Ένας κλινικός διάλογος

Ψωριασική νόσος: μύθοι και πραγματικότητα

Επιλέγοντας θεραπεία
Πως διαμορφώνουμε την κλινική μας απόφαση

Πατρίκος Δήμος
Ρευματολόγος

Μυτιληναίου Γ. Μαρία
Ρευματολόγος

SCAN ME

TO PROVIDE A DIGITAL EVALUATION OF THE SESSION

4° Πανελλήνιο Θερινό Συμπόσιο Μυοσκελετικής Υγείας

30/5-2/6/2024, Καλαμάτα, Ξενοδοχείο Filoxenia

Disclosures

Dr. Patrikos has received consultant and/or speaker fees from Janssen, Genesis, Amgen, Abbvie, Novartis, UCB, Pfizer

Dr. Mytilinaiou has received honoraria and/or research funding from UCB, Janssen

DISCLAIMER:

The symposium is organized and supported by Janssen, Pharmaceutical Companies of Johnson & Johnson

The views expressed in these slides are those of the individual faculty members and do not necessarily reflect the views of Janssen, Pharmaceutical Companies of Johnson & Johnson

The presentations may include discussions on off-label use of drugs

Κλινικό Σενάριο 1

- **Γυναίκα 40 ετών**
- **BMI: 34.6kg/m²** (Β:100kg, Υ: 170cm)
- **ΑΥ** και **υπερλιπιδαιμία** υπό αγωγή
- **Ινομυαλγία** υπό αγωγή
- **Ψωρίαση από 10ετίας ,ΨΑ από 3ετίας υπό αγωγή με κορτιζόνη 5mg και MTX SC 20mg/w**

- **Πολυαρθρίτιδα** (10 SJC / 15 TJC)
- **Ψωρίαση αγκώνων και τριχωτού κεφαλής** (BSA 3 %)
- **Ενθεσίτιδα αχιλλείων**
- **CRP 15mg/L**
- **Υψηλή ενεργότητα - DAPSA: 40,2**

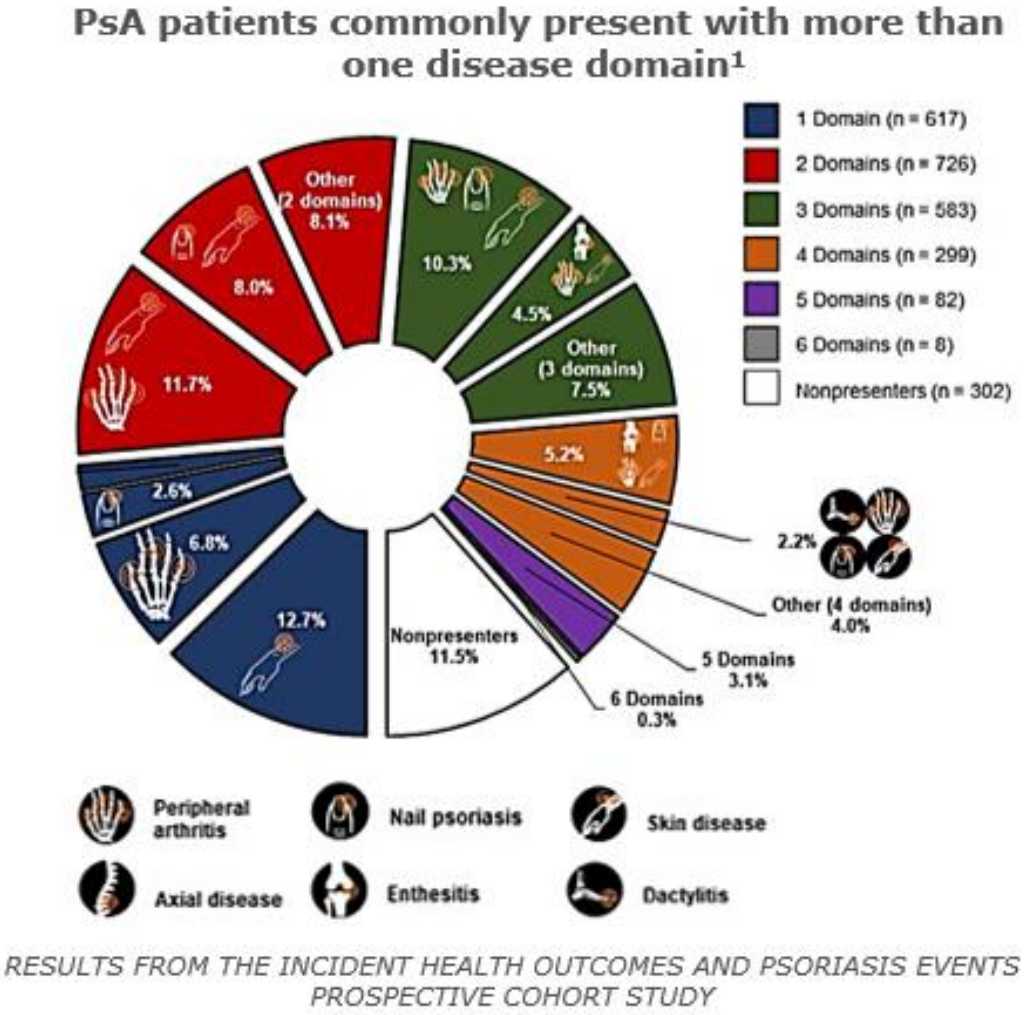
→ **Έναρξη στοχευμένης θεραπείας →Anti-TNF**

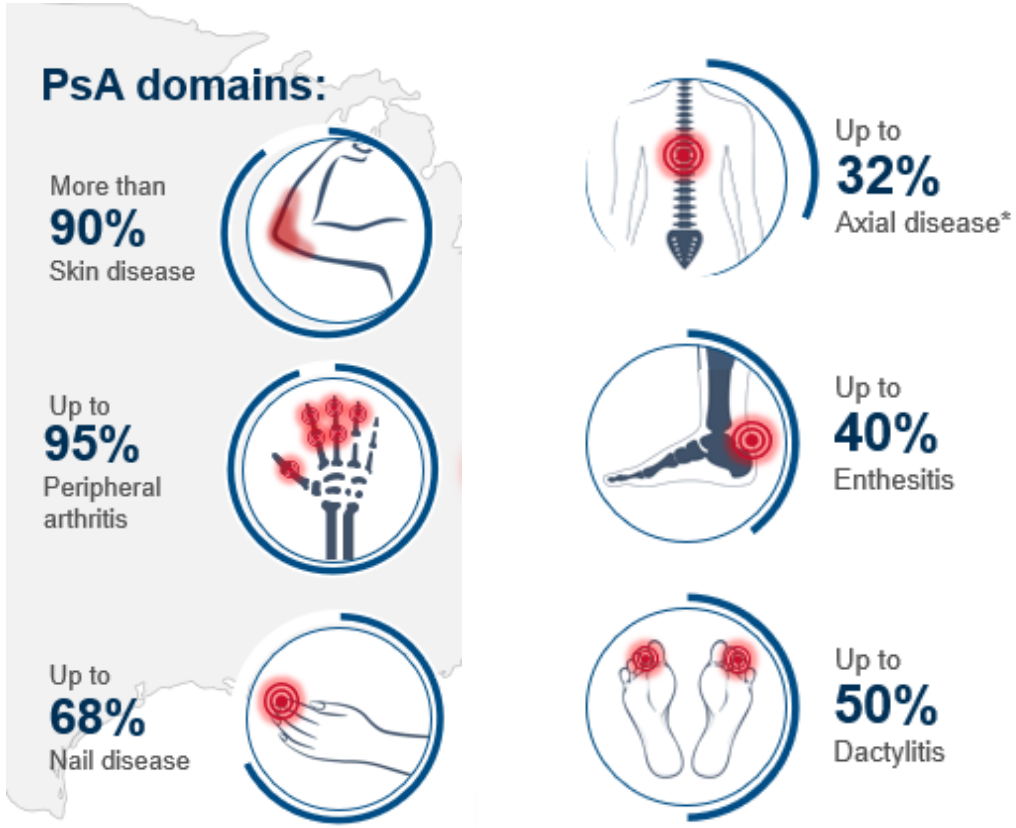
1 χρόνο μετά…

Υπό anti-TNF και MTX SC 20mg/w

- **Επιδείνωση ψωρίασης** (αγκώνες, γόνατα, τριχωτό κεφαλής, γεννητικά όργανα) **(BSA 7 %)**
- **1 SJC / 1 TJC**
- **Ήπια ευαισθησία στις ενθέσεις**
- **CRP κφ**
- **Χαμηλή ενεργότητα - DAPSA: 5**

Psoriatic Arthritis : A Complex, Heterogeneous Disease





Ogdie et al.Ann Rheum Dis; 78:922-923

Related Conditions and Common Comorbidities

Related Conditions

IBD
(Crohn's disease or ulcerative colitis; possibly extra-articular manifestation of the disease)

Uveitis
(possibly extra-articular manifestation of the disease)

Common Comorbidities

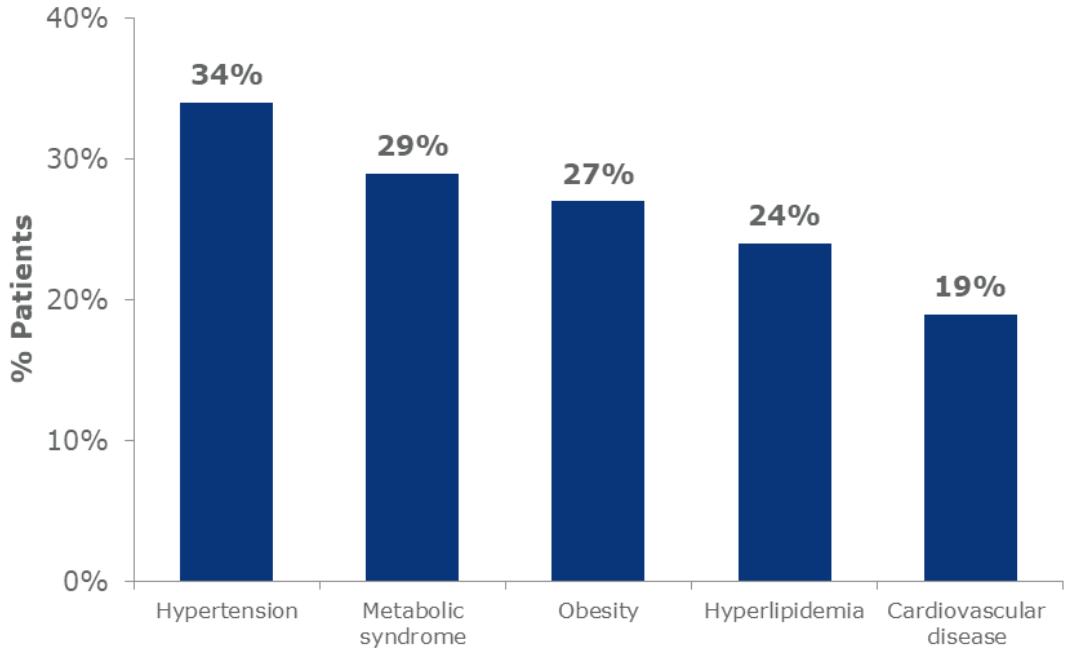
Depression/ Anxiety

NAFLD

Cardiovascular
CVD, hypertension, dyslipidemia

Metabolic
Obesity, insulin resistance, diabetes

most prevalent comorbidities amongst PsA patients



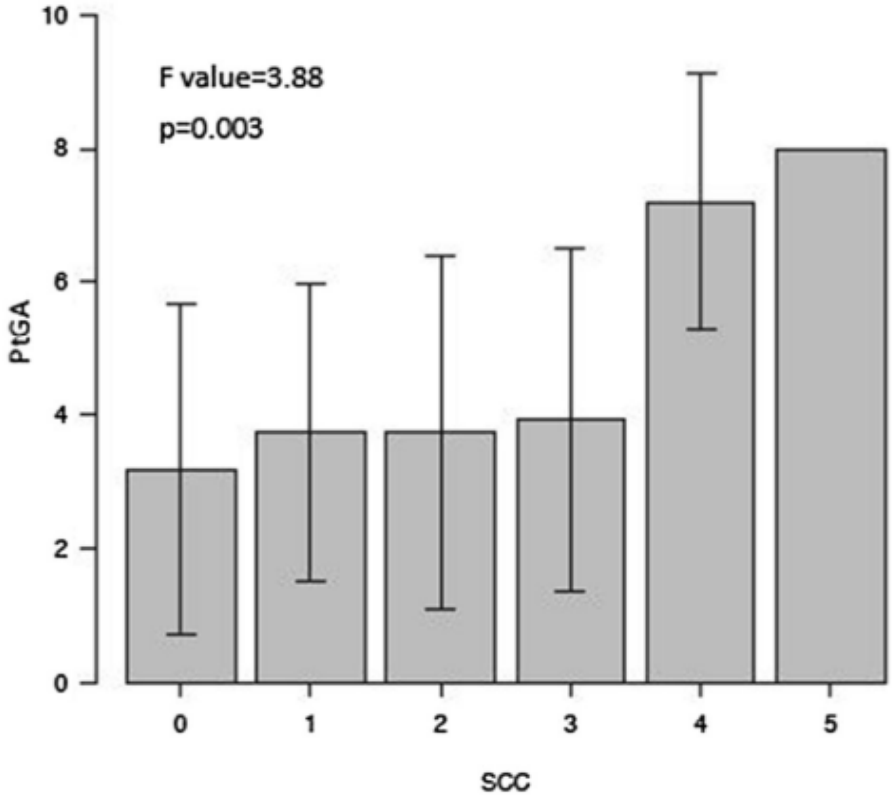
SYSTEMATIC REVIEW AND META-ANALYSIS

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

CVD, cardiovascular disease; IBD, inflammatory bowel disease; NAFLD, non-alcoholic fatty liver disease.

1. Coates LC, et al. *Arthritis Rheumatol*. 2016;68(5):1060-71. 2. Ogdie A, Weiss P. *Rheum Dis Clin North Am.* 2015;41(4):545-568. 3. Coates LC, et al. *Nat Rev Rheumatol*. 2022;18(8):465-479.

