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Optimizing Biologic Therapy in Psoriatic Arthritis: Translating Clinical Evidence into Patient-Centered Care

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- **Joseph F. Merola, MD, MMSc:** Consultant/investigator – Amgen, Astra-Zeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Abbvie, Dermavant, Eli Lilly, Moonlake, Novartis, Janssen, Oruka, UCB, Sanofi, Regeneron, Sun Pharma, Biogen, Pfizer

Learning Objectives

- Describe the pathophysiology of PsA and the therapeutic rationale for biologic therapies targeting its underlying pathways
- Evaluate recent safety/efficacy and head-to-head data for biologic therapies in PsA, including key efficacy endpoints (eg. ACR50, MDA) and study design factors
- Apply guideline-informed and evidence-based strategies to individualize PsA therapy selection, with considerations for disease domains, comorbidities, and safety to optimize outcomes

PsA = psoriatic arthritis; MDA = minimal disease activity; ACR = American College of Rheumatology.

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Part I: Disease State Overview, Pathogenesis, Overview of Treatment Approach, Co-Morbidities

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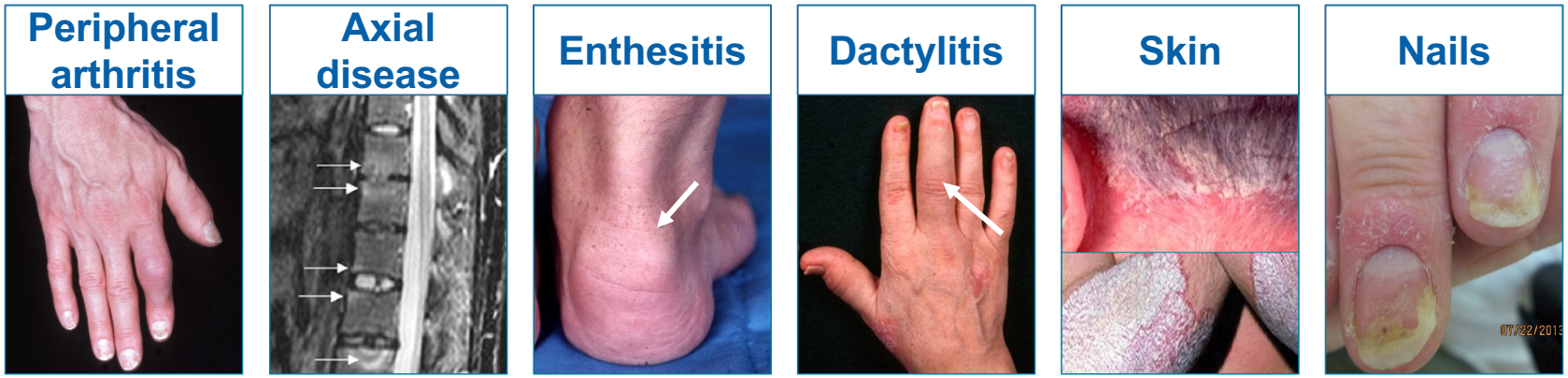
Reasons Why PsA Is SO Important to Diagnose and Treat

- PsA is common and easy to diagnose in many cases
- PsA is disabling
- PsA frequently goes undiagnosed (up to 41%)
- Cutaneous disease can precede arthritis by 10-12 years
- Dermatologists can be the first to detect arthritis
- Several classes have shown inhibition of radiographic progression
- Dermatologists can prevent disability by initiating treatment early on
- It is essential in the treatment of psoriasis to know first if the patient also has PsA
- Presence of PsA is independent of presenting psoriasis severity

Gottlieb A, et al. *J Dermatolog Treat*. 2020;31(7):662-679.

Disease State Overview: PsA

PsA Is Characterized by Diverse Clinical Features



Coates LC, et al. *Arthritis Rheumatol*. 2016;68(5):1060-1071. McQueen F, et al. *Arthritis Res Ther*. 2006;8(2):207. Wozel G. *Clin Dermatol*. 2008;26(5):448-459. American Academy of Dermatology Work Group. *J Am Acad Dermatol*. 2011;65(1):137-174. Manhart R, et al. *Clin Exp Rheumatol*. 2015;33(5)(suppl 93):S7-S13.

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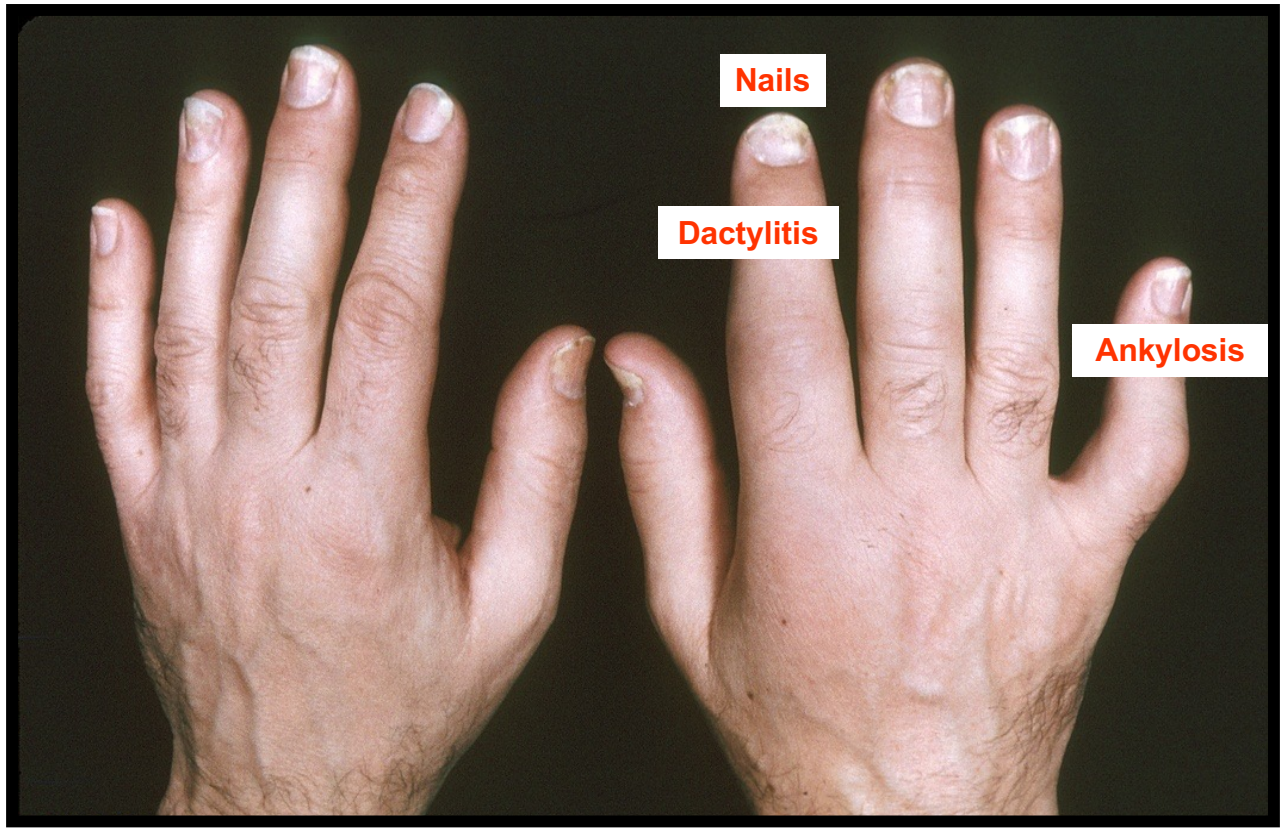
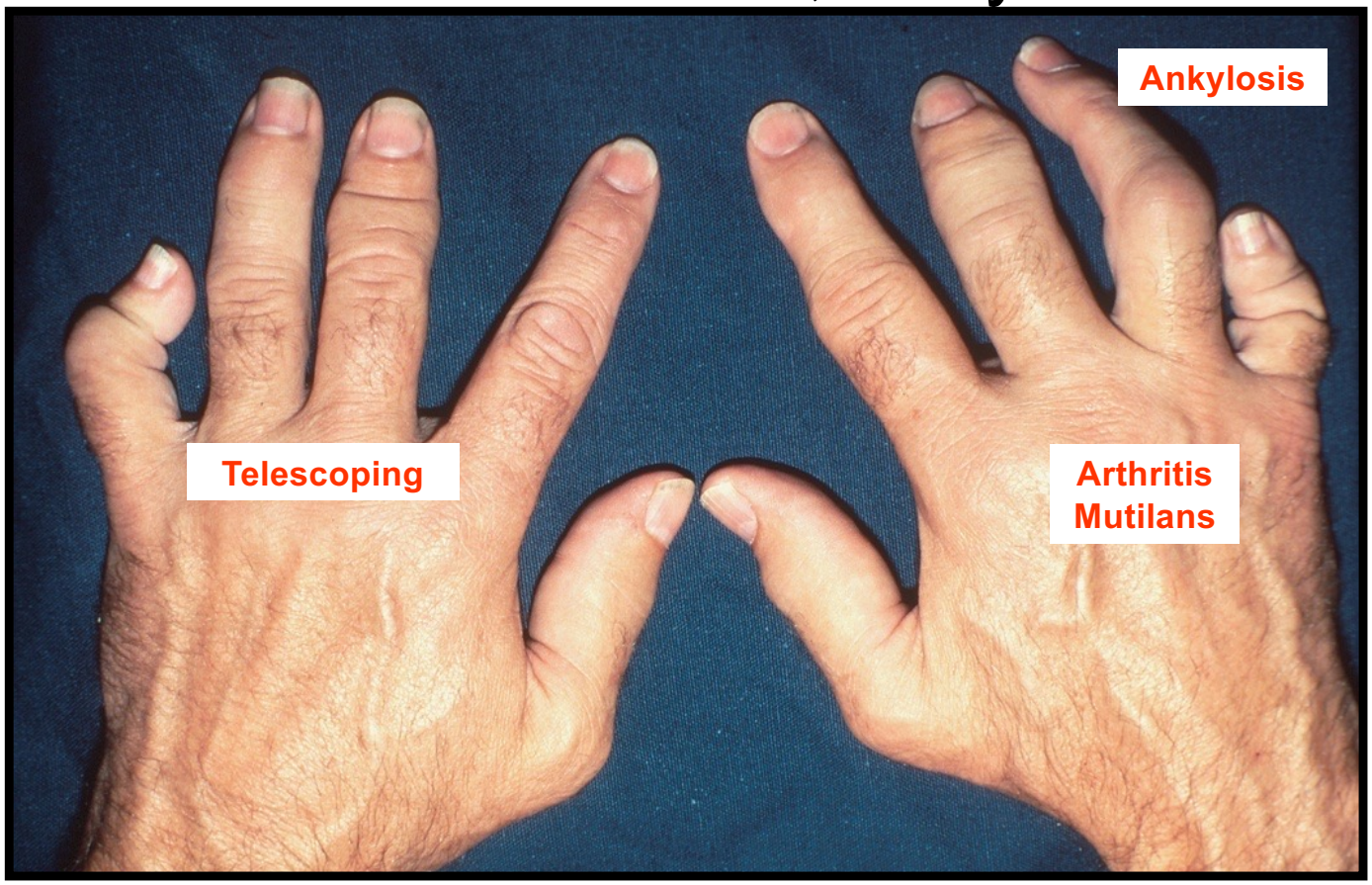
What Does PsA Look Like?

Asymmetric Arthritis, Dactylitis, Ankylosis



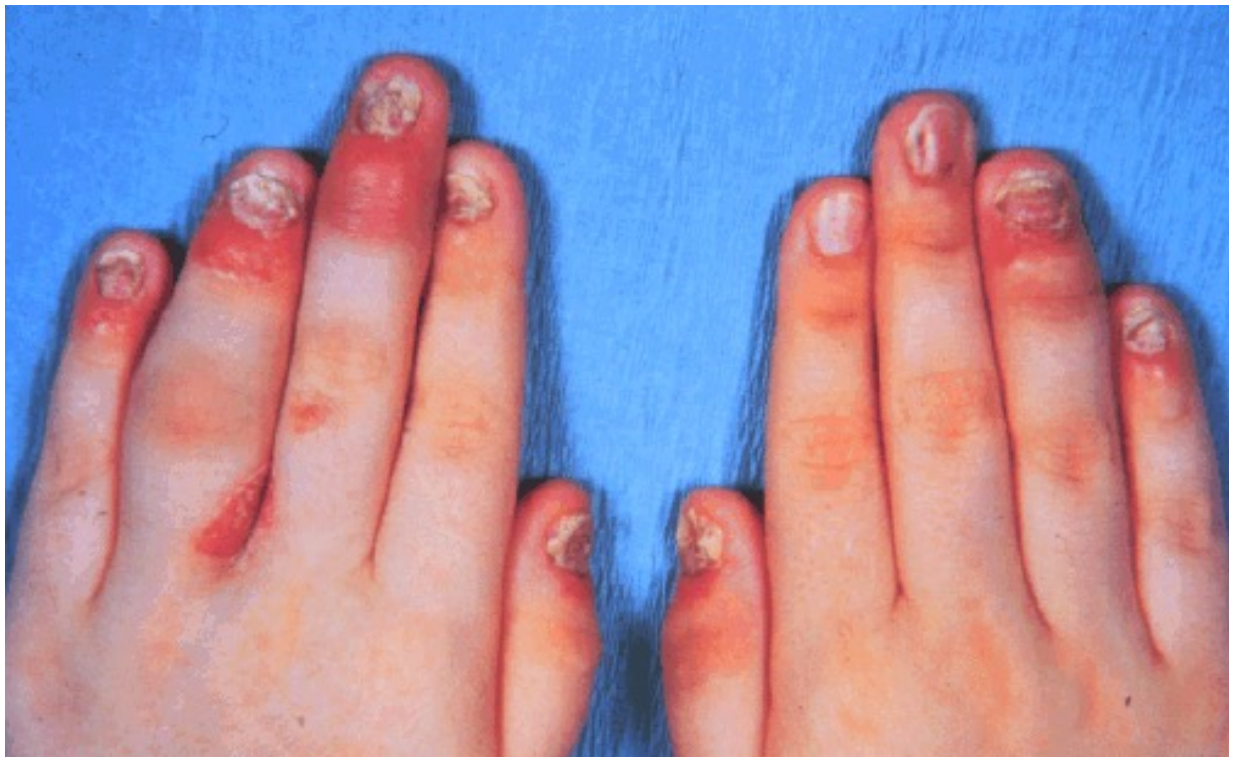
American College of Rheumatology.

Arthritis Mutilans, Ankylosis



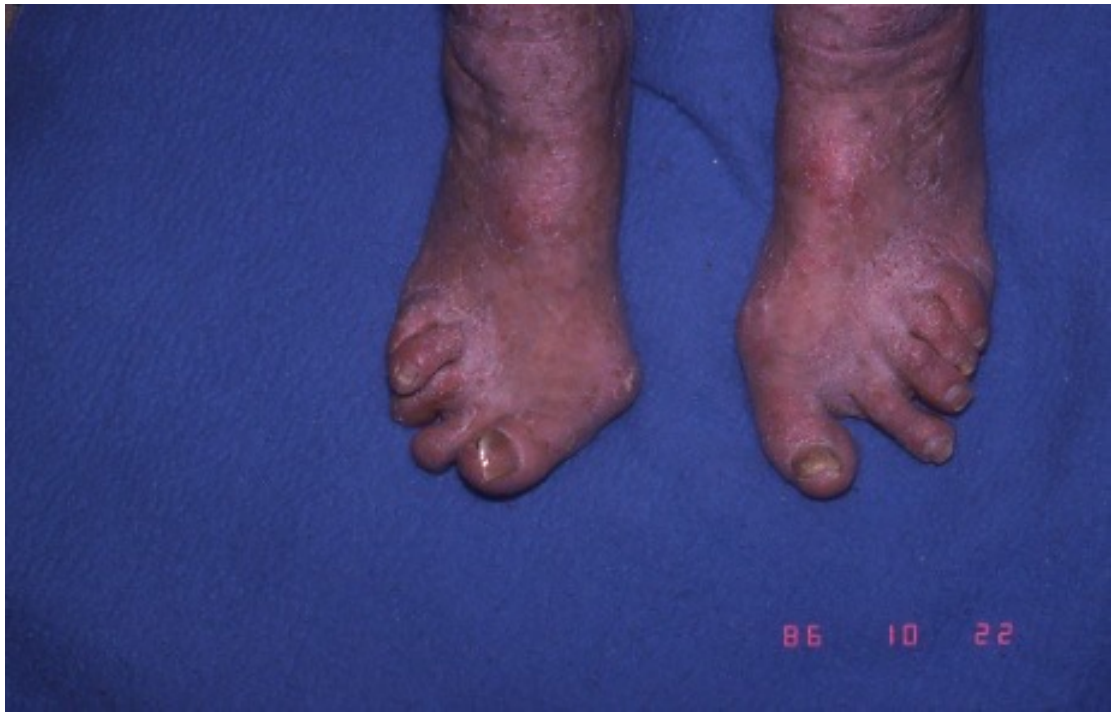
American College of Rheumatology.

PsA: Distal Interphalangeal Arthritis with Nail Involvement

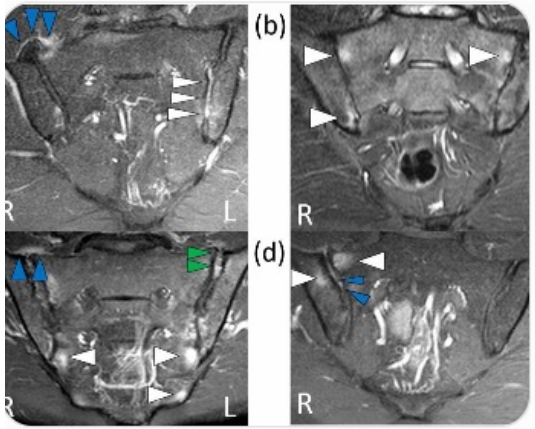


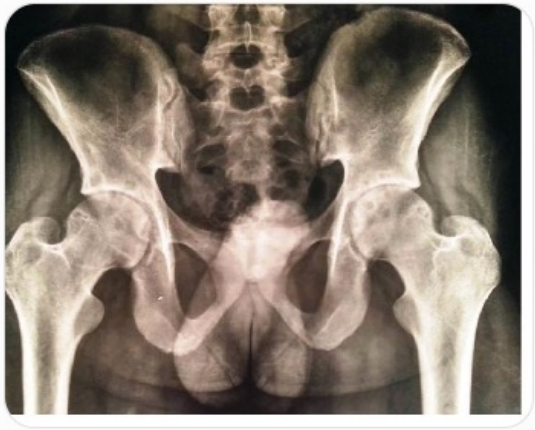
Martin BC, et al. *Dermatol Online J*. 2017;23(2):13030/qt36n2k4jw.

