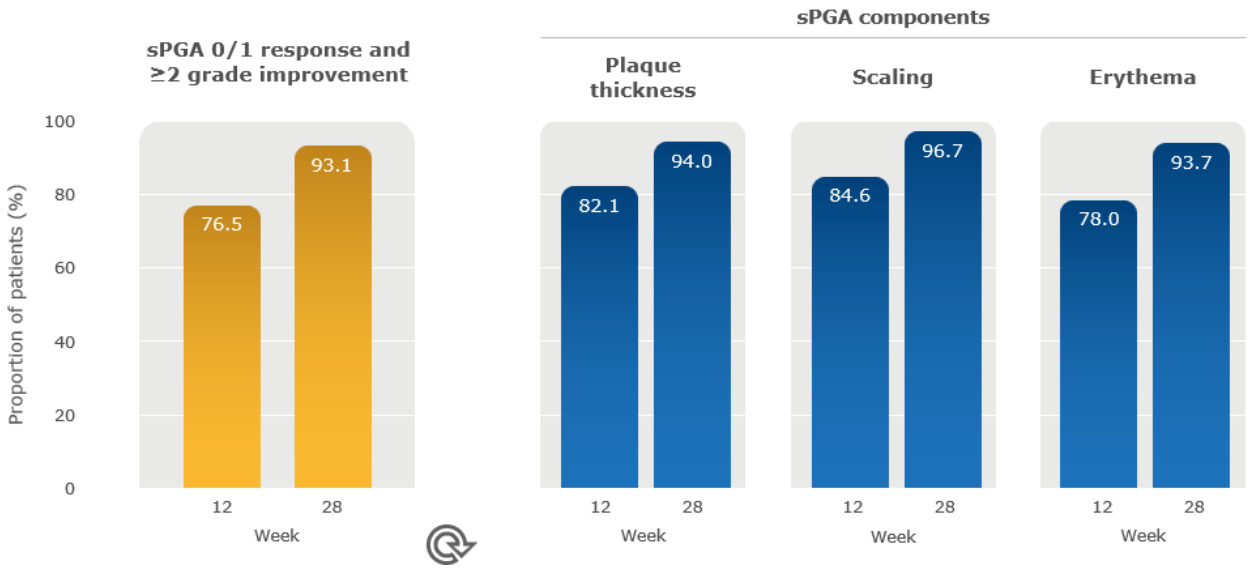
RWE

PERSIST: Scalp PsO

Patients with scalp PGA score ≥2 at baseline. As observed data.[1,2]
DLQI, Dermatology Life Quality Index; GUS, guselkumab; HRQoL, health-related quality of life; PGA, Physician's Global Assessment; PsO, psoriasis.1. cf. Gerdes S, et al. *J Dermatol* 2021;48:1854–1862.

Υψηλά επίπεδα κάθαρσης του δέρματος σε ασθενείς με πρωκτογεννητική ψωρίαση ανεξάρτητα σωματικού βάρους

sPGA* 0/1 response in patients with genital PsO treated with GUS

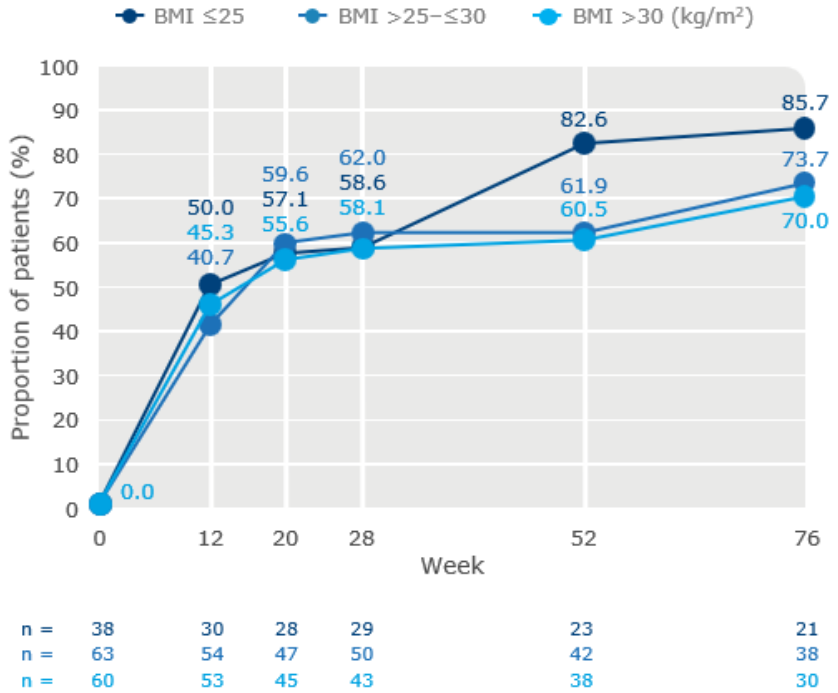


RWE

GULLIVER: Genital PsO

*sPGA categories: 0=clear; 1=almost clear; 2=mild; 3=moderate; 4=moderate-to-severe; 5=severe.
As part of this evaluation, 351 patients with facial and/or genital PsO were evaluated at baseline, and 348 and 331 patients respectively at Weeks 12 and 28. Of these, 204 patients had a predominantly genital manifestation at baseline.
GUS, guselkumab; PsO, psoriasis; sPGA, static Physician's Global Assessment.
Bonifati C, et al. Presented at EADV, Berlin, Germany, 11–14 October 2023. P2397.

aPGA=0 by BMI in patients receiving GUS*

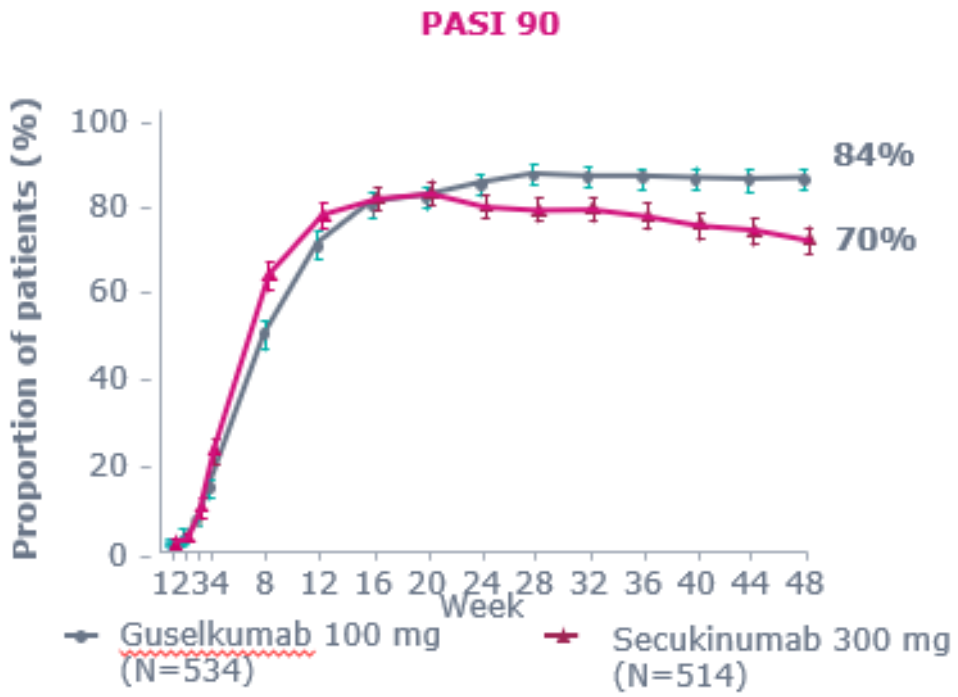


RWE

G-EPOSS: Anogenital areas

*Patients with aPGA score ≥1 at baseline. As observed data.
aPGA, Physician's Global Assessment – anogenital; BMI, body mass index; GUS, guselkumab; PsO, psoriasis.
Gerdes S, et al. Presented at AAD, San Diego, CA, US, 8–12 March 2024. P52880.

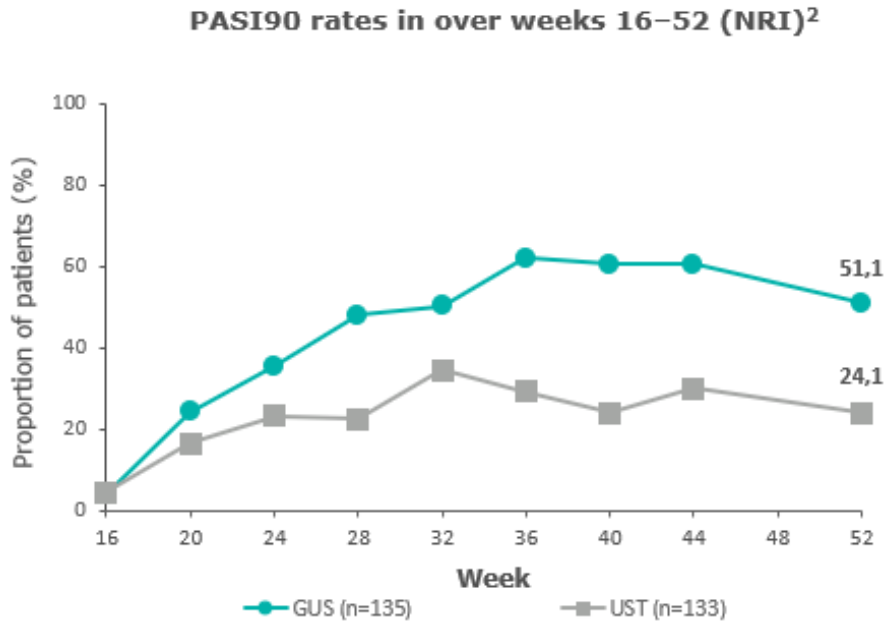
superiority of clinical response at week 48 for GUS vs SEC



ECLIPSE

Reich, K., et al. (2019). The Lancet, 394(10201), pp.831–839

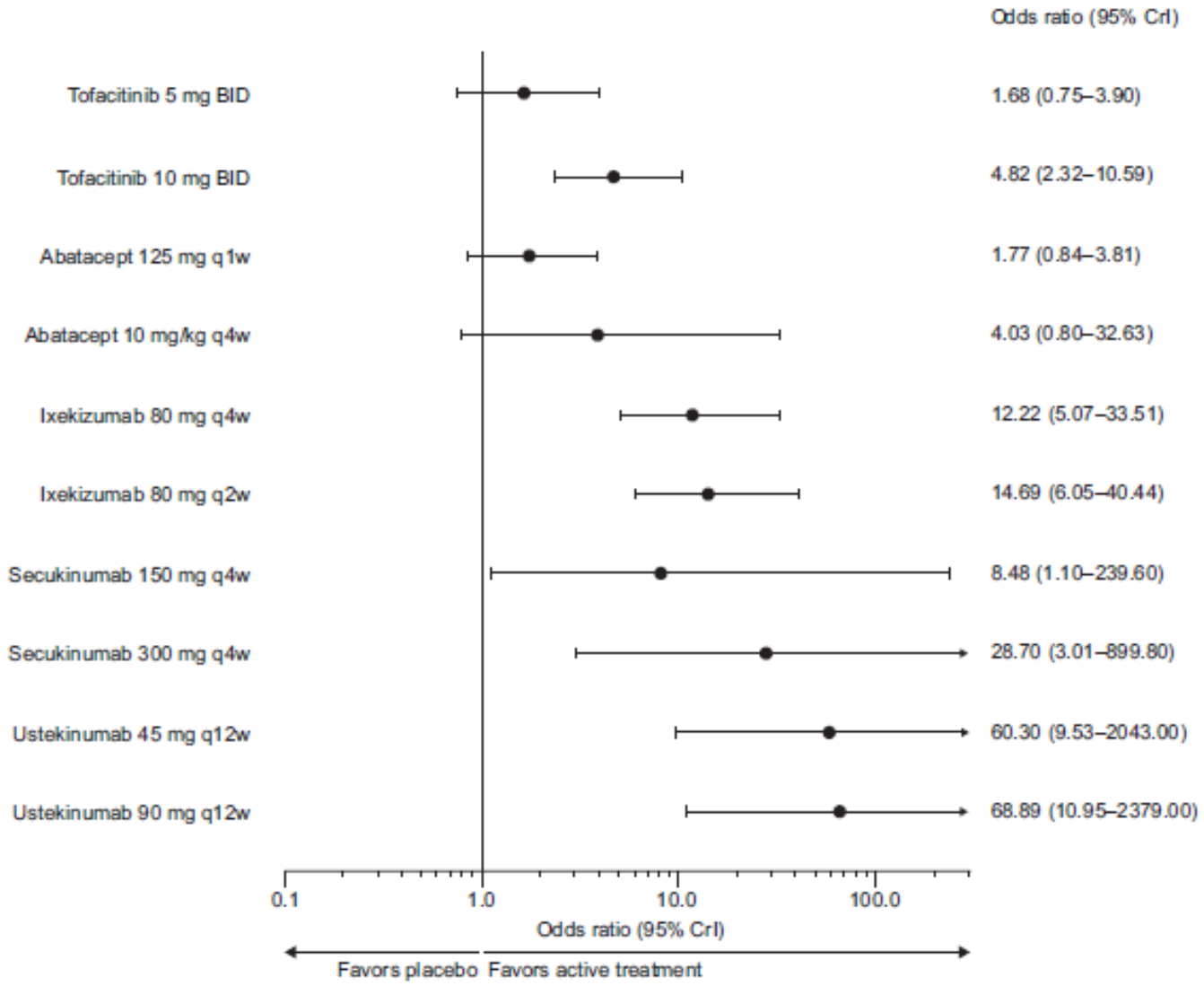
Patients treated with UST who did not achieve an IGA of 0/1 by week 16 derived significant benefit from switching to GUS



NAVIGATE

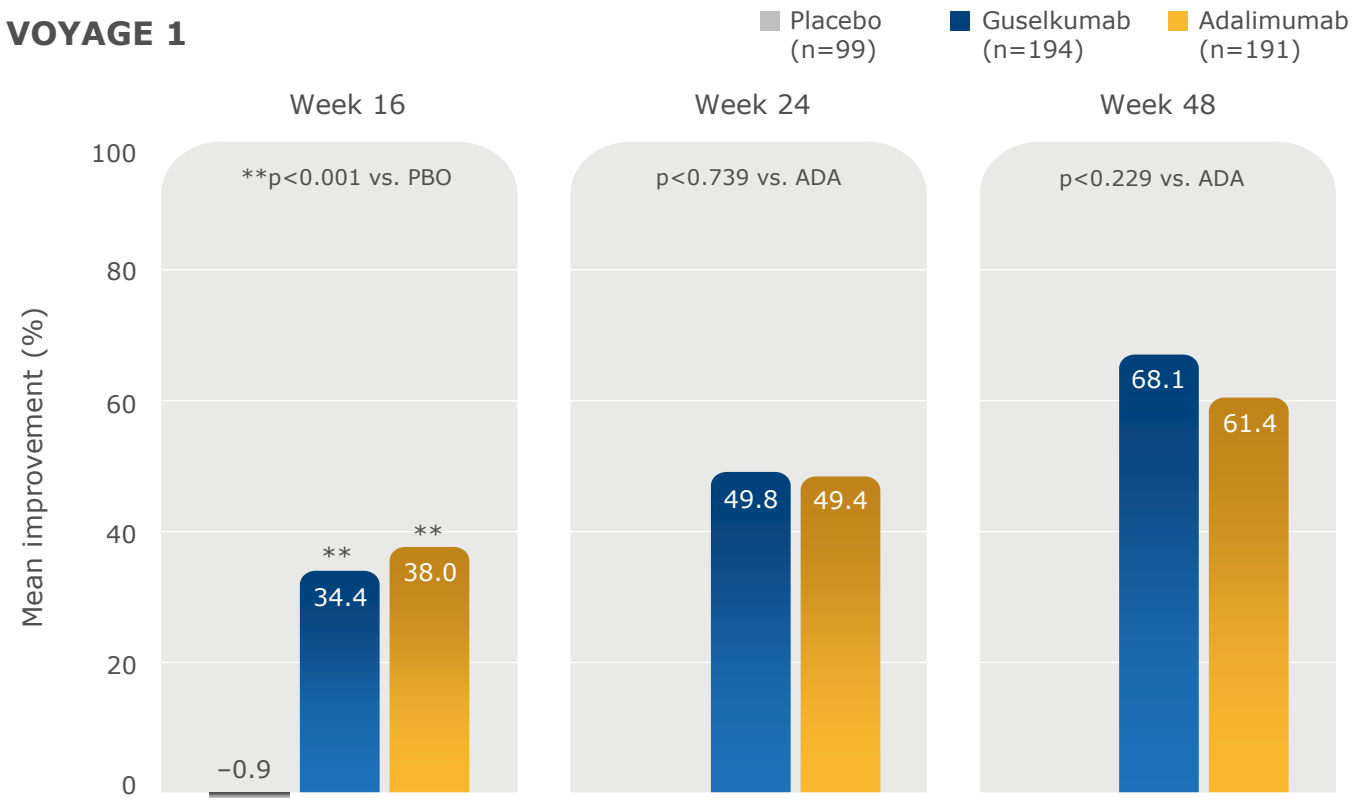
Langley, R.G., et al. (2018). British Journal of Dermatology, 178(1).