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



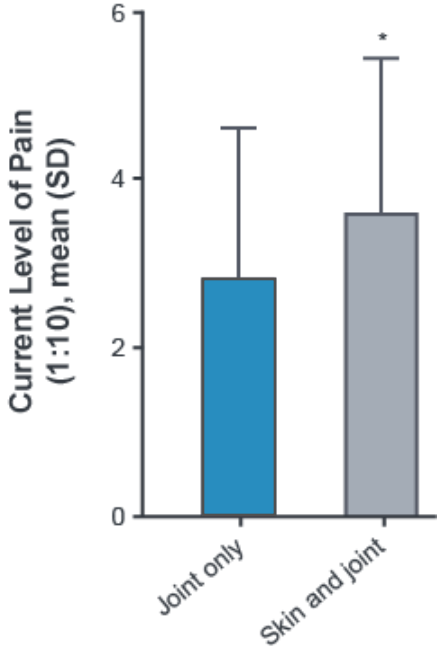
A Cross-Sectional Study

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

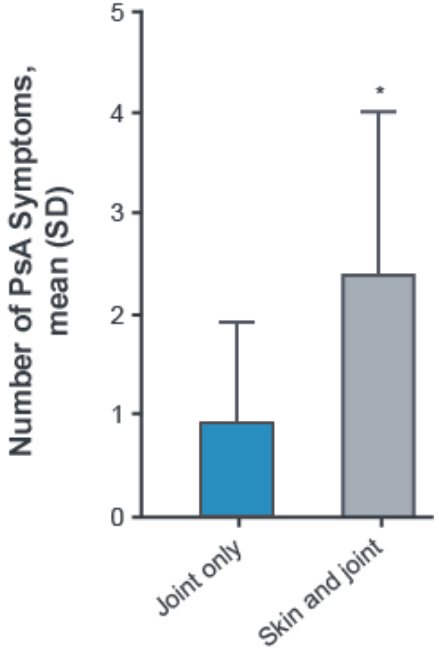
Rheumatol Ther (2020) 7:825–836 https://doi.org/10.1007/s40744-020-00229-0

Skin involvement in PsA worsens overall disease activity and patients' QoL

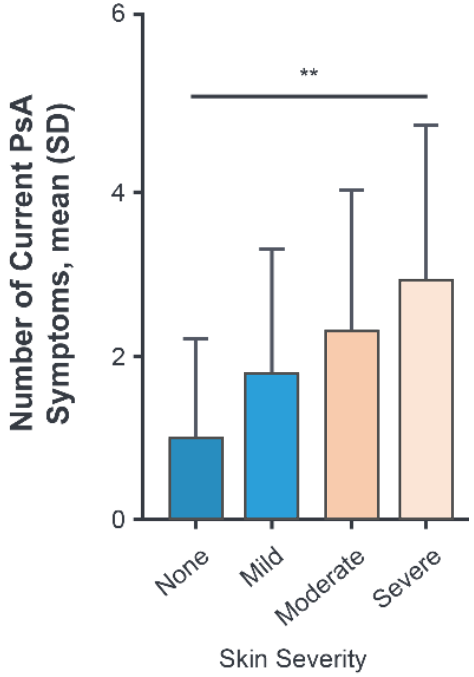
Patients experience greater pain with skin and joint involvement[1]



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



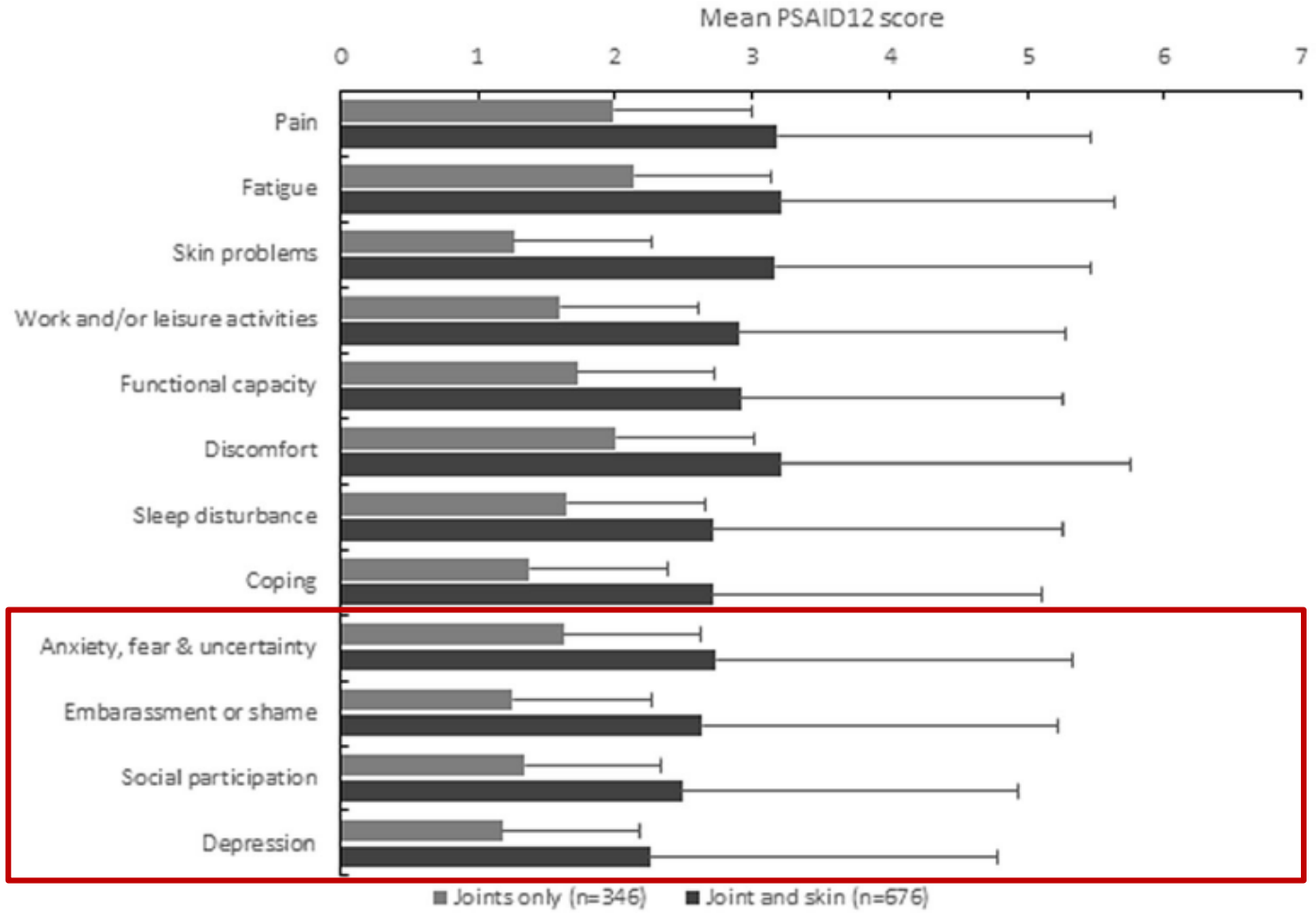
As skin severity increases patients experience greater PsA symptoms[1]



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

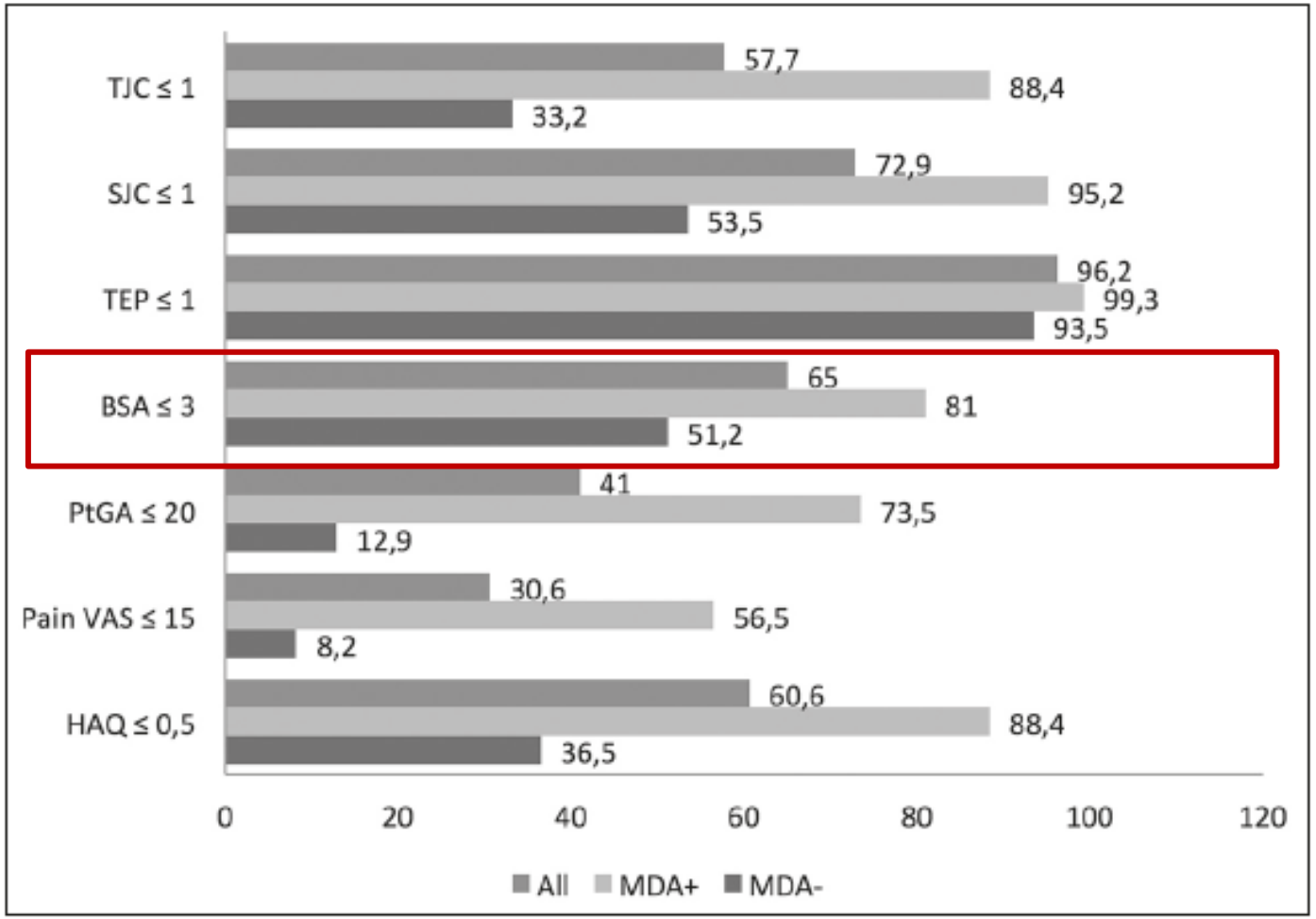
PsA patients who experience 'joint and skin' symptoms had significantly worse clinical outcomes, health-related QoL, and work productivity compared with patients with 'joint-only' symptoms



Analysis of individual PsAID12 scores in patients with 'joint-only' and 'joint and skin' symptoms. Significant ($p < 0.001$) differences between the two groups were seen for all questions making up the PsAID12 questionnaire. The joint only group contained a maximum of 346 patient responses and the joint and skin group contained a maximum of 679 patients. The joint only group contained a minimum of 344 patient responses and the joint and skin group contained a minimum of 672 responses

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

What are the main barriers to achieve minimal disease activity in psoriatic arthritis in real life?



The distribution of all fulfilled MDA domains in all patients, and in subtypes MDA+ and MDA–. Numbers are given as percentages.
TJC: tender joint counts; SJC: swollen joint counts; TEP: tender entheseal points; BSA: body surface area; PtGA: patient global activity; VAS: visual analogue scale; HAQ: Health Assessment Questionnaire.

Bakirci S et al. Clin Exp Rheumatol. 2019; 37:808-12

GRAPPA recommendations 2021

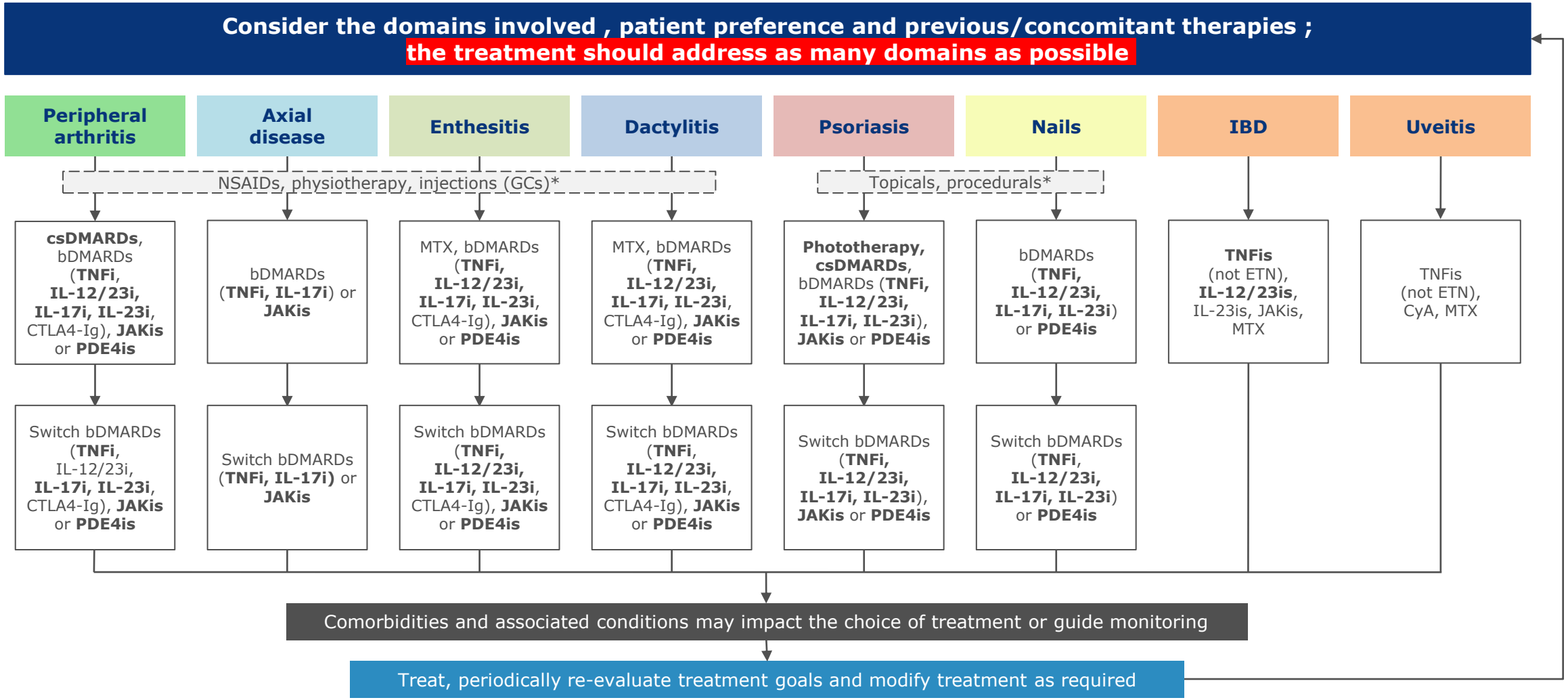


Figure adapted from Coates LC, et al. 2022. The order of the products in the boxes is sorted by mechanism of action and does not reflect guidance on relative efficacy or suggested usage.

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.

