Treatment Approaches in SpA Conditions: Best Practices for Selection, Intensification, and Shared Decision-Making

Robert Laugherty, JD, MBA, PA-C
Director of Rheumatology
PrismaHealth Medical Mall
Alcoa, Tennessee

Faculty Disclosures

- **Robert Laugherty** reports the following

Relationships	Manufacturer
Speakers Bureau	Amgen, BI, Lilly, UCB

- All relevant financial relationships have been mitigated
- During this lecture, faculty may mention the use of medications for Food and Drug Administration (FDA)-approved and non-FDA-approved indications

This activity is supported by an educational grant from Lilly.

CME Credit Reporting

Med Learning Group will report your CME credit directly to the Accreditation Council for Continuing Medical Education (ACCME).

To view your credits and download your transcript, create a free account at: www.cmepassport.org

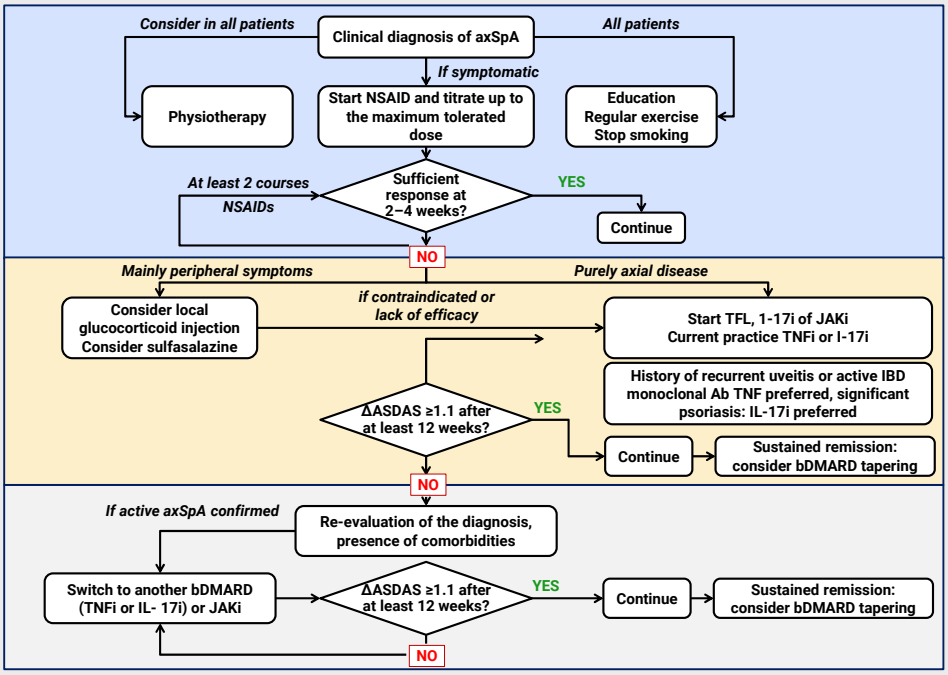
CME Passport is a secure and free platform provided by ACCME, the national accrediting authority for CME.

Learning Objectives

- Evaluate clinical data for current and emerging therapies for spondyloarthritis (SpA) conditions, including real-world and comparative data, to differentiate the benefit-risk profiles of agents across domains and sub-populations
- Describe guideline recommendations for treating patients with SpA conditions including strategies for treatment selection, modification, and intensification
- Utilize SDM and clinical considerations to individualize treatment for patients with SpA conditions

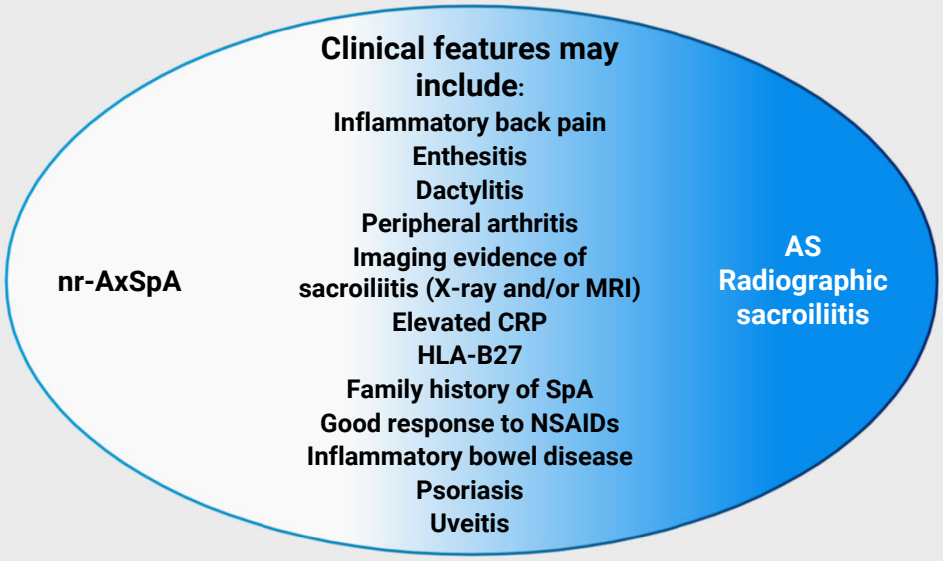
Guideline-Informed Treatment Selection and Sequencing for SpA Conditions and Treat-to-Target Recommendations for PsA

ASAS/EULAR Guidelines



Ramiro S, et al.
Ann Rheum Dis.
2023;82:19-34.