Μεταανάλυση: Σύγκριση PASI 75 Tofacitinib vs. IL-17, IL-12/23



GUS and ADA showed similar responses in patients with nail PsO

Mean improvement in NAPSI score from baseline[1,2]*

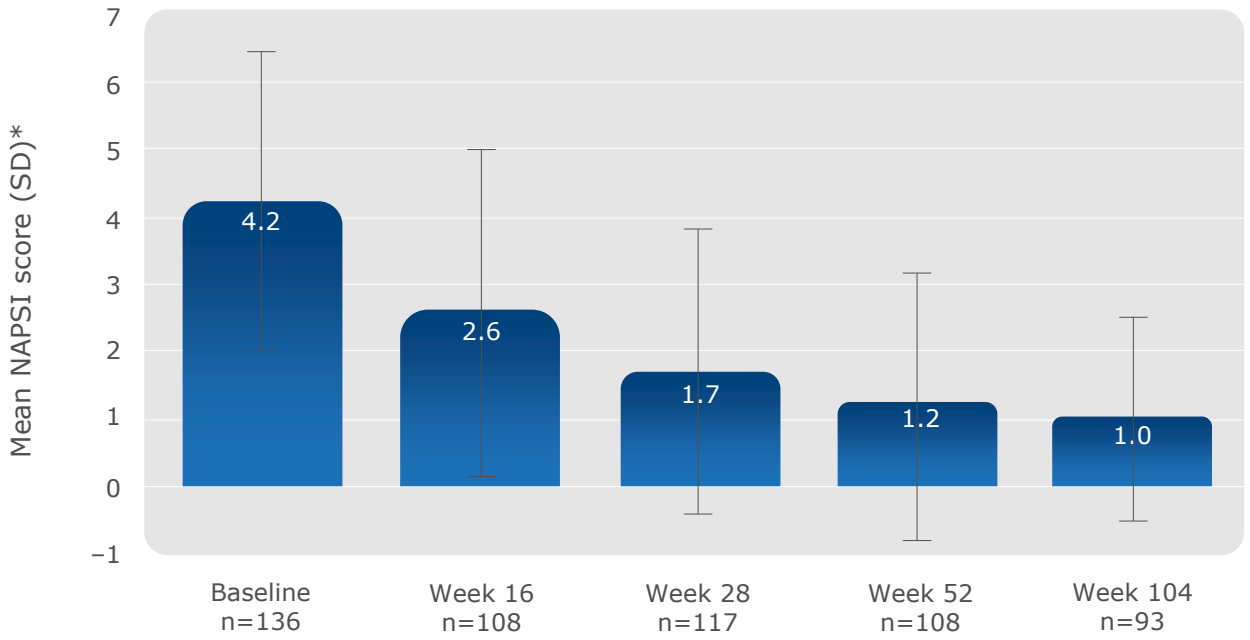


In VOYAGE 2, NAPSI scores were also comparable between GUS (n=280) and ADA (n=140)[3]*

*Patients with a baseline NAPSI score of >0.[1-3]
ADA, adalimumab; GUS, guselkumab; NAPSI, Nail Psoriasis Severity Index; PBO, placebo; PsO, psoriasis.
1. Blauvelt A, et al. *J Am Acad Dermatol* 2017;76:405–417; 2. Blauvelt A, et al. Presented at AAD, Orlando, FL, US, 3–7 March 2017. P4768; 3. Reich K, et al. *J Am Acad Dermatol* 2017;76:418–431.

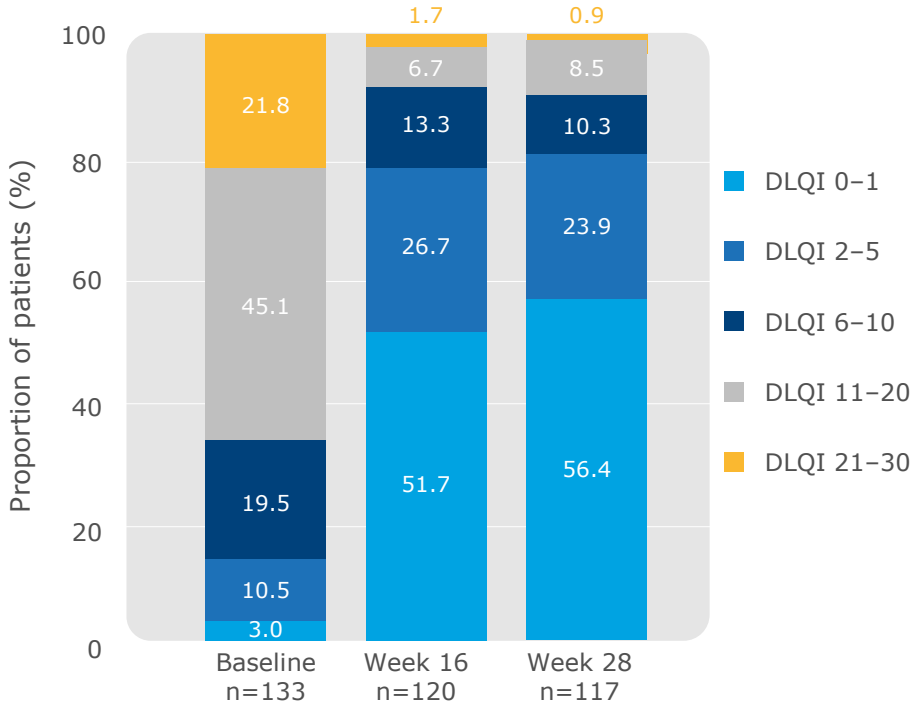
GUS demonstrated reductions in disease severity in patients with nail PsO and improvements in HRQoL

Mean NAPSI score in patients with nail PsO treated with GUS[1]*



Over 104 weeks, a 76.2% reduction in target NAPSI relative to baseline was observed[1]

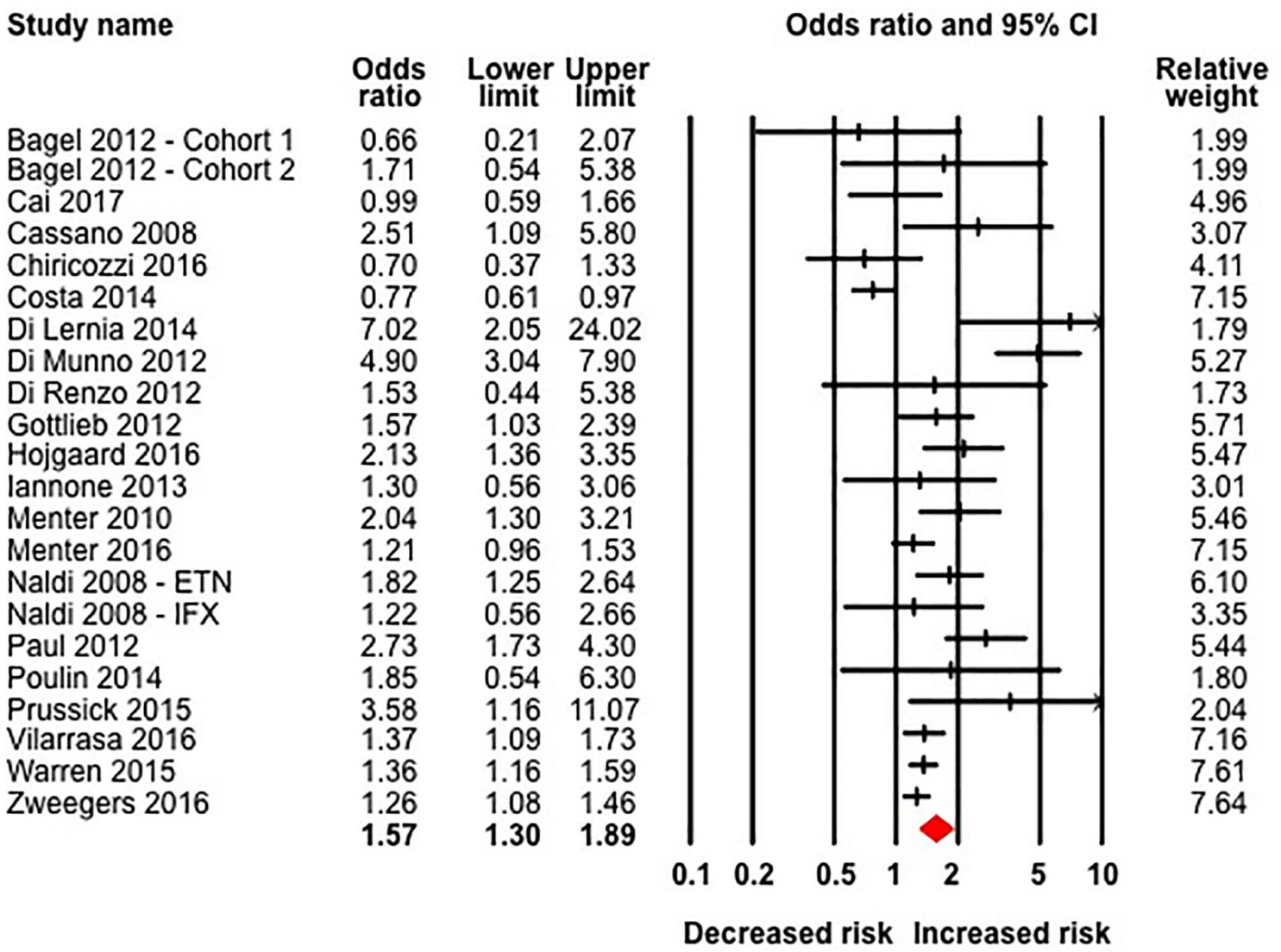
DLQI scores in patients with nail PsO treated with GUS[2]



*Patients with ≥1 affected nail at baseline. As observed data.[1]
DLQI, Dermatology Life Quality Index; GUS, guselkumab; HRQoL, health-related quality of life; NAPSI, Nail Psoriasis Severity Index; PsO, psoriasis; SD, standard deviation.
1. cf. Gerdes S, *et al. J Eur Acad Dermatol Venereol* 2023;10.1111/jdv.19296; 2. cf. Gerdes S, et al. *J Dermatol* 2021;48:1854–1862.

Comorbidities and Relevance to Therapeutic Choice?

Obesity and Failure of Anti-TNF Therapy - Psoriasis-Psoriatic Arthritis



Διατηρούμενη και βελτιωμένη ανταπόκριση ανεξάρτητα από τα αρχικά δημογραφικά χαρακτηριστικά

ACR20 Response

	GUS vs PBO Odds Ratio (95% CI)	Week 24 PBO n (%)	Week 24 GUS Q4W n (%)	Week 24 GUS Q8W n (%)	Week 52 PBO→GUS Q4W n (%)	Week 52 GUS Q4W n (%)	Week 52 GUS Q8W n (%)
All patients		109 (29)	232 (**62**)	225 (**60**)	229 (62)	267 (**72**)	261 (**70**)
Sex							
Male		59 (33)	141 (**68**)	125 (**64**)	117 (66)	162 (**78**)	145 (**74**)
Female		50 (26)	91 (**55**)	100 (**56**)	112 (58)	105 (**64**)	116 (**65**)
BMI (kg/m²)							
< 25		34 (37)	65 (**71**)	59 (**58**)	57 (61)	69 (**75**)	70 (**69**)
≥ 25 to < 30		34 (26)	74 (**60**)	76 (**58**)	84 (63)	92 (**75**)	93 (**72**)
≥ 30		41 (28)	93 (**59**)	90 (**63**)	88 (60)	106 (**67**)	98 (**68**)
Swollen joints (0-66)							
< 10		56 (29)	131 (**68**)	117 (**57**)	119 (62)	153 (**79**)	139 (**68**)
10 to 15		33 (32)	58 (**59**)	64 (**66**)	64 (62)	60 (**61**)	66 (**68**)
> 15		20 (26)	43 (**53**)	44 (**60**)	46 (60)	54 (**67**)	56 (**76**)
Tender joints (0-68)							
< 10		14 (26)	54 (**74**)	42 (**62**)	32 (60)	53 (**73**)	51 (**75**)
10 to 15		34 (30)	66 (**67**)	68 (**60**)	76 (67)	75 (**76**)	78 (**68**)
> 15		61 (30)	112 (**56**)	115 (**60**)	121 (59)	139 (**69**)	132 (**68**)
PsA duration (yrs)							
< 1		18 (33)	38 (**64**)	54 (**77**)	36 (67)	45 (**76**)	57 (**81**)
≥ 1 to < 3		28 (30)	61 (**73**)	55 (**63**)	62 (67)	63 (**75**)	64 (**74**)
≥ 3		63 (28)	133 (**58**)	116 (**53**)	131 (58)	159 (**69**)	140 (**64**)
CRP (mg/dL)							
< 1		54 (28)	125 (**61**)	114 (**59**)	113 (58)	145 (**71**)	133 (**69**)
1 to < 2		15 (22)	54 (**70**)	46 (**69**)	43 (63)	55 (**71**)	53 (**79**)
≥ 2		40 (36)	53 (**58**)	65 (**57**)	73 (66)	67 (**74**)	75 (**66**)
csDMARDs							
None		27 (23)	80 (**66**)	76 (**62**)	74 (63)	97 (**80**)	89 (**73**)
Any DMARDs		82 (32)	152 (**60**)	149 (**59**)	155 (61)	170 (**68**)	172 (**68**)
MTX		73 (32)	137 (**63**)	120 (**57**)	138 (61)	149 (**68**)	143 (**68**)