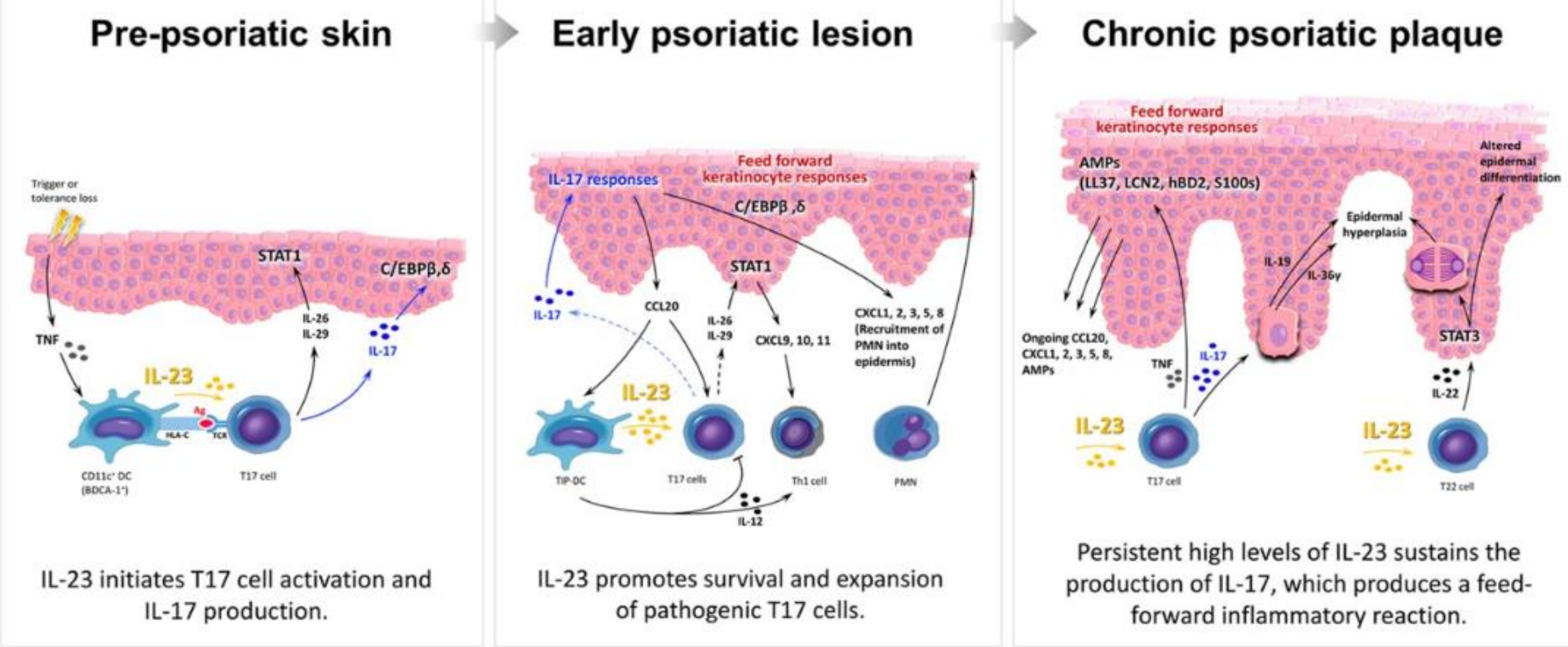
2023 EULAR Recommendations for the Management of PsA

	Overarching Principles	LoA (mean)
A.	Psoriatic arthritis is a heterogeneous and potentially severe disease, which may require multidisciplinary treatment.	10.0
B.	Treatment of psoriatic arthritis patients should aim at the best care and must be based on a shared decision between the patient and the rheumatologist, considering efficacy, safety, **patient preferences** and costs.	9.7
C.	Rheumatologists are the specialists who should primarily care for the musculoskeletal manifestations of patients with psoriatic arthritis; in the presence of clinically significant skin involvement, a rheumatologist and a dermatologist should collaborate in diagnosis and management.	9.7
D.	The primary goal of treating patients with psoriatic arthritis is to maximise health-related quality of life, through control of symptoms, prevention of structural damage, normalisation of function and social participation; abrogation of inflammation is an important component to achieve these goals.	9.9
E.	In managing patients with psoriatic arthritis, **consideration should be given to each musculoskeletal manifestation** and treatment decisions made accordingly.	9.8
F.	When managing patients with psoriatic arthritis, non-musculoskeletal manifestations (**particularly skin, eye and gastrointestinal tract**) should be taken into account; **comorbidities** such as **obesity**, metabolic syndrome, cardiovascular disease or depression should also be considered.	9.7
G.	**The choice of treatment should take account of safety considerations regarding individual modes of action to optimize the benefit-risk profile.**	9.9

New

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

Interleukin 23 in the skin



Χρόνια ψωριασική πλάκα:
Παρατεταμένα υψηλά επίπεδα IL-23 ενισχύουν/συντηρούν την ***επανατροφοδότηση*** *της φλεγμονής*

*Chan TC et al. Ther Adv Chronic Dis*2018, Vol. 9(5) 111–119

Κλινικό Σενάριο 2

- **Άνδρας 38 ετών**
- **BMI 32,7kg/m²** (ΒΣ: 100kg Υ: 1,75m)
- Βαρύς **καπνιστής**
- **PsO σε ηλικία 34 ετών/PsA σε ηλικία 36 ετών**
- **Υπό αγωγή με MTX 20mg/w SC και κορτιζόνη 5 mg/d**

Προσέρχεται με:

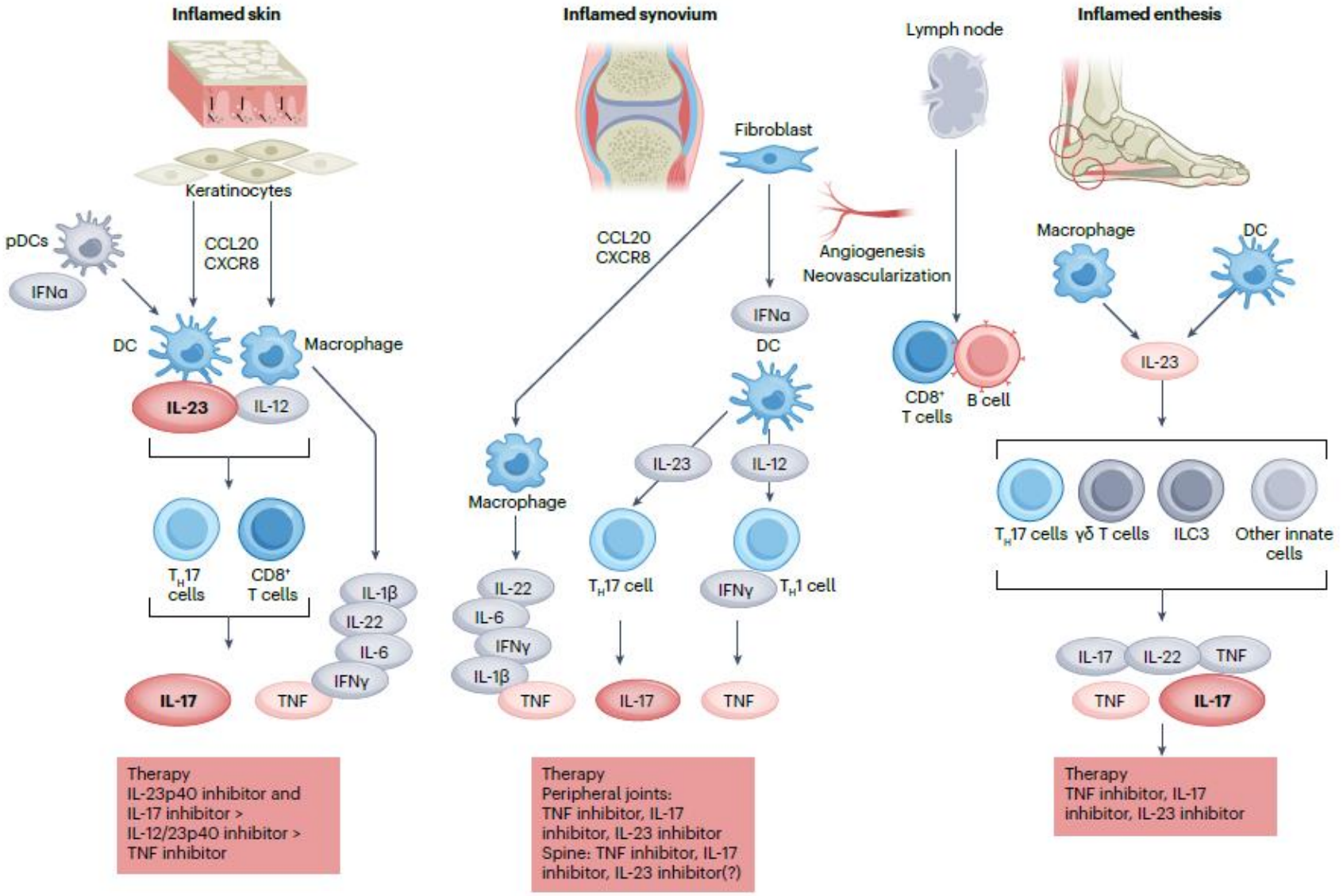
- **Πολυαρθρίτιδα** (8 SJC/9TJC,γόνατο ΑΡ)
- **Δακτυλίτιδα παράμεσου**
- **Ψωρίαση κατά πλάκας σε αγκώνες, γόνατα (BSA 2%)**
- **Ψωρίαση ονύχων**

Έναρξη στοχευμένης θεραπείας

θεραπευτικές επιλογές

- **Anti-TNFα**
- **Anti IL12/23**
- **Anti-IL17A**
- **Anti-IL23-p19**
- **JAK inhibitors**

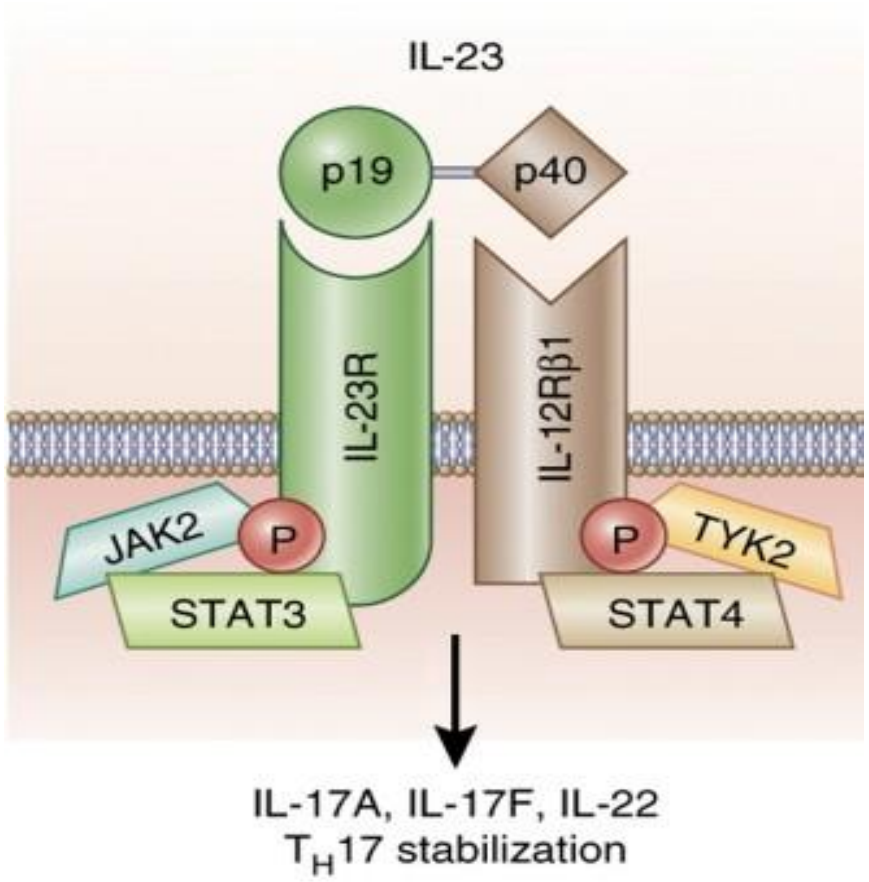
Different tissue and prominent pathogenetic mechanisms and response to current drug mechanisms of action



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

GUSELKUMAB

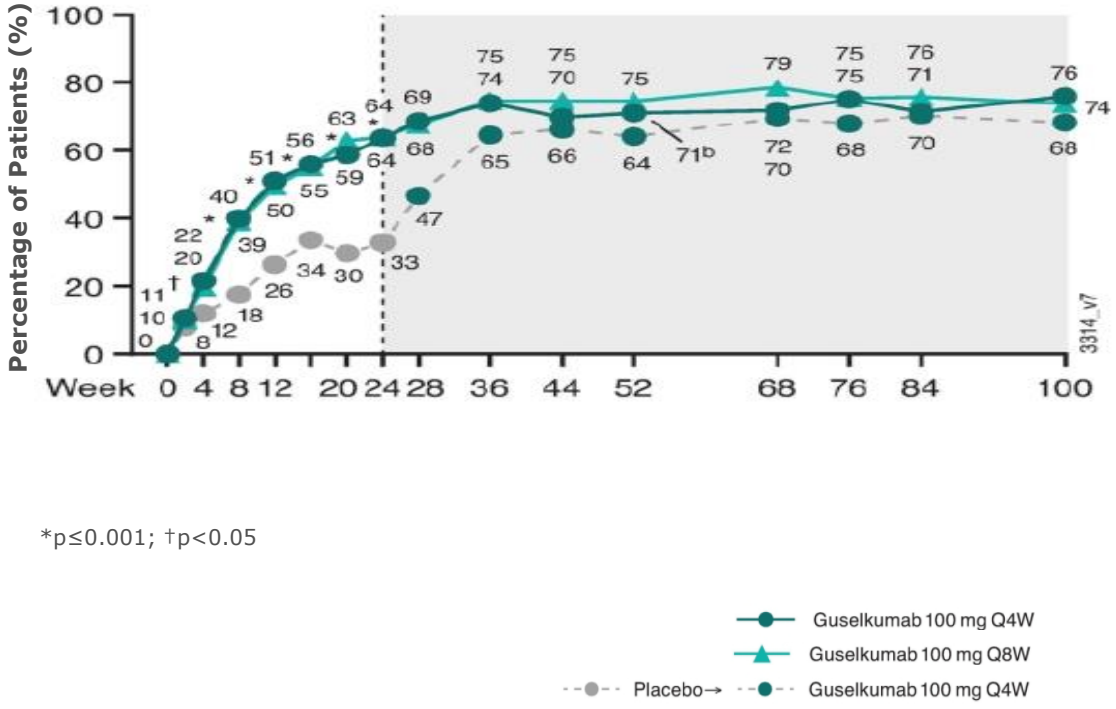
Πλήρως ανθρώπινο IgG1λ μονοκλωνικό αντίσωμα έναντι της υπομονάδας p19 της IL-23



IL-12 and IL-23 cytokines: from discovery to targeted therapies for immune-mediated inflammatory diseases
•Michele W L Teng et al. *Nature Medicine* **volume 21**, pages719–729 (2015)

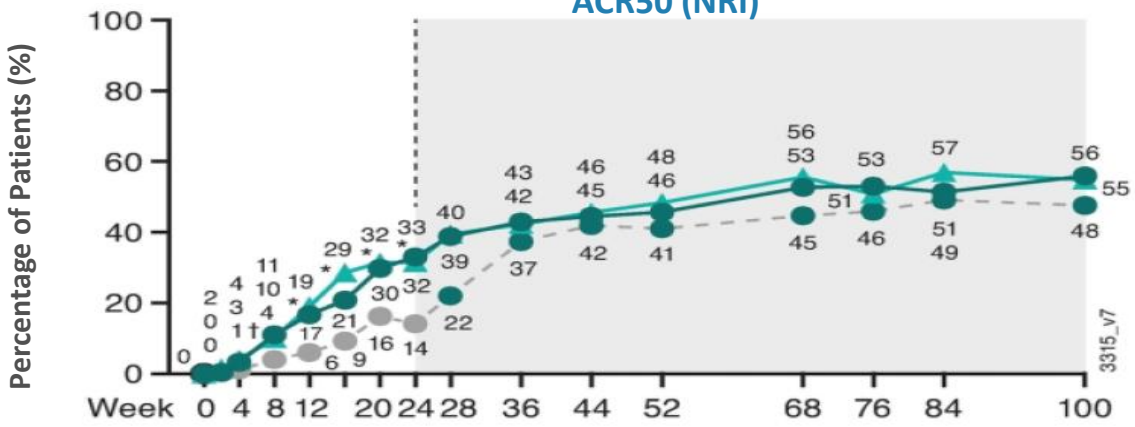
ACR20, ACR50 and ACR70 responses through 100 weeks in bio-naïve patients with PsA

ACR20 Response (NRI)