AxSpA Includes r-AxSpA (AS) and nr-AxSpA



AS = ankylosing spondylitis; axSpA = axial spondyloarthritis; CRP = C-reactive protein; HLA-B27 = human leukocyte antigen B27; MRI = magnetic resonance imaging; nr-axSpA = non-radiographic axSpA; NSAID = nonsteroidal anti-inflammatory drug; r-axSpA = radiographic axSpA; SpA = spondyloarthritis.

Magrey MN, et al. *Mayo Clin Proc*. 2020;95:2499-2508.

Modified New York Classification Criteria for AxSpA

1. Low back pain ≥ 3 months
   - Improved with exercise
   - Not relieved by rest
2. Limited lumbar motion
3. Reduced chest expansion

Definite AS equals:

≥ 1 criteria

+

4. Bilateral grade > 2 sacroiliitis on X-ray
5. Unilateral grade 3 or 4 sacroiliitis on X-ray

4. or 5.

AS = ankylosing spondylitis; axSpA = axial spondyloarthritis.

van der Linden S, et al. *Arthritis Rheum*. 1984;27:361-368. Goie The HS, et al. *Br J Rheumatol*. 1985;24:242-249.

ASAS/EULAR Guidelines

Rheumatologist's diagnosis of axial SpA

and

Elevated CRP or positive MRI-SIJ or radiographic sacroiliitis*

and

Failure of standard treatment

All patients
≥2 NSAIDs over 4 weeks (in total)

Patients with predominant peripheral manifestations
One local steroid injection if appropriate
Normally a therapeutic trial of sulfasalazine

and

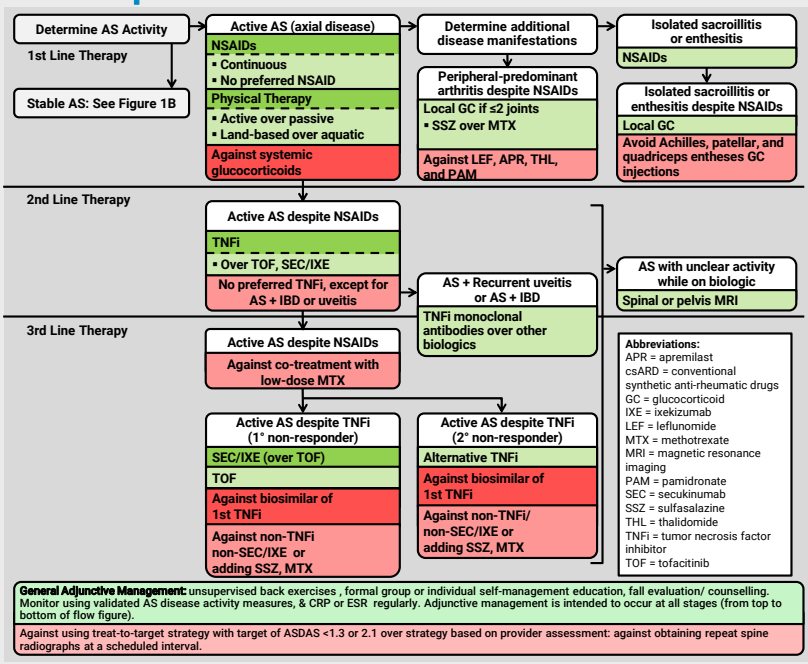
High disease activity: ASDAS ≥ 2.1

and

Positive rheumatologist's opinion

Ramiro S, et al. *Ann Rheum Dis*. 2023;82:19-34.

ACR/Spartan/SAA Guidelines



Ward MM, et al. *Arthritis Rheumatol*. 2019:71:1599-1613.

CASPAR Criteria

A patient must have inflammatory articular disease (joint, spine, or entheseal) and ≥ 3 points from the following categories:

Category	Description	Points
Evidence of current psoriasis or personal or family history of psoriasis	Current psoriasis: Psoriatic skin or scalp disease present today as judged by a rheumatologist or dermatologist Personal history: A history of psoriasis that may be obtained from a patient, family physician, dermatologist, rheumatologist, or other qualified healthcare provider Family history: A history of psoriasis in a first- or second-degree relative according to patient report	2 (current) or 1 (history)
Psoriatic nail dystrophy on current examination	Includes onycholysis, pitting, and hyperkeratosis observed on current physical examination	1
Negative rheumatoid factor	A negative test result for the presence of rheumatoid factor by any method except latex but preferably by enzyme-linked immunosorbent assay or nephelometry, according to the local laboratory reference range	1
Dactylitis (current or on history as recorded by rheumatologist)	Defined as swelling of an entire digit	1
Radiographic evidence of juxta-articular new bone formation	Appearing as ill-defined ossification near joint margins (but excluding osteophyte formation) on plain radiographs of the hand or foot	1

CASPAR = classification criteria for psoriatic arthritis.