3405_v8

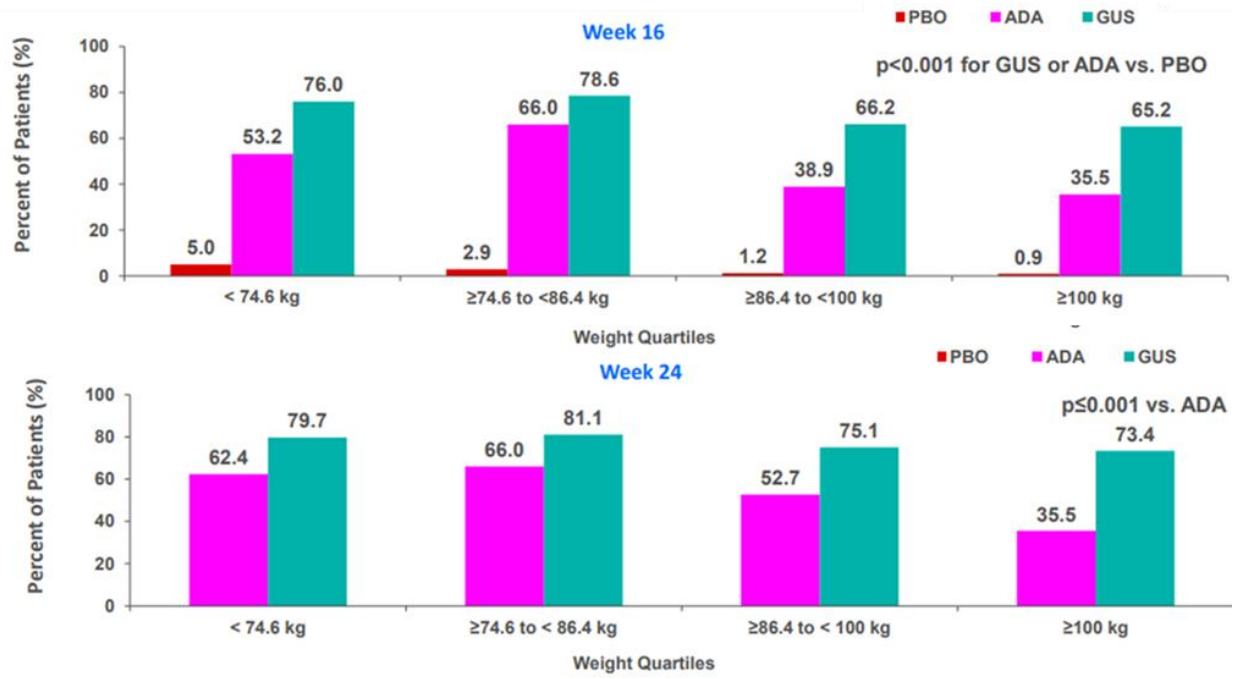
0.1 1 10 100

Placebo Better | Guselkumab Better

DISCOVER 2 _PsA

RMD Open 2022;8:e002195. doi:10.1136/rmdopen-2022-002195

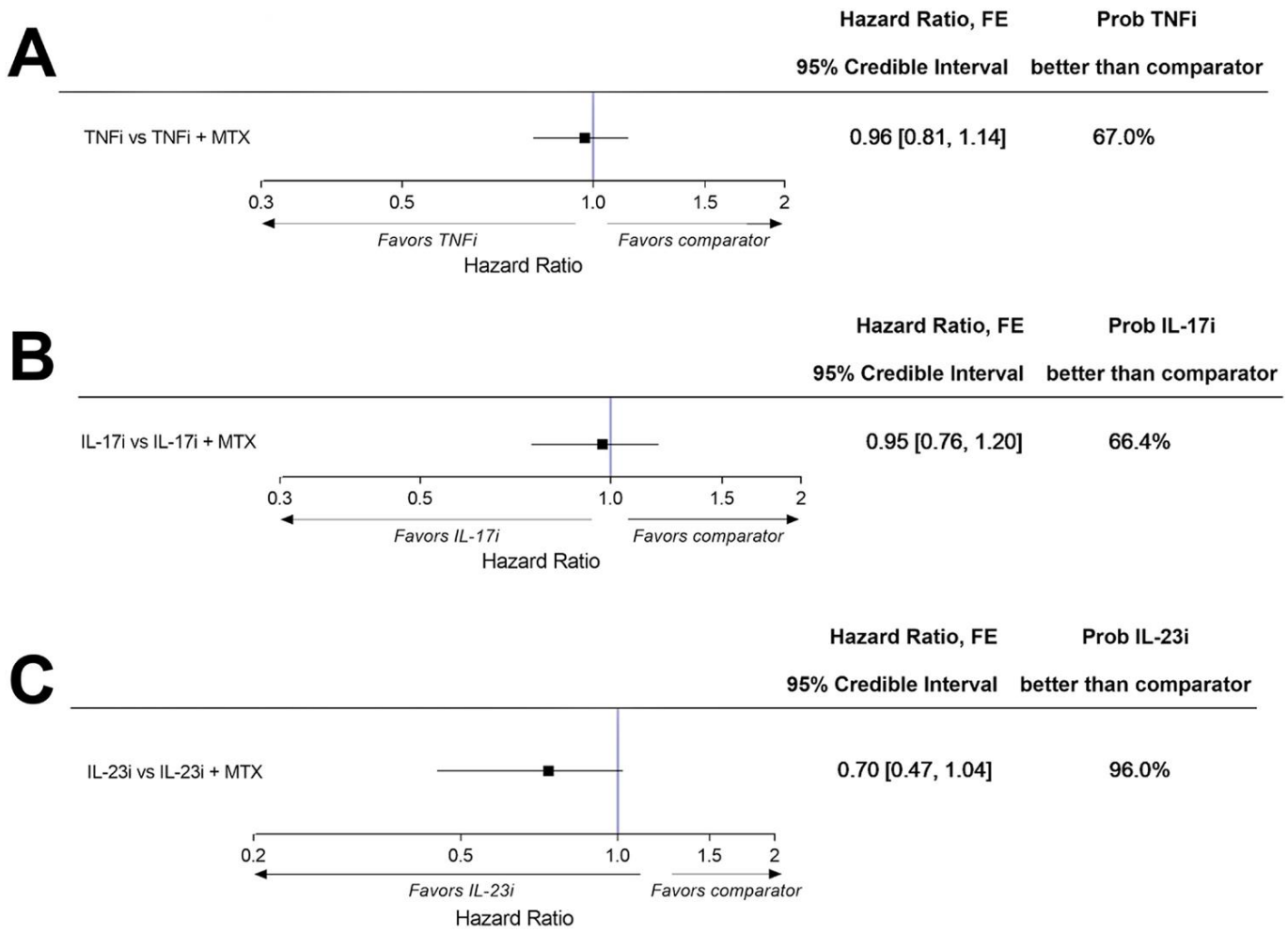
Effect of body weight to treatment response (PASI90)



VOYAGE 1 & 2 Pooled Data_PsO

Papp K, Crowley J, Rubel D, et al. AAD Annual Meeting; Feb 16-18, 2018; San Diego, CA. P6729

Efficacy results for ACR50 comparing treatments without and with MTX

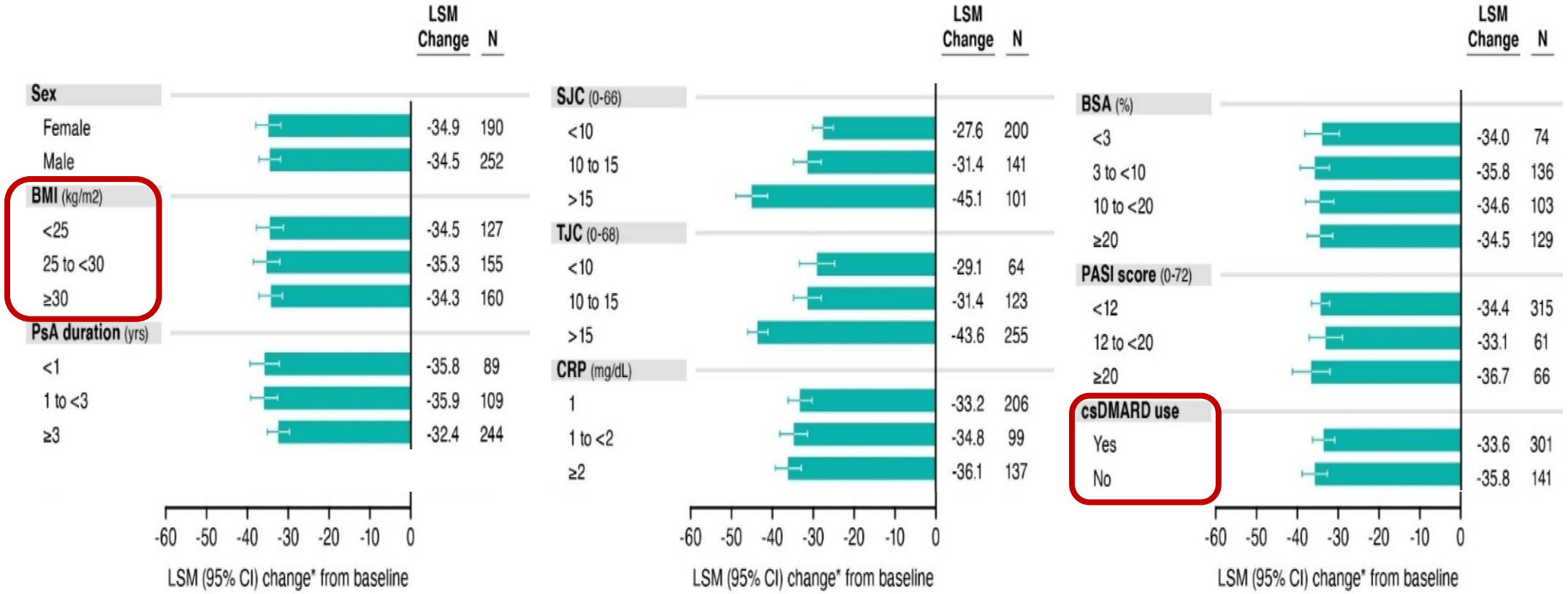


A) TNFi, B) IL-17 inhibitors, and C) IL-23 inhibitors.

Mease PJ, *et al*. *RMD Open* 2024;10:e003423. doi:10.1136/rmdopen-2023-003423

Guselkumab

LSM (95% CI) Change* in DAPSA score from BL to week 100 irrespective of BL characteristics



DAPSA 0-4 [remission], 5-14 [low], 15-28 [moderate], >28 [high]; PASI (0-72); LEI (0-6). *Derived from a multivariate linear model adjusting for BL subgroups; all p-values comparing LSM change from BL at Wk 100 are p<0.001BL: baseline;

JAKis και Καρδιαγγειακός Κίνδυνος

Identification of two tofacitinib subpopulations with different relative risk versus TNF inhibitors: an analysis of the open label, randomised controlled study ORAL Surveillance

Lars Erik Kristensen,[1] Silvio Danese,[2] Arne Yndestad,[3] Cunshan Wang,[4] Edward Nagy,[5] Irene Modesto,[6] Jose Rivas,[6] Birgitta Benda[7]

› Lancet Rheumatol. 2021 Apr;3(4):e270-e283. doi: 10.1016/S2665-9913(21)00010-2. Epub 2021 Mar 24.

Safety and efficacy of tofacitinib up to 48 months in patients with active psoriatic arthritis: final analysis of the OPAL Balance long-term extension study

Peter Nash [1], Laura C Coates [2], Dona Fleishaker [3], Alan J Kivitz [4], Philip J Mease [5], Dafna D Gladman [6], Oliver FitzGerald [7], Cunshan Wang [8], Joseph Wu [8], Ming-Ann Hsu [8], Sujatha Menon [8], Lara Fallon [9], Keith S Kanik [8]

Scientific Abstracts
Poster Tours Rheumatoid arthritis: JAKi and beyond

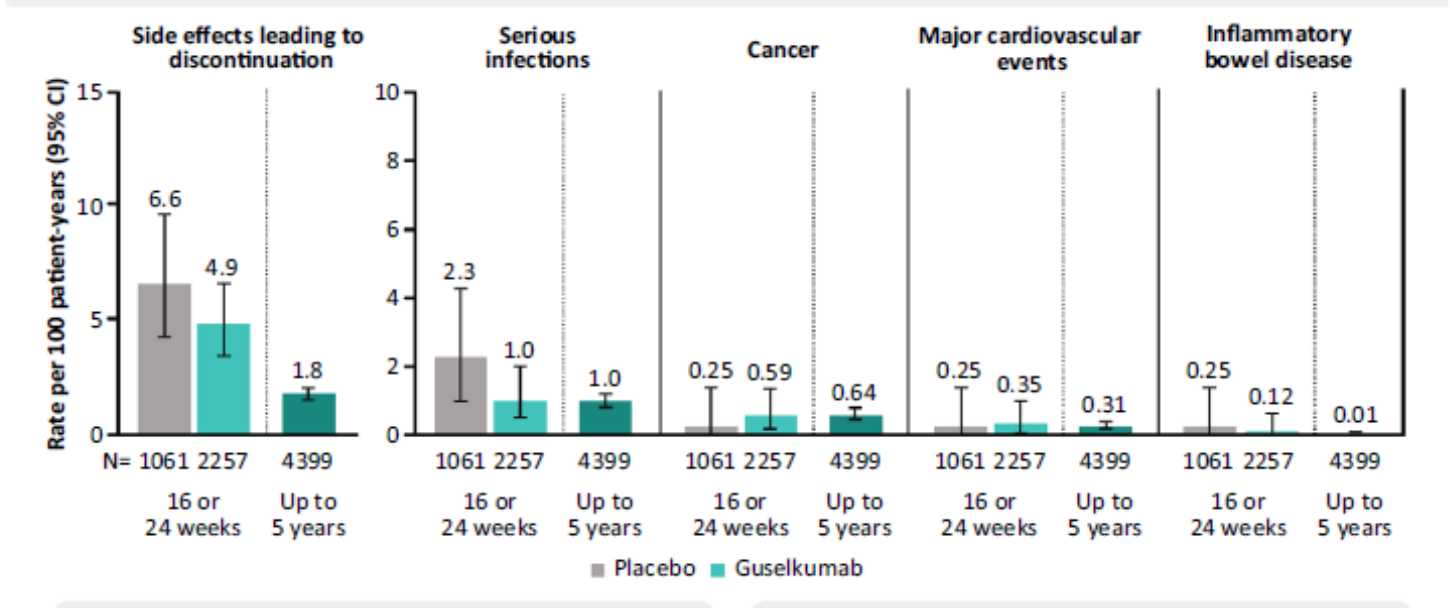
POS0237 MAJOR ADVERSE CARDIOVASCULAR EVENTS, MALIGNANCIES AND VENOUS THROMBOEMBOLISM BY BASELINE CARDIOVASCULAR RISK: A POST HOC ANALYSIS OF ORAL SURVEILLANCE FREE

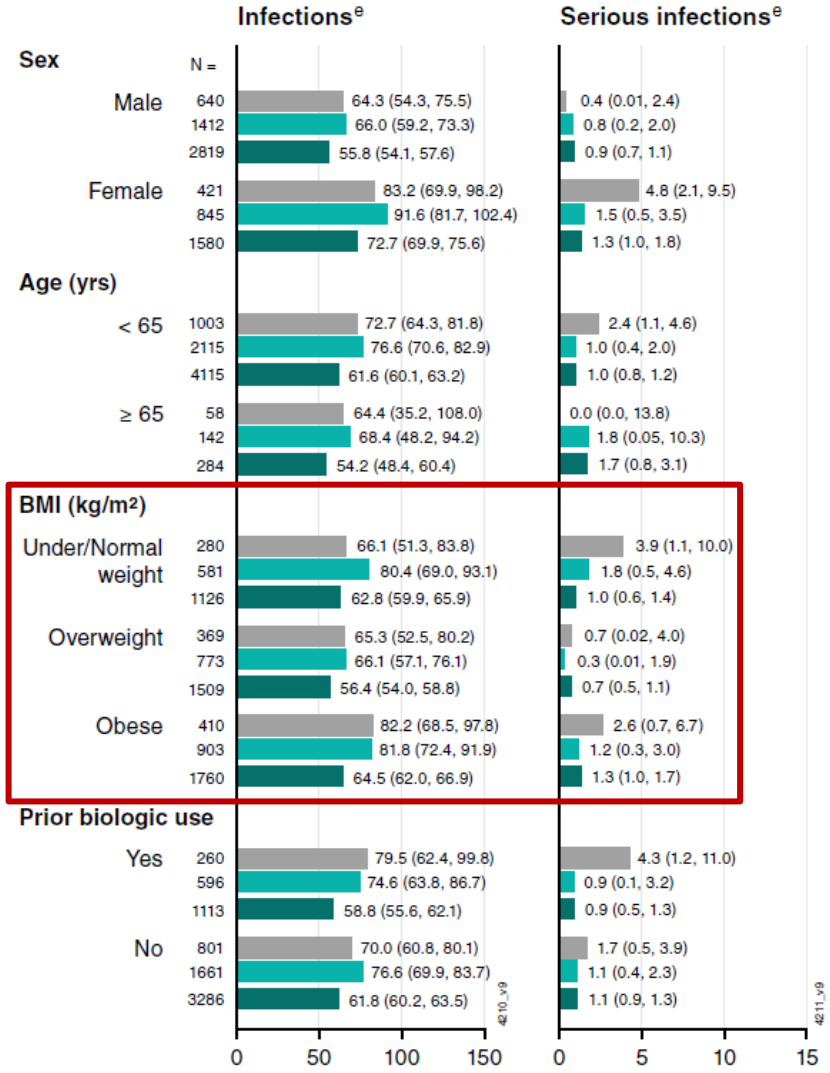
M. H. Buch [1], C. Charles-Schoeman [2], J. Curtis [3], M. Dougados [4,5], D. L. Bhatt [6], J. T. Giles [7], S. R. Ytterberg [8], G. G. Koch [9], I. Vranic [10], J. Wu [11], C. Wang [11], K. Kwok [12], S. Menon [11], J. L. Rivas [13], A. Yndestad [14], C. A. Connell [11], Z. Szekanecz [15]