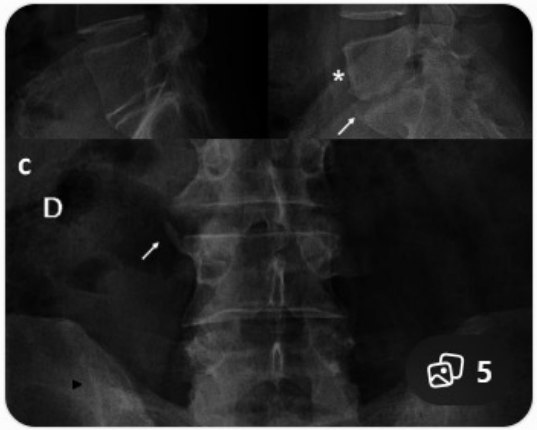
Symmetric Polyarthritis



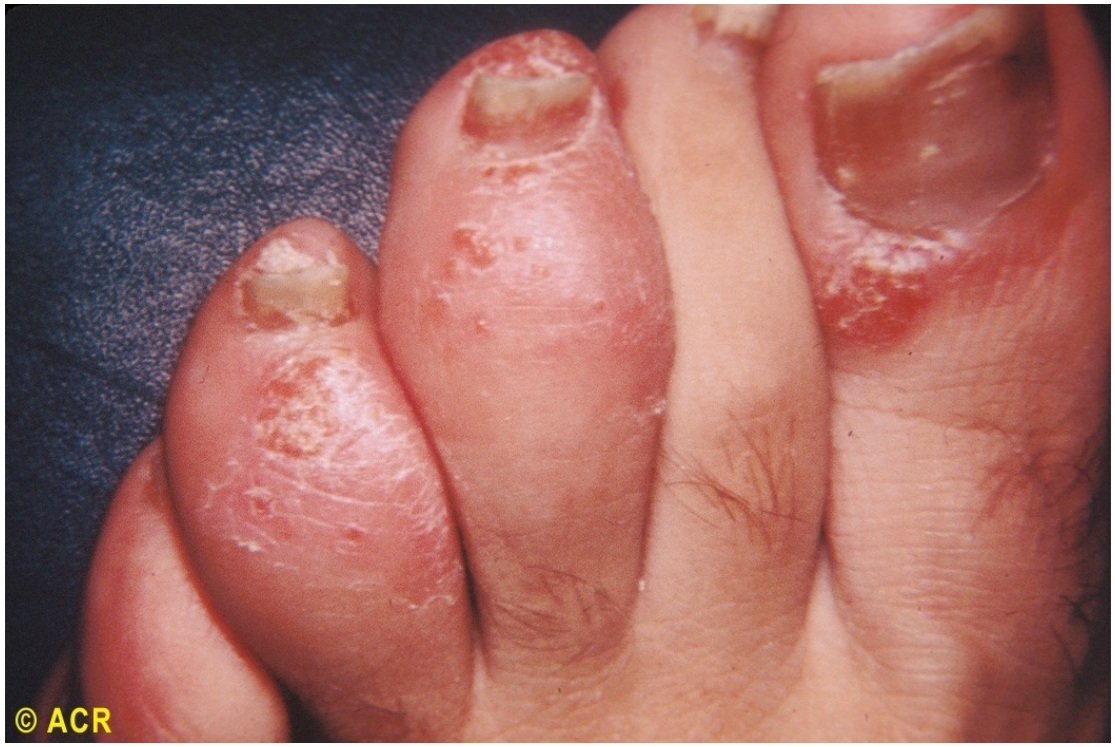
Psoriatic Arthritis Axial Disease





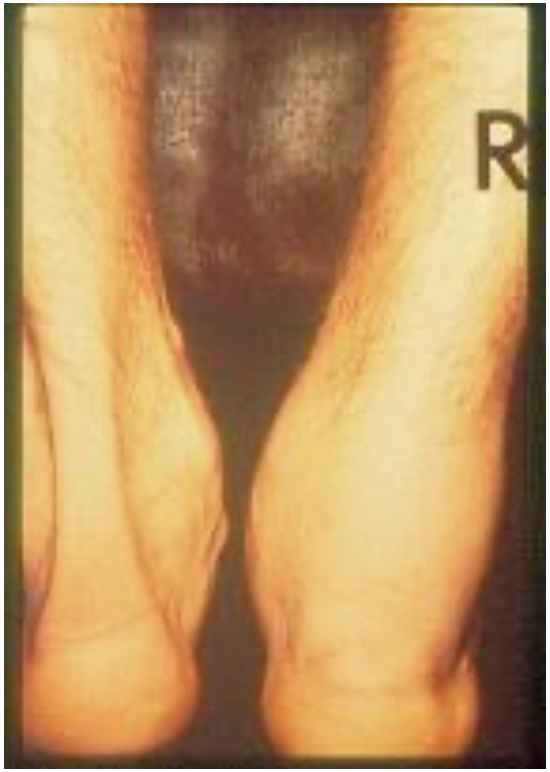


Dactylitis

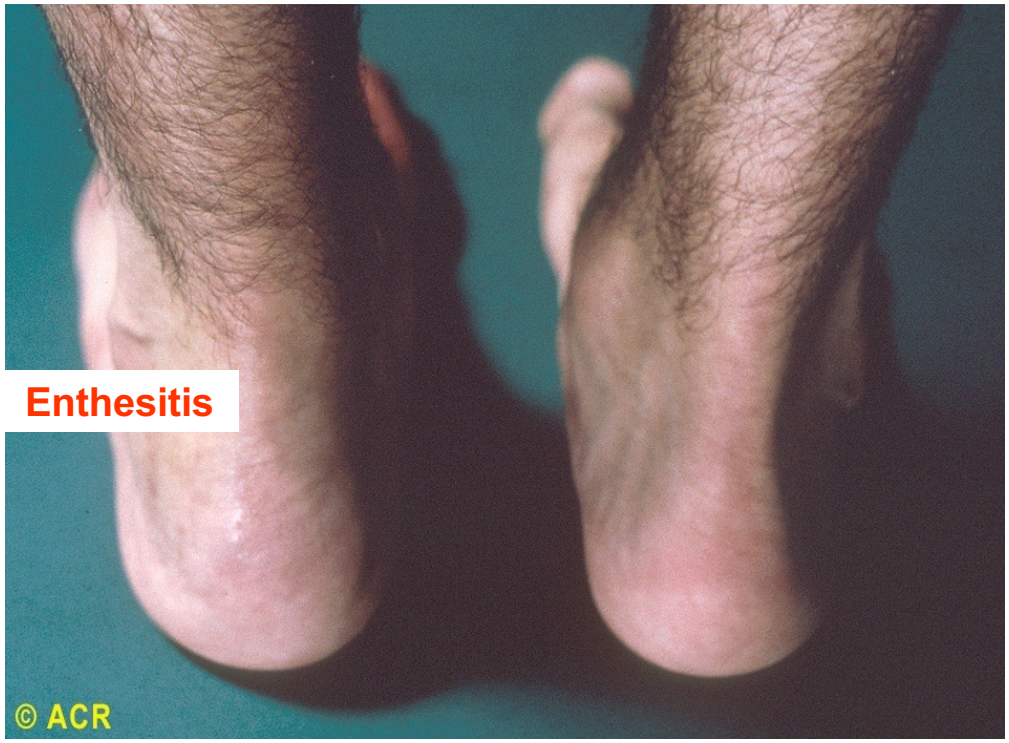


American College of Rheumatology.

Enthesiopathy vs Arthritis

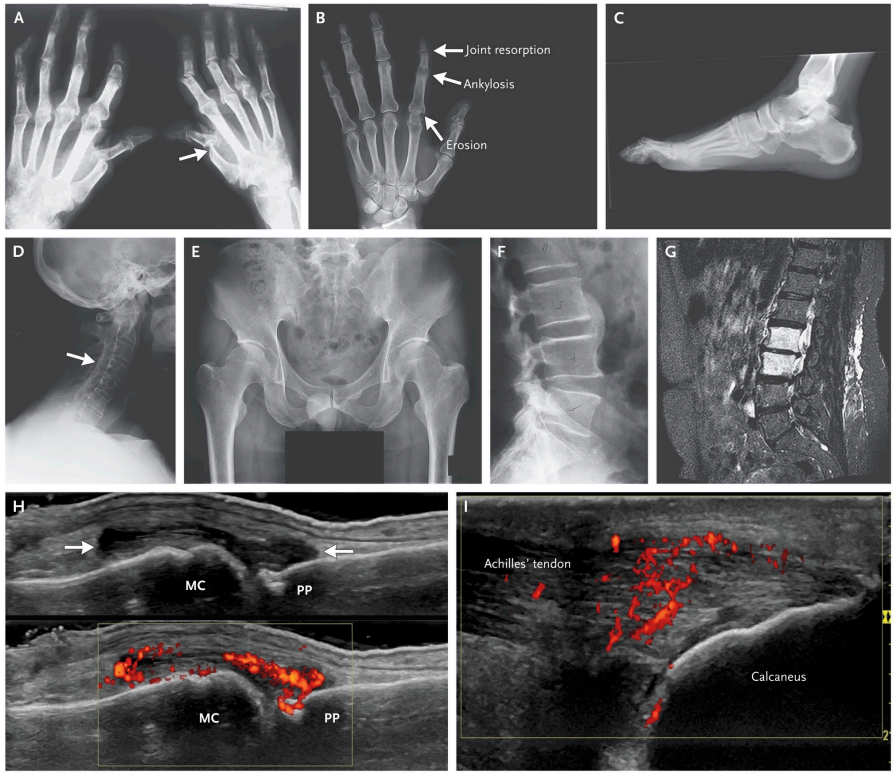


Enthesitis



American College of Rheumatology.

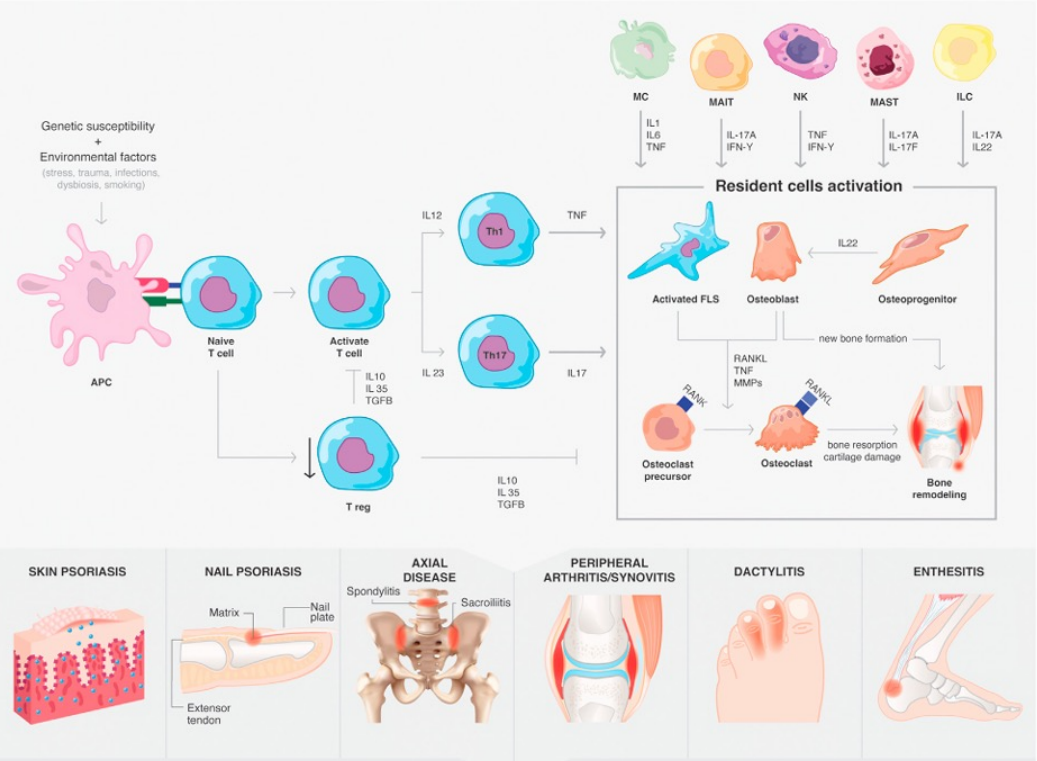
Radiographic Features of Psoriatic Arthritis



Ritchlin CT, et al. *N Engl J Med*. 2017;376(10):957-970.

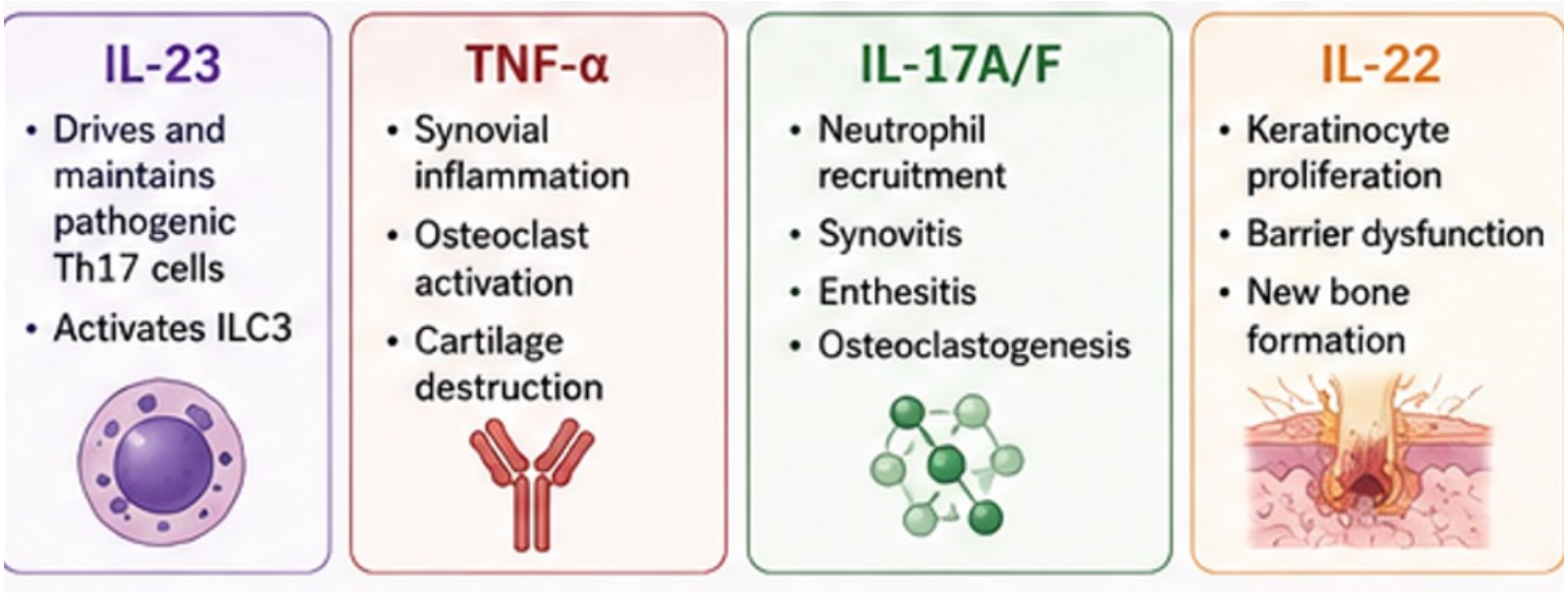
Pathogenesis of Disease in PsA

Pathogenesis of Psoriatic Arthritis



Perez-Chada LM ... Gottlieb AB, Merola JF, et al. *J Am Acad Dermatol*. 2025;92(5):969-982.

Key Cytokines and Pathways



IL = interleukin; TNF = tumor necrosis factor.
Adapted from Ritchlin CT, et al. *N Engl J Med*. 2017;376(10):957-970.

Co-Morbidities

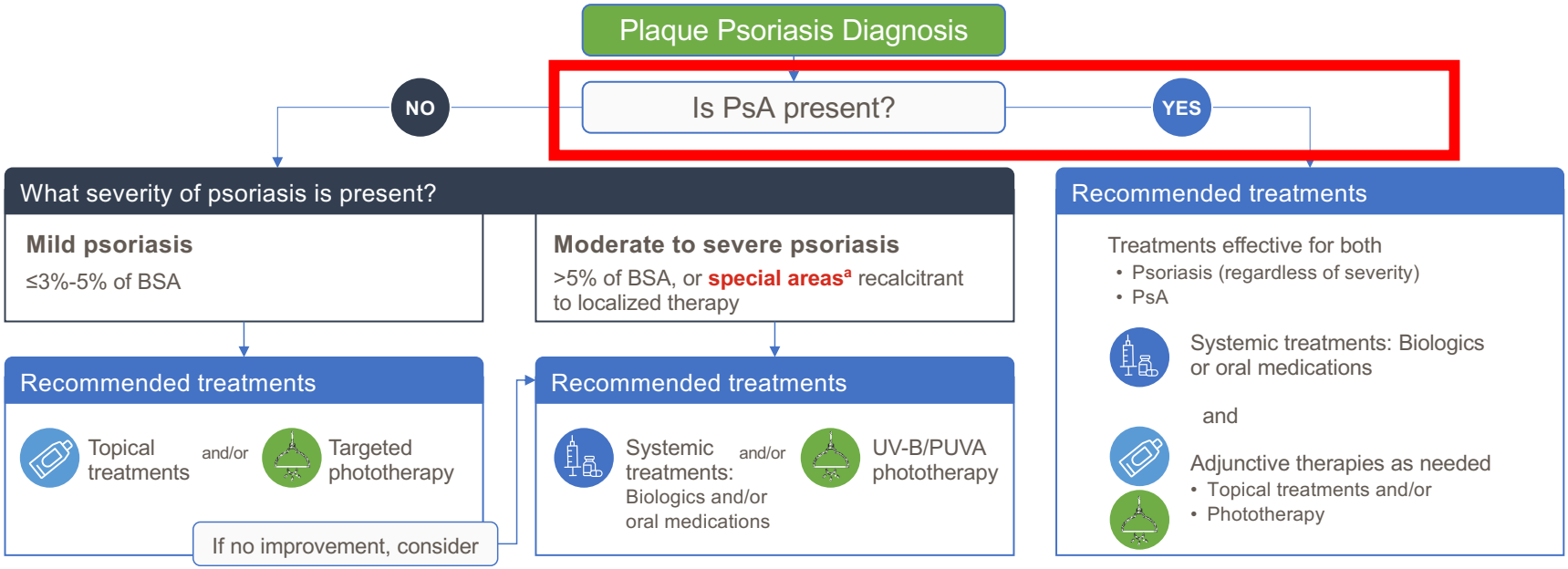
Comorbidities/Co-Prevalent Disease in Psoriatic Disease

- **Psoriasis/PsA**
- Uveitis
- Renal disease
- Hepatosteatosis
- COPD
- Sleep apnea
- Depression
- Alcoholism
- Smoking
- Metabolic syndrome
- Diabetes
- Dyslipidemia
- Obesity
- Peripheral vascular disease
- Myocardial infarction
- Stroke
- Cardiovascular death
- Gout

COPD = chronic obstructive pulmonary disease.
Jamnitski A, et al. *Ann Rheum Dis*. 2013;72(2):211-216. Yeung H, et al. *JAMA Dermatol*. 2013;149(10):1173-1179. Courtesy of JF Merola.

Approach to Treatment

Overall Treatment Approach to Psoriasis



[a]Special areas include the scalp, palms, soles, genitalia, and nails.

UV-B = ultraviolet B; PUVA = psoralen and UVA.