Taylor W, et al. *Arthritis Rheum*. 2006;54:2665-2673.

PROM: Key Areas Measured by Patient Reported Outcome Measures

- **Disease Activity:** Fatigue, spinal pain, joint pain/swelling, enthesitis (tenderness), and morning stiffness duration/severity
- **Physical Function:** Ability to perform daily activities, mobility, and range of motion
- **Quality of Life:** Overall well-being, emotional health, and impact on daily life domains (physical, mental, social)
- **Work Productivity:** Activity impairment, presenteeism (reduced productivity at work), and productivity loss

Keller S. AIR. 21 June 2017. https://www.air.org/resource/video/long-story-short-what-value-patient-reported-outcomes. CMS.gov. Types of measures. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/patient-reported-outcome. Concoff A, et al. *Rheumatol Adv Practice*. 2026;10:rkaf119.

Commonly Used PRO Tools

Commonly used PRO tools:

- Bath Ankylosing Spondylitis Disease Activity Index (BASDAI):
  Assesses disease activity through six questions covering fatigue, pain, stiffness, and tenderness
- Ankylosing Spondylitis Quality of Life (ASQoL) / ASQoL-FI (Functional Impairment):
  Evaluates functional ability and quality of life
- Patient-Reported Outcomes Measurement Information System (PROMIS):
  Measures aspects like depression and physical function, showing strong correlations with traditional measures
- Work Productivity and Activity Impairment Questionnaire (WPAI:SpA):
  Quantifies work-related impacts like absenteeism and presenteeism

https://qxmd.com/calculate/calculator_299/basdai#;https://pmc.ncbi.nlm.nih.gov/articles/PMC1754293/;https://doi.org/10.1093/occmed/kqaf097

Why PROs Matter

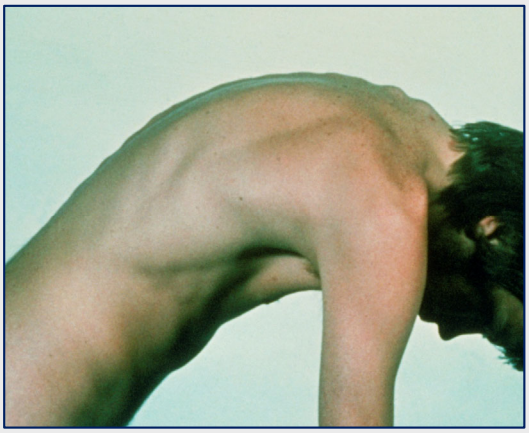
Why PROs matter:

- **Holistic Assessment:** Capture the patient's experience beyond objective signs, recognizing symptoms like fatigue
- **Treatment Efficacy:** Show improvements in pain, function, and quality of life with effective treatments (like biologics), leading to better daily living
- **Impact on Life:** Reveal the significant burdens of AS, including reduced work capacity and lower quality of life, with physical domains often most affected

Keller S. AIR. 21 June 2017. https://www.air.org/resource/video/long-story-short-what-value-patient-reported-outcomes.
CMS.gov. Types of measures. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/patient-reported-outcome.
Concoff A, et al. *Rheumatol Adv Practice.* 2026;10:rkaf119.

AxSpA

- A chronic, systemic, inflammatory disorder involving the sacroiliac joints, spine, and often hips
- Axial joints are *always* involved, peripheral joints are frequently affected
- Characterized by "inflammatory" back pain, loss of spinal mobility
- In severe cases, extensive fusion (ankylosis) of vertebrae can increase the risk of spinal deformity, fracture, and disability



AxSpA = axial spondyloarthritis.

Brophy S, et al. *J Rheumatol.* 2002;29:1236-1243. Magrey MN, et al. *Mayo Clin Proc.* 2020;95:2499-2508. Sieper J, et al. *Ann Rheum Dis.* 2002;61(suppl 3):iii8-iii18.

Acute Phase Reactants in PsA

CRP and ESR are not always elevated in PsA. While they are reliable markers of inflammation in diseases like rheumatoid arthritis, in PsA they may be normal even when patients have active disease.

Normal CRP and ESR should not be used to rule out a diagnosis of psoriatic arthritis, as these are increased in only about 40% of patients.

Regular Assessment: CRP and ESR can provide useful information, but their absence does not exclude active disease, and other clinical findings, such as joint counts and patient-reported symptoms, are also crucial in disease assessment.

CRP = C-reactive protein, ESR = erythrocyte sedimentation rate; PsA = psoriatic arthritis.

Kumthekar A, et al. *Curr Rheumatol Rep*. 2024;26:170-177. Tiwari V, Brent LH. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan. https://www.ncbi.nlm.nih.gov/books/NBK547710/.

Why are MDA Criteria Important for PsA?

- **Treatment Target:** MDA provides a clear, measurable goal for doctors and patients in managing PsA
- **Prevents Damage:** Achieving MDA significantly reduces the risk of long-term joint damage and disability
- **Comprehensive:** It considers joint, skin, pain, disability, and entheseal involvement, reflecting the multifaceted nature of PsA

AxSpA = axial spondyloarthritis; SI = sacroiliac.