Incidences of adverse events (number of patients with events per 100 person-years)

- ✓ 1·7 (1·2-2·5) for herpes zoster
- ✓ 1·0 (0·6-1·6) for serious infections
- ✓ 0·4 (0·1-0·8) for opportunistic infections
- ✓ 0·7 (0·4-1·2) for malignancies
- ✓ 0·9 (0·5-1·5) for NMSC
- ✓ 0·2 (0·1-0·6) for MACE
- ✓ 0·1 (0·0-0·3) for pulmonary embolism
- ✓ 0·4 (0·1-0·8) for arterial thromboembolism
- ✓ No deep vein thromboses occurred

GUS demonstrated a favourable safety profile over 10,787 PY across 11 studies

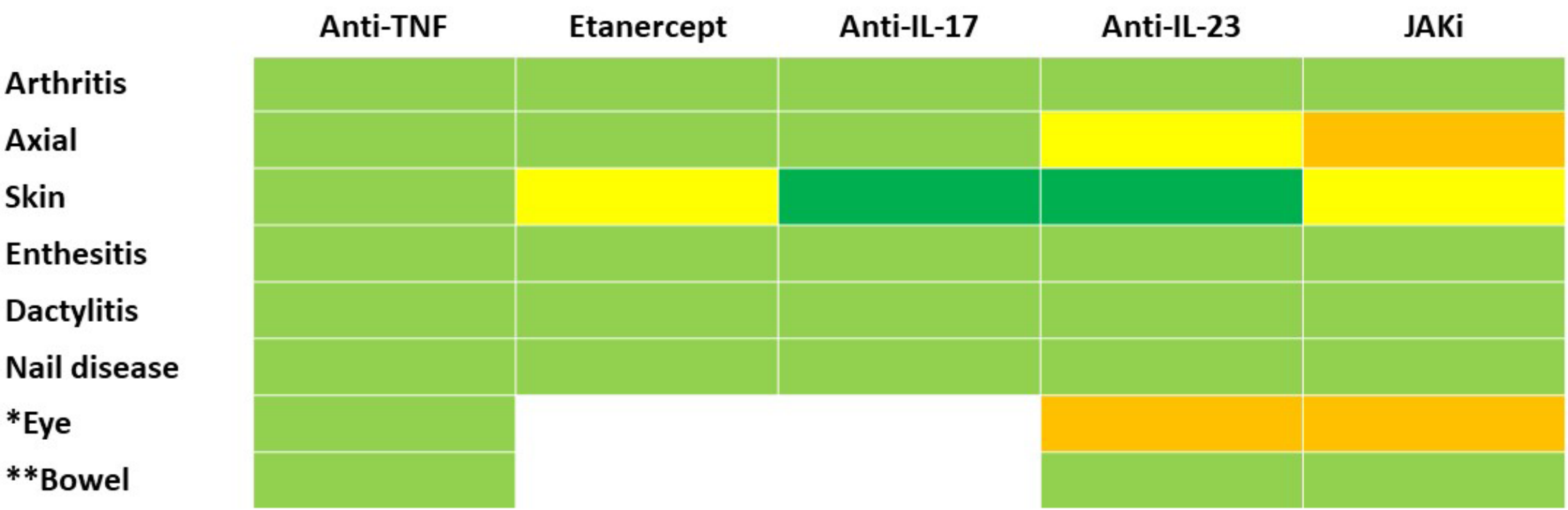




4400 adults with psoriatic disease treated for up to 5 years

11 Κλινικές Μελέτες Phase II/III PsO,PsA

Strober et al, Drug Safety (2024) 47:39–57 https://doi.org/10.1007/s40264-023-01361-w



Gialouri, Evangelatos, Fragoulis, Med J Rheumatol 2022

IL-17 vs. IL-23

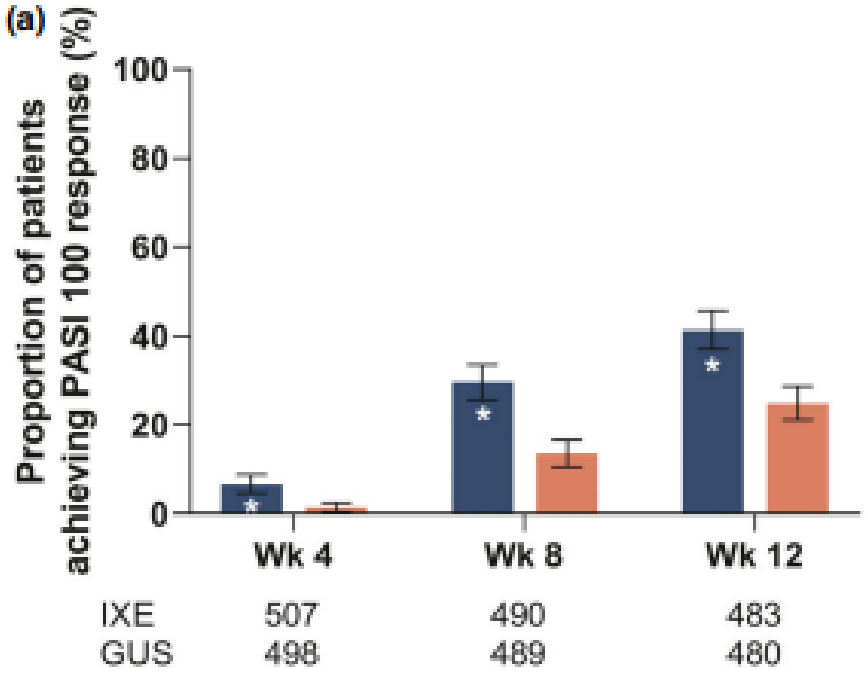
Pros and Cons

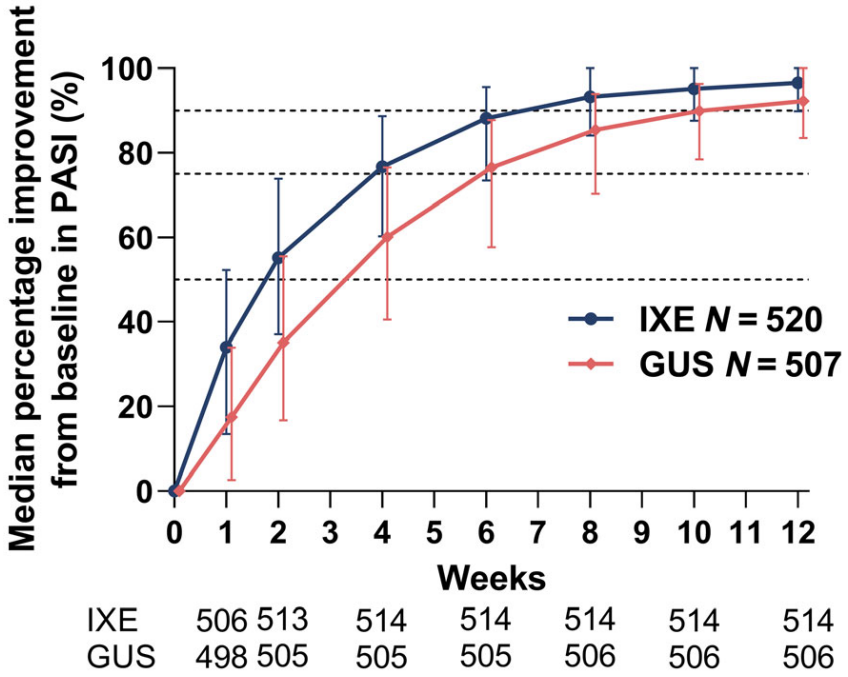
CLINICAL TRIAL

BJD
British Journal of Dermatology

A head-to-head comparison of ixekizumab vs. guselkumab in patients with moderate-to-severe plaque psoriasis: 12-week efficacy, safety and speed of response from a randomized, double-blinded trial*

A. Blauvelt,[1] K. Papp,[2] A. Gottlieb,[3] A. Jarell,[4] K. Reich,[5,6] C. Maari,[7] K.B. Gordon,[8] L.K. Ferris,[9] R.G. Langley,[10] Y. Tada,[11] R.G. Lima,[12] H. Elmaraghy,[12] G. Gallo,[12] L. Renda,[12] S.Y. Park,[12] R. Burge[12] and J. Bagel[13] on behalf of the IXORA-R Study Group





- The primary end point PASI 100 at week 12 was met [215/520 ixekizumab (41%); 126/507 guselkumab (25%); P < 0001].

Drug survival through 2 years

GUS RWE: Drug survival function for the biologic treatment cohorts

UK and Ireland – BADBIR

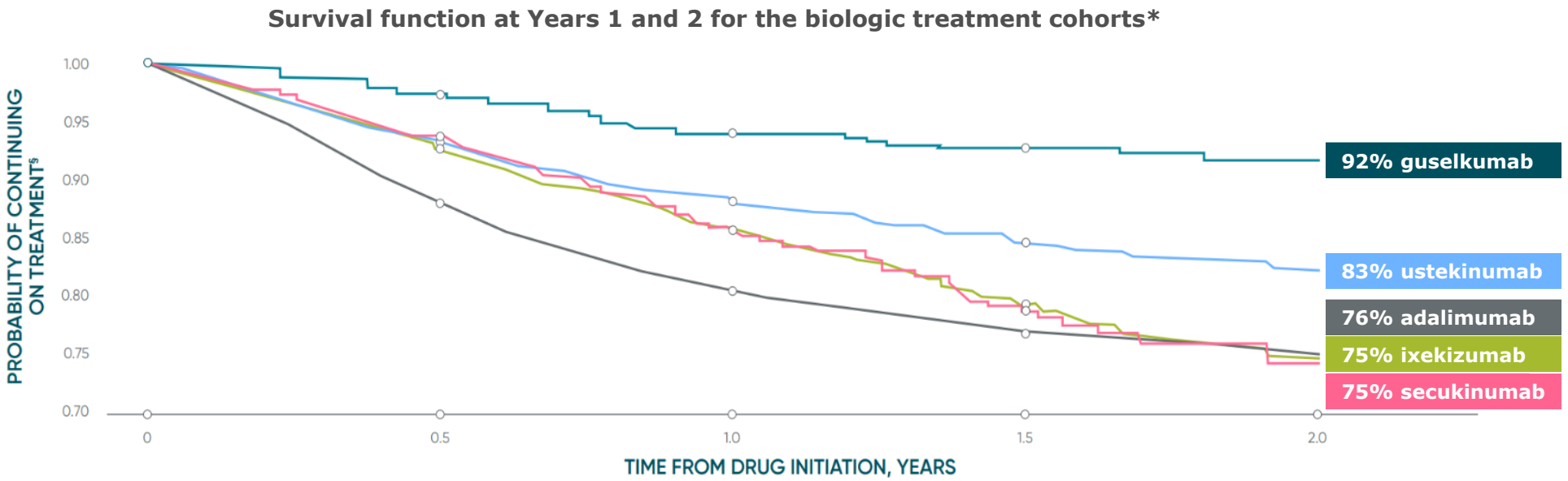


Figure adapted from Yiu ZZN et al. 2022.

Year	Total patients/No. of discontinuations				
	ADA (n=6607)	SEC (n=2677)	UST (n=5405)	IXE (n=703)	GUS (n=730)
Year 1	4693/1629	1942/467	4304/789	410/119	408/75
Year 2	3533/903	1262/342	3308/561	170/78	99/23

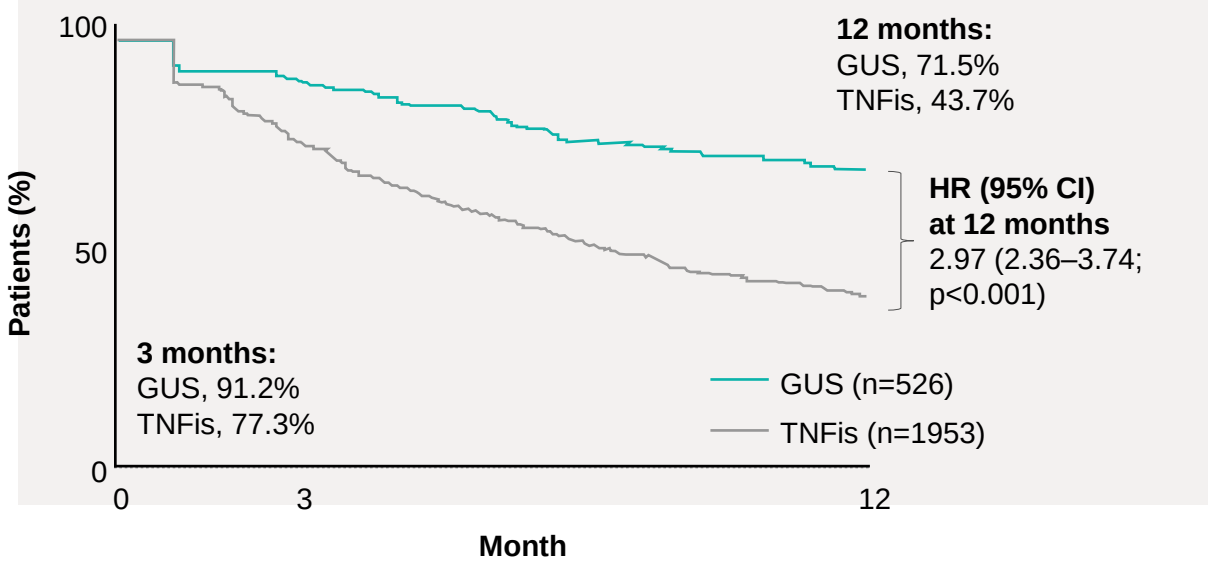
*Survival serves as a proxy for efficacy and safety. The y-axis starts from 0.70 for presentation clarity purposes.
ADA, adalimumab; GUS, guselkumab; IL, interleukin; IXE, ixekizumab; PsA, psoriatic arthritis; RWE, real-world evidence; SEC, secukinumab; UST, ustekinumab.
Yiu ZZN et al. *JAMA Dermatol* 2022;158:1131–1141.