Armstrong AW, et al. *JAMA*. 2020;323(19):1945-1960. Menter A, et al. *J Am Acad Dermatol*. 2019;80(4):1029-1072. Smith CH, et al. *Br J Dermatol*. 2009;161(5):987-1019. Menter A, et al. *J Am Acad Dermatol*. 2011;65(1):137-174. Courtesy of JF Merola.

PsA Treatment Options: 2026

Traditional DMARDs

- Methotrexate
- Leflunomide
- Sulfasalazine
- Cyclosporine

Anti-TNFa

- Adalimumab
- Etanercept
- Infliximab
- Golimumab
- Certolizumab

Other

- NSAIDs
- Corticosteroid injections
- Corticosteroids (oral)

Other targeted therapies

- Secukinumab (IL17A)
- Ixekizumab (IL17A)
- Ustekinumab (IL12/23)
- Tofacitinib (JAK)
- Abatacept (CTLA4-Ig)
- Apremilast (PDE4)
- Risankizumab (IL23)
- Upadacitinib (JAK)
- Guselkumab (IL23)
- Bimekizumab (IL17A/F)

In development

- Brodalumab (IL17R)
- Tildrakizumab (IL23)
- Deucravacitinib (TYK2)
- Sonelokimab (IL17A/F nanobody)
- Zasocitinib (TYK2)
- Icotrokinra (IL23R OTP)
- (Combinations)

NSAID = non-steroidal anti-inflammatory drug; JAK = Janus kinase; DMARD = disease-modifying antirheumatic drug.
Courtesy of JF Merola.

Treatment by Domains of Disease

	Peripheral Arthritis	Skin and Nail Disease	Axial Disease*	Dactylitis	Enthesitis	IBD	Uveitis
NSAIDs	✓		✓				
Intra-articular steroids	✓						
Topicals		✓					
UV therapy		✓					
csDMARDs (eg. MTX)	✓	✓	X	-	-	+/-	✓
Apremilast	✓	✓	X	✓	✓	X	
Anti-TNF**	✓	+	✓	✓	✓	✓	✓
Anti-IL-12/23	✓	++	X	✓	✓	✓	
Anti-IL-23 (p19)	✓	+++	?	✓	✓	✓	
Anti-IL-17**	✓	+++	✓†	✓	✓	X	
JAK inhibitors**	✓	+/-	✓	✓	✓	✓	
TYK2 inhibitor	?	++					

***Based on data from ankylosing spondylitis trials (used as surrogate for axial PsA); **≥1 in class have inhibition of radiographic progression in label; †Dedicated axial PsA study (MAXIMISE).**
csDMARDs = conventional synthetic DMARDs (such as methotrexate (MTX), sulfasalazine, leflunomide).
Elman SA ... Merola JF, et al. *J Am Acad Dermatol*. 2024:S0190-9622(24)00852-1. Courtesy of JF Merola.

Classification Criteria for PsA (CASPAR)

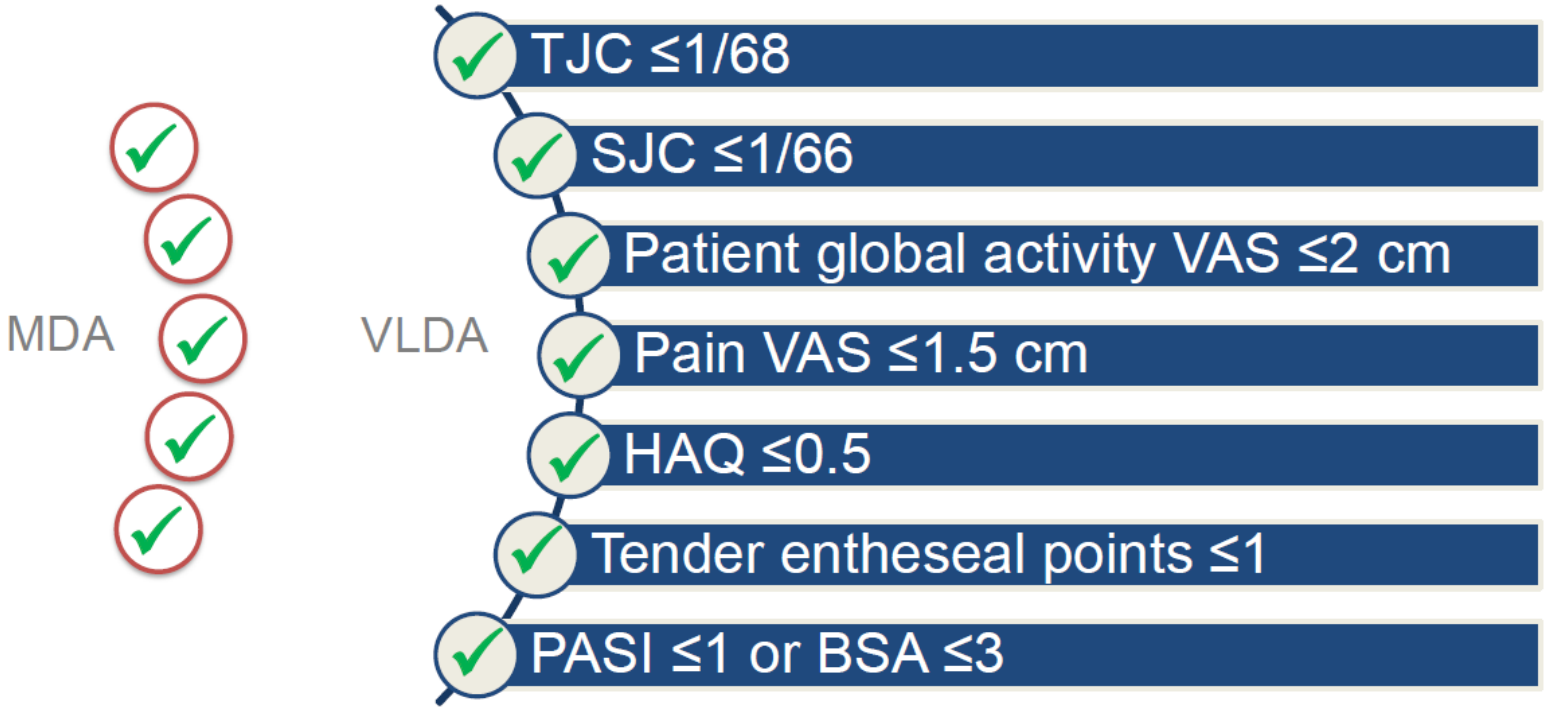
Table 1. Classification Criteria for Psoriatic Arthritis (CASPAR).*

Criterion	Explanation	Points
Evidence of psoriasis		
Current psoriasis	Current psoriatic skin or scalp disease as judged by a dermatologist or rheumatologist	2
Personal history of psoriasis	History of psoriasis according to the patient or a family doctor, dermatologist, or rheumatologist	1
Family history of psoriasis	History of psoriasis in a first- or second-degree relative according to the patient	1
Psoriatic nail dystrophy	Typical psoriatic nail dystrophy (e.g., onycholysis, pitting, or hyperkeratosis) according to observation during current physical examination	1
Negative test for rheumatoid factor	Based on reference range at local laboratory; any testing method except latex, with preference for ELISA or nephelometry	1
Dactylitis		
Current dactylitis	Swelling of an entire digit according to observation on current physical examination	1
History of dactylitis	According to a rheumatologist	1
Radiographic evidence of juxtaarticular new bone formation	Ill-defined ossification near joint margins (excluding osteophyte formation) on plain radiographs of hand or foot	1

* Psoriatic arthritis is considered to be present in patients with inflammatory musculoskeletal disease (disease involving the joint, spine, or enthesis) whose score on the five criteria listed in the table totals at least three points; the "evidence of psoriasis" criterion can account for either one point or two points. The criteria have a specificity of 98.7% and a sensitivity of 91.4%. ELISA denotes enzyme-linked immunosorbent assay.

Ritchlin CT, et al. *N Engl J Med*. 2017;376(10):957-970.

Minimal Disease Activity/Very Low Disease Activity in PsA

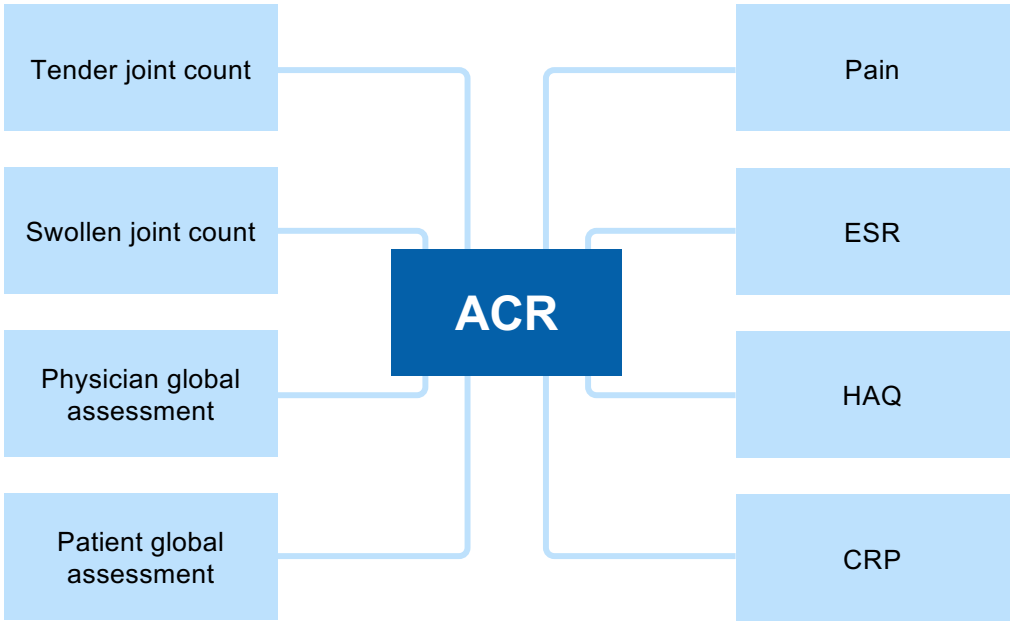


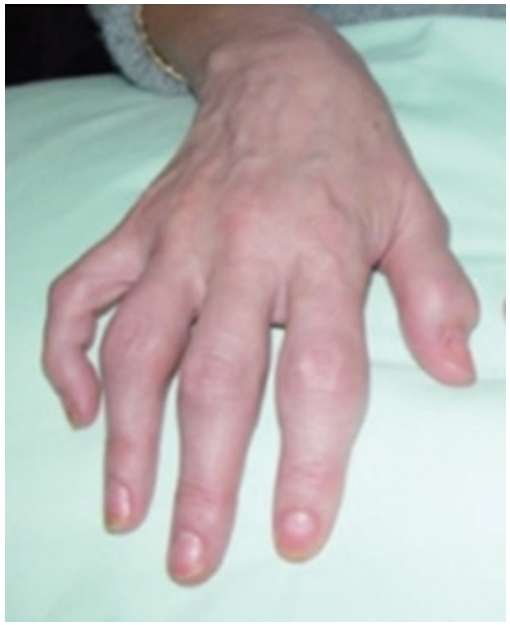
BSA = body surface area; HAQ = health assessment questionnaire; MDA = minimal disease activity; PASI = Psoriasis Area and Severity Index; SJC = swollen joint count; TJC = tender joint count; VAS = visual analogue scale; VLDA = very low disease activity.

Coates LC, et al. *Ann Rheum Dis*. 2010;69:48-53. Coates LC, et al. *Lancet*. 2015;386:2489-98. Courtesy of JF Merola.

Components of the ACR Outcome Measure for PsA

ACR20 response: ≥20% improvement in TJC and SJC, and a ≥20% improvement in 3 of the following criteria: Patient global assessment, physician global assessment, patient pain scale, HAQ-DI





ACR = American College of Rheumatology [Response]; CRP = C-reactive protein; ESR = erythrocyte sedimentation rate; HAQ = health assessment questionnaire; SJC = swollen joint count; TJC = tender joint count.

Ogdie A, et al. *Arthritis Care Res (Hoboken).* 2020;72 Suppl 10(Suppl 10):82-109. Courtesy of JF Merola.

Key Learning Points

- Dermatologists play a key role in diagnosis and treatment of PsA
- Several immune-inflammatory pathways contribute to PsA pathogenesis (IL-17, IL-23, TNF) and are the targets of current therapies
- Psoriasis and psoriatic arthritis have multiple co-morbidities which need to managed

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Part II: Data Overview of Current and Emerging Therapies in PsA, Cases

Joseph F. Merola, MD, MMSc

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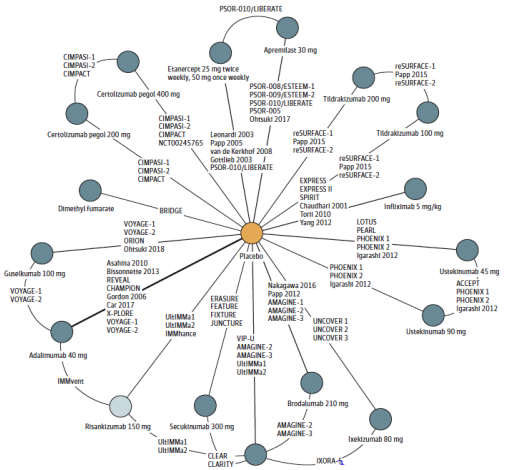
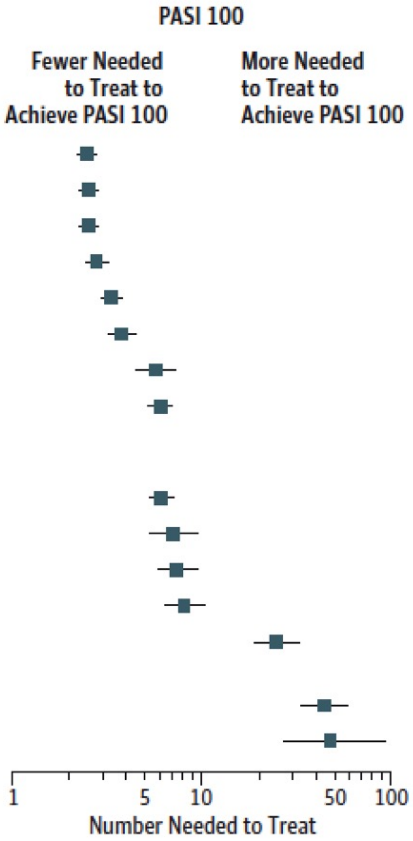
Professor of Medicine, Rheumatology
Professor, Peter O'Donnell Jr. School of Public Health (OSPH)
UT Southwestern Medical Center, Dallas, TX

Data Overview



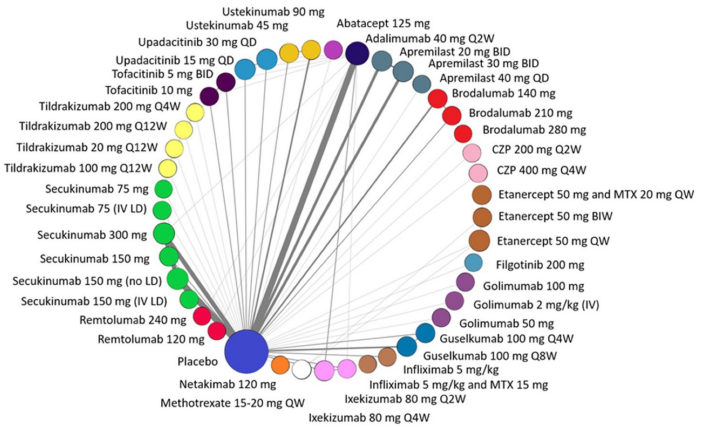
Number needed to treat to achieve PASI 100

	Response Rate (95% CrI), %
Risankizumab 150 mg	2.48 (2.23-2.79)
Ixekizumab 80 mg	2.54 (2.28-2.85)
Brodalumab 210 mg	2.56 (2.28-2.85)
Guselkumab 100 mg	2.81 (2.46-3.25)
Secukinumab 300 mg	3.36 (2.96-3.82)
Infliximab 5 mg/kg	3.79 (3.21-4.50)
Certolizumab pegol 400 mg	5.68 (4.50-7.30)
Ustekinumab 45 mg ≤100 kg 90 mg > 100 kg	6.02 (5.21-6.99)
Adalimumab 40 mg	6.10 (5.29-7.09)
Certolizumab pegol 200 mg	6.99 (5.35-9.43)
Tildrakizumab 200 mg	7.41 (5.88-9.52)
Tildrakizumab 100 mg	8.06 (6.37-10.42)
Etanercept 25 mg twice weekly, 50 mg once weekly	24.39 (18.87-32.26)
Apremilast 30 mg	43.48 (33.33-58.82)
Dimethyl fumarate	47.62 (27.03-90.91)



Armstrong AW, et al. *JAMA Dermatol*. 2020;156(3):258-269. Courtesy JF Merola. Do not reproduce.