Coates LC, et al. *Ann Rheum Dis*. 2010:69:48-53. https://doi.org/10.3899/jrheum.2024-1162.

MDA Criteria

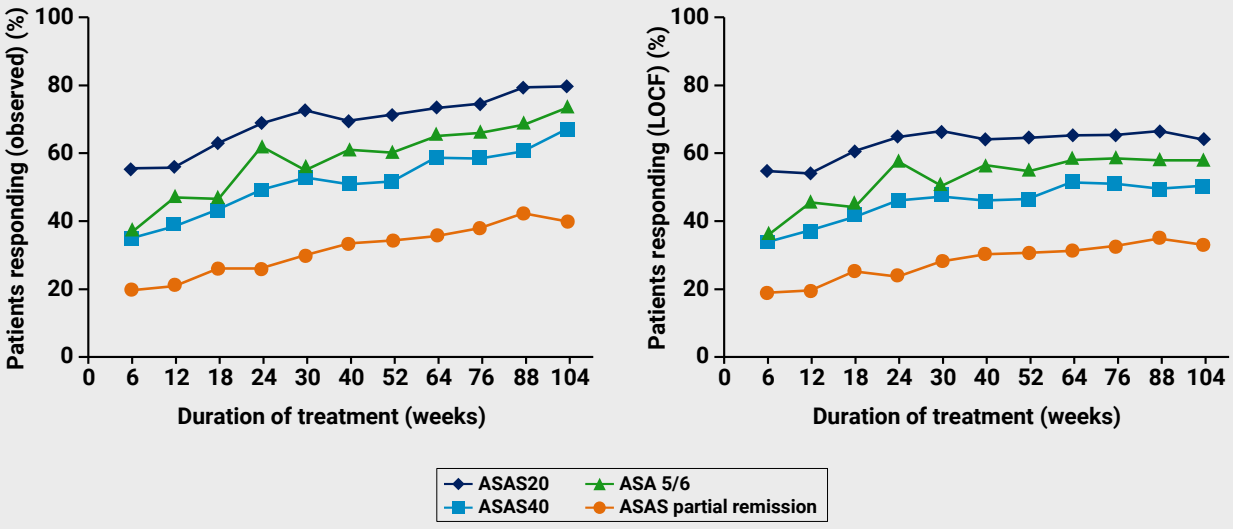
To achieve minimal disease activity in PsA, a patient must meet at least 5 out of 7 of the following specific targets:

- **Tender Joint Count (TJC):** ≤ 1 tender joint
- **Swollen Joint Count (SJC):** ≤ 1 swollen joint
- **Skin Psoriasis Activity:** Psoriasis Area and Severity Index (PASI) ≤ 1, or Body Surface Area (BSA) ≤ 3%
- **Patient Pain:** Pain Visual Analog Scale (VAS) ≤ 15 mm (or ≤ 1.5 cm)
- **Patient Global Disease Activity:** Patient Global Assessment (PtGA) VAS ≤ 20 mm (or ≤ 2 cm)
- **Disability:** Health Assessment Questionnaire (HAQ) Disability Index ≤ 0.5
- **Enthesitis:** Tender entheseal points (eg, Achilles tendon) ≤ 1

Coates LC, et al. *Ann Rheum Dis*. 2010:69:48-53. https://doi.org/10.3899/jrheum.2024-1162.

Treatments – Additional Data Slides

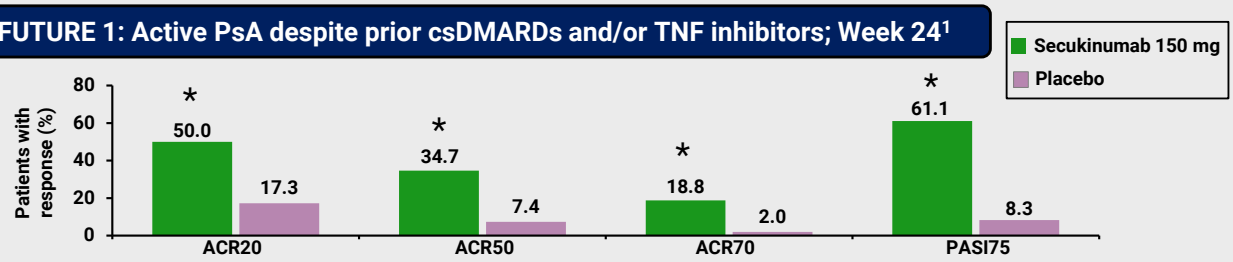
Adalimumab in AS (ATLAS Trial)