Comparison of on-label treatment persistence in real-world patients with psoriatic arthritis receiving Guselkumab vs. subcutaneous TNF inhibitors

This analysis included patients with PsA from the IQVIA Health Plan Claims Database who initiated GUS or a SC TNFi (i.e. adalimumab, certolizumab pegol, etanercept or SC golimumab) between 14 July 2020 and 31 March 2022

Key result: Weighted KM rates of on-label persistence at 3, 6, 9 and 12 months were 91.2%, 84.1%, 75.9% and 71.5%, for GUS vs. 77.3%, 61.6%, 50.0% and 43.7% for the SC TNFi cohort, respectively (all log-rank p<0.001)

On-label persistence in weighted GUS and SC TNFi cohorts



- **On-label persistence was defined as the absence of treatment discontinuation or any dose escalation/reduction relative to the label dosing instructions**
- **Discontinuation was defined as a treatment gap between consecutive days of drug supply of twice the duration of days of supply for a claim** (i.e. 2 × 56 = 112 days for GUS or 2 × 28 = 56 days for a SC TNFi)

Conclusions

- This real-world study assessing treatment persistence in PsA using administrative claims data demonstrated that **Guselkumab was associated with significantly longer on-label persistence through 12 months vs. SC TNFis**
- At 12 months, **patients in the guselkumab cohort were approximately three times more likely to remain persistent on treatment than patients in the SC TNFi cohort: 72% vs 44%**

CI, confidence interval; GUS, guselkumab; HR, hazard ratio; IL, interleukin; KM, Kaplan–Meier; MOA, mechanism of action; NA, not applicable; PsA, psoriatic arthritis; RWE, real-world evidence; SC, subcutaneous; TNF(i), tumour necrosis factor (inhibitor).

cf. Shiff NJ, et al. Presented at EULAR, Vienna, Austria, 12–15th June 2024. **Abstract AB0410**.

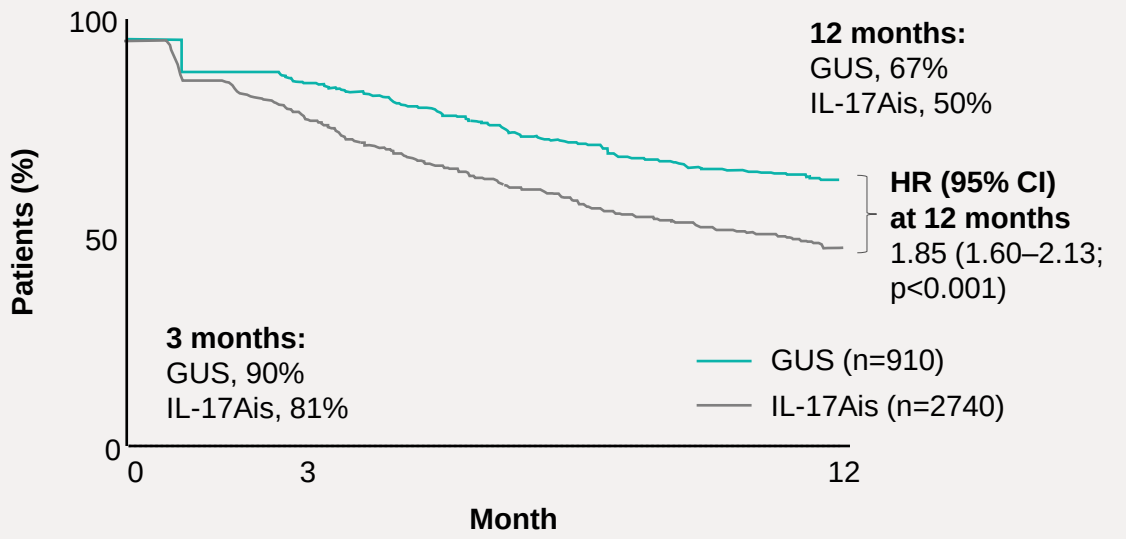
IQVIA

Comparison of on-label treatment persistence in real-world patients with psoriatic arthritis receiving Guselkumab vs. IL-17A inhibitors

This analysis included patients with PsA from the IQVIA Health Plan Claims Database who initiated GUS or a SC IL17i (secukinumab,ixekizumab) between 14 July 2020 and 30 June 2022

Key result: Patients in the GUS vs. SC IL-17Ai cohort were significantly more likely to remain persistent on treatment at 12 months

KM analysis of on-label persistence for GUS vs. IL-17Ais



Conclusions

- Patients in **the GUS vs. SC IL-17Ai cohort were significantly (~2×) more likely to remain persistent on treatment at 12 months**
- Rates of on-label GUS vs. SC IL-17Ai persistence at 12 months: **67% vs 50%**

[a] Propensity score (SMR) weighting was used to obtain a balanced sample. Weights were estimated using a multivariable logistic regression model. Baseline covariates included several demographic and clinical characteristics.
[b] Weighted Cox proportional hazard model was used to compare risk of discontinuation between the GUS and SC IL-17Ai cohorts.

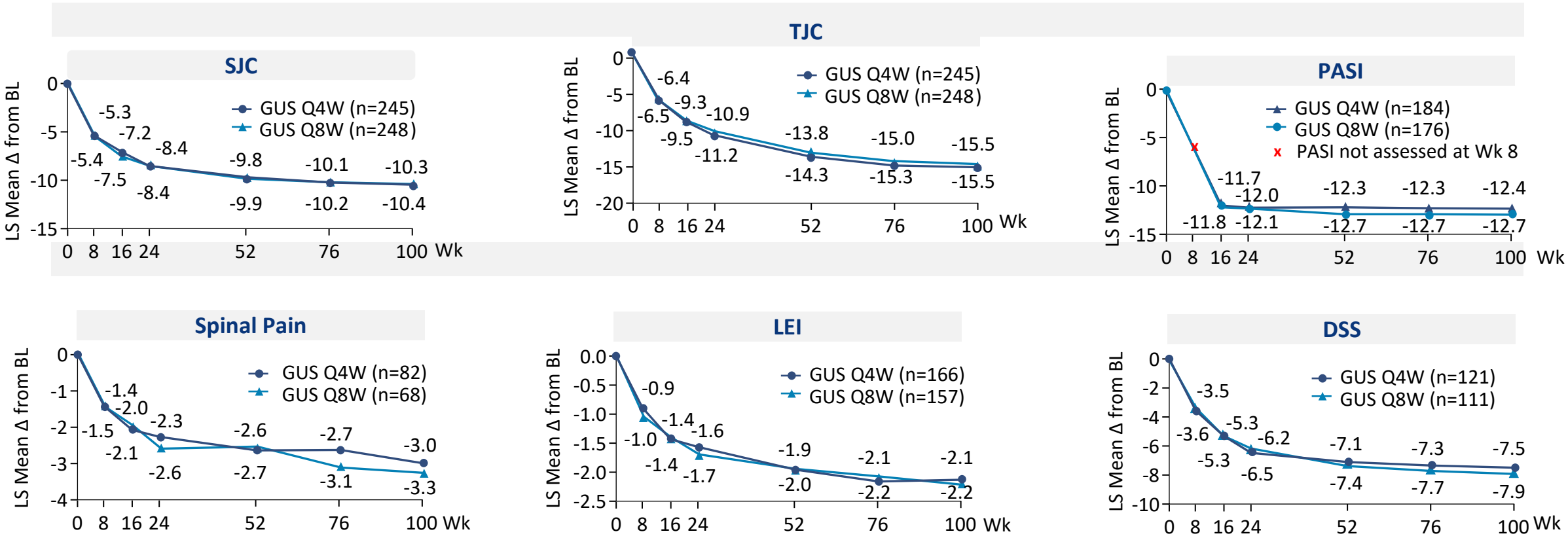
CI, confidence interval; FDA, US Food and Drug Administration; GUS, guselkumab; IL-17Ai, interleukin 17 inhibitor; IXE, ixekizumab; HR, hazard ratio; MOA, mechanism of action; NA, not applicable; PsA, psoriatic arthritis; RWE, real-world evidence; SC, subcutaneous; SEC, secukinumab.

Mease PJ, et al. Presented at EULAR, Vienna, Austria, 12–15th June 2024. Poster POS0984.

GUS Provides Continuous Improvement in PsA Domains Through 2 Years

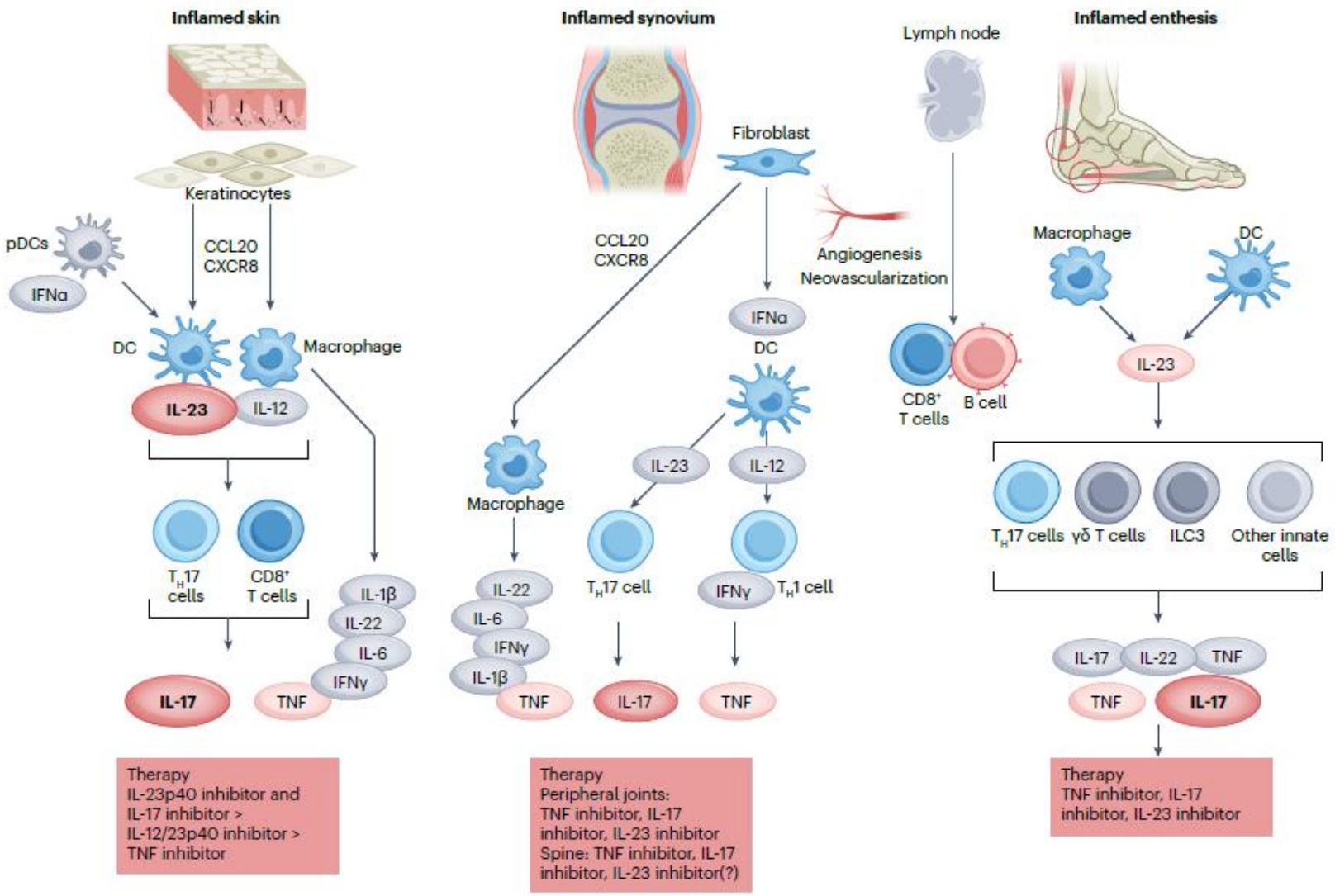
GUS efficacy was evaluated **using GRAPPA-recommended PsA domains** and related conditions of IBD and uveitis through 2 years

Continuous Outcomes Assessing Key PsA Domains – Δ from BL Through 2 Yrs**



Coates LC, *et al*. *RMD Open* 2024;10:e003977. doi:10.1136/rmdopen-2023-003977

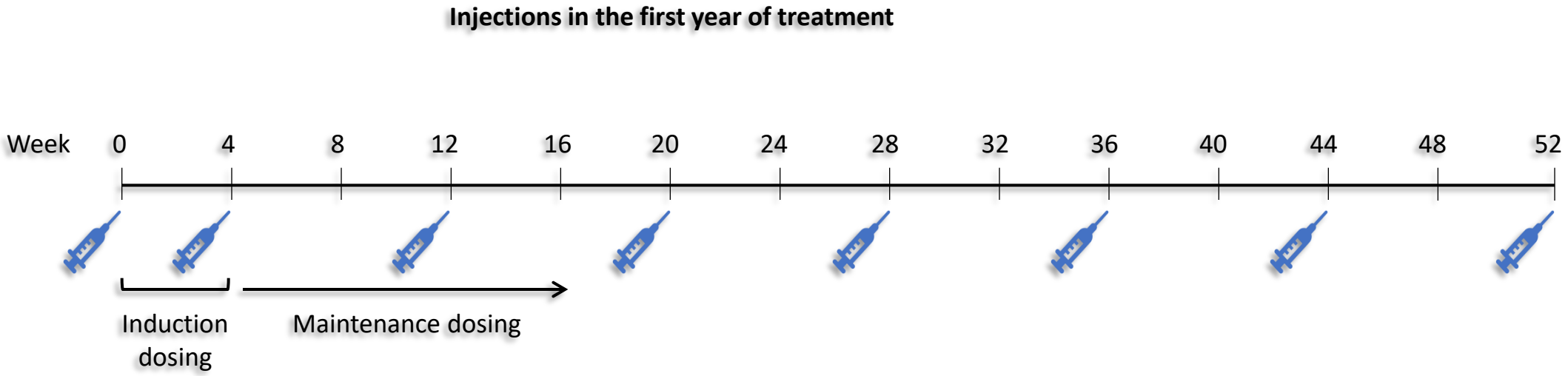
Different tissue and prominent pathogenetic mechanisms and response to current drug mechanisms of action



Najm et al. Nature reviews (2023) . https://doi.org/10.1038/s41584-022-00874-5

Ευέλικτο δοσολογικό σχήμα

Η συνιστώμενη δόση του **Guselkumab** στην **ΨΑ** είναι **100 mg** υποδορίως **τις εβδομάδες 0,4 και στη συνέχεια ανά 8 εβδομάδες**



Σε ασθενείς υψηλού κινδύνου για δομική βλάβη σύμφωνα με την κλινική κρίση,μπορεί να ληφθεί υπόψιν η δόση 100 mg ανά 4 εβδομάδες

Tremfya (guselkumab) Summary of Product Characteristics, 2022

Συμπεράσματα

- Συνολική αντιμετώπιση αρθρώσεων και δέρματος
- Δύσκολες εντοπίσεις
- Μη ανάγκη συγχορήγησης μεθοτρεξάτης για διατήρηση αποτελεσματικότητας
- Συννοσηρότητες – Μεταβολικό Σύνδρομο - Ασφάλεια
- Αποτελεσματικότητα ανεξαρτήτως ΣΒ
- Παραμονή στη θεραπεία
- Ευελιξία του δοσολογικού σχήματος

Ευχαριστώ για την Προσοχή σας!