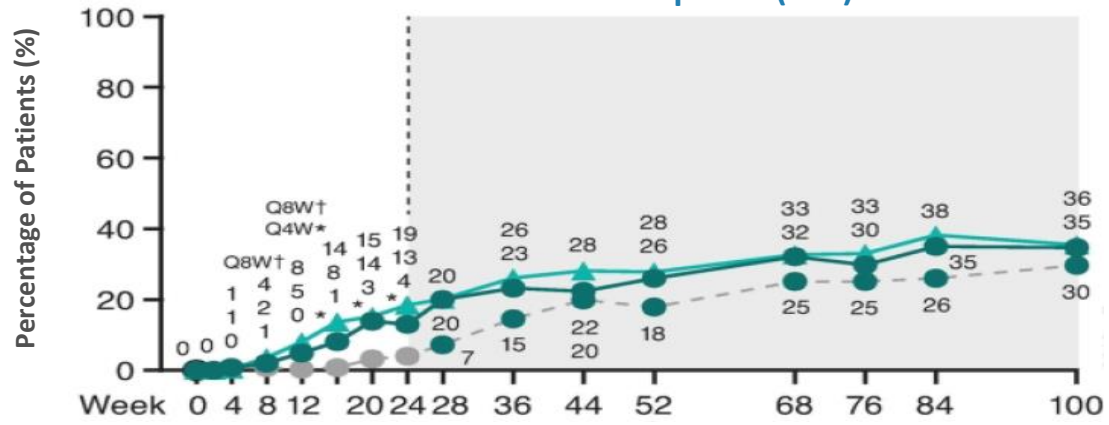


*p≤0.001; †p<0.05

ACR50 (NRI)



ACR70 Response (NRI)



*p≤0.001; †p<0.05

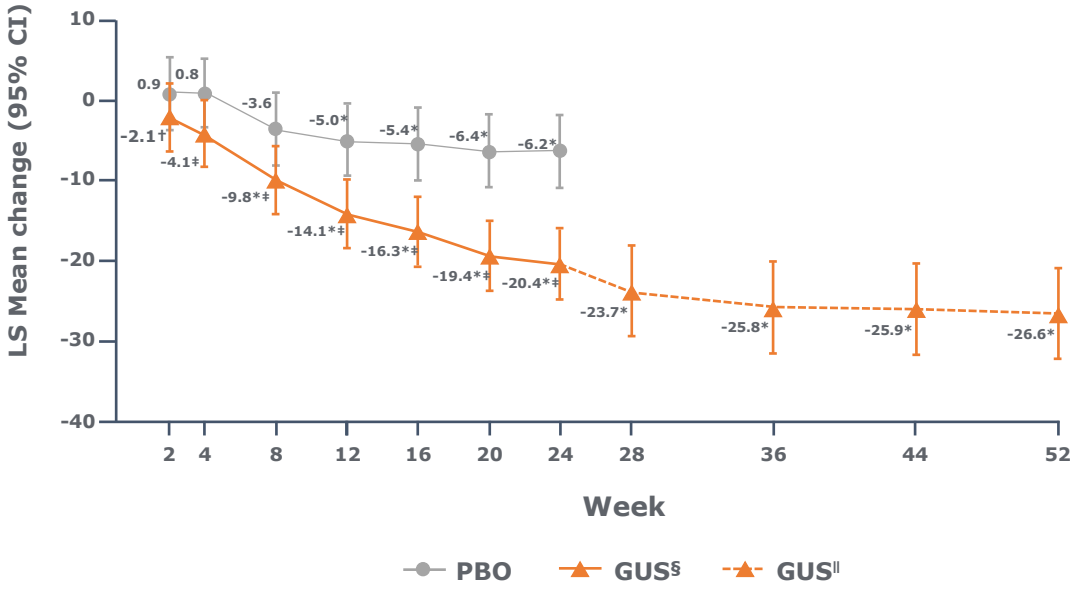
NRI: non-responder imputation

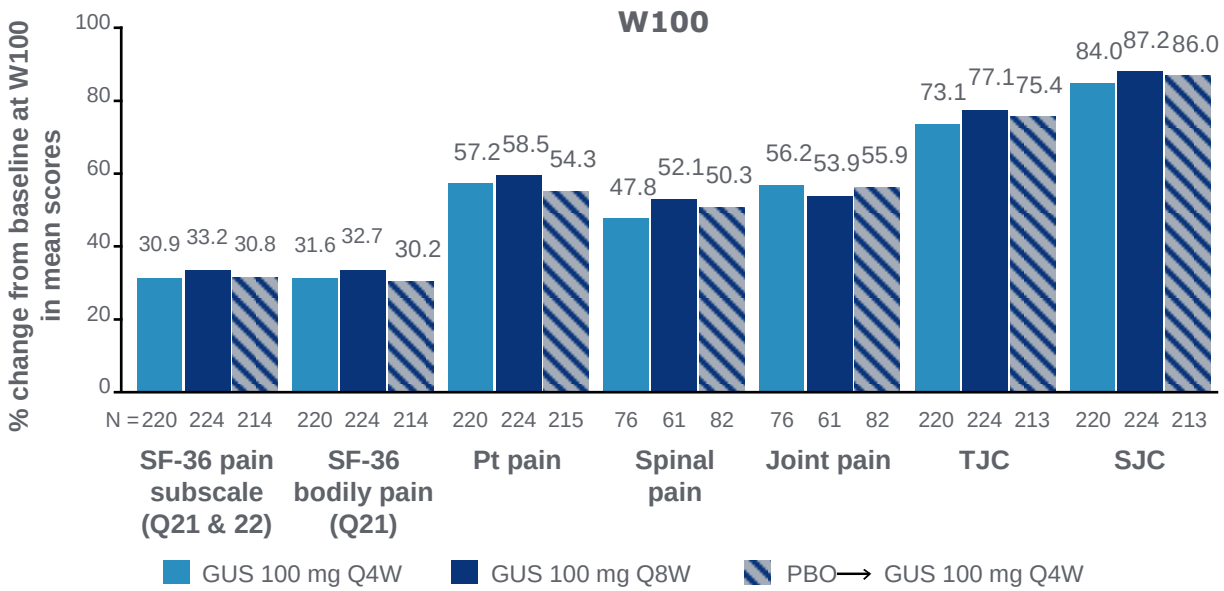
Το 88% των τυχαιοποιημένων ασθενών που έλαβαν θεραπεία ολοκλήρωσαν τη μελέτη

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

GUSELKUMAB demonstrates improvements in pain as early as week 2 which is maintained up to 2 years in PsA patients

Meaningful improvement in pain was observed as early as week 2 (DISCOVER-1&2 pooled data)[1]





* Significant change from BL, P<0.05, †GUS vs PBO, p=0.0059; ‡GUS vs PBO, p<0.0001 § Least square mean (LSMean) changes from a repeated measures generalized linear mixed model adjusting for baseline pain score, treatment type (GUS vs PBO), baseline fatigue, medical history of fibromyalgia, baseline SF-36 MCS, baseline use of NSAIDs, treatment by time interaction, baseline pain score by time interaction.‖ LSMean changes from a repeated measures generalized linear mixed model adjusting for baseline pain score, baseline TJC, baseline fatigue, medical history of fibromyalgia, baseline SF-36 MCS, baseline use of NSAIDs, and time. GUS treatment only.

Multivariate models through 24 weeks (PBO + GUS) and 52 weeks (GUS only).

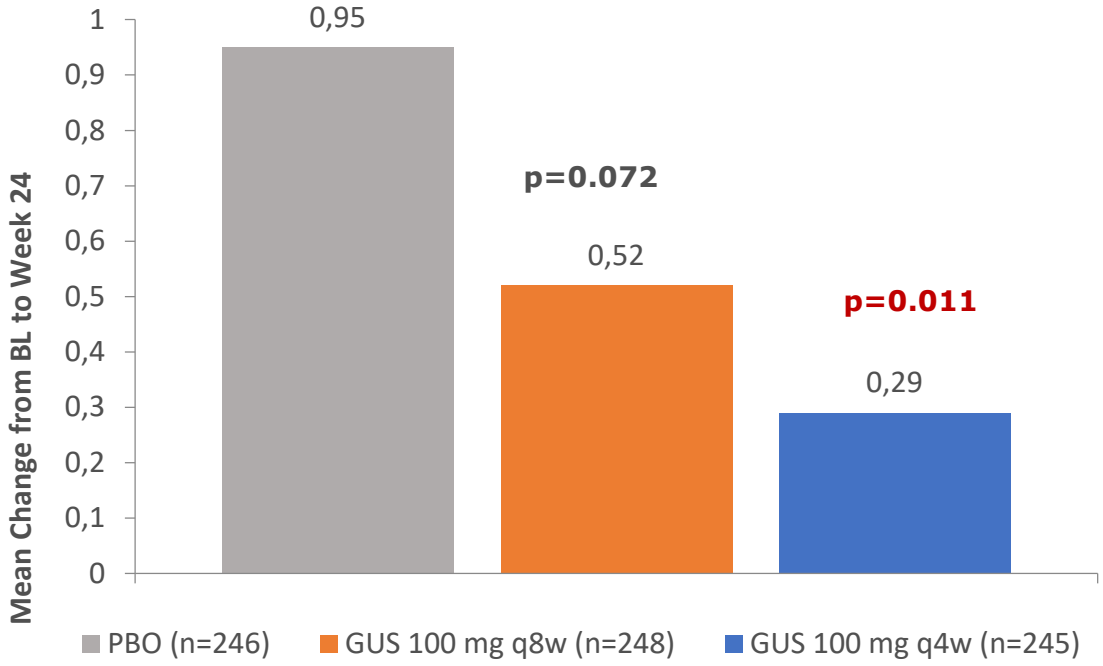
GUS, guselkumab; VAS, visual analogue scale; W, week

Nash P. et al. EULAR 2022 #POS1070

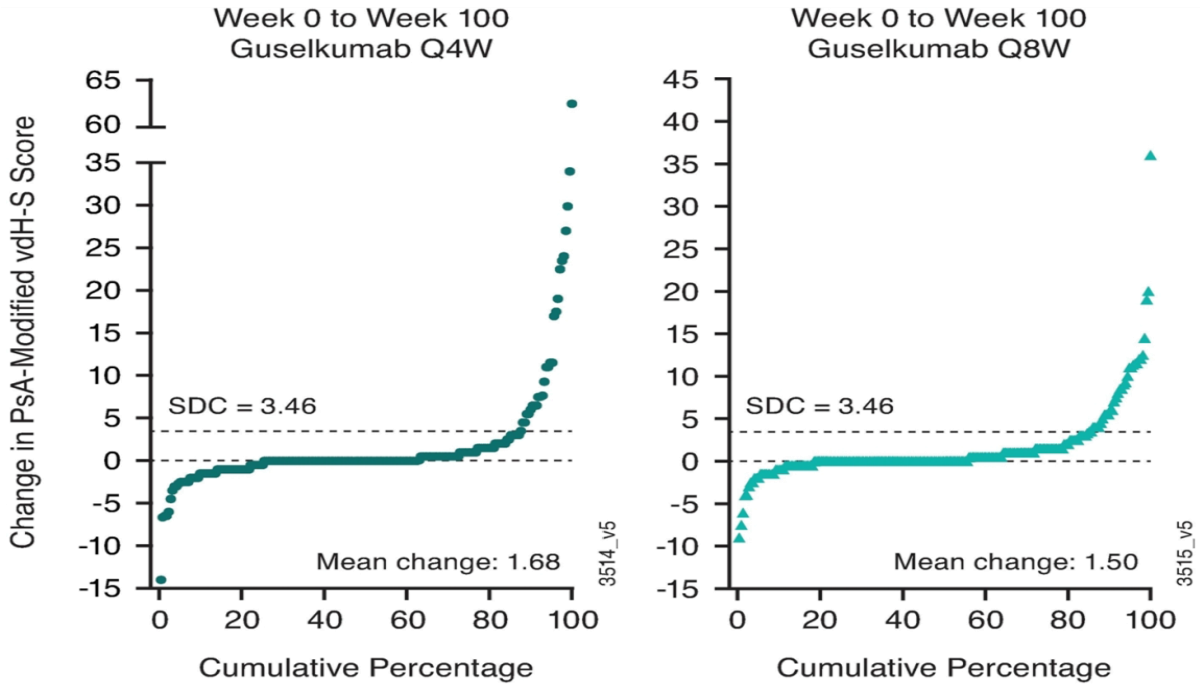
Nash P. et al. EULAR, 2022. POS1044

Low rates of radiographic progression across patients treated with GUS

LS Mean Change in modified vdHSS from BL to Week 24



Cumulative probability plot through Wk 100[1]

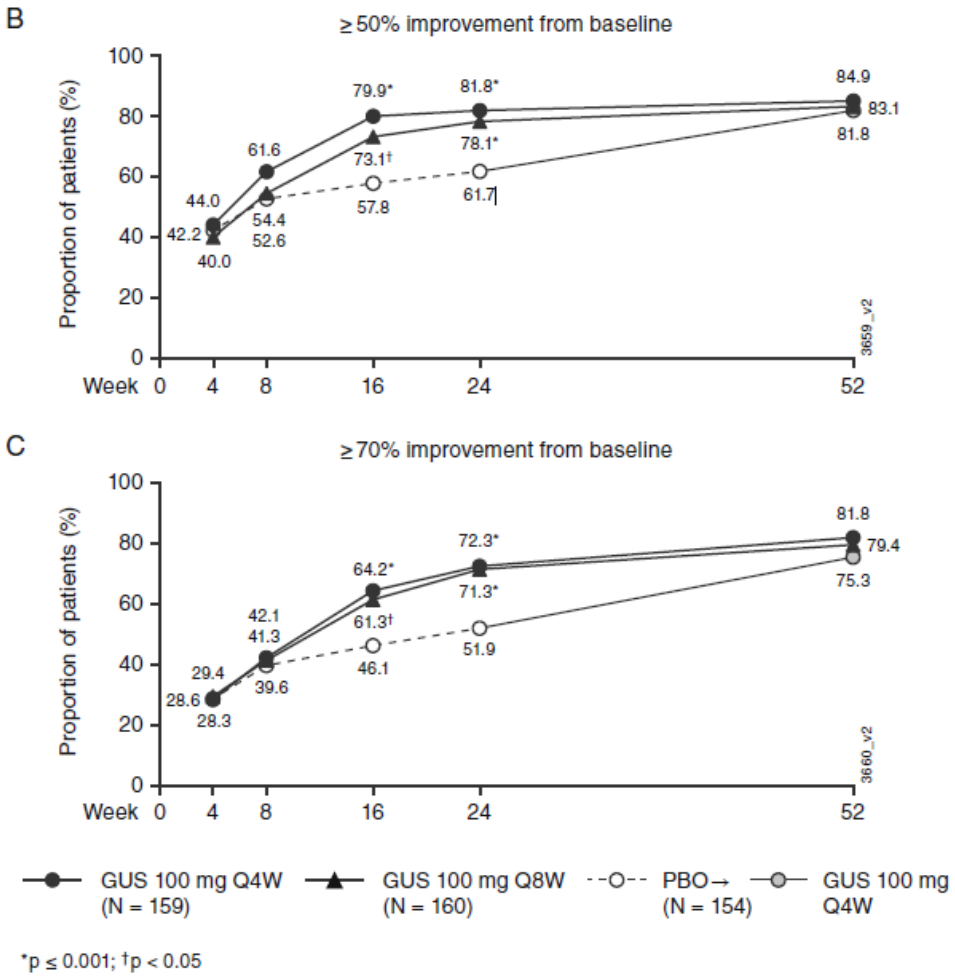


Mease P, et al. Published online March 13, 2020 https://doi.org/10.1016/S0140-6736(20)30263-4