Network Meta-Analysis



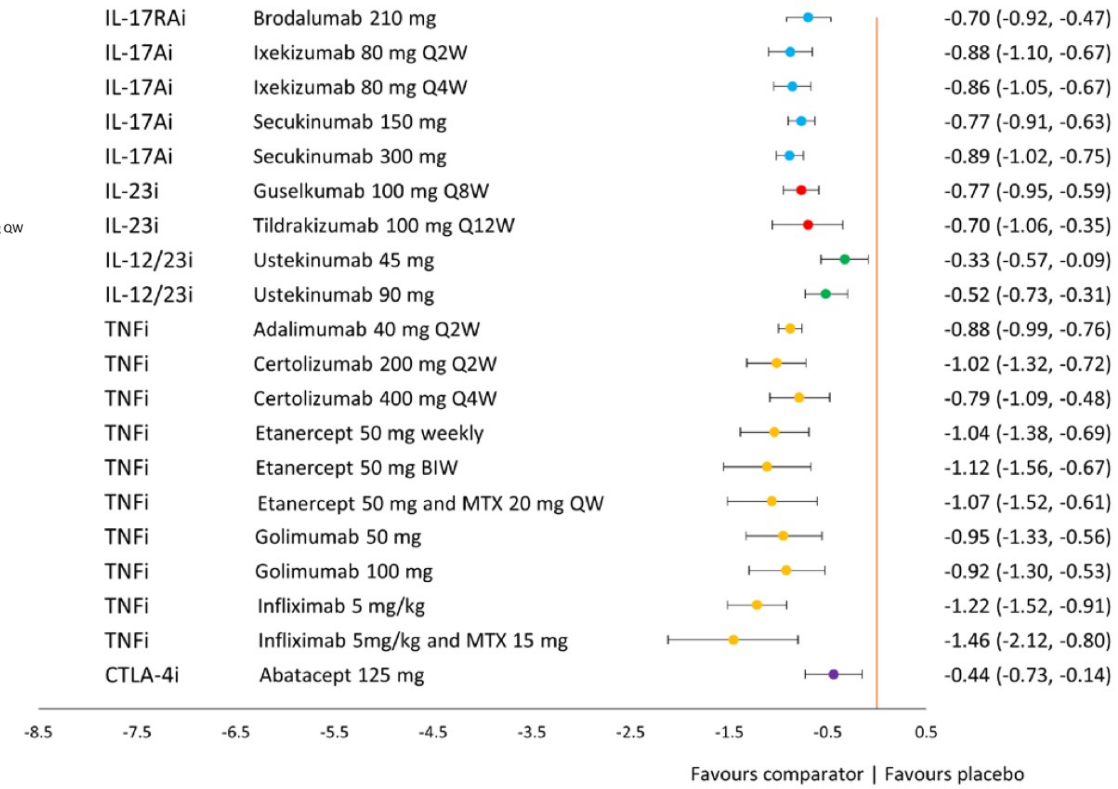
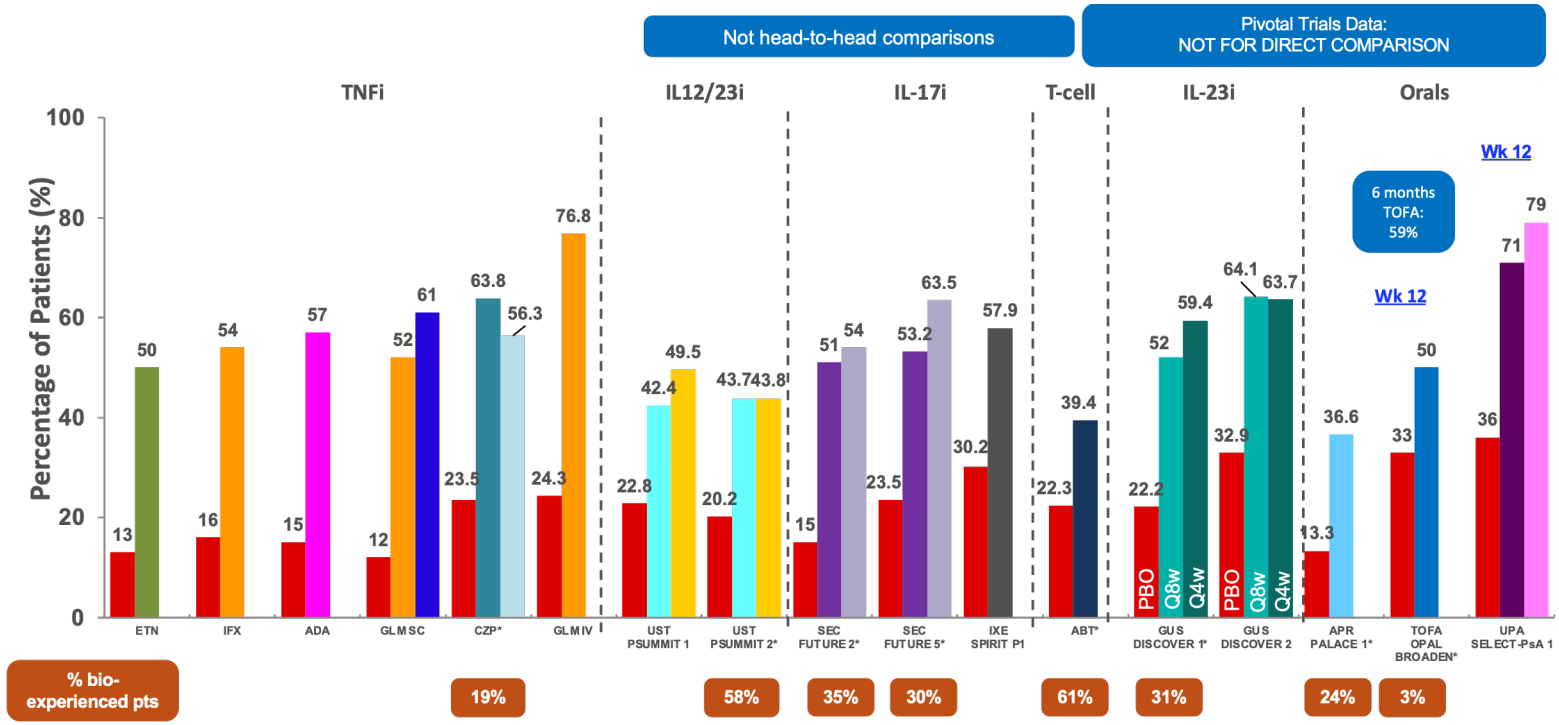


Figure 3 Forest plot of treatment effects for key comparators versus placebo on ACR response. ACR overall treatment effect was based on a random-effects model with placebo adjustment. median treatment effects and 95% credible intervals are plotted on the probit scale. Key comparators include bDMARDs at doses licensed for use in PSA or PSO. ACR, American College of Rheumatology; bDMARD, biological disease modifying anti-rheumatic drug; BIW, twice weekly; MTX, methotrexate; PSA, psoriatic arthritis; PSO, psoriasis; QD, once daily; QW, weekly; Q2W, every two weeks; Q4W, every four weeks; Q8W, every eight weeks; Q12W, every twelve weeks.

PsA Comparison: ACR20 Response at Week 24: Overall Study Population

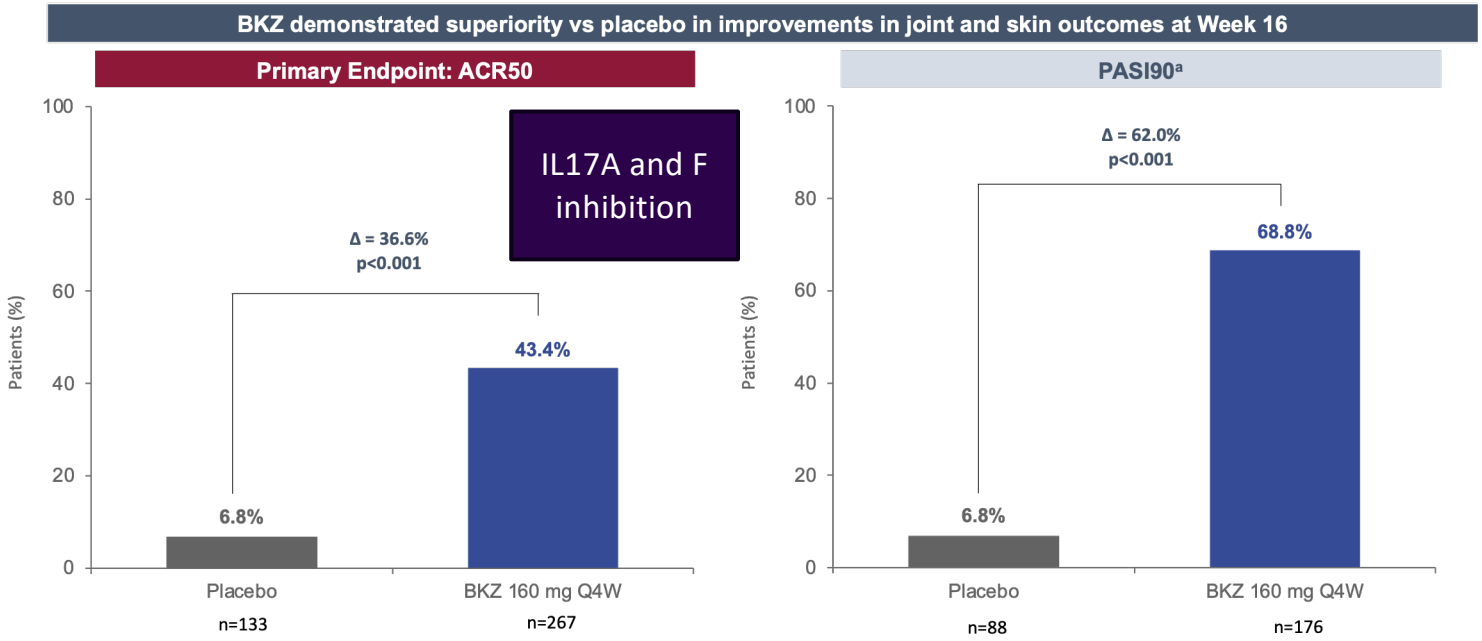


*Trial consists of a mixed population, including biological DMARD (bDMARD) naive and bDMARD experienced patients.

Mease PJ, et al. *Arthritis Rheum*. 2004;50:2264-2272. van der Heijde, et al. *Arthritis Rheum*. 2007;56:2698-2707. Mease PJ, et al. *Arthritis Rheum*. 2005;52(10):3279-3289. Kavanaugh A, et al. *Arthritis Rheum*. 2009;60(4):976-86. Mease PJ, et al. *Ann Rheum Dis*. 2014;73:48-55. Kavanaugh A, et al. *Arthritis Rheum*. 2017;69:2151-2161. McInnes IB, et al. *Lancet*. 2013;382(9894):780-789. Ritchlin C, et al. *Ann Rheum Dis*. 2014;73(6):990-999. McInnes IB, et al. *Lancet*. 2015;386:1137-1146. Mease PJ, et al. *Ann Rheum Dis*. 2018;77(6):890-897. Mease PJ, et al. *Ann Rheum Dis*. 2017;76:79-87. Mease PJ, et al. *Ann Rheum Dis*. 2017;76:1550-1558. Kavanaugh A, et al. *Ann Rheum Dis*. 2014;73:1020-1026. Mease P, et al. *N Engl J Med*. 2017;377(16):1537-1550. McInnes IB, et al. *Rheumatol Ther*. 2023;10(1):275-292. Courtesy JF Merola. Do not reproduce.

Bimekizumab in Patients with Active PsA and an Inadequate Response to TNFi: 16-Week Efficacy and Safety from BE COMPLETE, a Phase 3, Multicenter, Randomized, Placebo-Controlled Study

Efficacy: ACR50 and PASI90 Responses at Week 16 (NRI)



Randomized set. *p*-values were obtained from logistic regression with treatment, prior TNF inhibitor exposure and region as factors. [a]In patients with PSO involving ≥3% BSA at baseline.

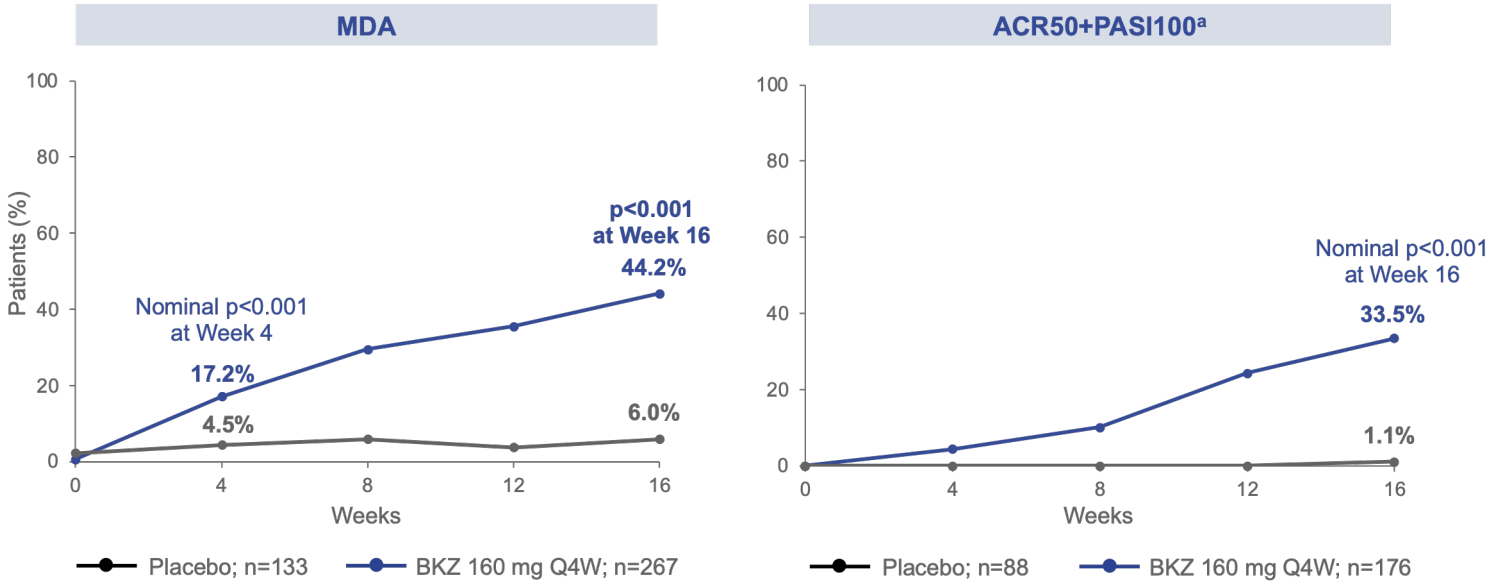
BKZ = bimekizumab; BSA = body surface area; PSO = psoriasis; NRI = non-responder imputation.

Merola JF, et al. *Lancet*. 2023;401(10370):38-48. Courtesy JF Merola. Do not reproduce.

Efficacy: Proportion of Patients Achieving MDA and ACR50+PASI100 (NRI)

IL17A and F inhibition

BKZ demonstrated superiority vs placebo in achievement of the MDA composite at Week 16



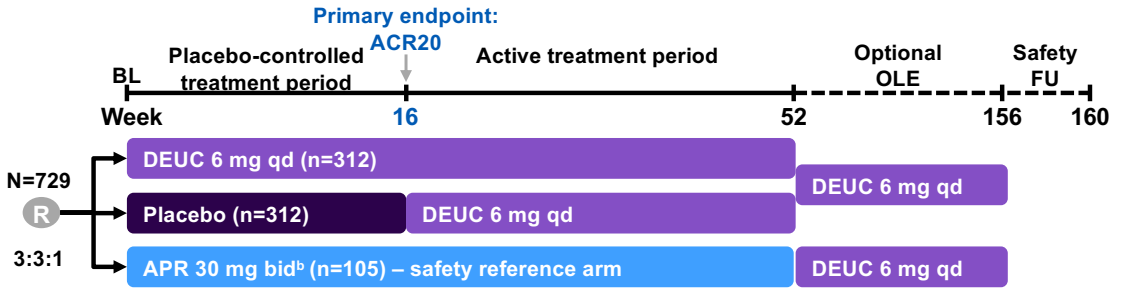
Randomized set. *p*-values obtained from logistic regression with treatment, prior TNFi exposure, and region as factors. Nominal *p* values were not powered or adjusted for multiplicity and should not be used to assess statistical significance. MDA response defined as achievement of at least five of the seven following criteria: TJC ≤1; SJC ≤1; PASI ≤1 or BSA ≤3%; Patient's Assessment of Arthritis Pain ≤15 mm; Patient's Global Assessment-PsA ≤20 mm; HAQ-DI ≤0.5; LEI ≤1. [a]In patients with PSO involving ≥3% of BSA at baseline.

POETYK PsA-2: Phase 3, Randomized, Double-blind Trial of the Efficacy and Safety of Deucravacitinib for Patients with Active PsA

Inclusion criteria
- PsA (CASPAR criteria)
- Active or documented history of psoriasis
- Active arthritis (≥3 swollen joints, ≥3 tender joints, and hsCRP ≥3 mg/L)
- bDMARD naïve or TNF-IR

Randomization stratification factors
- TNF inhibitor exposure (yes/no)
- Screening hsCRP (<10 mg/L vs ≥10 mg/L)
- csDMARD use at baseline (yes/no)

Endpoints
- **Primary:** Patients achieving ACR20 at Week 16
- **Secondary (hierarchical order) at Week 16**
  - Change from baseline in HAQ-DI score
  - Patients achieving PASI 75
  - Change from baseline in SF-36 PCS score
  - Patients achieving MDA
  - Patients achieving enthesitis resolution[a]
  - Change from baseline in FACIT-Fatigue score
  - Patients achieving dactylitis resolution[a]
  - Change from baseline in DAS28-CRP score

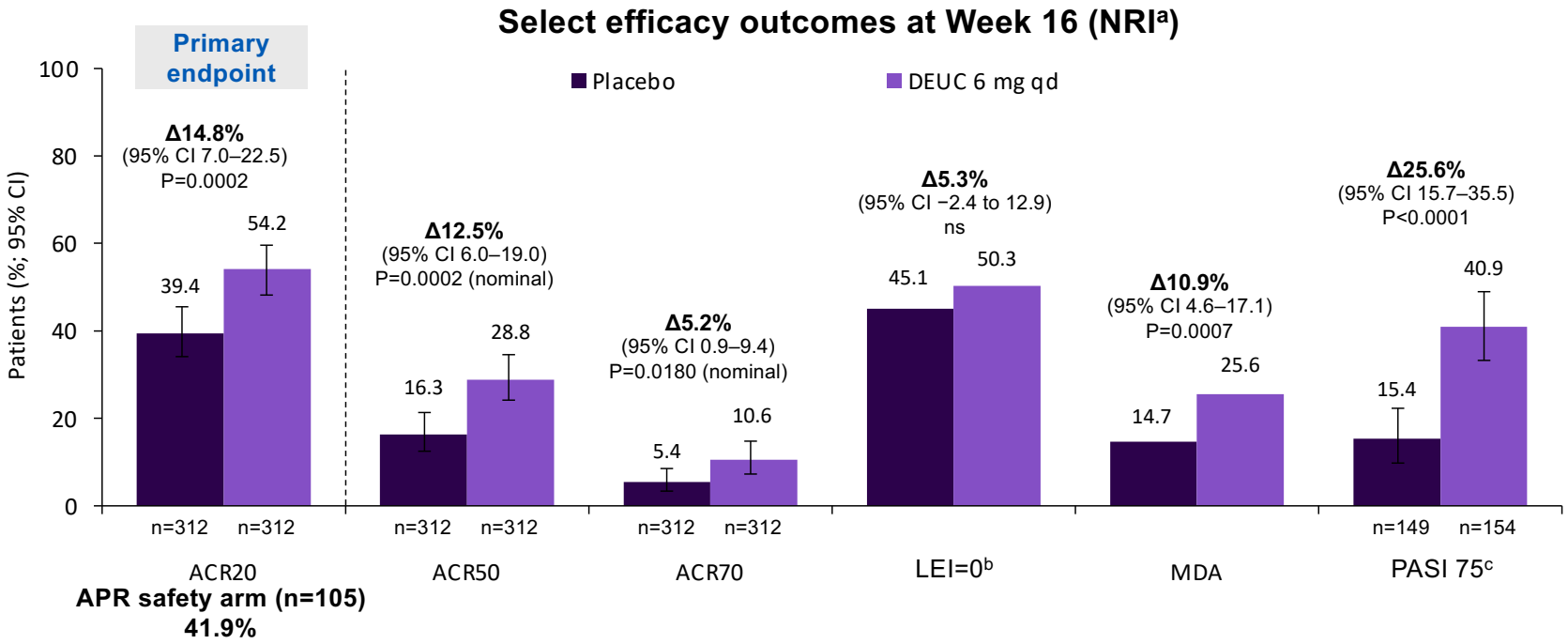


Baseline characteristics	Placebo (n=312)	DEUC 6 mg qd (n=312)	APR 30 mg bid[b] (n=105)
Prior TNFi use	45 (14)	39 (13)	14 (13)
Baseline csDMARD use	196 (63)	194 (62)	68 (65)
Disease duration, years	5.9 ±6.9	5.0 ±6.0	4.7 ±6.5
TJC (68)	16.6 ±11.5	15.2 ±10.9	16.8 ±11.9
SJC (66)	9.6 ±7.5	9.2 ±6.5	10.6 ±7.1
PASI score >1	244 (78)	260 (83)	75 (71)
PASI score	8.5 ±6.9	9.1 ±7.1	8.8 ±7.8

Data are n (%) or mean ±SD unless otherwise stated

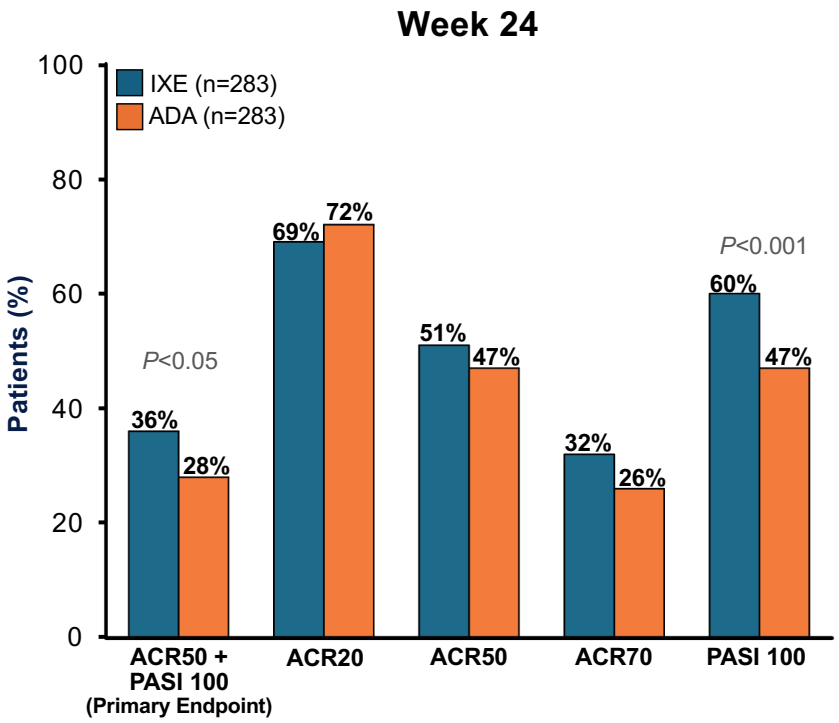
[a]Pooled analysis from POETYK PsA-1 and POETYK PsA-2 studies; [b]Safety reference arm: No comparisons for efficacy were planned or made with APR.