Johnson&Johnson
Innovative Medicine

5ο Πανελλήνιο Θερινό Συμπόσιο Μυοσκελετικής Υγείας
8-11 Μαίου 2025, AKS Porto Heli Conference Center, Πορτο Χελι

ΔΟΡΥΦΟΡΙΚΗ ΔΙΑΛΕΞΗ

Διαχείριση της ψωριασικής νόσου: Το μονοπάτι του ιατρού την κλινική απόφαση

Προεδρείο: *Χ. Παπαγόρας*

- **Υπάρχει τυπικός ασθενής με ΨΑ;**
  Χ. Παπαγόρας
- **Πώς τα κλινικά χαρακτηριστικά οδη τη θεραπευτική απόφαση;**
  Ε. Καμπυλαυκά

Παρασκευή 9 Μαΐου 2025
19:30-20:00

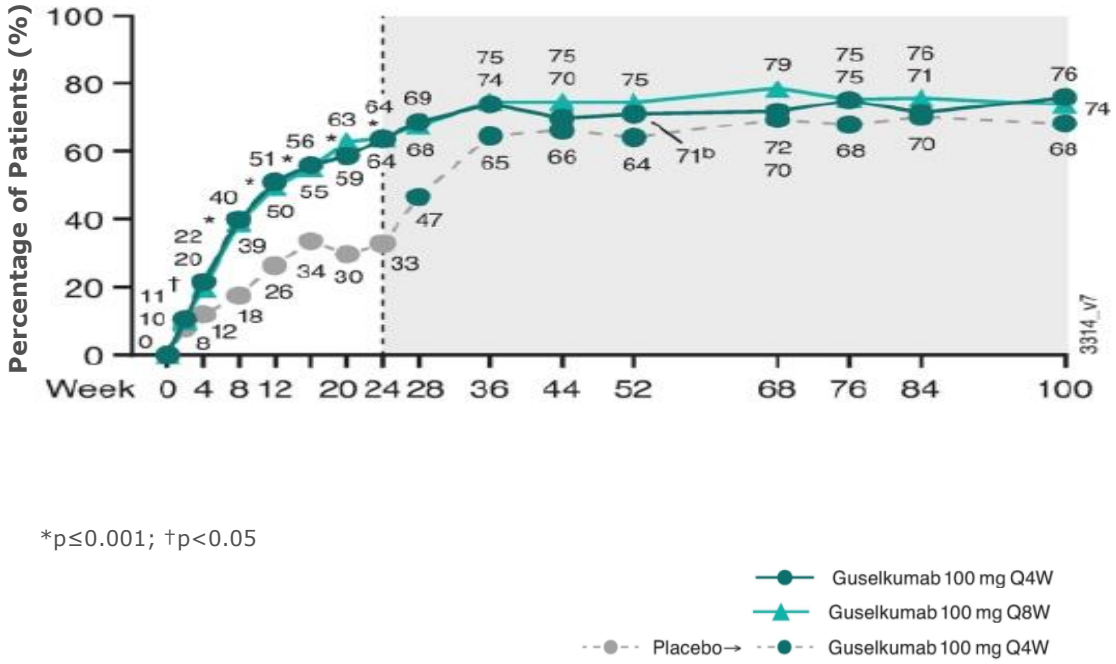
AKS Porto Heli Conference Center, Πορτο Χελι

Αξιολογήστε τη δορυφορική διάλεξη σκανάροντας το QR code

ACR20, ACR50 and ACR70 responses through 100 weeks in bio-naïve patients with PsA

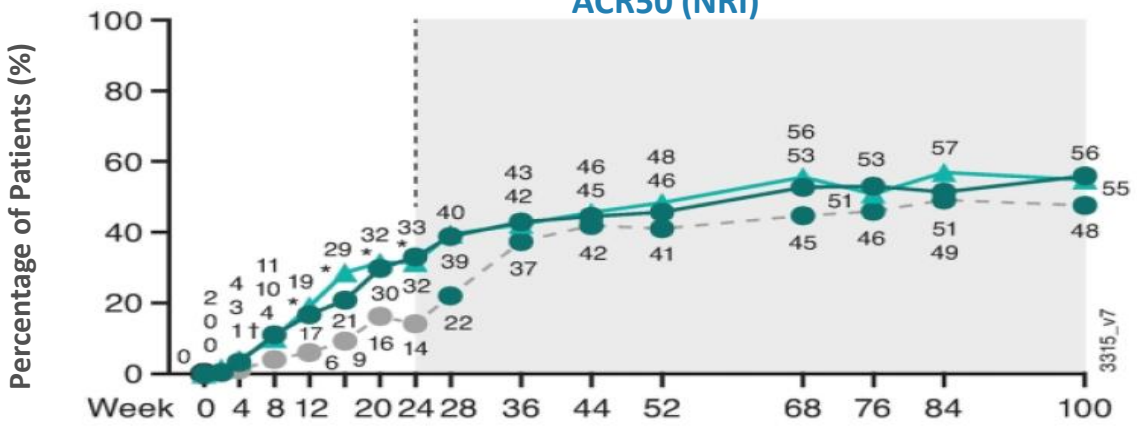
Το 88% των τυχαιοποιημένων ασθενών που έλαβαν θεραπεία ολοκλήρωσαν τη μελέτη

ACR20 Response (NRI)

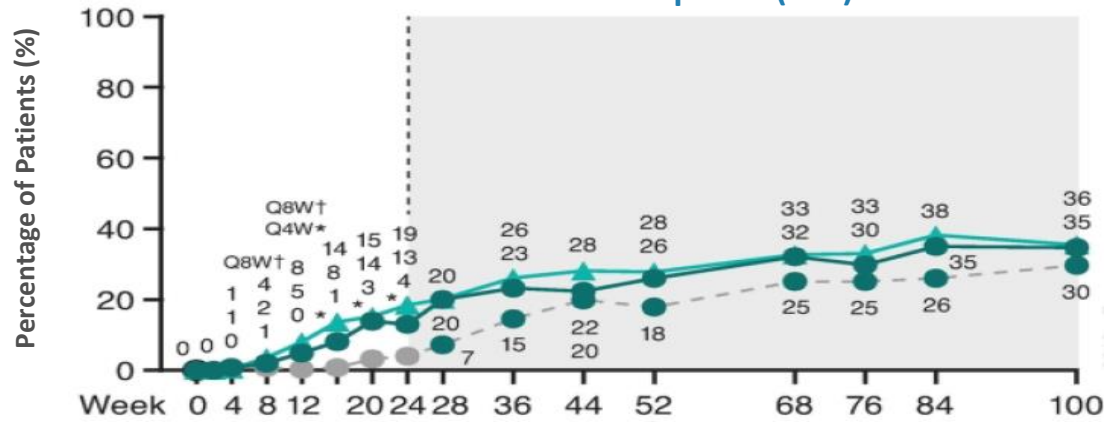


*p≤0.001; †p<0.05

ACR50 (NRI)



ACR70 Response (NRI)



*p≤0.001; †p<0.05

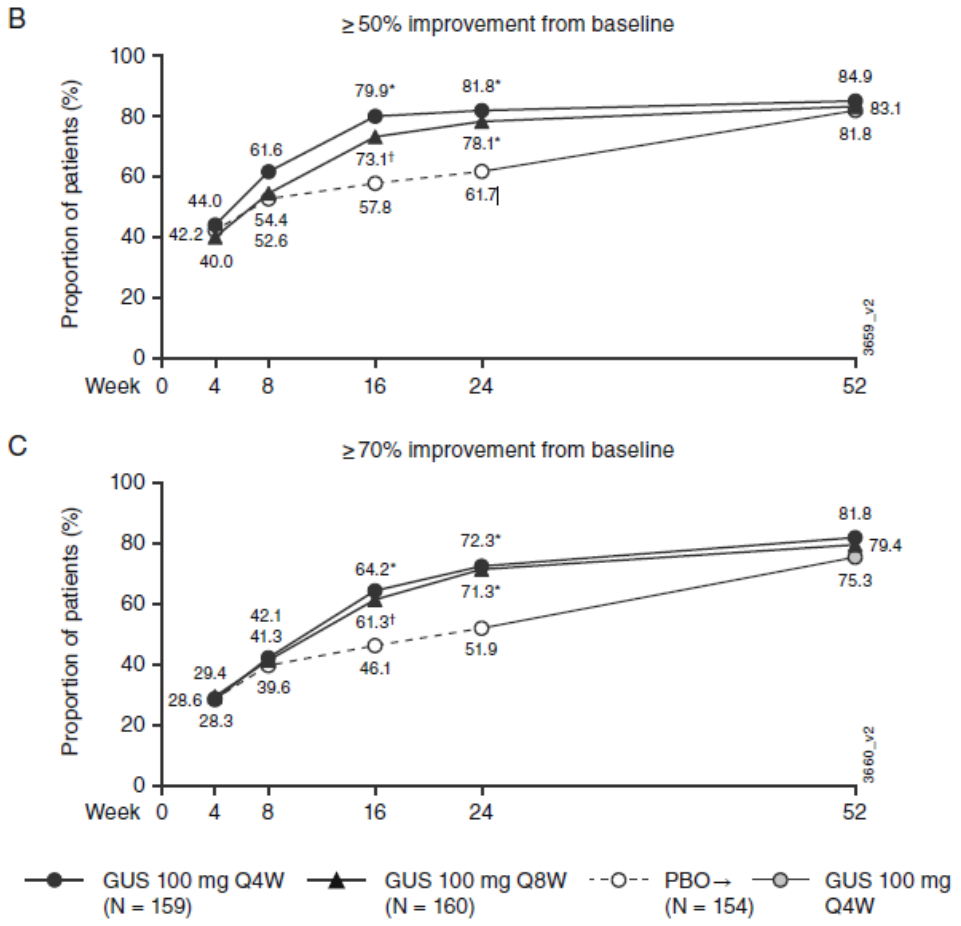
NRI: non-responder imputation

McInnes IB et al. *Arthritis Rheumatol* 2022;74(3):475–485

Dactylitis

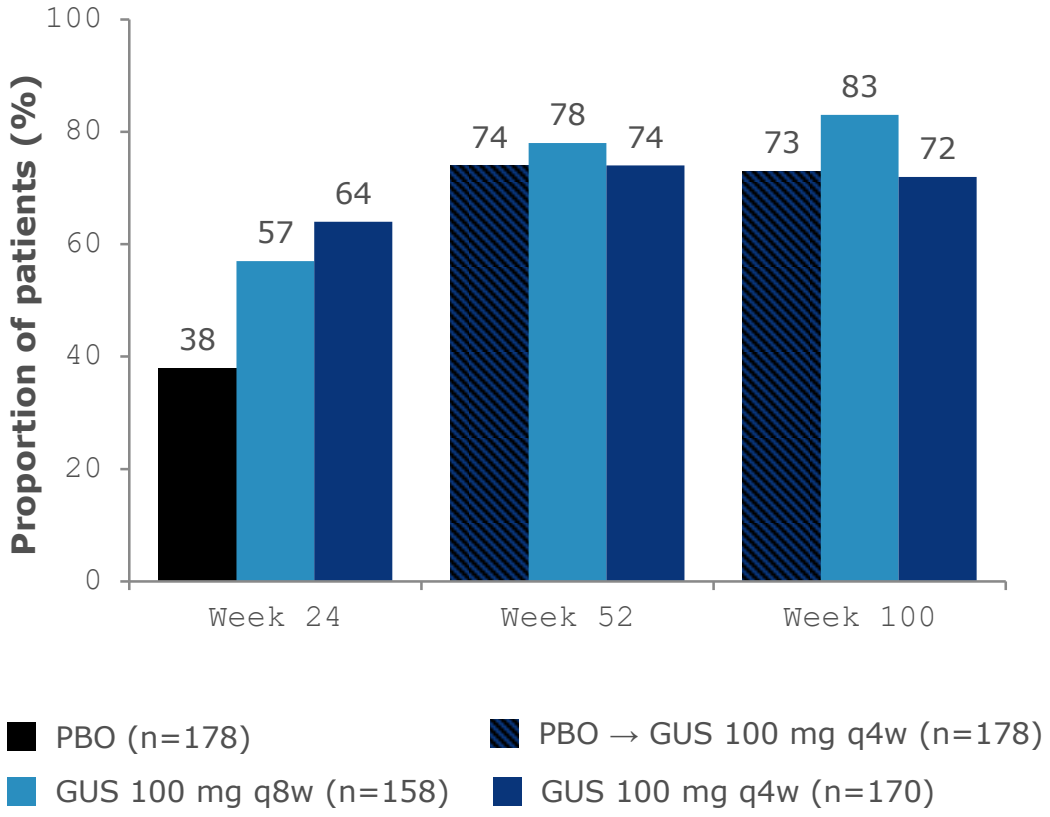
Dactylitis resolution in bio naïve patients through Week 100

% improvement in DSS from baseline for patients with DSS 1 or higher at baseline



*p ≤ 0.001; †p < 0.05

Dactylitis resolution through Week 100 (NRI)



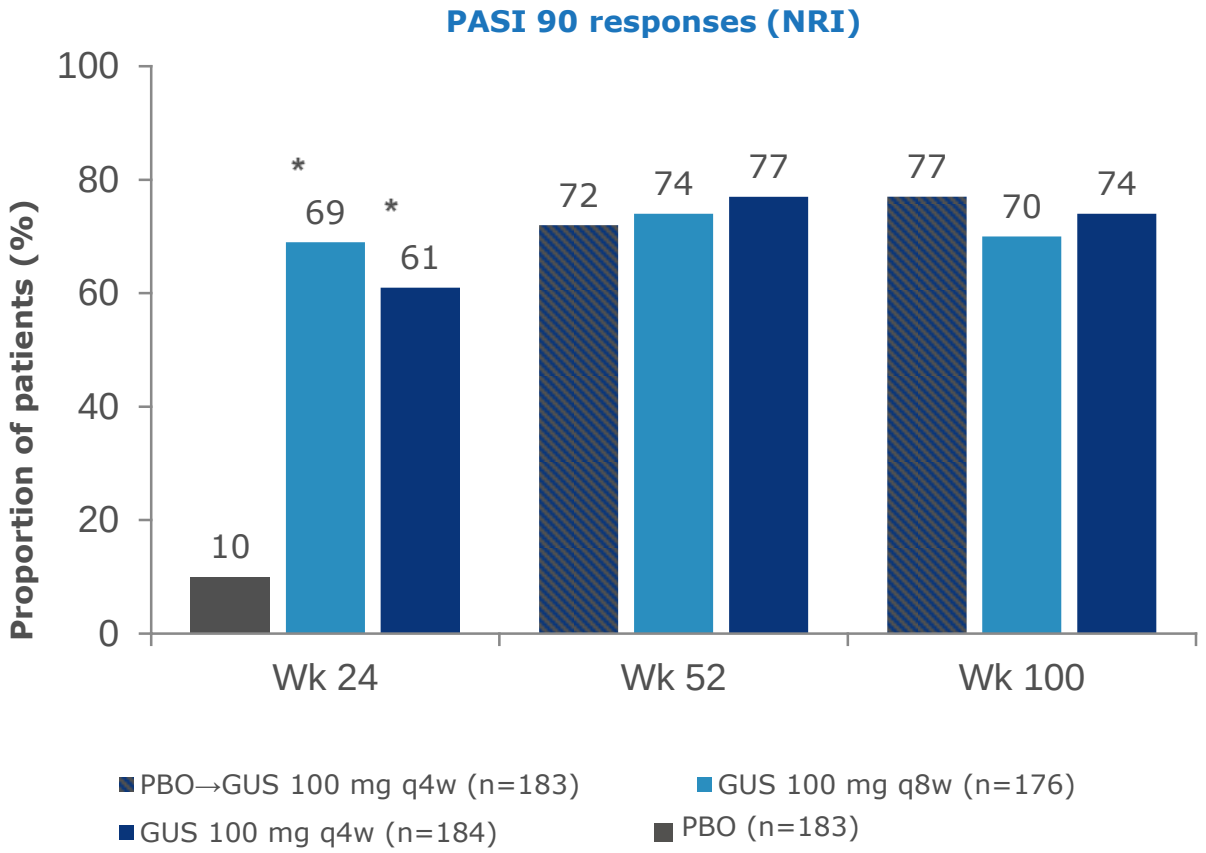
GUS, guselkumab; NRI, non-responder imputation; PBO, placebo; q4w, every 4 weeks; q8w, every 8 weeks.