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

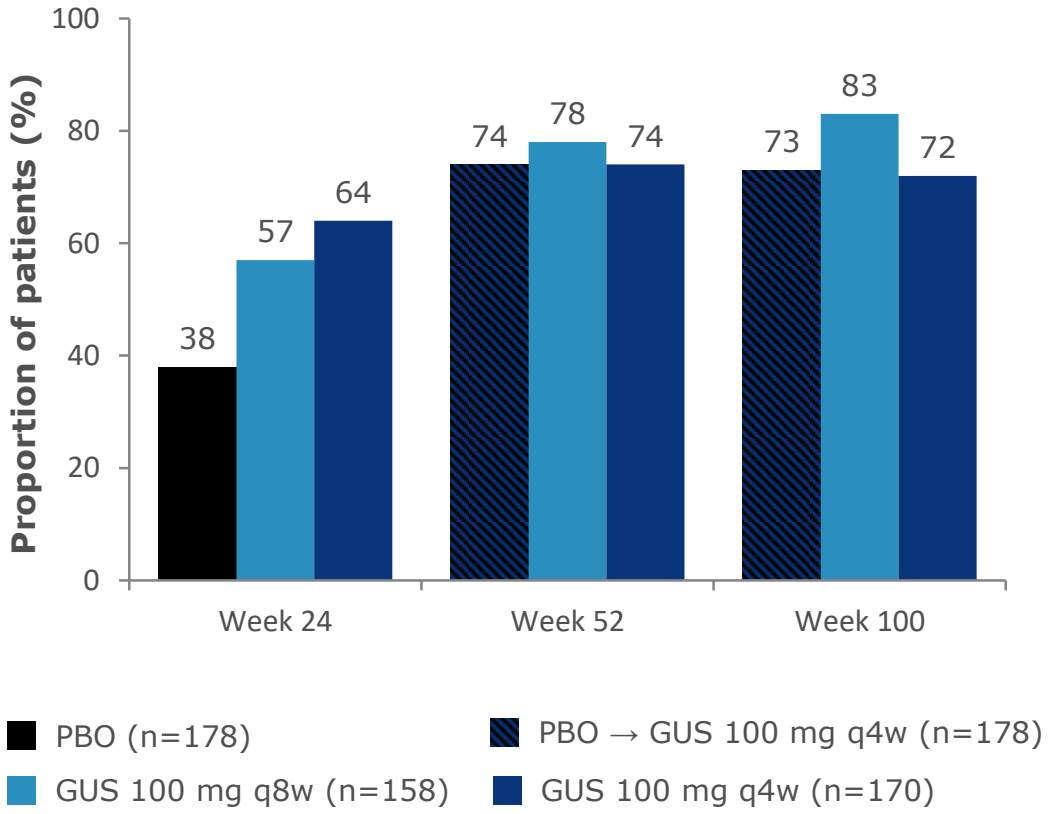
Dactylitis resolution in bio naïve patients through Week 100

% 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.

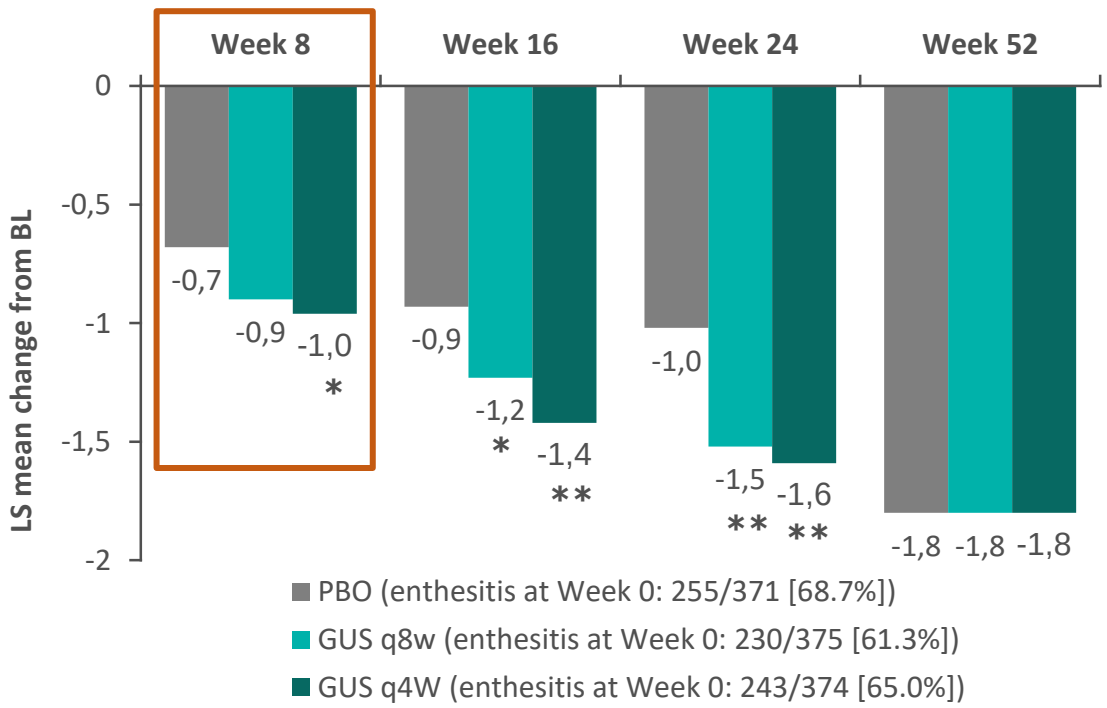
McInnes IB et al. Arthritis Rheumatol 2022;74:475–485

Pooled DISCOVER1&2

Enthesitis resolution through Week 100

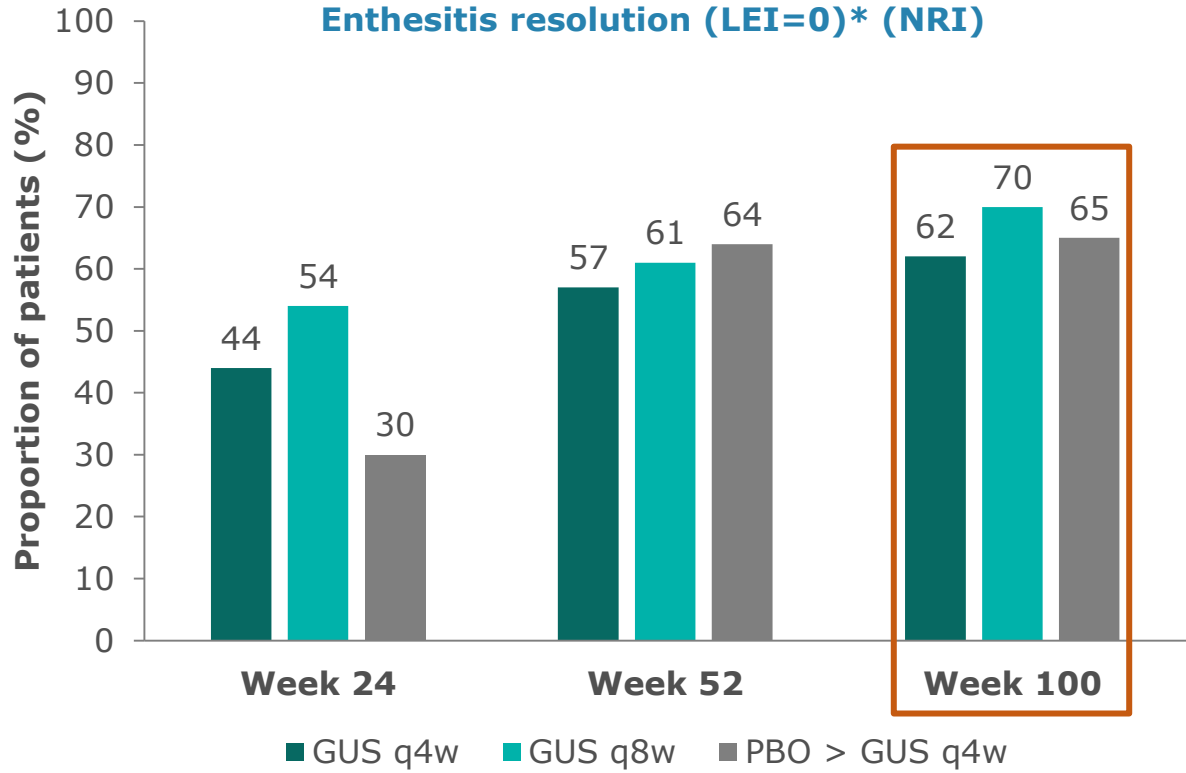
728 patients with enthesitis at BL_mean LEI score 2.8

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)..

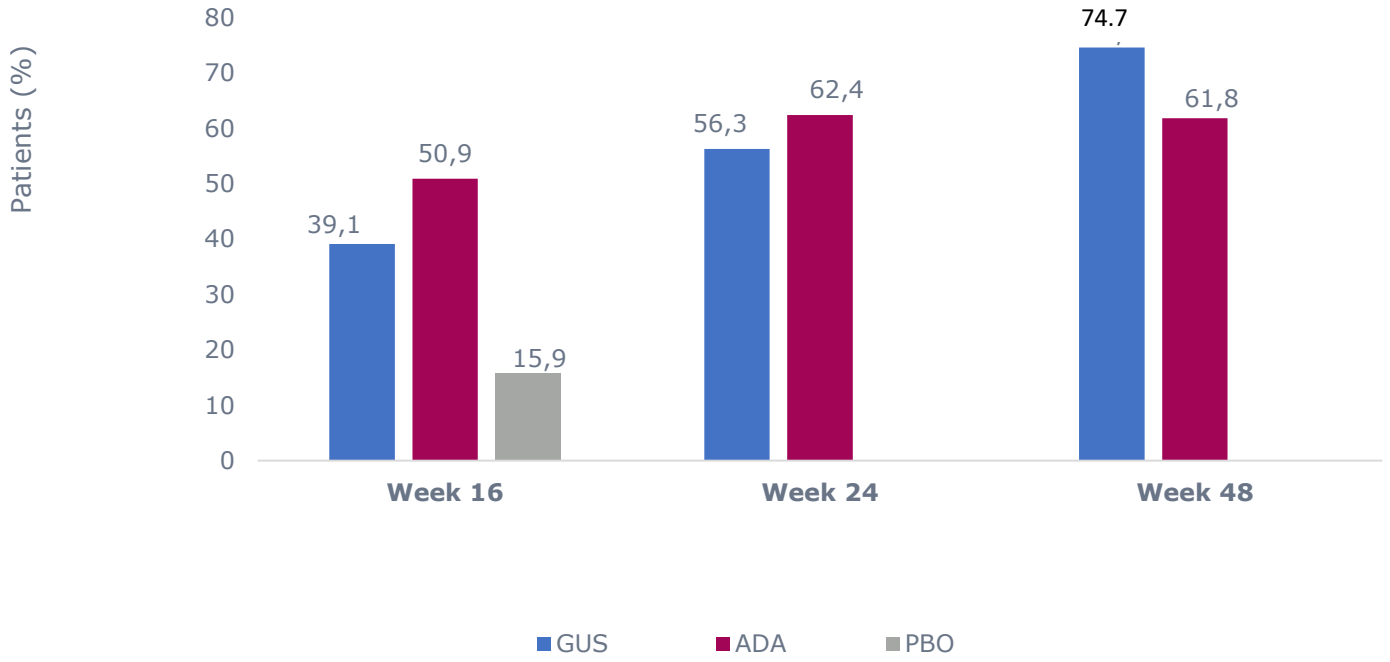
McGonagle D et al. Presented at EULAR 2020. #AB0801;

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

VOYAGE 1

The impact of GUSELKUMAB on nail psoriasis in PsO patients

Proportion of patients achieving **f-PGA 0/1† with GUS vs ADA** at Weeks 16, 24 and 48[1]



f-PGA:Fingernail Physician's Global Assessment,clear [0], minimal [1], mild [2], moderate [3], severe [4]).

† Includes only patients also achieving ≥ 2-grade improvement in ss-IGA and hf-PGA scores and ≥1-grade improvement in f-PGA score.

Blauvelt, A.,et al. (2017). Journal of the American Academy of Dermatology, 76(3), pp.405–417

2 main definitions of disease control in PsA: MDA and DAPSA LDA/REM

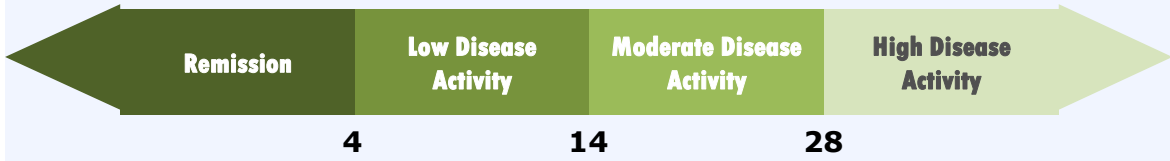
MDA – Fulfilment of five of seven criteria:[1]

- TJC ≤ 1/68
- SJC ≤ 1/66
- PASI ≤ 1 or BSA ≤ 3
- Enthesitis ≤ 1
- PtGA (by VAS, 1-10 cm) ≤ 2 cm
- Pain VAS (1-10 cm) ≤ 1.5 cm
- HAQ ≤ 0.5

DAPSA – Sum of:[1]

- SJC66
- TJC68
- PtGA (in cm)
- Pain VAS (in cm)
- CRP (mg/dL)

DAPSA disease activity states[2]



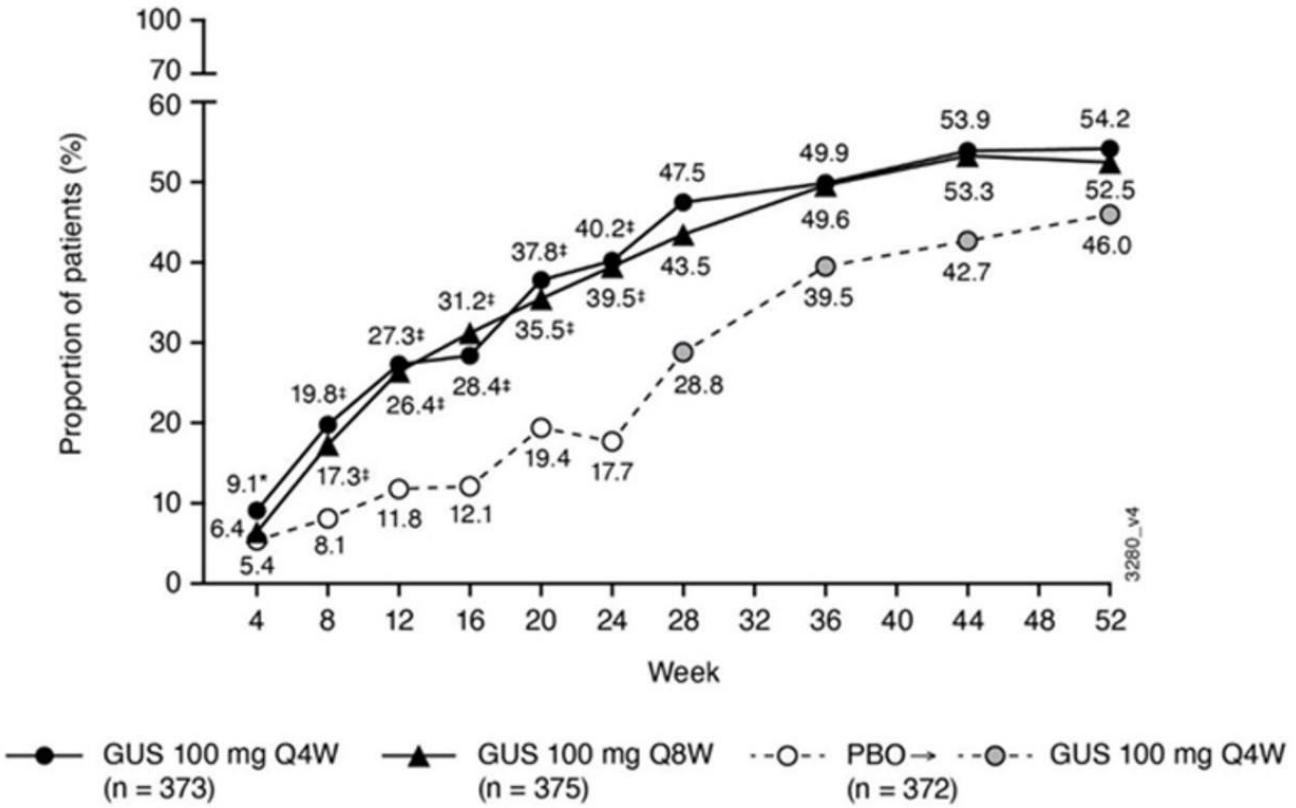
Components of MDA and DAPSA[1]	Laboratory (CSR/ESR)	Swollen joints	Tender joints	Patient global VAS	Patient pain VAS	Enthesitis	Function	Skin
MDA[1]	-	✓	✓	✓	✓	✓	✓	✓
DAPSA[1]	✓	✓	✓	✓	✓	-	-	-

Although several composite measures have been proposed to define remission or low disease activity in PsA, international recommendations advocate the use of MDA and DAPSA[1,2]

BSA, body surface area; CRP, C-reactive protein; DAPSA, disease activity index for PsA; ESR, erythrocyte sedimentation rate; HAQ, health assessment questionnaire; LDA, low disease activity; MDA, minimal disease activity; PASI, psoriasis area severity index; PsA, psoriatic arthritis; PtGA, patient's global assessment; REM, remission; SJC, swollen joint count; TJC, tender joint count; VAS, visual analogue scale.