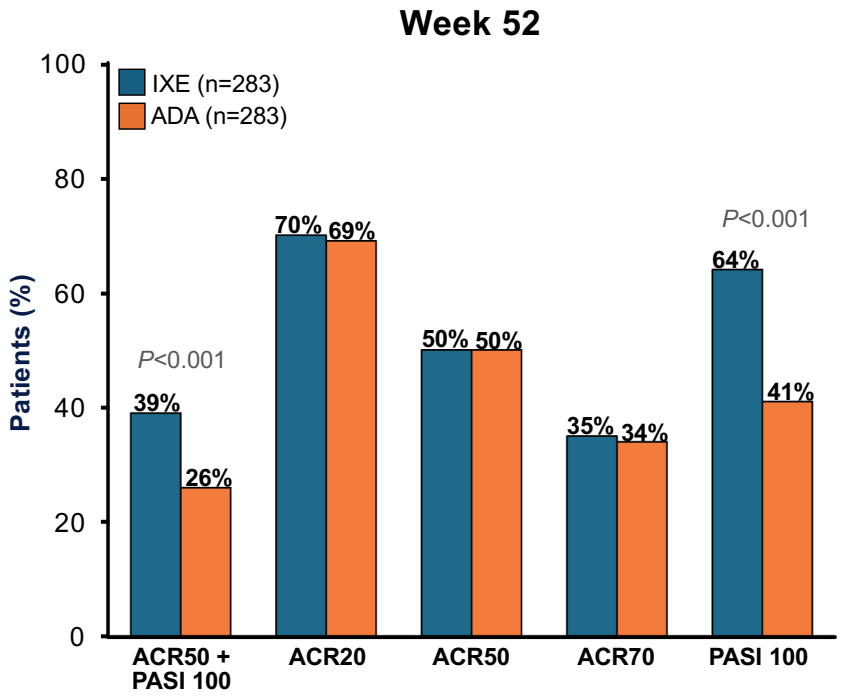
POETYK PsA-2: Efficacy Outcomes after 16 Weeks of Treatment with Deucravacitinib among Patients with Active PsA



[a]No imputation method reported for LEI=0 and MDA; [b]Pooled analysis from POETYK PsA-1 and POETYK PsA-2 in patients with enthesitis by LEI at baseline; [c]n represents patients with ≥3% BSA affected and sPGA score ≥2 at baseline. A Cochran–Mantel–Haenszel test stratified by TNF inhibitor use (yes/no), screening hsCRP concentration (<10 mg/L vs ≥10 mg/L), and csDMARD use at baseline (yes/no) was used to compare response rates.

SPIRIT H2H Study: Key Outcomes at Week 24 and 52 (NRI)

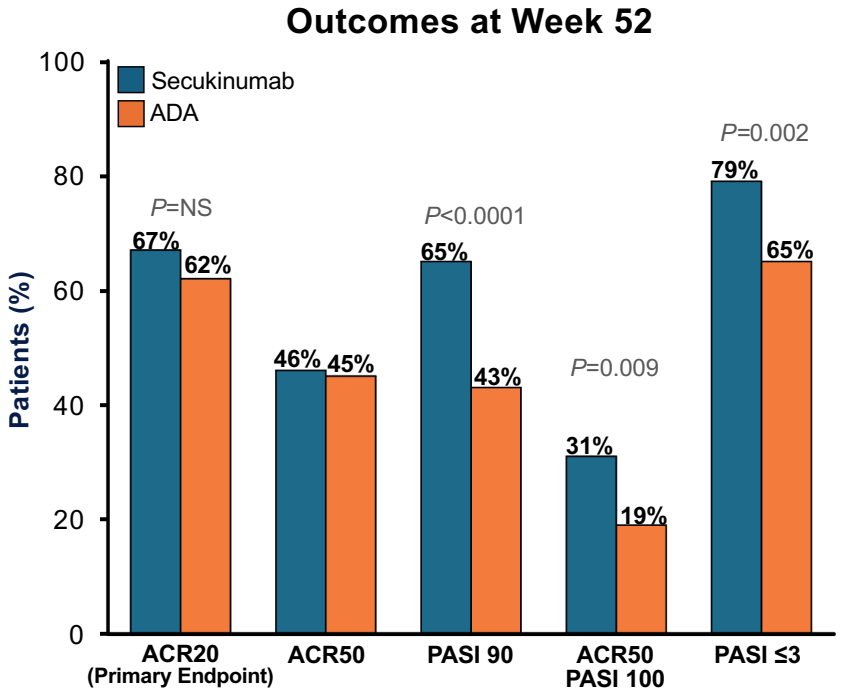




Mease PJ, et al. *Ann Rheum Dis*. 2020;79:123-131. Smollen JS, et al. *Ann Rheum Dis*. 2020;79:1310-1319.

EXCEED Trial: Key Outcomes at Week 52

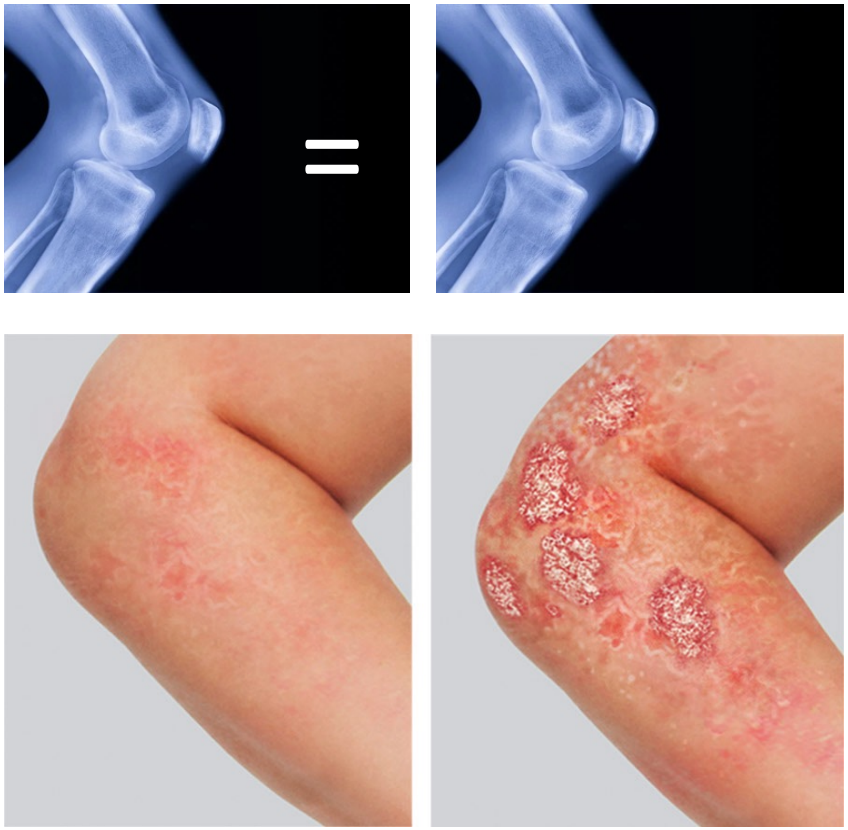
- Primary endpoint (ACR20)
  - Superiority of secukinumab was not established
- Secukinumab showed higher skin responses versus adalimumab
  - PASI 75/90/100 (*P*<0.001)
  - Combined ACR50 + PASI 100 (*P*=0.002)
- Similar outcomes in both groups
  - Improvements in HAQ-DI scores
  - Proportion achieving enthesitis resolution



Secukinumab (n=426 for ACR20/50; n=215 for PASI outcomes). ADA (n=427 for ACR20/50; n=202 for PASI outcomes).
HAQ-DI = Health Assessment Questionnaire-Disability Index.
McInnes IB, et al. *Lancet.* 2020;395:1496-1505. Courtesy JF Merola. Do not reproduce.

Summary: Prior Head-to-Head Trials in PsA

- Minimal H2H data in PsA
- IL17 vs TNF inhibitors
  - SPIRIT H2H
    - Primary endpoint composite: ACR50+PASI100
    - Take home
      - Endpoints as good as "gold standard" anti-TNF in joints (ACR)
      - Better skin efficacy (PASI)
  - EXCEED
    - See above



Mease PJ, et al. *Ann Rheum Dis*. 2020;79:123-131. Smollen JS, et al. *Ann Rheum Dis*. 2020;79:1310-1319. McInnes IB, et al. *Lancet*. 2020;395:1496-1505. Courtesy JF Merola. Do not reproduce.

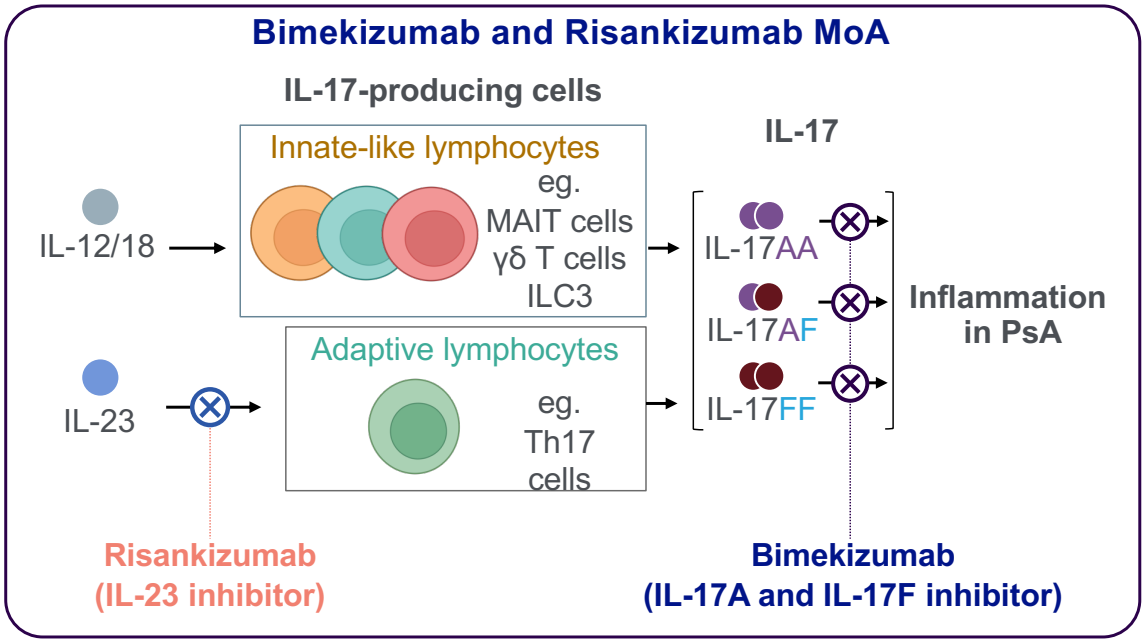
Bimekizumab Efficacy & Safety vs Risankizumab in Patients with Active PsA: 16-Week Results from a Head-to-Head, Multicenter, Randomized, Phase 3b Study (BE BOLD)

With 24-Week Results

McInnes IB, et al. Presented at: EULAR 2026; June 3-6, 2026; London, UK. LB0001

Background

- Bimekizumab (BKZ), a selective inhibitor of interleukin (IL)-17A and IL-17F from IL-23-dependent and -independent sources, and risankizumab (RZB), an IL-23 inhibitor, are both approved treatments that have demonstrated efficacy and tolerability in psoriatic arthritis (PsA)
- **BE BOLD is the first head-to-head (H2H) study comparing an IL-17A and IL-17F inhibitor with an IL-23 inhibitor in patients with PsA.**



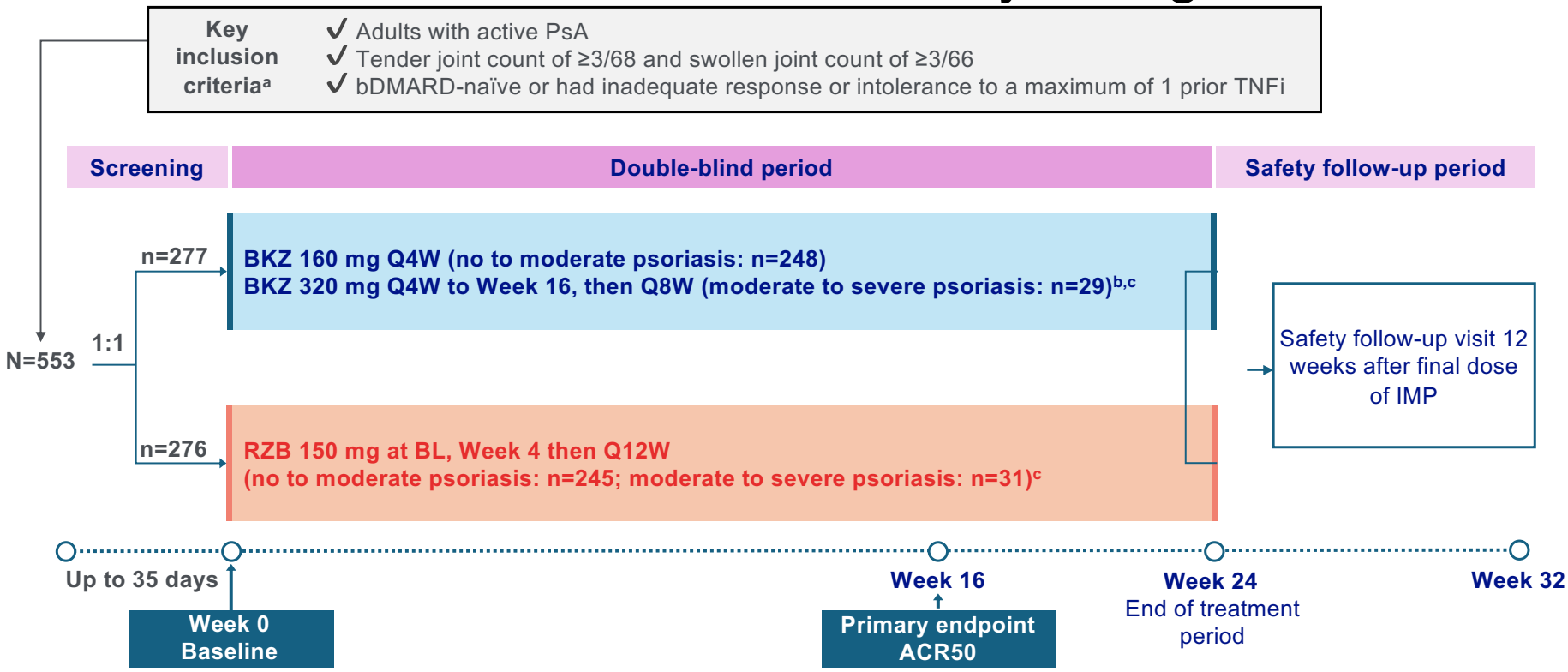
OBJECTIVE: To directly compare the efficacy and safety of BKZ and RZB at approved doses in patients with active PsA to 24 weeks, utilising the joint-focused primary endpoint of ACR50.

The abstract reported data to Week 16 but data to Week 24 have become available since abstract submission and are presented here.

ILC3 = group 3 innate lymphoid cells; MAIT = mucosal-associated invariant T; MoA = mechanism of action

Gossec L. *Rheumatology (Oxford).* 2026:keag118. Kristensen LE, et al. *Rheumatol Ther* 2024;11(13):617-632. Östör A, et al. *Rheumatol Ther.* 2024;11:633-648. Tsukazaki H, Kaito T. *Int J Mol Sci.* 2020;21:6401. Cole S, et al. *Front Immunol.* 2020;11:585134. Łukasik Z, et al. *Rheumatology (Oxford)* 2021;60(Suppl 4):iv16–27. Wang EA,et al. *Eur J Rheumatol.* 2017;4:272-277. Pang Y, et al. *Clin Transl Sci.* 2024;17:e13706. Glatt S, et al. *Ann Rheum Dis.* 2018;77(4):523-532.

Methods: BE BOLD Study Design

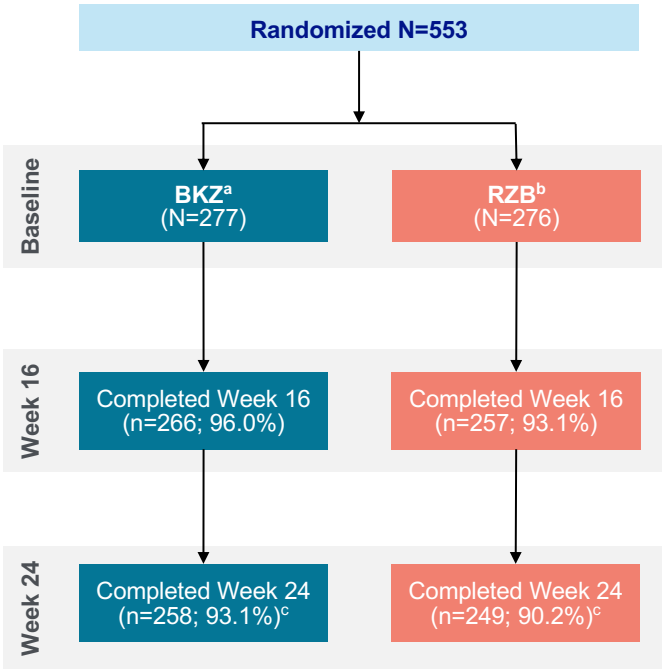


[a]Eligible patients had active PsA according to the CASPAR criteria, ≥1 active psoriatic lesion and/or history of chronic plaque-type psoriasis; concomitant stable doses of csDMARDs were permitted; [b]This is the approved dose for BKZ in patients with moderate to severe PsO; [c]Moderate to severe PsO defined as baseline BSA ≥10%, IGA ≥3 and PASI ≥12.