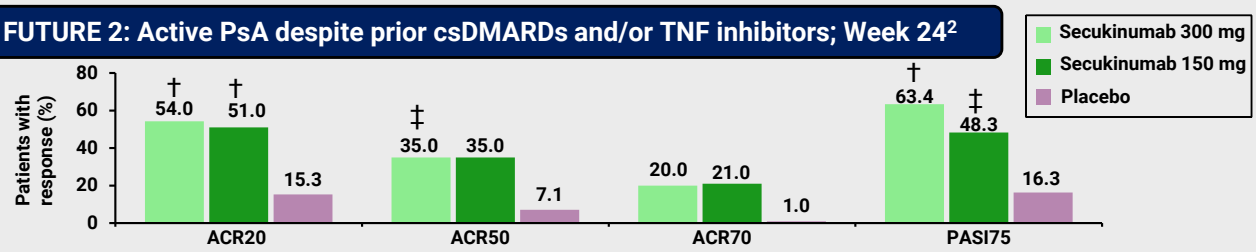
ATLAS = Adalimumab Trial Evaluating Long-term Efficacy and Safety for AS; LOCF = last observation carried forward.
van der Heijde D, et al. *Ann Rheum Dis.* 2009;68:922-929.

Secukinumab: Efficacy in PsA

FUTURE 1: Active PsA despite prior csDMARDs and/or TNF inhibitors; Week 24[1]



FUTURE 2: Active PsA despite prior csDMARDs and/or TNF inhibitors; Week 24[2]



*P < .001; †P < .0001; ‡P < .05 vs placebo.

ACR = American College of Rheumatology; ACR20/50/70 = ACR criteria 20%/50%/70% improvement; csDMARDs = conventional synthetic disease-modifying antirheumatic drugs; PASI75 = Psoriasis Area and Severity Index improvement of ≥ 70%; PsA = psoriatic arthritis; TNF = tumor necrosis factor.

1. Mease PJ, et al. *N Engl J Med*. 2015;373:1329-1339 and suppl. 2. McInnes IB, et al. *Lancet*. 2015;386:1137-1146.

Secukinumab Long-term Safety

- Pooled analysis of long-term safety profile demonstrated in 1380 patients across three phase 3 trials (FUTURE 1-3)

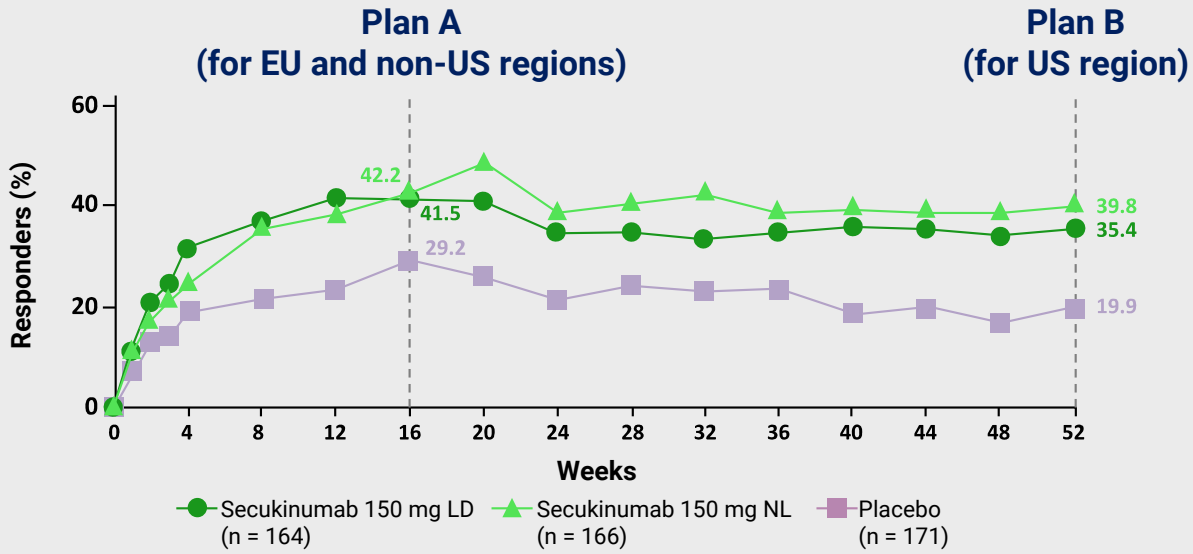
PsA Safety Profile Through Year 5

Adverse events of special interest (COSENTYX® any dose, EAIR/100 PY)	Year 1 N = 1380	Year 2 N = 1183	Year 3 N = 948	Year 4 N = 587	Year 5 N = 290
Serious infections	2.3	2.4	1.4	2.5	1.7
***Candida* infections**	2.3	2.1	1.1	0.7	0.0
Crohn's disease	0.08	0.00	0.3	0.0	0.0
Ulcerative colitis	0.08	0.09	0.1	0.0	0.0
IBD unclassified	0.08	0.00	0.1	0.0	0.0
Major adverse cardiac events	0.4	0.6	0.7	0.7	0.0
Malignancy	1.2	1.2	1.1	2.0	0.8

EAIR = exposure-adjusted incidence rate; IBD = inflammatory bowel disease; PsA = psoriatic arthritis; PY = patient-years.

Secukinumab (Cosentyx®). https://www.cosentyxhcp.com/rheumatology/safety/psoriatic-arthritis.