Adapted from:
1. Smolen JS et al. Ann Rheum Dis. 2018;77:3–17; 2. Smolen JS et al. Clin Exp Rheumatol. 2015;33:S48–50.

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



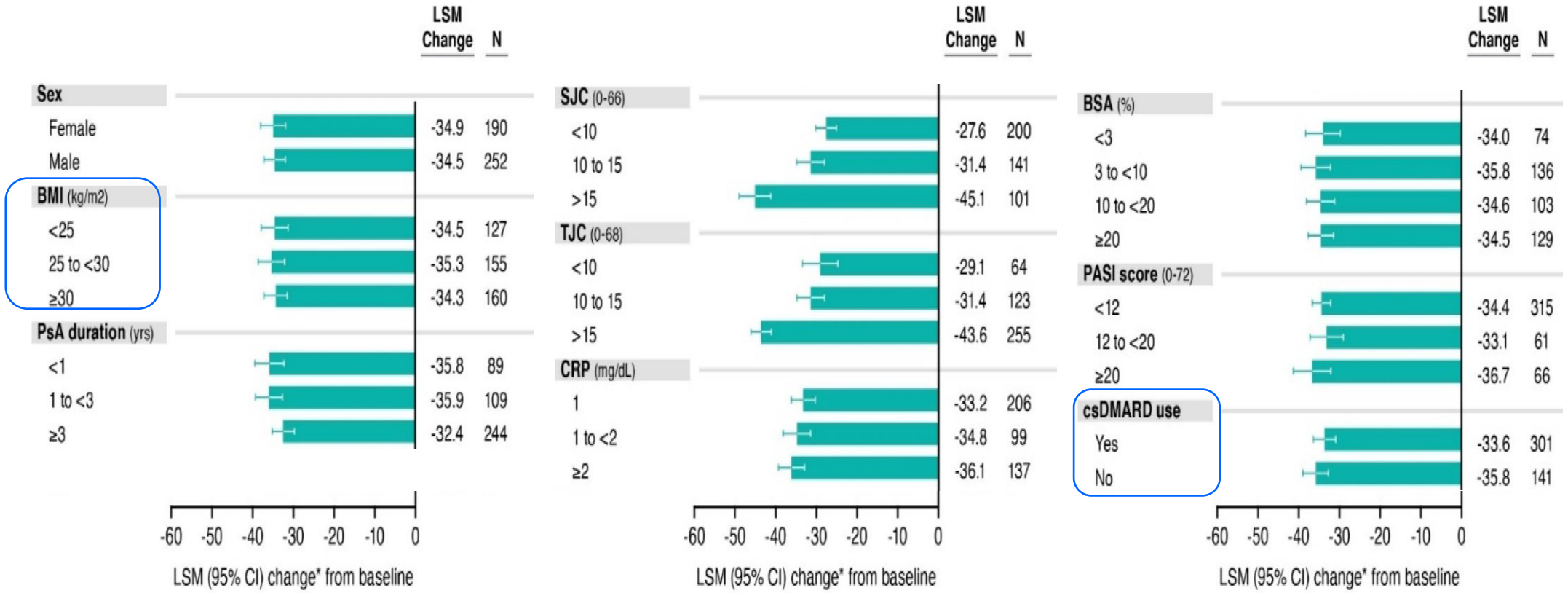
Missing data imputed as nonresponse.

*, +, ‡ $p < 0.05, 0.01, 0.001$, 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

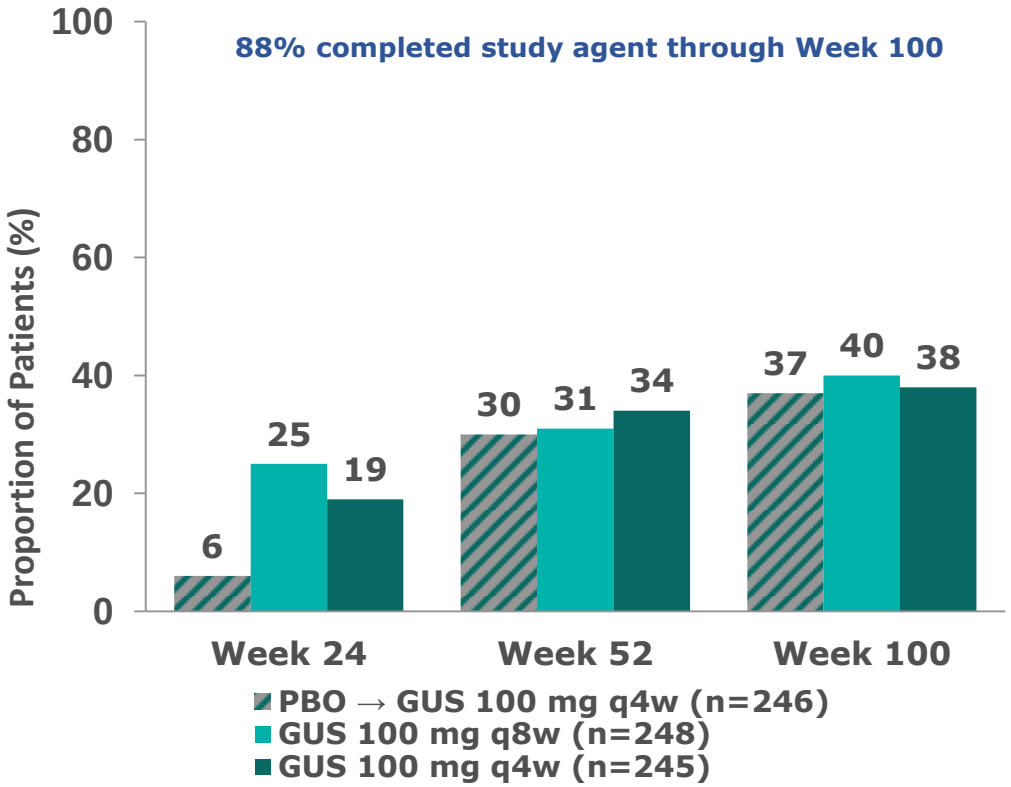
LSM (95% CI) Change* in DAPSA score from BL to week 100 irrespective of BL characteristics



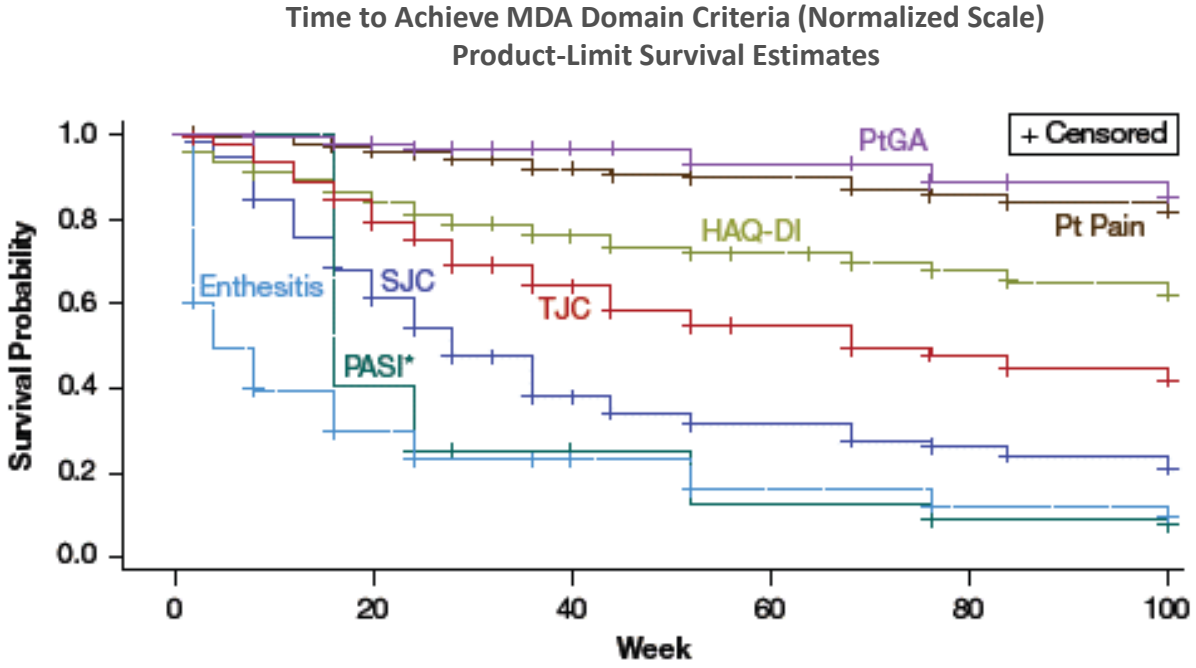
DAPSA 0-4 [remission], 5-14 [low], 15-28 [moderate], >28 [high]; PASI (0-72); LEI (0-6). *Derived from a multivariate linear model adjusting for BL subgroups; all p-values comparing LSM change from BL at Wk 100 are p<0.001BL: baseline;

MDA score through Week 100 (NRI)

MDA for biologic naïve patients through Week 100 (NRI)



Domains contributing to MDA achievement and factors influencing MDA achievement



*p <0.05; †p <0.01; ‡p ≤0.0001..

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

Coates *et al. BMC Rheumatology* (2024) 8:6 https://doi.org/10.1186/s41927-024-00375-w

Κλινικό Σενάριο 3

- **Γυναίκα 30 ετών**
- **BMI 24kg/m²** (ΒΣ: 60kg Υ: 1,60m)
- **Ψωρίαση από ηλικίας 18 ετών**
- **N.Crohn** υπό μεσαλαζίνη **– σε ύφεση**
- **Υπό αγωγή με anti TNF από 2ετίας λόγω ΨΑ → καλή ανταπόκριση στις αρθρώσεις, μικρό εξάνθημα στο τριχωτό της κεφαλής**

ΚΛΙΝΙΚΗ ΕΙΚΟΝΑ

- **Ασύμμετρη Ολιγοαρθρίτιδα** (4SJC/5TJC)
- **Ψωρίαση κατά πλάκας** (BSA 7%)
- **Οσφυαλγία από 3μήνου**
- **CRP 10 mg/L**
- **MRI ιερολαγονίων: παρουσία εστιών οστικού οιδήματος εκατέρωθεν**
- **DAPSA: 22** (moderate disease activity)
- **ASDAS (5/7/5/7/10): 3,56** (very high disease activity)

Κλινικό Σενάριο 3

- **Γυναίκα 30 ετών**
- **Περιφερική αρθρίτιδα**
- **Αξονική προβολή**
- **Εκτεταμένη ψωρίαση**
- **N.Crohn σε κλινική ύφεση**
- **Αντένδειξη για αναστολείς IL17**
- **Αποτυχία σε anti TNF**

Ustekinumab in Ankylosing Spondylitis

American College of Rheumatology
Education · Treatment · Research

Arthritis & Rheumatology
Vol. 71, No. 2, February 2019, pp 258–270
DOI 10.1002/art.40728

Three Multicenter, Randomized, Double-Blind, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Ustekinumab in Axial Spondyloarthritis

Atul Deodhar,[1] Lianne S. Gensler,[2] Joachim Sieper,[3] Michael Clark,[4] Cesar Calderon,[4] Yuhua Wang,[4] Yiying Zhou,[4] Jocelyn H. Leu,[4] Kim Campbell,[4] Kristen Sweet,[4] Diane D. Harrison,[4] Elizabeth C. Hsia,[5] and Désirée van der Heijde[6]

Objective. To evaluate the efficacy and safety of ustekinumab in 3 randomized, placebo-controlled studies in patients with axial spondyloarthritis (SpA). Studies 1 and 2 included patients with radiographic axial SpA (anti–tumor necrosis factor [anti-TNF]–naive patients and patients with inadequate response or intolerance to anti-TNF, respectively); study 3 patients had nonradiographic axial SpA.

Conclusion. In these 3 placebo-controlled trials, **efficacy of ustekinumab in the treatment of axial SpA was not demonstrated**. The safety profile was consistent with that of studies in other indications.

Arthritis & RheumatologyVol. 71, No. 2, February 2019, pp 258–270DOI 10.1002/art.40728© 2018, American College of Rheumatology

OPEN ACCESS

EXTENDED REPORT

Risankizumab, an IL-23 inhibitor, for ankylosing spondylitis: results of a randomised, double-blind, placebo-controlled, proof-of-concept, dose-finding phase 2 study

Dominique Baeten,[1] Mikkel Østergaard,[2,3] James Cheng-Chung Wei,[4,5] Joachim Sieper,[6] Pentti Järvinen,[7] Lai-Shan Tam,[8] Carlo Salvarani,[9,10] Tae-Hwan Kim,[11] Alan Solinger,[12] Yakov Datsenko,[13] Chandrasena Pamulapati,[12] Sudha Visvanathan,[12] David B Hall,[12] Stella Aslanyan,[12] Paul Scholl,[12] Steven J Padula[14]

Conclusions **Treatment with risankizumab** did not meet
the study primary endpoint and **showed no evidence of clinically meaningful improvements compared with
placebo in patients with active AS**.