IGA = Investigator's Global Assessment; IMP = investigational medicinal product.

McInnes IB, et al. Presented at: EULAR 2026; June 3-6, 2026; London, UK. LB0001

Patient Disposition and Baseline Characteristics



	BKZ[a] (N=277)	RZB[b] (N=276)
Age, years, mean (SD)	51.1 (13.6)	50.7 (12.7)
Sex, male, n (%)	141 (50.9)	142 (51.4)
BMI, kg/m^2, mean (SD)	29.1 (6.1)	29.2 (6.4)
Time since first diagnosis of PsA, years, mean (SD)	6.5 (7.3)	6.0 (6.9)
Prior TNFi, n (%)	55 (19.9)	58 (21.0)
Any csDMARDs at baseline, n (%)[d]	191 (69.0)	195 (70.7)
Concomitant methotrexate, n (%)[e]	166 (59.9)	165 (59.8)
TJC (of 68 joints), mean (SD)	17.3 (12.7)	16.6 (12.2)
SJC (of 66 joints), mean (SD)	10.1 (7.4)	9.5 (6.8)
Moderate to severe psoriasis, n (%)[f]	29 (10.5)	31 (11.2)
Psoriasis BSA, n (%)		
<3%	101 (36.5)	100 (36.2)
≥3 to ≤10%	113 (40.8)	108 (39.1)
>10%	63 (22.7)	68 (24.6)
PASI, mean (SD)[g]	8.9 (7.5)	8.2 (7.1)
Enthesitis, LEI >0, n (%)	130 (46.9)[h]	133 (48.2)[h]
Dactylitis, LDI >0, n (%)	44 (15.9)[h]	41 (14.9)[h]
hs-CRP ≥6 mg/L, n (%)	84 (30.3)	83 (30.1)
PtGA-PsA, mean (SD)	59.8 (21.0)	58.5 (20.3)

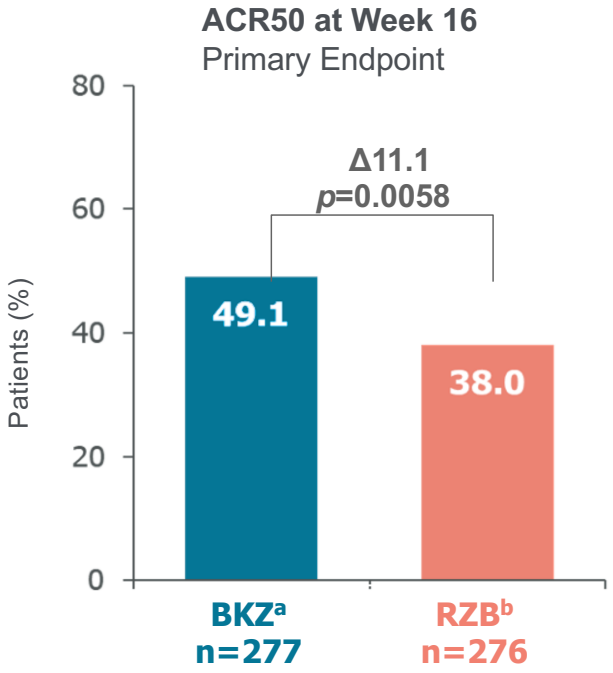
Randomized set. [a]BKZ 160 mg Q4W and BKZ 320 mg Q4W/Q8W; [b]RZB 150 mg at baseline, Week 4 and Week 16; [c]3 (1.1%) BKZ pts and 2 (0.7%) RZB pts completed the double-blind treatment period not on randomized treatment; [d]Includes methotrexate, sulfasalazine and leflunomide; [e]Based on safety set (n=275 for RZB); [f]Moderate to severe PsO defined as BSA ≥10%, IGA ≥3 and PASI ≥12; [g]In pts with baseline PsO ≥3% BSA: BKZ Total n=176 (BKZ 160 mg Q4W n=147; BKZ 320 mg Q4W/Q8W n=29); RZB n=176; [h]Data missing for 1 pt.

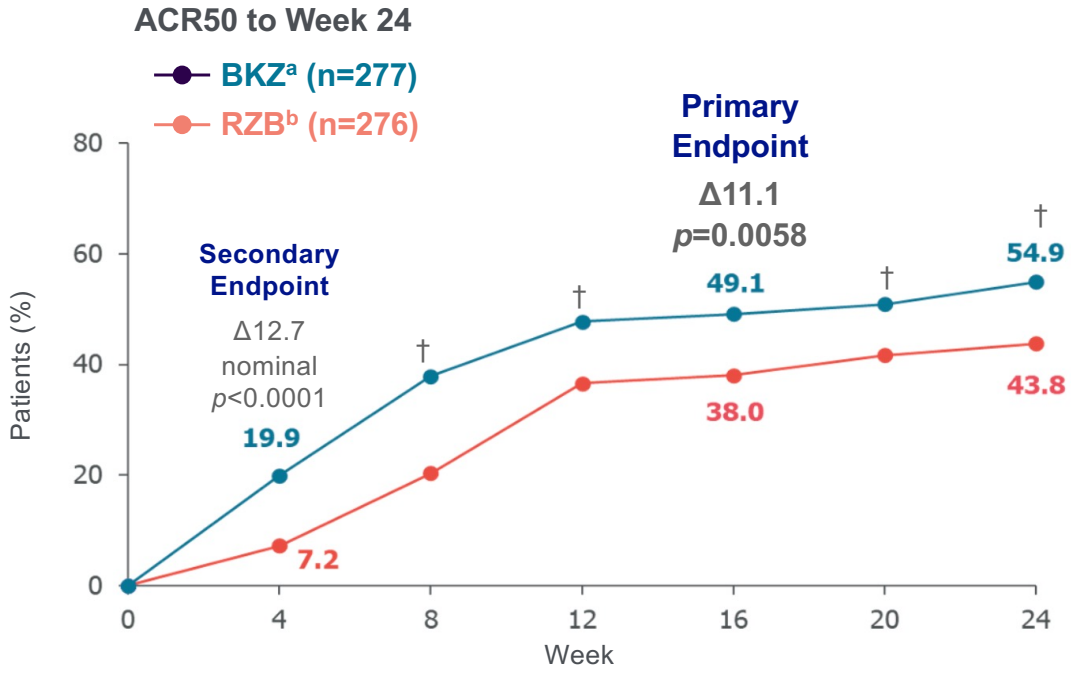
BMI = body mass index; hs-CRP = high-sensitivity C-reactive protein; LDI = Leeds Dactylitis Index; LEI = Leeds Enthesitis Index; PtGA-PsA: Patient's Global Assessment for PsA; SD = standard deviation; SJC = swollen joint count.

McInnes IB, et al. Presented at: EULAR 2026; June 3-6, 2026; London, UK. LB0001

Primary Endpoint: ACR50 at Wk 16 and over Time to Wk 24 (NRI)

- BKZ demonstrated superior efficacy in joints, with more patients achieving ACR50 than RZB across all timepoints to Week 24





Randomzed set. ACR50 at Week 4 was a multiplicity-controlled endpoint; [a]BKZ 160 mg Q4W and BKZ 320 mg Q4W/Q8W; [b]RZB 150 mg at baseline, Week 4 and Week 16; †Pre-specified *p* values and differences between BKZ and RZB results are displayed for comparisons in the statistical testing hierarchy only. For endpoints outside the testing hierarchy, nominal *p* values for BKZ vs RZB were $p<0.0001$ at Week 8, $p=0.0055$ at Week 12, $p=0.0179$ at Week 20 and $p=0.0059$ at Week 24.

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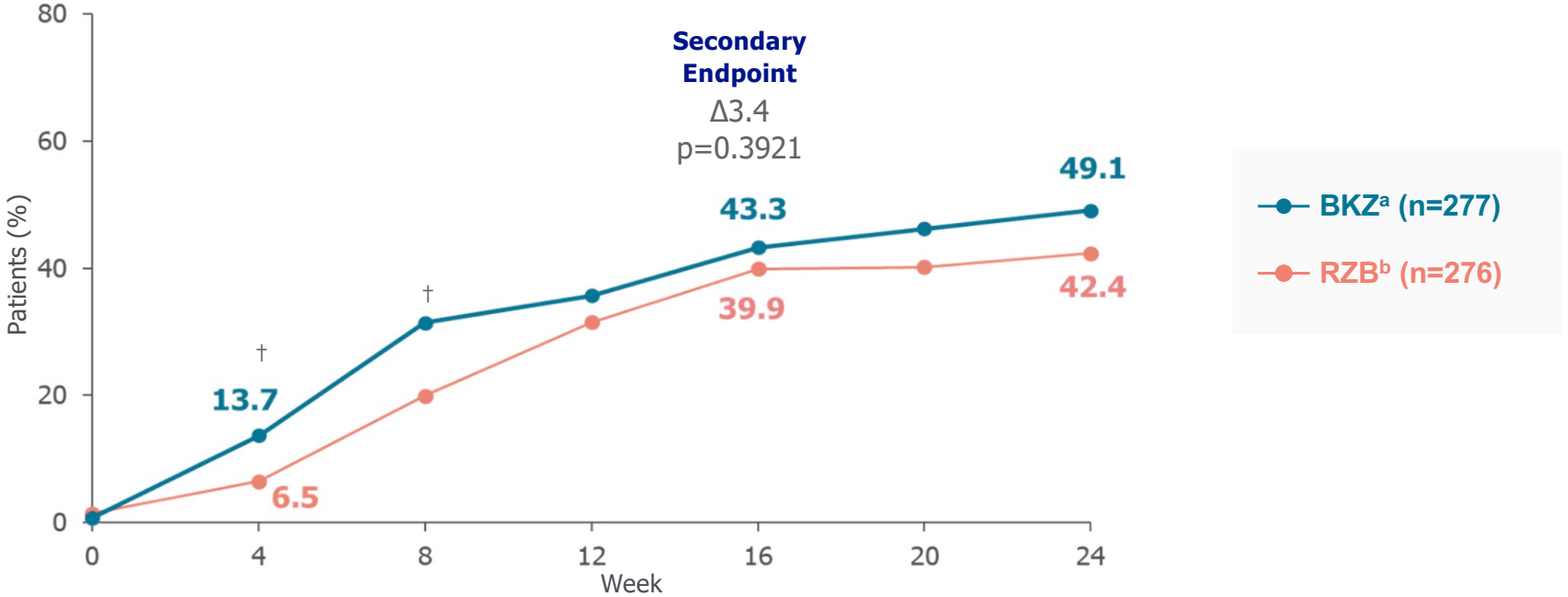
MDA over Time to Week 24 (NRI)

- Significance for the secondary endpoint of MDA response at Week 16 was not met; MDA was numerically higher for BKZ- vs RZB-treated patients at all timepoints to Week 24



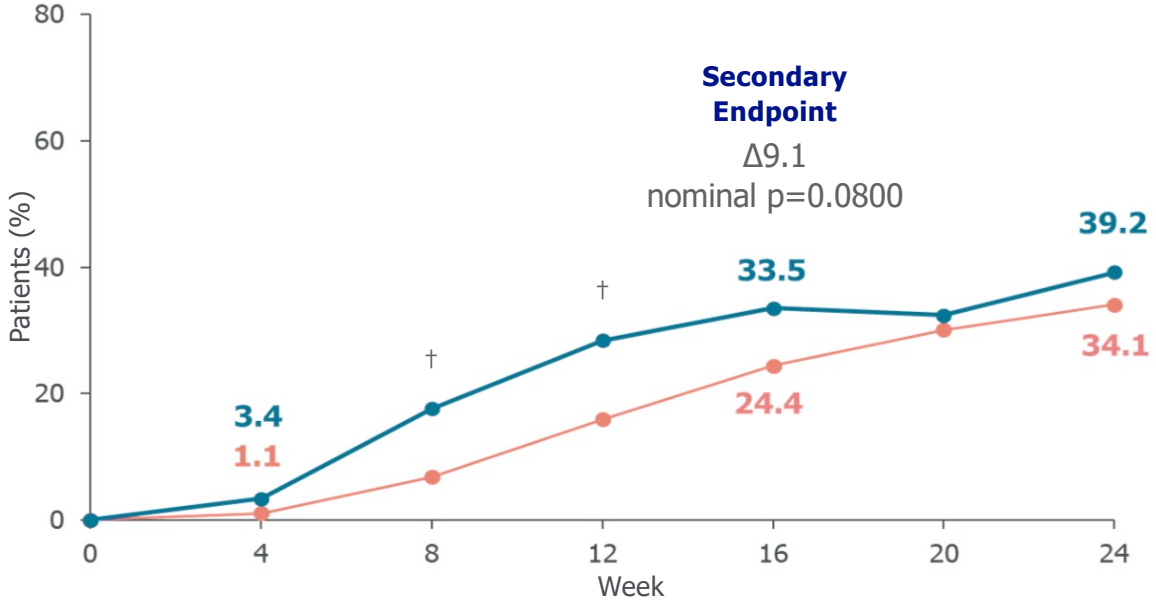
Randomzed set. MDA at Week 16 was a secondary endpoint. [a]BKZ 160 mg Q4W and BKZ 320 mg Q4W/Q8W; [b]RZB 150 mg at baseline, Week 4 and Week 16; †Pre-specified *p* values and differences between BKZ and RZB results are displayed for comparisons in the statistical testing hierarchy only. For endpoints outside the testing hierarchy, nominal *p* values for BKZ vs RZB were *p*=0.0035 at Week 4 and *p*=0.0015 at Week 8.

McInnes IB, et al. Presented at: EULAR 2026; June 3-6, 2026; London, UK. LB0001

ACR50+PASI100 over Time to Week 24 (NRI)

In patients with ≥3% BSA at baseline

- ACR50+PASI100 response was numerically higher for BKZ- vs RZB-treated patients at all timepoints to Week 24; most BKZ patients had mild to moderate psoriasis and received BKZ 160mg Q4W



BKZ (n=176)

- **Mild to moderate psoriasis**: BKZ 160 mg Q4W, n=147 (**83.5%**)
- **Moderate to severe psoriasis**: BKZ 320 mg Q4W/Q8W, n=29 (16.5%)[a]

RZB[b] (n=176)

Randomized set. ACR50+PASI100 at Week 16 was a secondary endpoint; [a]This is the approved dose for BKZ in patients with moderate to severe psoriasis; moderate to severe psoriasis defined as BSA ≥10%, IGA ≥3 and PASI ≥12; [b]RZB 150 mg at baseline, Week 4 and Week 16. †Pre-specified *p* values and differences between BKZ and RZB results are displayed for comparisons in the statistical testing hierarchy only. For endpoints outside the testing hierarchy, nominal *p* values for BKZ vs RZB were *p*=0.0022 at Week 8 and *p*=0.0038 at Week 12.

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Safety to Week 24

- Treatment arms not disclosed for all safety topics of interest to preserve blinding of the ongoing study; safety was comparable between treatment arms and no new safety signals were identified

Safety Overview

	BKZ N=277	RZB N=275
Total time at-risk, PY	161.7	158.1
Any TEAE, n (%)	161 (58.1)	152 (55.3)
Serious TEAEs, n (%)	5 (1.8)	9 (3.3)
Severe TEAEs, n (%)	5 (1.8)	5 (1.8)
Discontinuations due to TEAEs, n (%)	4 (1.4)	3 (1.1)

- One death occurred, deemed unrelated to treatment by the Investigator, with a reported cause of myocardial infarction in a patient with coronary artery disease, hypertension, and hyperlipidaemia

Safety Topics of Interest[a]

- Cases of serious infection, IBD (1), malignancy, neutropenia, hypersensitivity, hepatic events and cardiovascular events were **low across both treatment arms**
- ***Candida* infections** were more frequent in BKZ-treated patients
  - **All were mild or moderate**
  - None were serious, systemic or led to study discontinuation
- There were **no cases** of **suicidal ideation and behaviour**, **anaphylaxis** or **active tuberculosis**

Safety set. Safety is reported for all data available up to the cut-off date of 20 April 2026; some but not all safety follow-up data are available and included. TEAEs were classified using the Medical Dictionary for Regulatory Activities v27.0. [a]Treatment arm has not been disclosed to preserve blinding of the ongoing study.
TEAE = treatment-emergent adverse event.
McInnes IB, et al. Presented at: EULAR 2026; June 3-6, 2026; London, UK. LB0001

Conclusions

- Dual inhibition of IL-17A and IL-17F with BKZ was **superior for the primary endpoint of ACR50 at Week 16** vs IL-23 inhibition with RZB, in patients with active PsA
- **A numerically higher proportion of BKZ-treated patients achieved secondary outcomes** encompassing **joint, skin** and **overall disease activity vs RZB-treated patients** over **24 weeks**

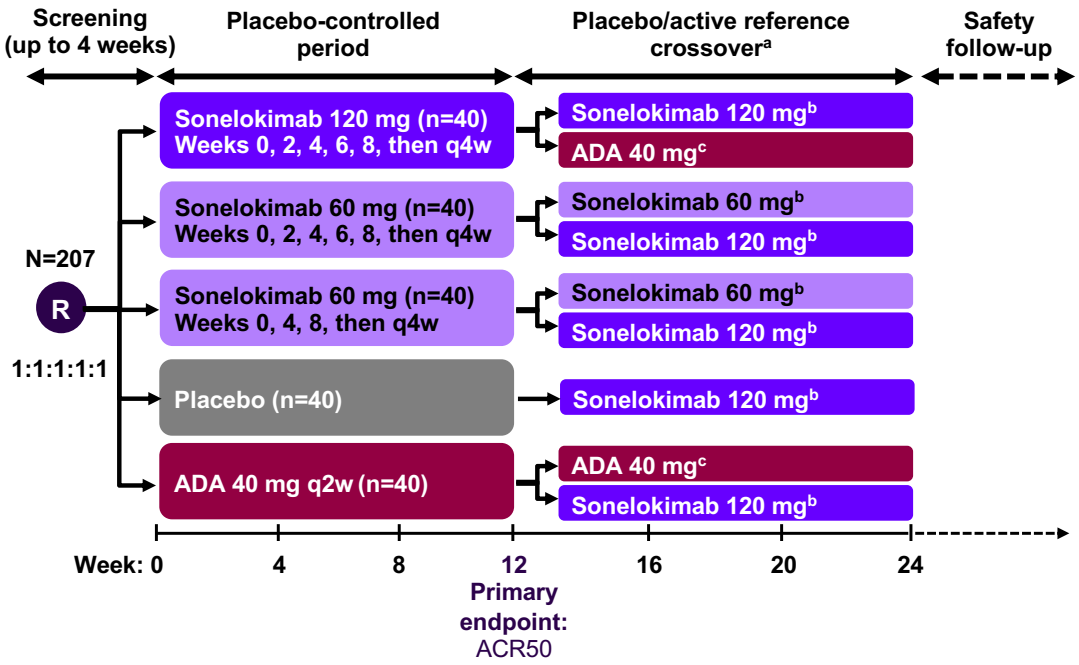
- **Overall safety profiles were comparable between treatments**, except for *Candida* infections which were more frequent for BKZ, as anticipated by the mechanism of action
- Full safety data will be presented following the database lock