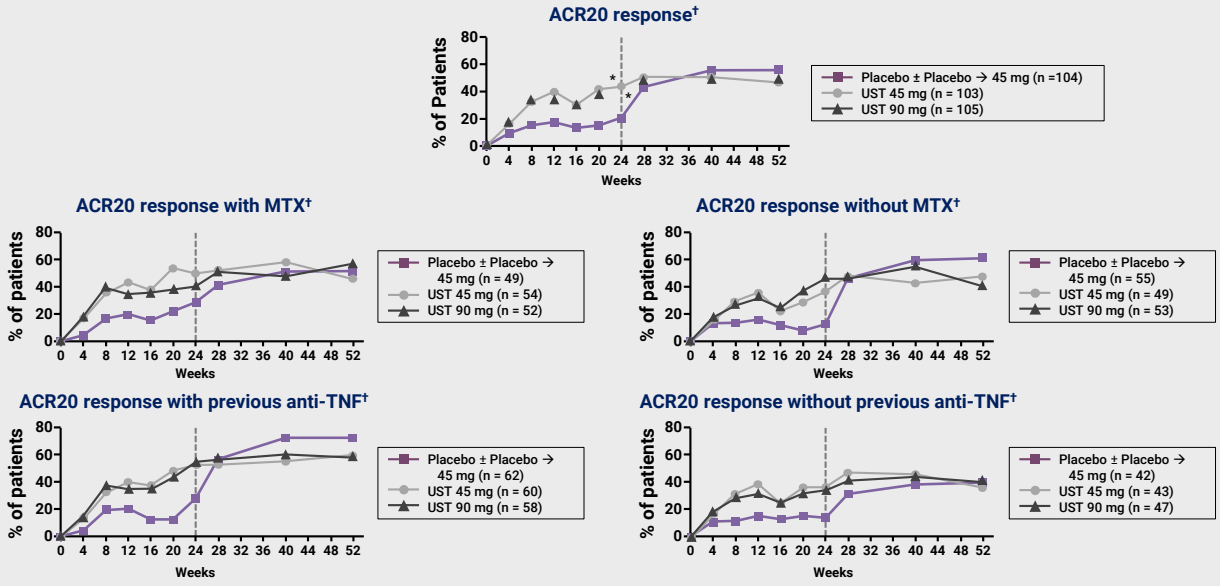
PREVENT: Secukinumab in nr-AxSpA



EU = European Union; LD = loading dose; NL = non-loading dose; nr-axSpA = non-radiographic axial spondyloarthritis; US = United States.

Deodhar A, et al. *Arthritis Rheumatol*. 2021;73:110-120.

Ustekinumab Efficacy Data (PSUMMIT 2 TRIAL)



*P < .001 vs placebo. †For patents who qualified for early escape, data at or prior to week 16 were carried forward through week 24. After week 24, observed data were used.

Ritchlin C, et al. *Ann Rheum Dis*. 2014;73:990-999.

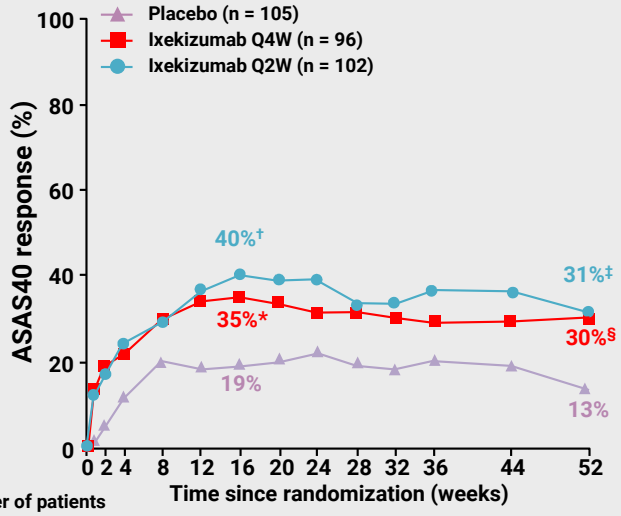
Ustekinumab SAFETY DATA

	Ustekinumab 90 mg	Ustekinumab 45 mg	Placebo
Patients treated, n	308	308	309
Average duration of follow-up, weeks	16.01	16.15	15.79
Average exposure, number of administrations	1.97	1.99	1.96
Patients with AEs, n (%)	152 (49.4)	149 (48.4)	148 (47.9)
Most common AEs (occurring in >3% of patients)			
Nasopharyngitis, n (%)	21 (6.8)	16 (5.2)	13 (4.2)
Headache, n (%)	9 (2.9)	15 (4.9)	6 (1.9)
Upper respiratory tract infection, n (%)	12 (3.9)	10 (3.2)	14 (4.5)
Arthralgia, n (%)	10 (3.2)	9 (2.9)	4 (1.3)
Serious AEs, n (%)	4 (1.3)	4 (1.3)	9 (2.9)
Infections, n (%)	66 (21.4)	64 (20.8)	68 (22.0)
Serious infections, n (%)	0	0	1 (0.3)
Infections requiring treatment, n (%)	30 (9.7)	28 (9.1)	38 (12.3)
AEs leading to discontinuation, n (%)	4 (1.3)	3 (1.0)	11 (3.6)
Malignancies, n (%)	1 (0.3)	0	0

Ustekinumab (Stelara®) Proven Safety Profile. https://www.stelarahcp.com/psoriatic-arthritis/safety-profile/.