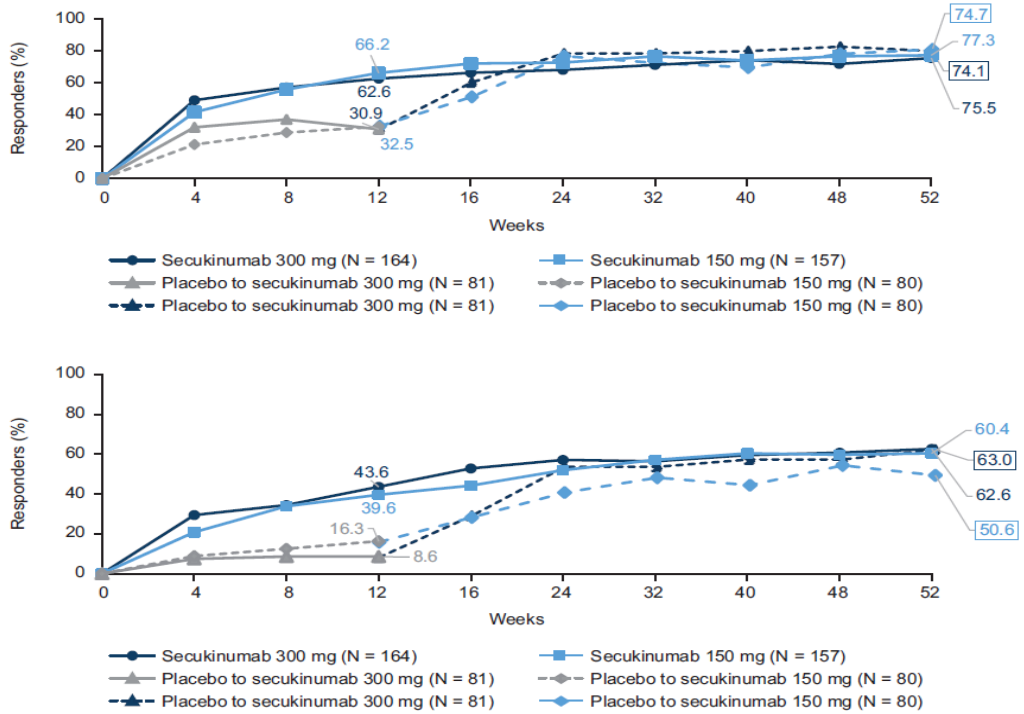
Risankizumab in Ankylosing Spondylitis

Ann Rheum Dis: first published as 10.1136/annrheumdis-2018-213328

MAXIMISE → Η μοναδική , έως τώρα , μελέτη αποκλειστικά για ψωριασική σπονδυλίτιδα

498 patients enrolled

Primary endpoint was ASAS20 response with secukinumab 300 mg at week 12



OPEN ACCESS

CLINICAL SCIENCE

Secukinumab in patients with psoriatic arthritis and axial manifestations: results from the double-blind, randomised, phase 3 MAXIMISE trial

Xenofon Baraliakos,[1] Laure Gossec ,[2,3] Effie Pournara,[4] Slawomir Jeka,[5] Antonio Mera-Varela ,[6] Salvatore D'Angelo ,[7] Barbara Schulz,[4] Michael Rissler,[4] Kriti Nagar,[8] Chiara Perella,[4] Laura C Coates [9]

Around 60% of patients had a positive MRI with inflammation in the spine and/or SIJ at baseline

Baraliakos X, et al. Ann Rheum Dis 2020;**0**:1–9. doi:10.1136/annrheumdis-2020-218808

Rheumatol Ther (2023) 10:1637–1653
https://doi.org/10.1007/s40744-023-00592-8

ORIGINAL RESEARCH

Efficacy of Guselkumab on Axial-Related Symptoms Through up to 2 Years in Adults with Active Psoriatic Arthritis in the Phase 3, Randomized, Placebo-Controlled DISCOVER-2 Study

Philip J. Mease · Dafna D. Gladman · Denis Poddubnyy · Soumya D. Chakravarty · May Shawi · Alexa P. Kollmeier · Xie L. Xu · Stephen Xu · Atul Deodhar · Xenofon Baraliakos

N=246 patients

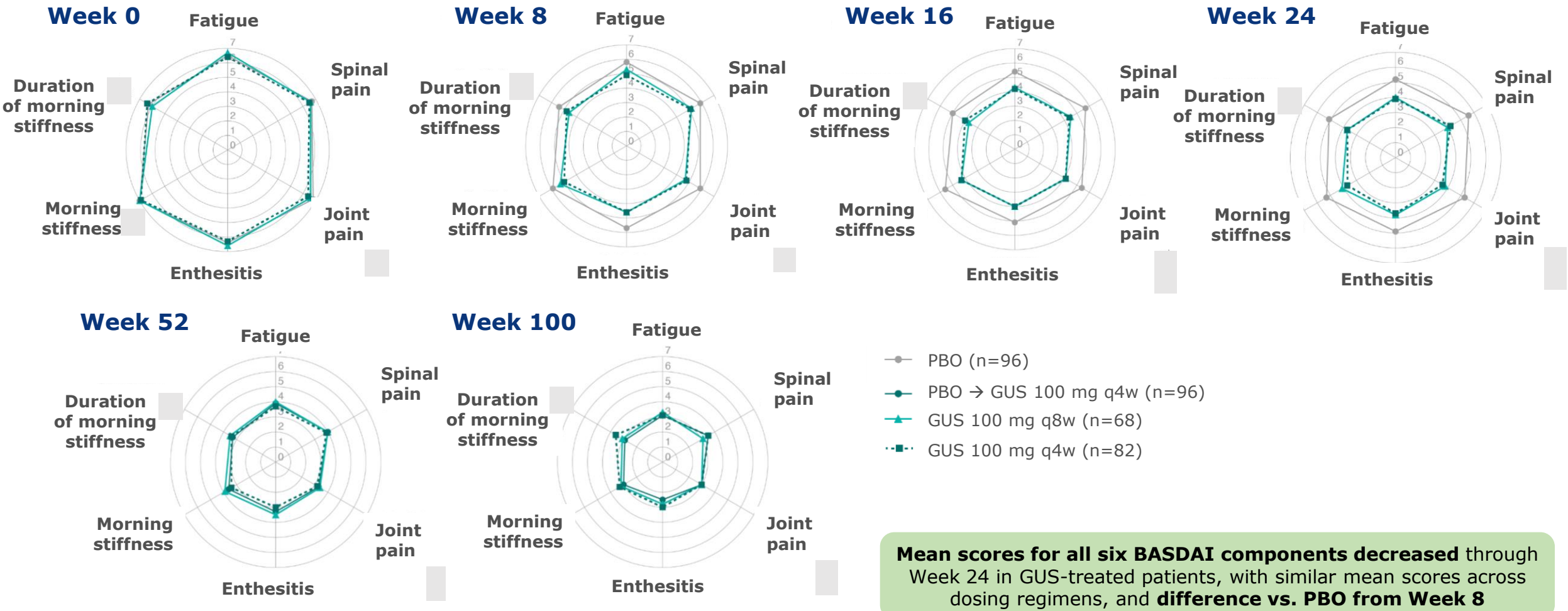
κλινική ενεργότητα με
μέσο BASDAI 6,5 και μέσο ASDAS 4
ΚΑΙ
επιβεβαιωμένη ιερολαγονίτιδα είτε με **ακτινογραφία ή με MRI ιερολαγονίων** στο BL σύμφωνα με τη γνώμη του ερευνητή

Baseline characteristics of patients with PsA and investigator-confirmed sacroiliitis in DISCOVER-2

	GUS Q4W N=82	GUS Q8W N=68	PBO N=96
Age (years), mean (SD)	44.2 (12.0)	45.0 (10.7)	44.2 (11.3)
Male, n (%)	54 (66%)	40 (59%)	59 (62%)
Duration of PsA (years), mean (SD)	5.2 (5.7)	4.9 (5.4)	5.9 (5.2)
BMI (kg/m^2), mean (SD)	27.7 (5.9)	28.0 (6.5)	28.4 (6.5)
Swollen joint count (0–66), mean (SD)	13.4 (9.1)	11.3 (5.6)	11.4 (7.1)
Tender joint count (0–68), mean (SD)	24.7 (15.7)	21.2 (12.4)	21.5 (13.2)
IGA score (≥2), n (%)	68 (83%)	55 (81%)	87 (91%)
Patient with enthesitis, n (%)	65 (79%)	53 (78%)	70 (73%)
Enthesitis score (LEI; 1–6), mean (SD)	2.8 (1.8)	2.6 (1.5)	2.8 (1.7)
Patients with dactylitis, n (%)	49 (60%)	37 (54%)	42 (44%)
Dactylitis score (1–60), mean (SD)	9.0 (10.0)	9.1 (9.5)	8.0 (8.3)
CRP (mg/dL), mean (SD)	2.3 (3.1)	2.7 (3.1)	2.5 (3.1)
DAPSA score,* mean (SD)	53.1 (24.0)	48.2 (20.2)	48.4 (18.6)
BASDAI (0–10), mean (SD)	6.5 (1.6)	6.6 (1.9)	6.6 (1.6)
Fatigue/spinal pain/joint pain/enthesitis scores, VAS (0–10 cm)	6.4/6.5/6.4/6.3	6.7/6.6/6.6/6.6	6.5/6.7/6.8/6.4
Qualitative/quantitative morning stiffness, VAS (0–10 cm)	6.9/6.4	7.0/6.0	7.0/6.3
ASDAS, mean (SD)	3.9 (0.8)	4.1 (1.0)	4.0 (0.8)

Disease activity through Week 100: BASDAI component scores

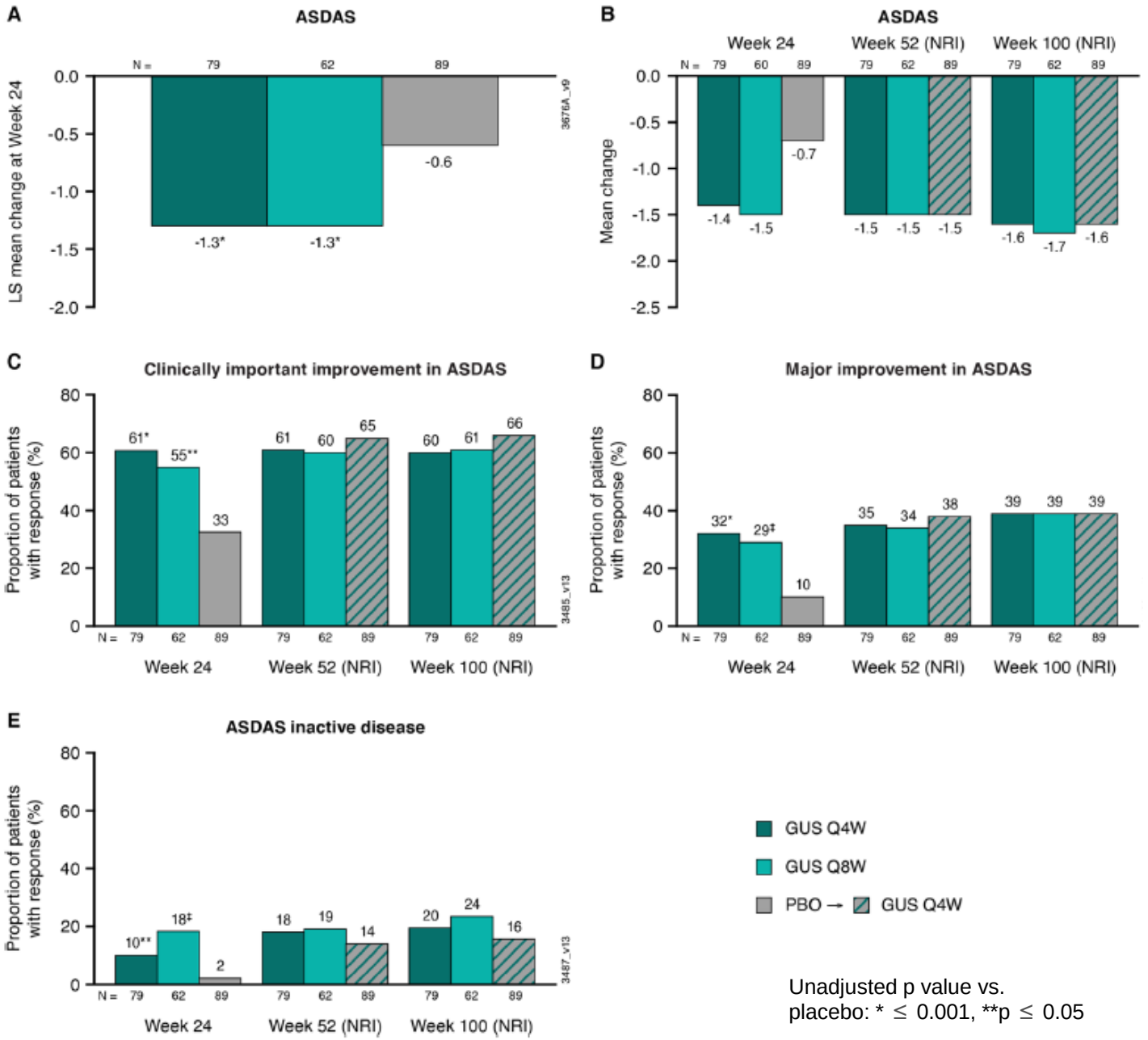
Mean BASDAI component scores through Week 100 with GUS



Mean scores for all six BASDAI components decreased through Week 24 in GUS-treated patients, with similar mean scores across dosing regimens, and **difference vs. PBO from Week 8**

Figure adapted from Mease P, et al. 2023.
BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; GUS, guselkumab; PBO, placebo; q4w, every 4 weeks; q8w, every 8 weeks.
Mease P, et al. *Rheumatol Ther* 2023; doi:10.1007/s40744-023-00592-8; [Epub ahead of print].