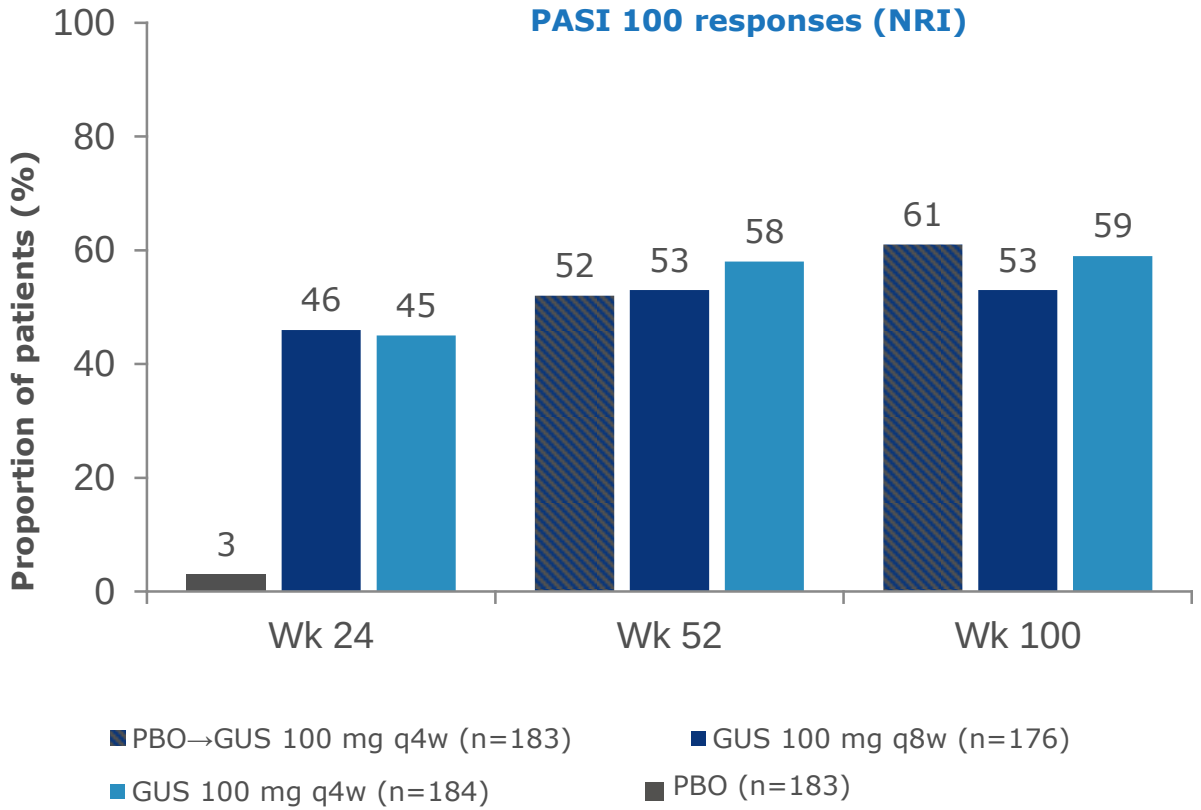
McInnes IB et al. Arthritis Rheumatol 2022;74:475-485

ACR Open Rheumatology Vol. 5, No. 4, April 2023, pp 227–240 DOI 10.1002/acr2.11537

PASI90 and PASI100 through Week 100

Bio naive patients with BSA ≥ 3% και IGA ≥ 2 στο BL

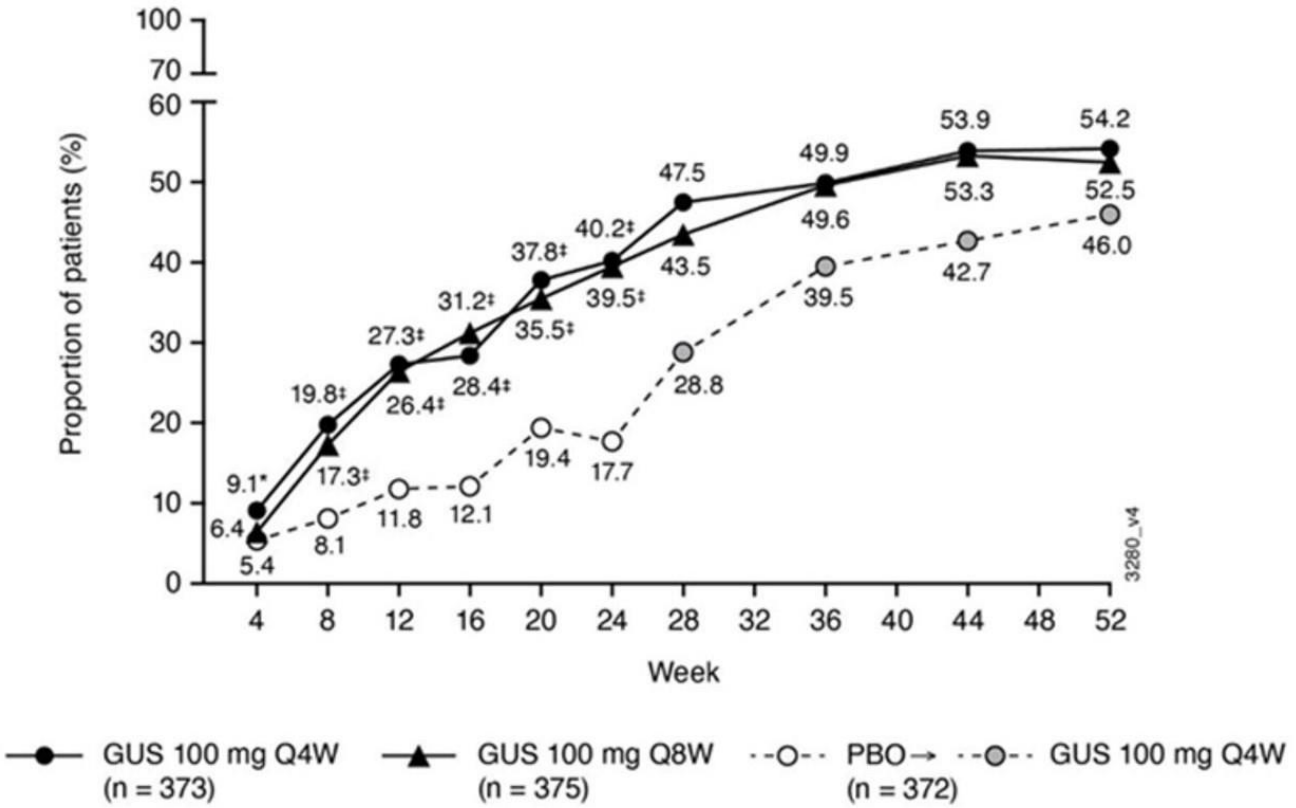




*unadjusted p-value p<0.0001

McInnes IB et al. *Arthritis Rheumatol* 2022;74(3):475–485

DAPSA LDA score (NRI) in bio naive and anti-TNF experienced through week 52



Missing data imputed as nonresponse.

*, +, ‡ $p < 0.05, 0.01, 0.001$, respectively, vs placebo. Unadjusted (nominal) p values are not controlled for multiplicity and are descriptive/supportive only; no statistical significance should be implied.

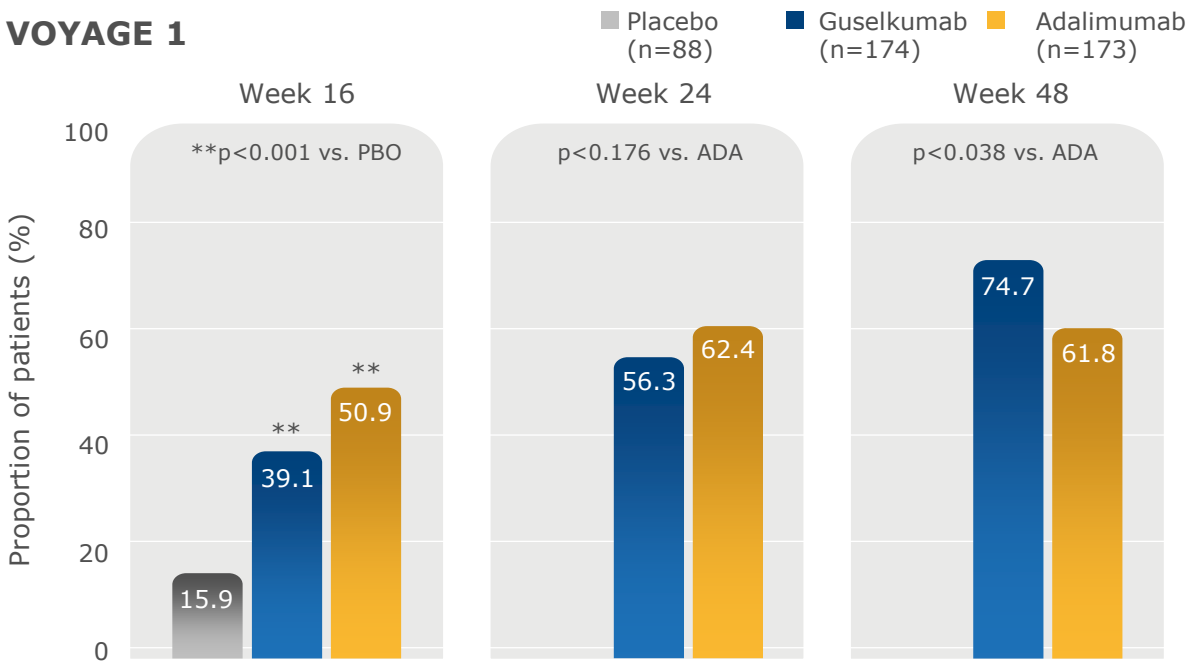
a The DAPSA score is derived from tender joint count (0–68), swollen joint count (0–66), CRP (mg/dL), patient assessment of pain (0–10 cm VAS), and patient global assessment of disease activity (arthritis, 0–10 cm VAS). DAPSA LDA: ≤14. DAPSA Remission: ≤4.

Rheumatology 2023;62:606–616 https://doi.org/10.1093/rheumatology/keac375 supl

GUS demonstrated improvements in patients with nail PsO

GUS showed nail responses generally comparable with ADA[1–3]

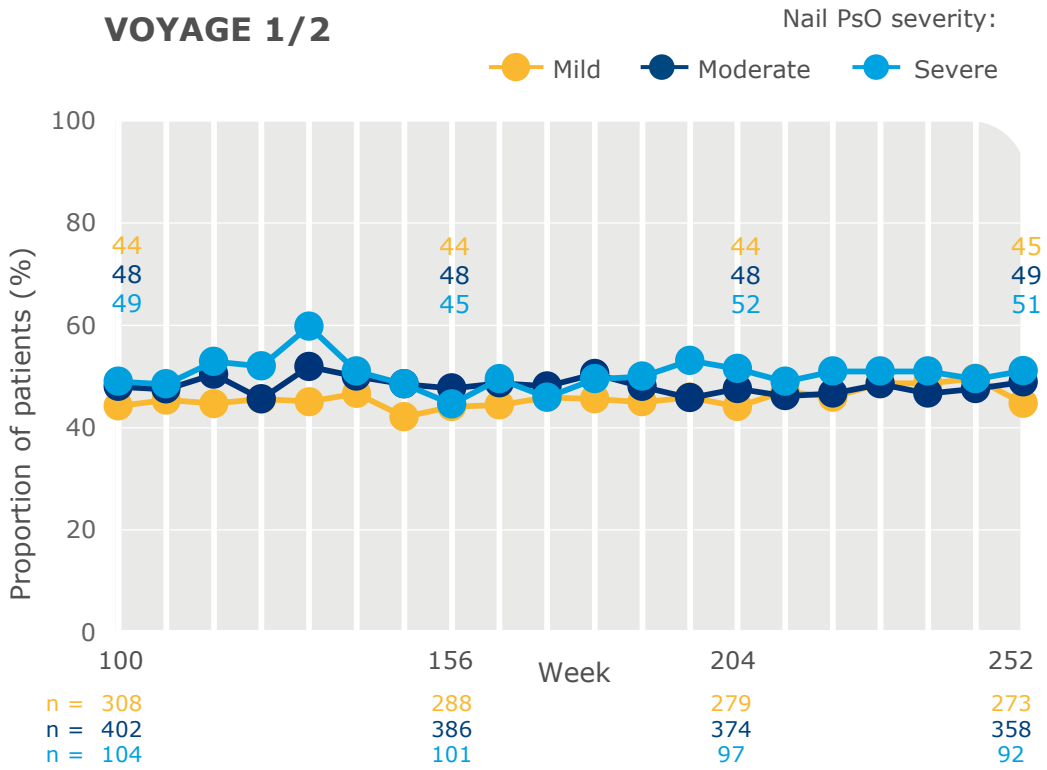
f-PGA score of 0/1 and an improvement of ≥1 point from baseline[1,2]*



In VOYAGE 2, the proportion of patients achieving f-PGA 0/1 was comparable between GUS (n=246) and ADA (n=124) through Week 24[3]**

Nail responses were sustained regardless of disease severity[4]

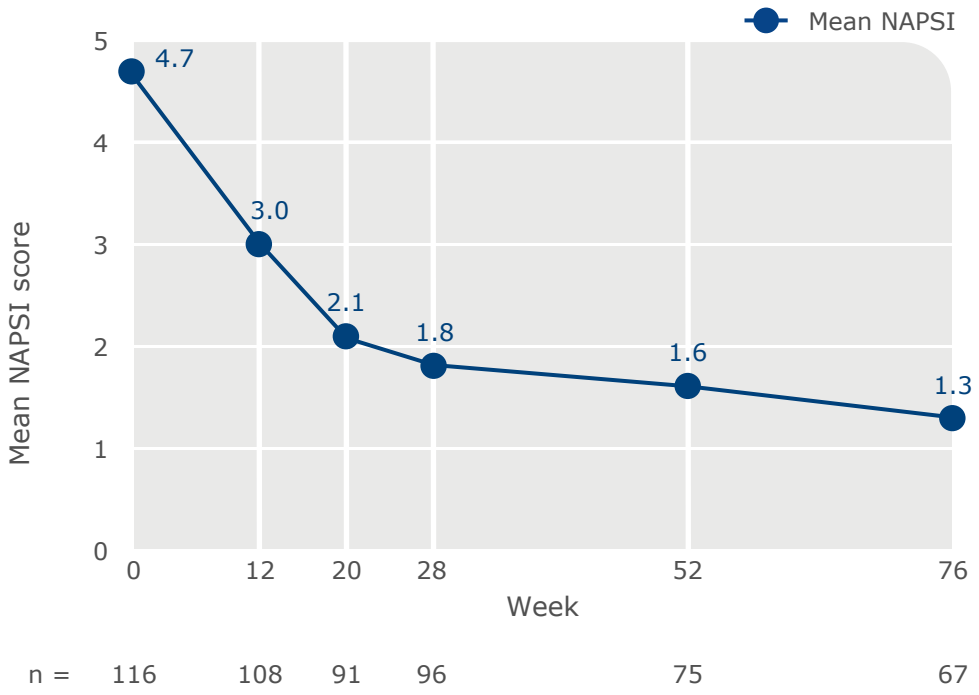
PASI100 response in patients with nail PsO who received GUS[4]*



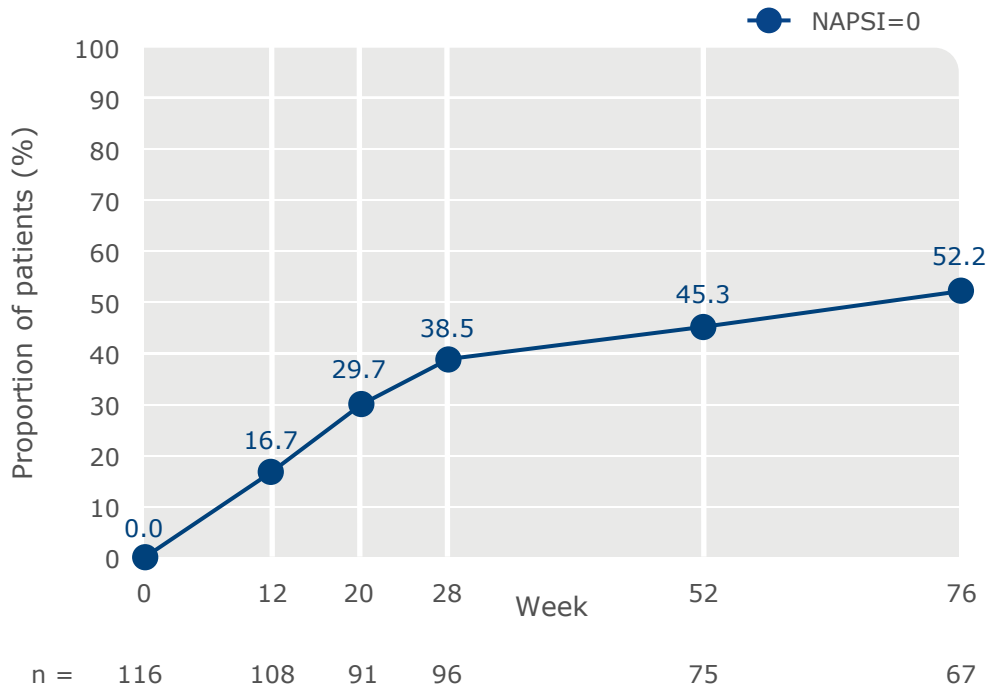
*Patients with a baseline f-PGA score of ≥2. f-PGA score: 0=clear, 1=minimal lesions.[1–4]
ADA, adalimumab; f-PGA, Physician's Global Assessment – fingernail; GUS, guselkumab; PASI100, 100% improvement in Psoriasis Area and Severity Index score; PBO, placebo; PsO, psoriasis.
1. Blauvelt A, et al. *J Am Acad Dermatol* 2017;76:405–417; 2. Blauvelt A, et al. Presented at AAD, Orlando, FL, US, 3–7 March 2017. P4768; 3. Reich K, et al. *J Am Acad Dermatol* 2017;76:418–431; 4. Puig L, et al. Presented at EADV, Milan, Italy, 7–10 September 2022. P1578.