COAST-X Trial: Ixekizumab in nr-AxSpA

- 303 patients with nr-axSpA who met ASAS classifications (but not New York criteria) and had inflammation on MRI and/or elevated CRP
- Patients randomized 1:1:1 to ixekizumab 80 mg Q4W, ixekizumab 80 mg Q2W, or placebo; at Week 16, escape to open-label ixekizumab Q2W allowed
- Frequency of serious adverse events that led to treatment discontinuation was low and similar across all arms; no new safety signals identified



Number of patients												
Placebo	99	55	50	43	43	39	36	34
Ixekizumab Q4W	96	68	64	63	59	56	54	53
Ixekizumab Q2W	98	73	64	61	60	58	56	52

*P = .0094; †P = .0016; ‡P = .0037; and §P = .0045 vs placebo.

ASAS = Assessment of SpondyloArthritis international Society; ASAS40 = ASAS 40% response; CRP = C-reactive protein; MRI = magnetic resonance imaging; nr-axSpA = non-radiographic axial spondyloarthritis; Q2W = every 2 weeks; Q4W = every 4 weeks.

Deodhar A, et al. *Lancet*. 2020;395:53-64.

Ixekizumab: Long-term Safety

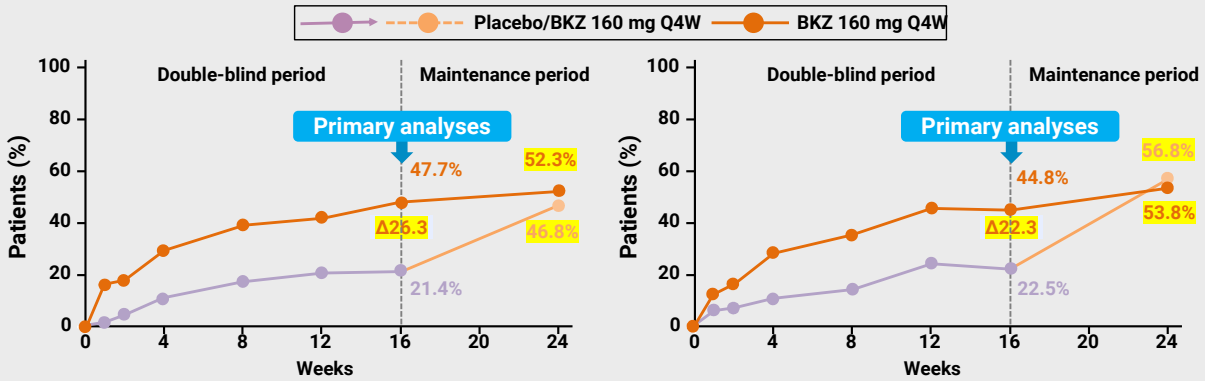
Safety population (N = 932)

	IXE Q4W (N = 454)		IXE Q2W (N = 604)		Total IXE (N = 932)	
	n (%)	IR (95% CI) PYs = 878.2	n (%)	IR (95% CI) PYs = 1219.5	n (%)	IR (95% CI) PYs = 2097.7
Injection site reactions	53 (11.7)	6.0 (4.6–7.9)	107 (17.7)	8.8 (7.3–10.6)	156 (16.7)	7.4 (6.4–8.7)
Mild	40 (8.8)	4.6 (3.3–6.2)	79 (13.1)	6.5 (5.2–8.1)	115 (12.3)	5.5 (4.6–6.6)
Moderate	12 (2.6)	1.4 (0.8–2.4)	23 (3.8)	1.9 (1.3–2.8)	35 (3.8)	1.7 (1.2–2.3)
Severe	1 (0.2)	0.1 (0.0–0.8)	5 (0.8)	0.4 (0.2–1.0)	6 (0.6)	0.3 (0.1–0.6)
Allergic reactions/hypersensitivities	39 (8.6)	4.4 (3.2–6.1)	52 (8.6)	4.3 (3.2–5.6)	88 (9.4)	4.2 (3.4–5.2)
Infections	248 (54.6)	28.2 (24.9–32.0)	309 (51.2)	25.3 (22.7–28.3)	540 (57.9)	25.7 (23.7–28.0)
Serious	9 (2)	1.0 (0.5–2.0)	14 (2.3)	1.1 (0.7–1.9)	23 (2.5)	1.1 (0.7–1.6)
Herpes zoster	6 (1.3)	0.7 (0.3–1.5)	6 (1)	0.5 (0.2–1.1)	12 (1.3)	0.6 (0.3–1.0)
Candida infections						
Oral candidiasis	3 (0.7)	0.3 (0.1–1.1)	2 (0.3)	0.2 (0.0–0.7)	5 (0.5)	0.2 (0.1–0.6)
Vulvovaginal candidiasis*	3 (2.3)	0.3 (0.1–1.1)	4 (2.1)	0.3 (0.1–0.9)	7 (2.5)	0.3 (0.2–0.7)
Skin candidiasis	0 (0)	0.0 (0.0–0.9)	2 (0.3)	0.2 (0.0–0.7)	2 (0.2)	0.1 (0.0–0.4)
Genital candidiasis	0 (0)	0.0 (0.0–0.9)	1 (0.2)	0.1 (0.0–0.6)	1 (0.1)	0.0 (0.0–0.3)
Esophageal candidiasis	2 (0.4)	0.2 (0.1–0.9)	2 (0.3)	0.2 (0.0–0.7)	4 (0.4)	0.2 (0.1–0.5)
IBD	11 (2.4)	1.3 (0.7–2.3)	6 (1)	0.5 (0.2–1.1)	17 (1.8)	0.8 (0.5–1.3)
Crohn's disease	5 (1.1)	0.6 (0.2–1.4)	2 (0.3)	0.2 (0.0–0.7)	7 (0.8)	0.3 (0.2–0.7)
Ulcerative colitis	6 (1.3)	0.7 (0.3–1.5)	4 (0.7)	0.3 (0.1–0.9)	10 (1.1)	0.5 (0.3–0.9)
Uveitis	28 (6.2)	3.2 (2.2–4.6)	30 (5)	2.5 (1.7–3.5)	58 (6.2)	2.8 (2.1–3.6)
MACE	2 (0.4)	0.2 (0.1–0.9)	4 (0.7)	0.3 (0.1–0.9)	6 (0.6)	0.3 (0.1–0.6)
Malignancies	3 (0.7)	0.3 (0.1–1.1)	6 (1)	0.5 (0.2–1.1)	9 (1)	0.4 (0.2–0.8)
Depression	6 (1.3)	0.7 (0.3–1.5)	13 (2.2)	1.1 (0.6–1.8)	19 (2)	0.9 (0.6–1.4)
Cytopenia	8 (1.8)	0.9 (0.5–1.8)	21 (3.5)	1.7 (1.1–2.6)	28 (3)	1.3 (0.9–1.9)