- This is the first H2H study in PsA to demonstrate superiority for a joint-focused primary endpoint
- These findings may help **guide treatment decisions** and **inform clinical recommendations** for the **management of PsA**

McInnes IB, et al. Presented at: EULAR 2026; June 3-6, 2026; London, UK. LB0001

Emerging and Hot Topics

ARGO: Efficacy and Safety of Subcutaneous Sonelokimab, an IL17A/F Nanobody, for Patients with PsA



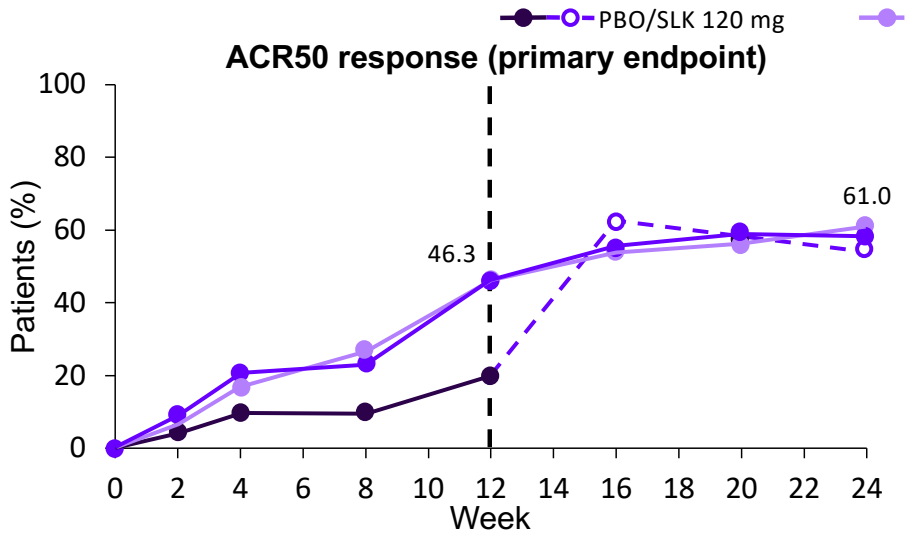
Key secondary endpoint
- PASI90 at Weeks 12 and 24

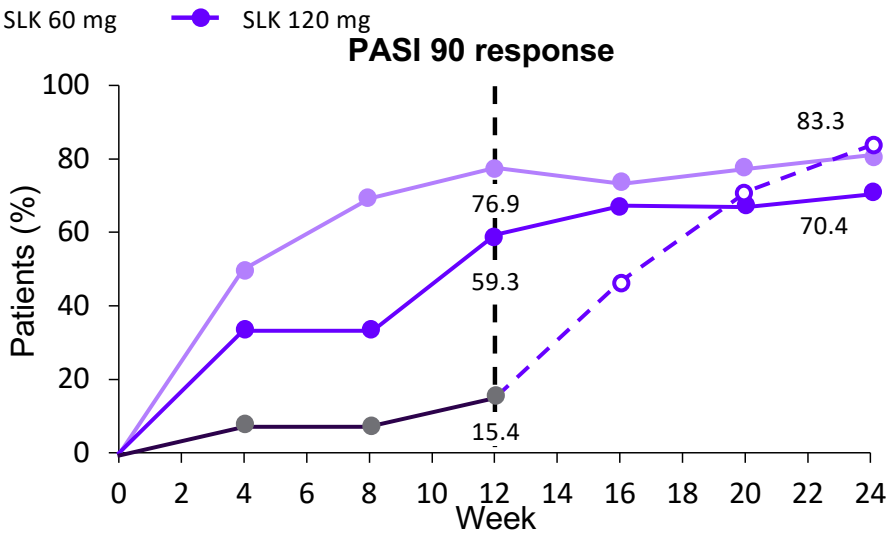
Some crossover arms not analyzed separately due to small samples
- eg, 5-7 patients per arm

[a]Participants on sonelokimab 120 mg who did not achieve an adequate response starting at Week 12 in crossover period switched to adalimumab 40 mg Q2W until Week 24; participants on sonelokimab 60 mg (started at baseline Q2W or Q4W) who did not achieve an adequate response switched to sonelokimab 120 mg Q4W until week 24; participants on adalimumab who did not achieve an adequate response switched to sonelokimab 120 mg Q4W until Week 24. [b]q4w; [c]q2w.

McInnes I ... Merola JF, et al. *Arthritis Rheumatol*. 2024;76 (suppl 9). Courtesy JF Merola. Do not reproduce.

ARGO: ACR50 and PASI 90 Responses with Sonelokimab among Patients with PsA

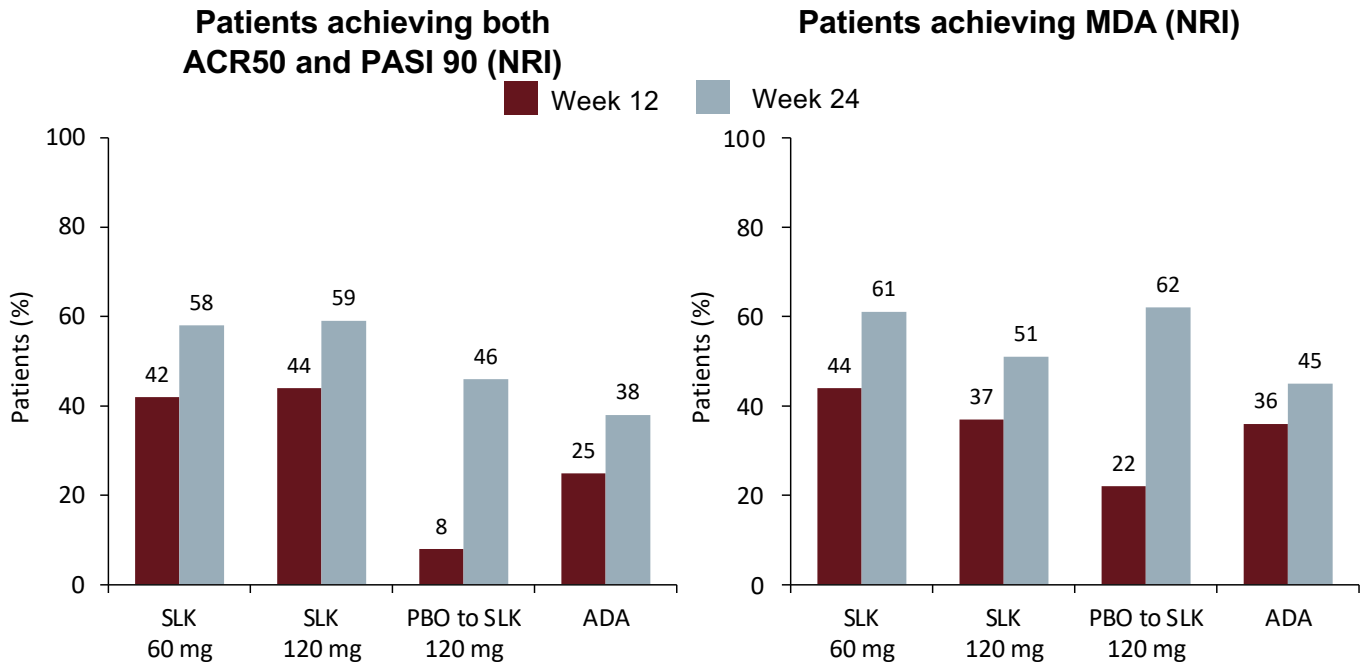




- Joint improvement to Week 24
  - Approximately 60% of patients reached ACR50 after SLK 60 mg or SLK 120 mg treatment
- Skin outcome improvement to Week 24
  - >70% of patients achieved PASI 90 after SLK 60 mg or SLK 120 mg treatment

SLK = sonelokimab.
McInnes I ... Merola JF, et al. *Arthritis Rheumatol*. 2024;76 (suppl 9). Courtesy JF Merola. Do not reproduce.

ARGO: Composite Outcomes with Sonelokimab among Patients with PsA



- Approximately 60% of patients achieved composite joint and skin outcomes with 24-week SLK treatment
- Over 50% of patients reached MDA across all SLK arms

McInnes IB ... Merola JF, et al. *Ann Rheum Dis.* 2024;83(Suppl 1):154-155. Courtesy JF Merola. Do not reproduce.

Tildrakizumab (IL-23p19) in Active PsA: INSPIRE-1 & INSPIRE-2 Phase 3 Results

Primary Endpoint (Week 24)

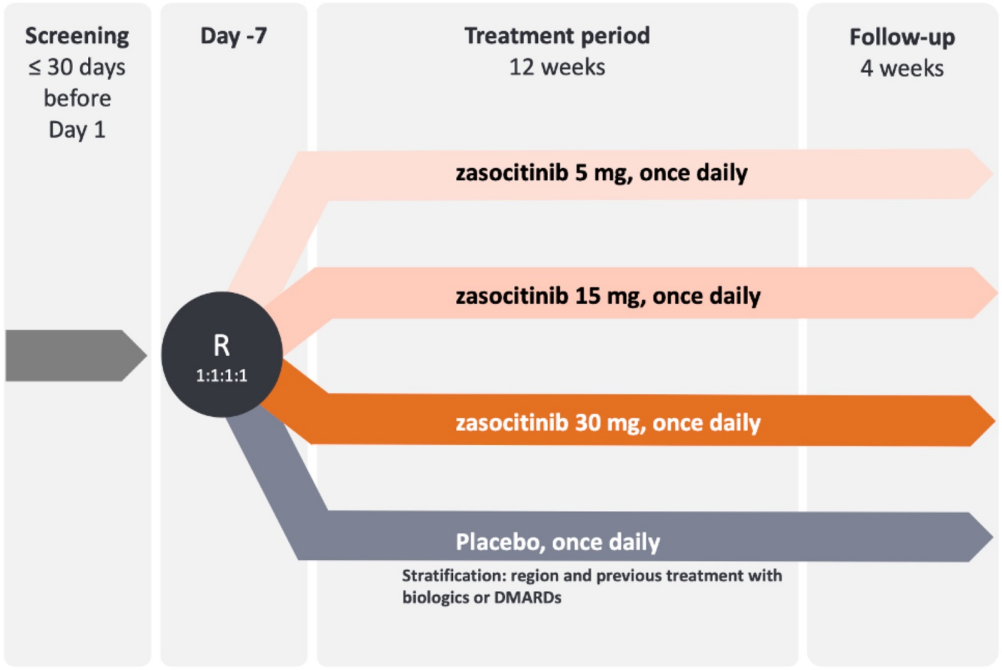
- Significantly greater **ACR20** response vs placebo in both trials
- Both INSPIRE-1 and INSPIRE-2 met primary endpoint

- **Study design**
  - Phase 3, randomized, double-blind, placebo-controlled
  - 52-week global multicenter trials
  - INSPIRE-1: Prior anti-TNF exposure
  - INSPIRE-2: TNF-naïve population
  - Dose: 100 mg at Week 0, then every 12 weeks

- **Secondary & aafety**
  - Secondary endpoints included ACR50, ACR70, PASI75
  - Safety profile consistent with prior psoriasis data
  - No new safety signals reported

Mease PJ, et al. Presented at: ACR Convergence 2025; October 24-29, 2025; Chicago, IL. Bosslett M. *Dermatology Times.* July 22, 2025. Accessed July 10, 2026. https://www.dermatologytimes.com/view/sun-pharma-announces-positive-phase-3-results-for-tildrakizumab-in-psoriatic-arthritis. Courtesy JF Merola. Do not reproduce.

TYK2 Inhibitor: Zasocitinib (TAK-279) Phase 2b PsA Study Design



Key Eligibility Criteria

- Age ≥ 18 years
- PsA symptoms for ≥ 6 months before screening
- Met CASPAR criteria
- ≥ 3 TJC and SJC at enrollment despite prior NSAID, DMARD, or biologic treatment
- Minimum hsCRP level not required
- Patients with diseases that confound effects of zasocitinib or those with lack of response to anti IL-12, IL-17 and/or IL-23 were excluded

Primary Endpoint:

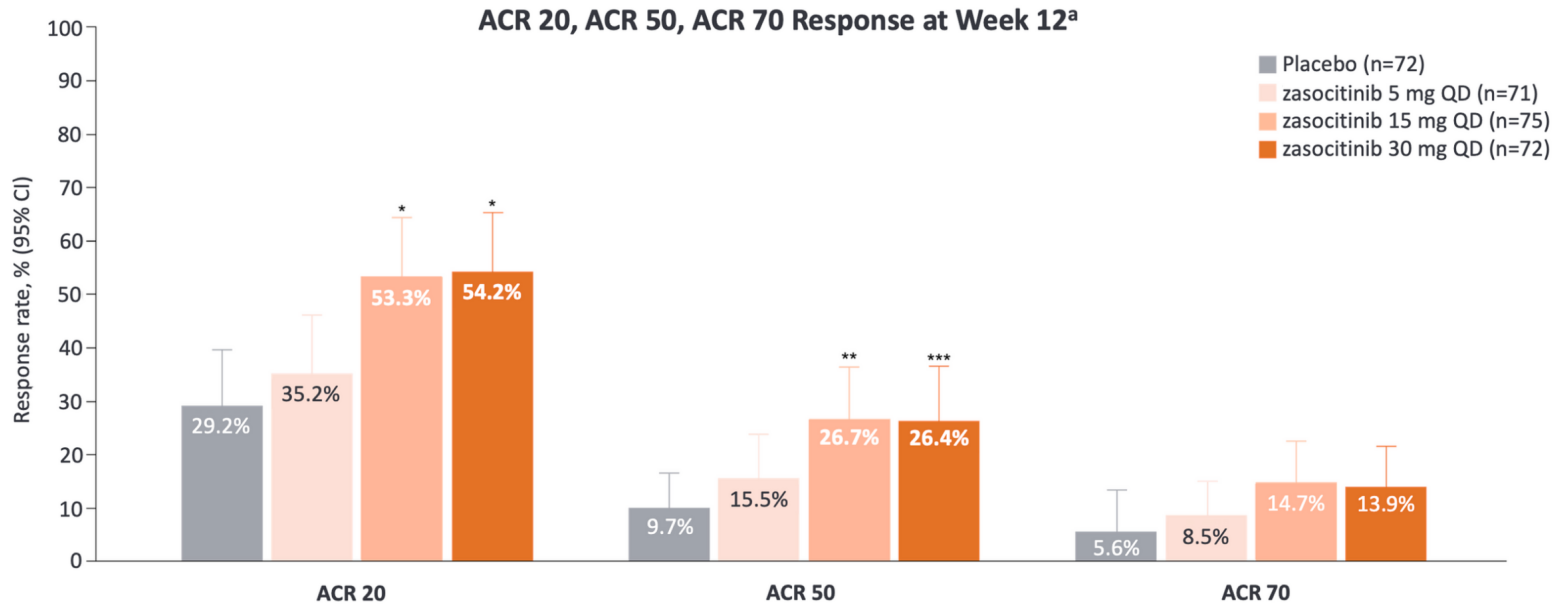
- ACR 20 response at Week 12

Selected Secondary Endpoints (at Week 12):

- ACR 50/ACR 70
- TJC/SJC changes from baseline
- PGA of psoriatic arthritis change from baseline
- MDA
- Patients with PGA of psoriasis score of 0/1 and a ≥ 2-point improvement from baseline among patients with PGA of psoriasis ≥ 2 at baseline

Kivitz A, et al. Presented at: 2023 ACR Annual Meeting; November 14, 2023; San Diego, CA. L12.

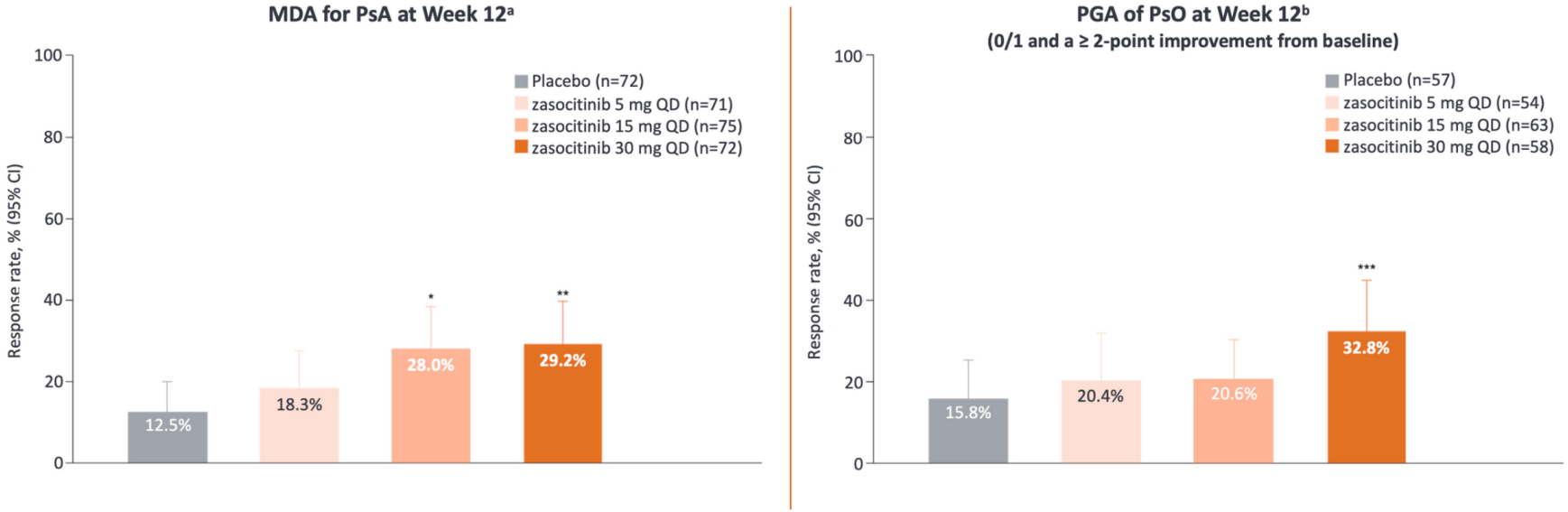
Primary and Secondary Endpoints: Patients Achieving ACR 20, ACR 50, or ACR 70 at Week 12



[a]**ACR20/50/70 are composite measures defined as both improvement of 20%/50%/70% in the number of tender and swollen joints, and a 20%/50%/70% improvement in three of the following criteria: PGA of disease activity, PGA of psoriatic arthritis pain, PGA of psoriatic arthritis, HAQ–DI, and hs-CRP. ACR20 and ACR50: *P*=0.002, P=0.005, *P*=0.009 vs placebo. *P* values for secondary endpoints (ACR50, ACR70, Physician's Global Assessment of PsA, MDA, PASI75, Physician's Global Assessment of PsO) are nominal.**

Kivitz A, et al. Presented at: 2023 ACR Annual Meeting; November 14, 2023; San Diego, CA. L12.