Over 50% of patients achieved complete resolution of nail PsO with GUS at Week 76

Mean NAPSI score in patients with nail PsO treated with GUS*



NAPSI=0 score in patients with nail PsO treated with GUS*



*Patients with a NAPSI score ≥1 at baseline. As observed data.
GUS, guselkumab; NAPSI, Nail Psoriasis Severity Index; PsO, psoriasis.
Gerdes S, et al. Presented at AAD, San Diego, CA, US, 8–12 March 2024. P53723.

G-EPOSS: NAPSI

P1464

Guselkumab and IL-17 Inhibitors show comparable treatment persistence and effectiveness in psoriatic arthritis: 6-month interim results of the PsABIOnd observational cohort study

Gossec L,[1] Sharaf M,[2] Baraliakos X,[3] Kishimoto M,[4] Lubrano E,[5] Rahman P,[6] Rampakakis E,[7,8] Köleséri L,[9] Koivunen M,[10] Lavie F,[11] Soriano ER,[12] Silva RQ,[13] Behrens F,[14] Siebert S,[15]

[1]Sorbonne Université, Pitie-Salpetriere Hospital, Paris France; [2]Immunology EMEA Medical Affairs, Johnson & Johnson Middle East FZ LLC, Dubai United Arab Emirates; [3]Ruhr-University Bochum, Rheumazentrum Ruhrgebiet Herne, Germany; [4]Department of Nephrology and Rheumatology, Kyorin University School of Medicine, Tokyo, Japan; [5]Vincenzo Tiberio Department of Medicine and Health Sciences, University of Molise, Campobasso, Italy; [6]Faculty of Medicine, Division of Rheumatology, Memorial University of Newfoundland, St. Johns, Canada; [7]Department of Pediatrics, McGill University, Montreal, Canada; [8]Scientific Affairs, JSS Medical Research, Inc, Montreal, Canada; [9]Data Sciences Staffing Solutions, IQVIA, Inc, Budapest, Hungary; [10]Janssen-Cilag Oy, Espoo, Finland; [11]Immunology Global Medical Affairs, Janssen Cilag Global Medical Affairs, Issy les Moulineaux, France; [12]Rheumatology Section, Internal Medicine Service, Hospital Italiano de Buenos Aires and University Institute Hospital Italiano de Buenos Aires, Argentina; [13]Rheumatology Division & ISPA Translational Immunology Division, Hospital Universitario Central de Asturias, Oviedo University, Oviedo, Spain; [14]Rheumatology and Fraunhofer IME - Translational Medicine and Pharmacology, Goethe University, Frankfurt, Germany; [15]School of Infection & Immunity, University of Glasgow, Glasgow, UK

J&J Innovative Medicine

Immunology

Study design, patient demographics and disease characteristics at baseline

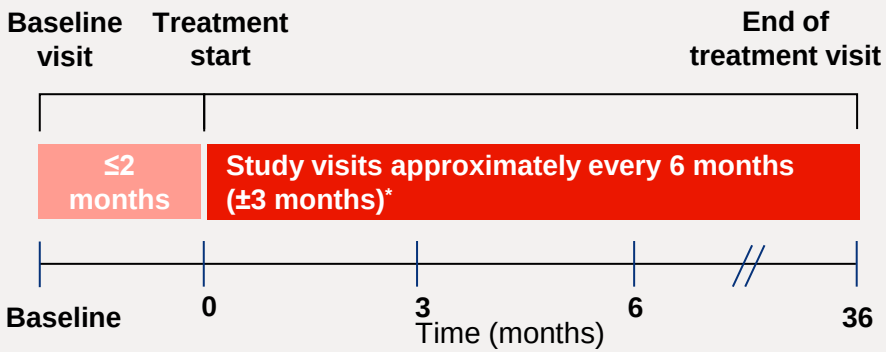
Aim

- To assess treatment persistence and achievement of clinical PsA outcomes at the 6-month visit in participants initiating treatment with either GUS or an IL-17i in a real-world setting

Methods

- Adults with PsA who initiated GUS or an IL-17i as 1st-to-4th-line biologic therapy (monotherapy or in combination) were enrolled from 20 countries

Study design



Selected demographics and baseline characteristics were mainly comparable between cohorts, though participants initiating GUS had more severe skin disease and a higher proportion were on their 4th treatment line

PsABIOnd Interim Analysis Cohorts		GUS (n=360)	IL-17i (n=326)
Demographics			
	Age, years	52.0 (13.1)	53.6 (11.9)
	Females	62%	61%
	BMI, kg/m²	30.3 (6.4)[a]	29.3 (6.3)[b]
Characteristics			
	PsA disease duration, years	7.6 (7.7)[c]	7.6 (8.9)[d]
	cDAPSA (0–154; ModDA 13–27, HDA >27)	24.5 (14.5)[e]	27.6 (17.7)[f]
	Enthesitis	49%[g]	53%[h]
	Dactylitis	18%[g]	20%[h]
	Psoriatic BSA		
	<3%	51%[d]	61%[i]
	3 to 10%	36%[d]	31%[i]
	>10%	13%[d]	8%[i]
	bDMARD treatment line		
	1st	37%	36%
	2nd	26%	35%
	3rd	20%	19%
	4th	17%[j]	9%[k]

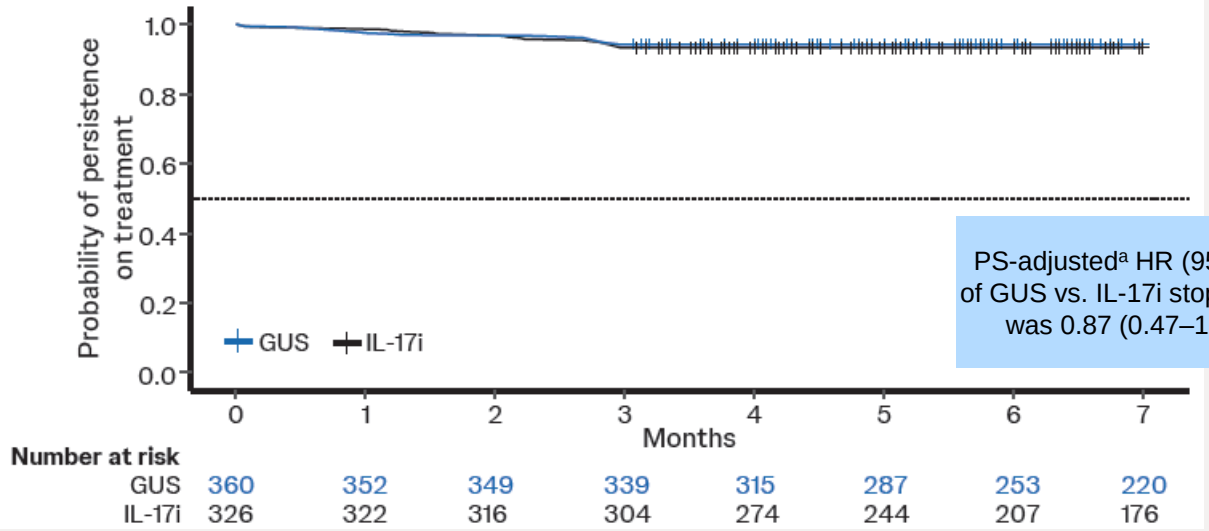
Data shown in Table are mean (SD) unless otherwise indicated. *Among patients with polyarticular PsA at baseline; [a]n=334; [b]n=285; [c]n=355; [d]n=325; [e]n=312; [f]n=286; [g]n=265; [h]n=225; [i]n=349; [j]n=315; [k]n=295; [l]n=362; [m]n=328.
BMI, body mass index; BSA, body surface area; (c)DAPSA, (Clinical) Disease Activity Index for PsA; GUS, guselkumab; IL-17i, interleukin-17 inhibitor; IL-23, interleukin-23; MOA, mechanism of action; NA, not applicable; Obs, observational; PsA, psoriatic arthritis; SD, standard deviation.
Gossec L, et al. Presented at ACR, Washington DC, USA, 14–19th November 2024. Poster P1464.

Persistence and reasons for discontinuation at 6 months

Key result: Persistence on treatment was high with both GUS and IL-17i at the 6-month visit – ~94% of participants initiating GUS and IL-17i remained on their initial treatment line

Key result: Very few participants discontinued their initial treatment, with reasons for discontinuation being comparable between cohorts

Probability of persistence up to 6 months



PS-adjusted[a] HR (95% CI) of GUS vs. IL-17i stop/switch was 0.87 (0.47–1.61)

Patients initiating 1st-to-4th line of biologic therapy were pooled per treatment group for this analysis. Results are shown through Month 7 to account for variation in visit scheduling. [a]Adjusted for potential confounders at baseline including initial bDMARD treatment line among others.

Reasons for discontinuation

Reason for discontinuation[a] n (%)	GUS (n=360)	IL-17i (n=326)
Adverse event	5 (1.4)	5 (1.5)
Primary failure	8 (2.2)	9 (2.8)
Drug holiday	1 (0.3)	0 (0)
Other	2 (0.6)	1 (0.3)

An additional seven patients from each cohort discontinued their initial treatment without reporting a reason. [a]More than one reason for treatment discontinuation could be reported per event.

[a] More than one reason for treatment discontinuation could be reported per event.

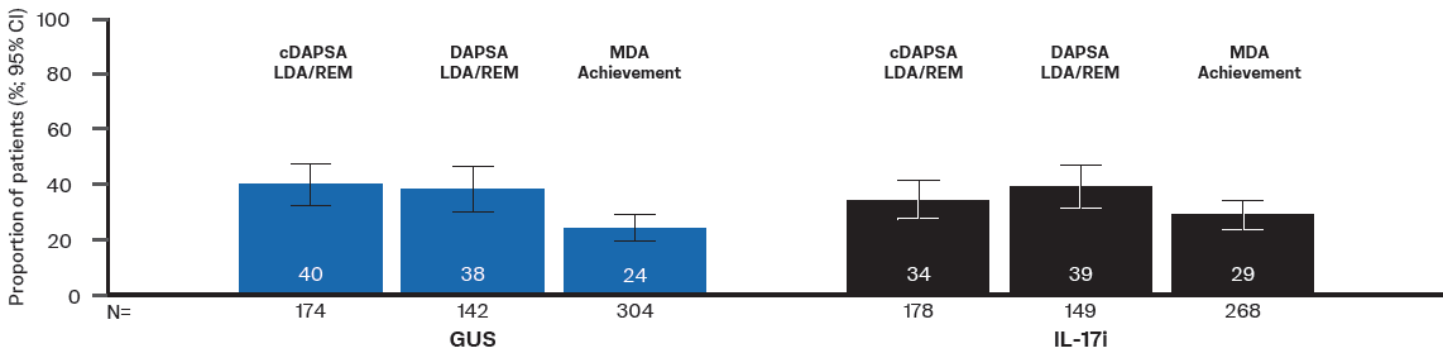
bDMARD, biologic disease-modifying anti-rheumatic drug; CI, confidence interval; GUS, guselkumab; HR, hazard ratio; IL-17i, interleukin-17 inhibitor; IL-23, interleukin-23; MOA, mechanism of action; NA, not applicable; Obs, observational; PS, propensity score; SD, standard deviation.

Gossec L, et al. Presented at ACR, Washington DC, USA, 14–19th November 2024. 2024. Poster P1464.

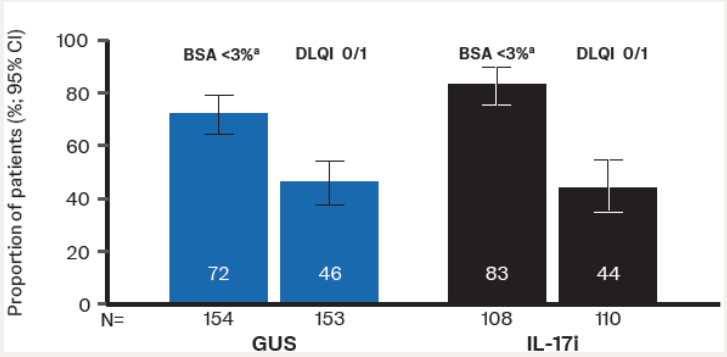
Treatment effectiveness at 6 months

Key result: Treatment effectiveness was similar with GUS and IL-17i across PsA clinical outcomes at the 6-month visit

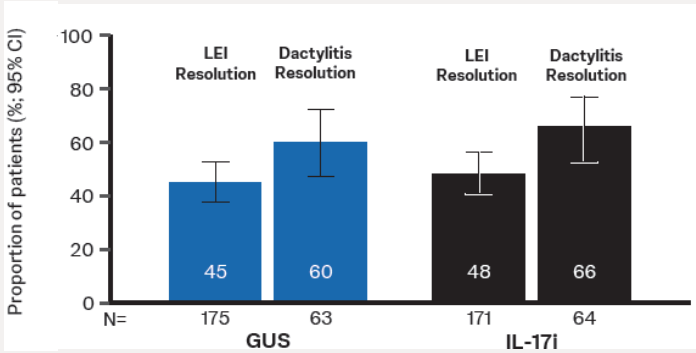
Composite outcome measures



Skin domain



LEI and dactylitis resolution



Number of participants (N) indicated under the x-axis correspond to the number of participants included in each respective analysis. [a]Reported proportions were corrected after submission of the abstract.
BSA, body surface area; (c)DAPSA, (Clinical) Disease Activity Index for PsA; CI, confidence interval; DLQI, Dermatology Life Quality Index; GUS, guselkumab; IL-17i, interleukin-17 inhibitor; IL-23, interleukin-23; LDA/REM, low disease activity or remission; LEI, Leeds Enthesitis Index; MDA, minimal disease activity; MOA, mechanism of action; NA, not applicable; Obs, observational; PsA, psoriatic arthritis.
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