LS mean changes from baseline to week 100 in patients from DISCOVER-2 with active psoriatic arthritis and investigator-verified, imaging-confirmed sacroiliitis



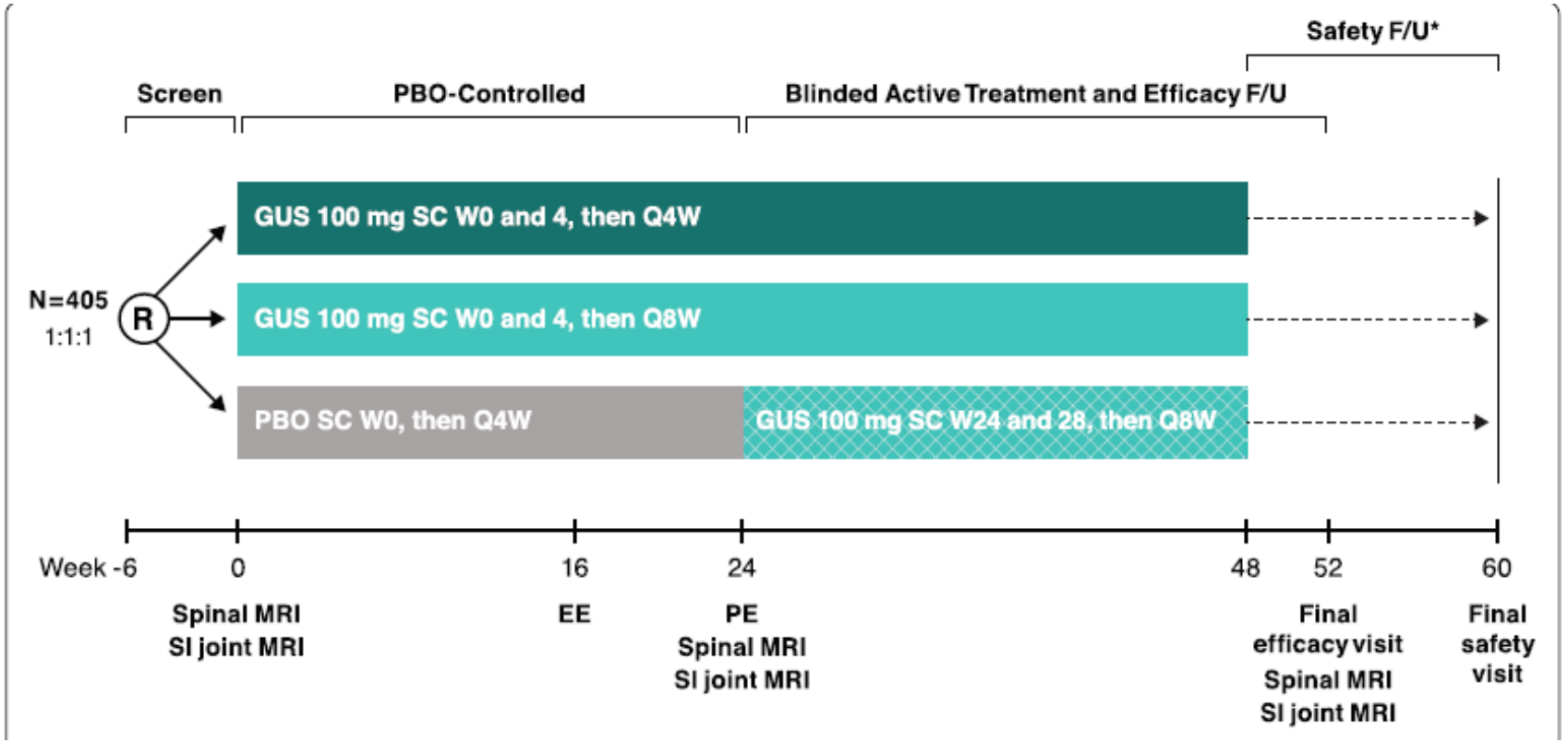
Unadjusted p value vs. placebo: * ≤ 0.001, **p ≤ 0.05

Rheumatol Ther (2023) 10:1637–1653 https://doi.org/10.1007/s40744-023-00592-8

STAR: Study design

Active PsA axial disease for ≥6 months

(spine or SI + MRI), ≥3 TJC/SJC, CRP ≥0.3 mg/dL, BASDAI ≥4, spinal pain score ≥4



At Week 16, patients in all treatment groups who had <10% improvement from baseline in both total back pain and morning stiffness measures (Questions #5 and 6 of BASDAI) at both Week 12 and Week 16 will be allowed to initiate or increase the dose of one of the permitted concomitant medications up to the maximum allowed dose, as selected by the investigator.

Gladman D, et al. *Trials* 2022;23:743.

STAR

frontiers in Immunology

PERSPECTIVE
published: 18 February 2021
doi: 10.3389/fimmu.2020.623874

IL-23 Inhibition in Ankylosing Spondylitis: Where Did It Go Wrong?

Dominique Baeten[1,2*] *and Iannis E. Adamopoulos*[3]

[1] *Clinical Immunology and Rheumatology, Amsterdam University Medical Center, Amsterdam, Netherlands,* [2] *Immunology Therapeutic Area, UCB, Slough, United Kingdom,* [3] *Department of Medicine, Division of Rheumatology and Clinical Immunology, Beth Israel Medical Deaconess Center, Boston, MA, United States*

Why did IL-23p19 inhibition fail in AS: a tale of tissues, trials or translation?

Stefan Siebert, Neal L Millar, Iain B McInnes

RHEUMATOLOGY

Rheumatology 2021;60:iv28–iv33
doi:10.1093/rheumatology/keab617

IL-23 and axial disease: do they come together?

Philip Mease [1,2] and Filip van den Bosch [3]

Rheumatology 2021;60:iv28–iv33
doi:10.1093/rheumatology/keab617
Front. Immunol. 11:623874. doi: 10.3389/fimmu.2020.623874
Siebert S, et al. Ann Rheum Dis August 2019 Vol 78 No 8

RHEUMATOLOGY

Rheumatology 2020;59:1340–1346
doi:10.1093/rheumatology/kez457
Advance Access publication 8 October 2019

Original article

Is axial psoriatic arthritis distinct from ankylosing spondylitis with and without concomitant psoriasis?

Joy Feld[1,2], Justine Yang Ye[1], Vinod Chandran[1,2,3,4], Robert D. Inman[1,2,5], Nigil Haroon[1,2,4], Richard Cook[6] and Dafna D. Gladman[1,2,3]

Abstract

Objective. The aim of this study was to compare patients with ankylosing spondylitis with psoriasis (ASP) and without psoriasis (AS), to axial PsA (axPsA) patients.

Methods. Two adult cohorts were recruited from the AS clinic: ASP and AS. These two cohorts were compared with two adult cohorts recruited from the PsA clinic: axPsA (radiographic sacroiliitis: ⩾bilateral grade 2 or unilateral grade 3 or 4); and Peripheral PsA. All patients were followed prospectively according to the same protocol. The demographic, clinical and radiographic variables were compared. Adjusted means were used to account for varying intervals between visits. A logistic regression was performed and adjusted for follow-up duration.

Results. There were 477 axPsA patients, 826 peripheral PsA, 675 AS and 91 ASP patients included. AS patients were younger ($P < 0.001$), more male and HLA-B*27 positive (76%, 72% *vs* 64%, $P \leqslant 0.001$, 82%, 75%, *vs* 19%, $P = 0.001$). They had more back pain at presentation (90%, 92% *vs* 19%, $P = 0.001$), worse axial disease activity scores (bath ankylosing spondylitis disease activity index: 4.1, 3.9 *vs* 3.5 $P = 0.017$), worse back metrology (bath ankylosing spondylitis metrology index: 2.9, 2.2 *vs* 1.8, $P < 0.001$), worse physician global assessments (2.4, 2.2 *vs* 2.1, $P < 0.001$), were treated more with biologics (29%, 21% *vs* 7%, $P = 0.001$) and had a higher grade of sacroiliitis (90%, 84% *vs* 51%, $P < 0.001$). Similar differences were detected in the comparison of ASP to axPsA and in a regression model.

Conclusion. AS patients, with or without psoriasis, seem to be different demographically, genetically, clinically and radiographically from axPsA patients. axPsA seems to be a distinct entity.

THE AXIAL INVOLVEMENT IN PSORIATIC ARTHRITIS (AXIS) STUDY

The AXIS study is a prospective cross-sectional study that has been conducted under the umbrella of **ASAS** and **GRAPPA**.

The overarching aim of the AXIS study is to systematically evaluate clinical and imaging manifestations indicative of axial involvement (based on local and central assessments) in patients with PsA to develop classification criteria and a unified nomenclature for axial involvement in PsA that would allow defining a homogeneous subgroup of patients for research.

https://doi.org/10.1177/1759720X211057975

Efficacy results of randomised controlled trials stratified by mode of action and disease domain

Target	Disease Domain					
	Arthritis (ACR 70)	Physical function (HAQ)	Skin (PASI 75)	Enthesitis*	Dactylitis*	Radiographic damage (PsA-mSvdHS)
TNF (ADA, CZP, ETN, IFX, GOL)						
IL-17A (IXE, SEC)						
IL-17A/F (BKZ)						
IL-12/23 (UST)						
IL-23-p19 (GUS, RIS)						GUS / RIS
JAK (TOFA, UPA)				TOFA / UPA	TOFA / UPA	TOFA / UPA
CD80/86 (ABA)						
PDE-4 (APR)						

Statistically superior compared to placebo (primary or secondary endpoints)	No difference compared to placebo
Superior compared to placebo; pre-specified post-hoc analysis	Not evaluated / reported
Not statistically different compared to placebo; numerically better results	

Kerschbaumer A, et al. Ann Rheum Dis 2024;0:1–15. doi:10.1136/ard-2024-225534

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

ORIGINAL RESEARCH ARTICLE

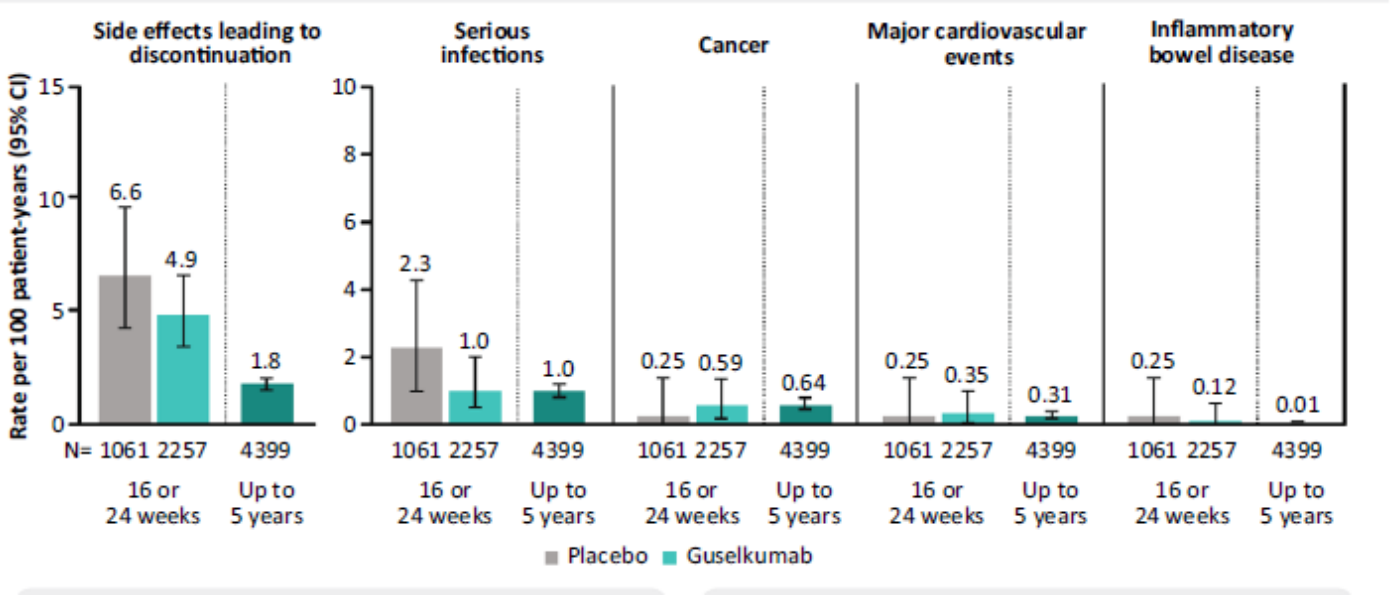
Long-Term Safety of Guselkumab in Patients with Psoriatic Disease: An Integrated Analysis of Eleven Phase II/III Clinical Studies in Psoriasis and Psoriatic Arthritis

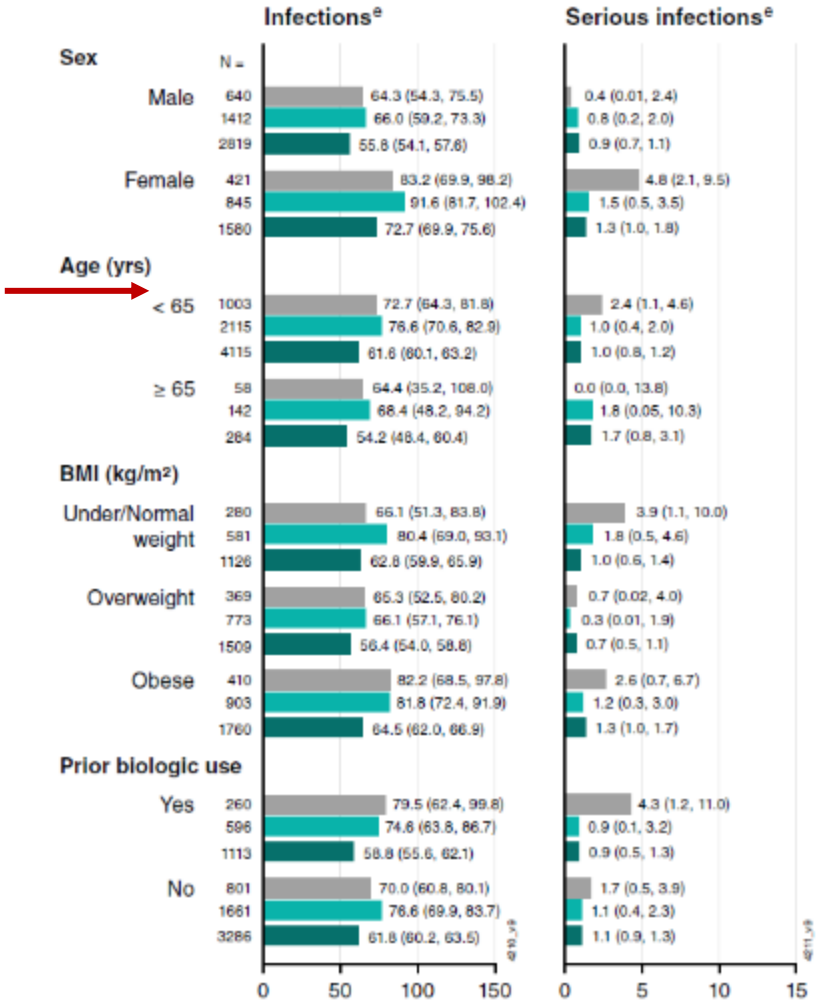
Bruce Strober[1,2] · Laura C. Coates[3] · Mark G. Lebwohl[4] · Atul Deodhar[5] · Evan Leibowitz[6] · Katelyn Rowland[6] · Alexa P. Kollmeier[7] · Megan Miller[6] · Yanli Wang[8] · Shu Li[8] · Soumya D. Chakravarty[6,9] · Daphne Chan[6] · May Shawi[10] · Ya-Wen Yang[11] · Diamant Thaçi[12] · Proton Rahman[13]

11 Κλινικές Μελέτες
Phase II/III PsO,PsA

4400 adults with psoriatic disease treated for up to **5 years**

11,000 PY follow up





CONCLUSIONS

- **Η προσβολή του δέρματος στην ΨΑ είναι μία σημαντική παράμετρος που δεν πρέπει να αγνοείται από τον ρευματολόγο αλλά να αντιμετωπίζεται εξίσου αποτελεσματικά**

- **Η IL-23 ενεργοποιεί αλλά και επανατροφοδοτεί τη φλεγμονώδη διεργασία στο δέρμα ασθενών με ψωρίαση και ΨΑ**

- **Η αναστολή της IL-23 είναι εξ' ίσου αποτελεσματική στην άρθρωση και την ένθεση όσο είναι και στο δέρμα**

- **Δεδομένα αποτελεσματικότητας από τις μελέτες του Guselkumab αλλά και από την κλινική εμπειρία**

- **Ο ρόλος της αναστολής της IL-23 στην ψωριασική σπονδυλίτιδα είναι αντικείμενο τρέχουσας μελέτης**

CONCLUSIONS

Το Guselkumab αποτελεί μία εύστοχη θεραπευτική επιλογή στην Ψωριασική Αρθίτιδα

✓ Αντιμετωπίζει επιτυχώς όλες τις εκφάνσεις της νόσου

Target	Disease Domain						
	Arthritis (ACR 70)	Physical function (HAQ)	Skin (PASI 75)	Enthesitis*	Dactylitis*	Radiographic damage (PsA-mSvdHS)	
IL-23-p19 (GUS, RIS)						GUS	RIS

✓ Έχει εξαιρετικό profil ασφαλείας

SCAN ME

TO PROVIDE A DIGITAL EVALUATION OF THE SESSION

4° Πανελλήνιο Θερινό Συμπόσιο Μυοσκελετικής Υγείας

30/5-2/6/2024, Καλαμάτα, Ξενοδοχείο Filoxenia

janssen Immunology

PHARMACEUTICAL COMPANIES OF Johnson&Johnson