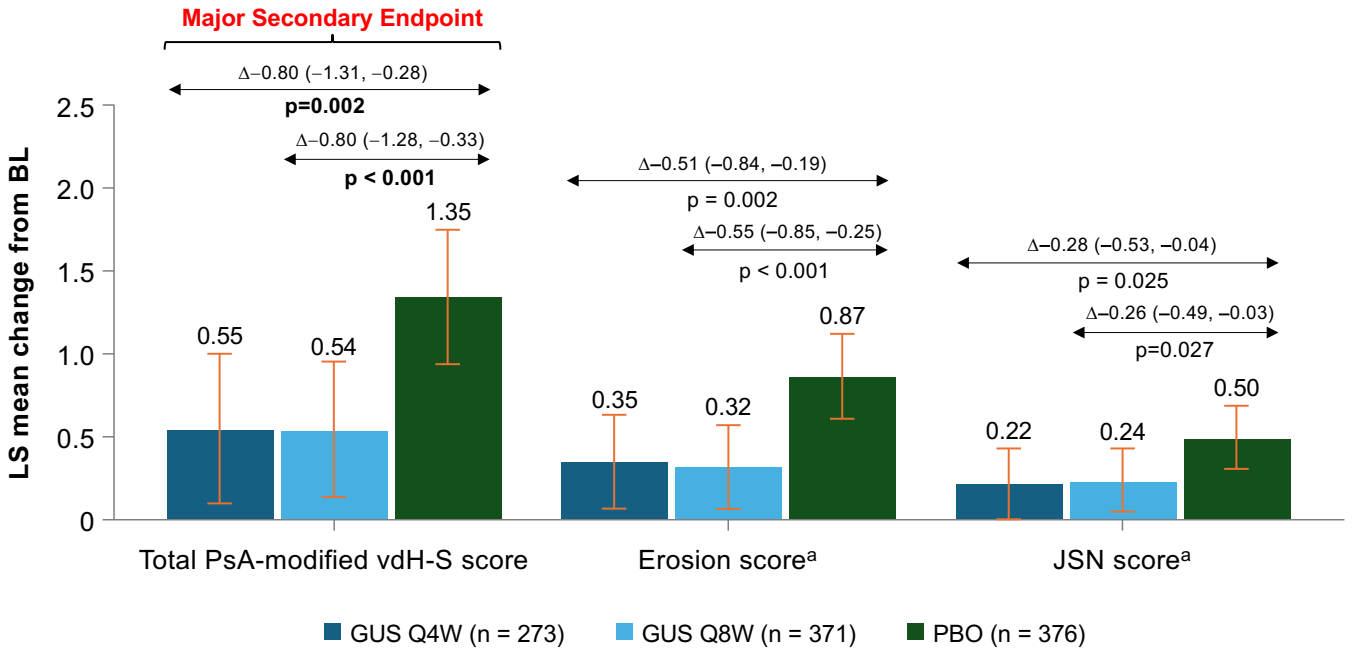
Secondary Endpoint: MDA for PsA and PGA of PsO at Week 12



[a]MDA measured as follows: The patient meets ≥5 of the seven criteria: TJC ≤1; SJC ≤1; PASI score ≤1 or BSA ≤3%; PGA of psoriatic arthritis pain, VAS score ≤15; PGA of psoriatic arthritis, VAS score ≤20; HAQ-DI score ≤0.5; tender entheseal points using the LEI ≤1; [b]In patients achieving a PGA of psoriasis of 0/1 and a ≥2-point improvement from baseline among patients with PGA of psoriasis ≥2 at baseline: Placebo, n=57; zasocitinib 5 mg, n=54; zasocitinib 15 mg, n=63; zasocitinib 30 mg, n=58. *P*=0.017, P=0.014, *P*=0.034 vs placebo. *P* values for secondary endpoints (ACR50, ACR70, Physician's Global Assessment of PsA, MDA, PASI75, Physician's Global Assessment of PsO) are nominal.

Kivitz A, et al. Presented at: 2023 ACR Annual Meeting; November 14, 2023; San Diego, CA. L12.

APEX Study: Guselkumab Exhibited Significantly Lower Rates of Radiographic Progression vs Placebo at Week 24



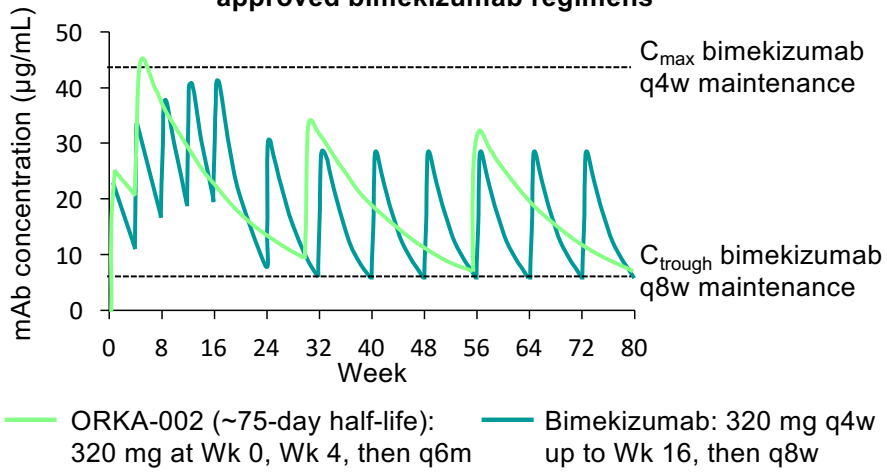
Major secondary endpoint (PsA-modified vdH-S score) *p*-values are multiplicity controlled using a fixed sequence testing procedure and can be used to determine statistical significance. Statistics are based on analysis of covariance across multiply imputed datasets. [a]Italicized *p*-values are nominal. Δ=treatment difference (95% CI).

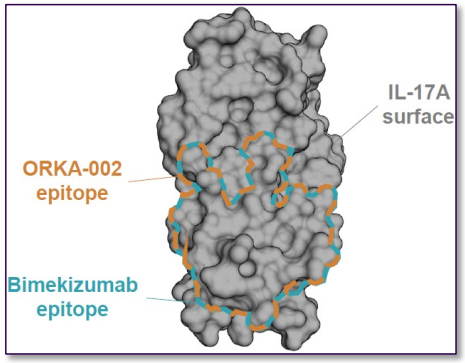
Mease PJ, et al. Presented at: EULAR 2025; June 11-14, 2025; Barcelona, ES. LB0010. Courtesy JF Merola. Do not reproduce.

Characterization of ORKA-002, a Novel Extended Half-Life Monoclonal Antibody Targeting IL-17A/F for the Treatment of PsO and Other Indications

- ORKA-002 is a novel, extended half-life, humanized monoclonal antibody that potently inhibits IL-17A/F
- ORKA-002 binds IL-17A and IL-17F at a similar epitope as BZB and with similar affinity
- ORKA-002 demonstrated a half-life of >30 days in cynomolgus monkeys, which exceeds that of BZB by >3-fold
- ORKA-002 has the potential to match BZB on potency while requiring only 2 or 3 doses per year

Projected exposure of illustrative ORKA-002 regimens vs approved bimekizumab regimens





Kwan B, et al. Presented at AAD 2025; March 7-11; Orlando FL. P64919. Courtesy JF Merola. Do not reproduce.

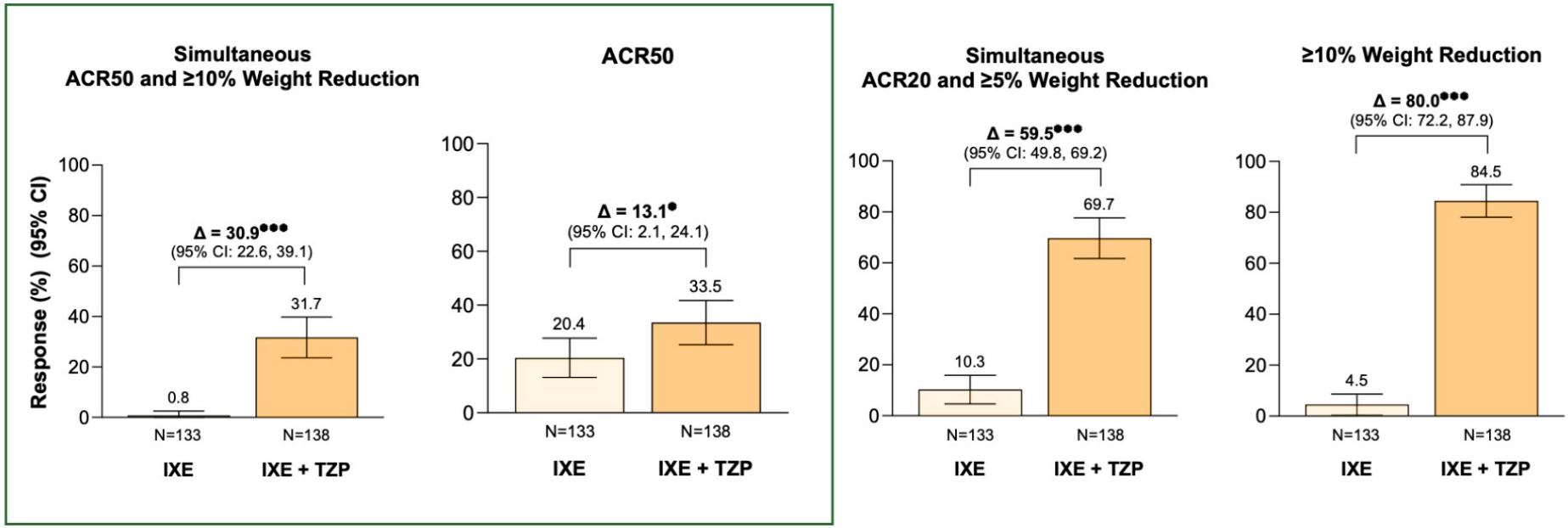
Concomitant Therapy with Ixekizumab plus Tirzepatide in Adults with Psoriatic Arthritis and Overweight or Obesity Demonstrated Superior Disease Control Compared to Ixekizumab Alone: Results from the Ph3b TOGETHER-PsA Trial

Joseph F. Merola, Philip Mease, Alan Kivitz, Naveed Sattar, Laura C Coates, Cynthia E. Kartman, Peter Fischer, Luna Sun, Anabela Cardoso, Mark C. Genovese, Alexis Ogdie

Late-Breaking Presentation AAD 2026!!

RESULTS: Multiplicity Controlled Primary and Key Secondary Outcomes at Week 36

Primary and key secondary outcomes were all statistically significant and clinically meaningful

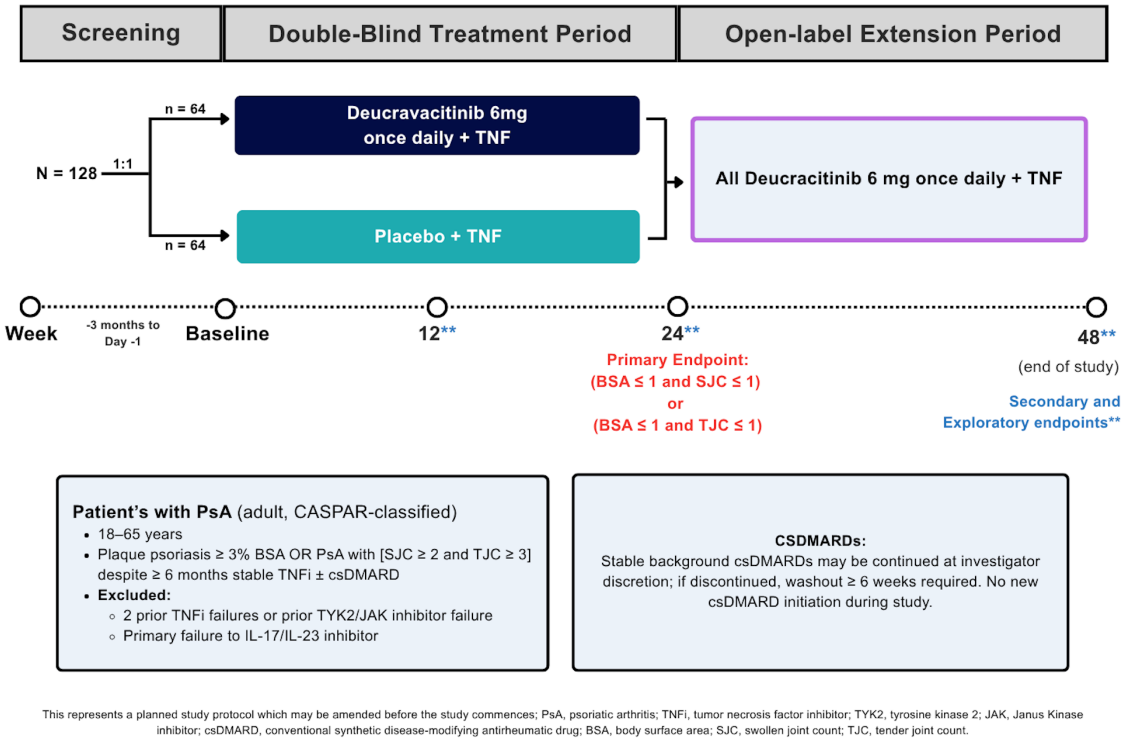


vs IXE: **p*<0.05; ****p*<0.001. Δ designates treatment difference between treatment arms. Outcomes are shown for the mITT population. Intercurrent events are use of prohibited medication or discontinuation of treatment, hypothetical estimand was used with multiple imputation. Logistic regression was used as working model to estimate unconditional risk difference.

IXE = ixekizumab; mITT = modified intent-to-treat; TZP = tirzepatide.

Merola JF, et al. *Arthritis Rheumatol*. 2026. [Online ahead of print.]

COMBo Study Design



This represents a planned study protocol which may be amended before the study commences; PsA, psoriatic arthritis; TNFi, tumor necrosis factor inhibitor; TYK2, tyrosine kinase 2; JAK, Janus Kinase inhibitor; csDMARD, conventional synthetic disease-modifying antirheumatic drug; BSA, body surface area; SJC, swollen joint count; TJC, tender joint count.

Monitoring and Safety

Joint position statement from the National Psoriasis Foundation Medical Board and the International Psoriasis Council on routine testing for latent tuberculosis infection prior to and during treatment of psoriasis patients with interleukin 17 or interleukin 23 inhibitors

Andrew Blauvelt, MD, MBA,[a] Bruce E. Strober, MD, PhD,[b] Guy S. Eakin, PhD,[c] Leah McCormick Howard, JD,[c] Christy Langan, BS,[d] Peter C. M. van de Kerkhof, MD, PhD,[d,e] Lluís Puig, MD, PhD,[f] Mark G. Lebwohl, MD,[g] Ricardo Romiti, MD,[h] April W. Armstrong, MD, MPH,[i] Siew Eng Choon, MD,[j] Ravi Ramessur, MD,[k] Joel M. Gelfand, MD, MSCE,[l] Joseph F. Merola, MD, MMSc,[i] Kevin L. Winthrop, MD,[m] and Tiago Torres, MD, PhD[n]

Background: Although testing for latent tuberculosis (TB) infection has been standard practice for psoriasis patients being treated with interleukin (IL) 17 or IL-23 inhibitors, evidence for this practice is weak.

Objectives: To review evidence on safety of IL-17 and IL-23 inhibitors in the setting of latent TB infection and to provide a new Joint Position Statement on this topic.

Methods: Experts from the National Psoriasis Foundation and the International Psoriasis Council reviewed evidence regarding progression of latent TB infection to active disease in psoriasis patients receiving IL-17 or IL-23 blockers. A Joint Position Statement was formulated and approved to provide updated guidance to clinicians.

Results: 87.5% of the members from the National Psoriasis Foundation Medical Board and International Psoriasis Council approved a new Joint Position Statement regarding psoriasis patients being treated with IL-17 or IL-23 inhibitors, stating that testing for latent TB infection is not required.

Limitations: This position statement allows for exceptions where continued testing for late nt TB infection could be considered, including for patients on concomitant immunosuppressive therapy and for those living in TB endemic areas.

… "psoriasis patients being treated with IL17 or IL23 inhibitors… testing for latent TB infection is NOT required"

Table I. FAERS reports of extra-pulmonary internal organ TB in patients with psoriasis treated with IL-17, IL-23, or TNF inhibitors in the United States

Exposure	Total no. of adverse event reports (any cause)	No. of extra-pulmonary internal organ TB reports
IL-17 inhibitors		
Secukinumab	43,725	0
Ixekizumab	12,078	0
Brodalumab	1913	0
Bimekizumab	286	0
IL-23 inhibitors		
Guselkumab	7630	0
Tildrakizumab	513	0
Risankizumab	30,206	0
TNF inhibitors		
Etanercept	67,566	7
Infliximab	1765	4
Adalimumab	66,359	15
Certolizumab	4135	0

FAERS = FDA Adverse Event Reporting System.

Blauvelt A ... Merola JF, et al. *J Am Acad Dermatol*. 2026;94(3):802-809. Courtesy JF Merola. Do not reproduce.

Cases

Patient Case Study 1: Joint-Dominant PsA with Minimal Skin Involvement

- A 42-year-old woman presents with 8 months of progressive joint pain, morning stiffness lasting more than 60 minutes, and swelling involving the right wrist, several MCP and PIP joints, and the left ankle. She reports intermittent heel pain and difficulty walking in the morning. Skin examination reveals only subtle erythematous scaling behind the ears and mild nail pitting, which she had not previously considered significant. She has no known diagnosis of psoriasis, but her father has a history of plaque psoriasis
- Laboratory evaluation shows elevated CRP, negative rheumatoid factor, and negative anti-CCP antibodies. Radiographs demonstrate early erosive changes in the hands, and ultrasound confirms active synovitis and enthesitis. The overall presentation is consistent with joint-dominant psoriatic arthritis with minimal skin involvement

PIP = proximal inter-phalangeal; MCP = metacarpophalangeal; CCP = cyclic citrullinated peptide.

Patient Case Study 2: PsA with Moderate-to-Severe PsO

- A 51-year-old man with a 15-year history of plaque psoriasis presents with worsening joint pain and stiffness over the past year. He has extensive plaques involving the scalp, elbows, knees, trunk, and lower back, with an estimated body surface area involvement of 12% and significant impact on sleep and quality of life due to itch and scaling. He also reports swelling of several fingers, tenderness at the Achilles tendon insertion, and morning stiffness lasting approximately 90 minutes
- Examination reveals moderate-to-severe plaque psoriasis, nail onycholysis and pitting, dactylitis of the right second toe, tenderness at bilateral Achilles insertions, and synovitis of multiple small joints of the hands. Laboratory testing shows elevated inflammatory markers, with negative rheumatoid factor and anti-CCP antibodies. Imaging demonstrates inflammatory changes consistent with psoriatic arthritis. The overall presentation is consistent with psoriatic arthritis with moderate-to-severe psoriasis

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Thank you