*Denominator is different because this was a sex-specific event for females.
CI = confidence interval; IBD = inflammatory bowel disease; IR = incidence rate per 100 patient-years; IXE = ixekizumab; MACE = major adverse cerebro-cardiovascular event; PYs = patient-years; Q2W = every 2 weeks; Q4W = every 4 weeks.
Deodhar A, et al. *J Rheumatol*. 2023;50:1020-1028.

BE MOBILE 1 and BE MOBILE 2: Bimekizumab in AS

BE MOBILE 1 (nr-axSpA) **ASAS40 (NRI)** **BE MOBILE 2 (r-axSpA)**

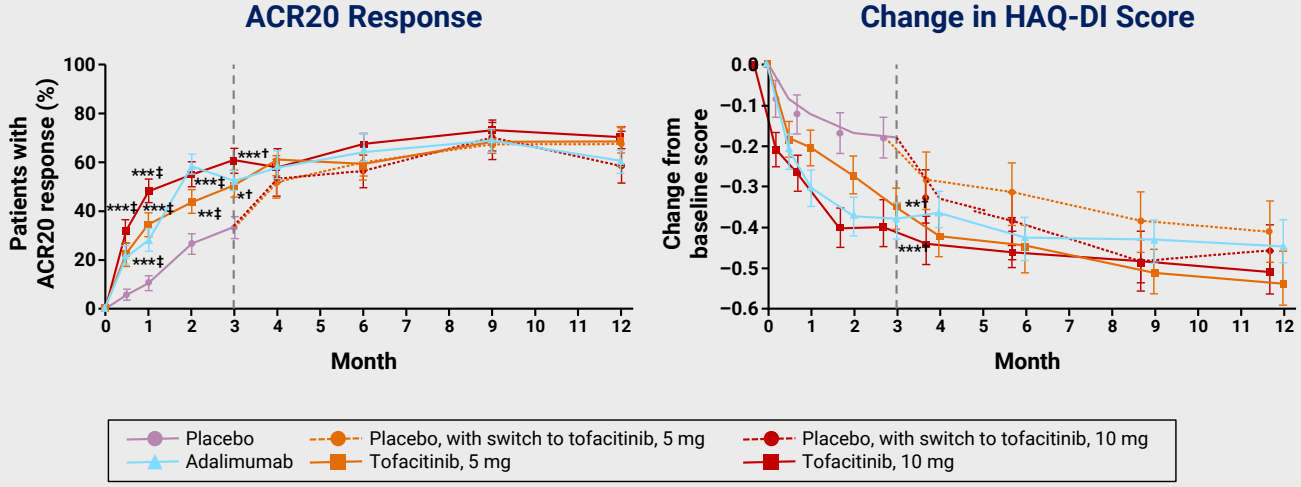


Safety overview for the double-blind treatment (Weeks 0–16) and overall periods (Weeks 0–52)

	Double-blind treatment period Weeks 0–16		Maintenance period Weeks 16–52	Overall Weeks 0–52
N (%), overall period (EAIR/100 patient-years)	Placebo	BKZ 160 mg Q4W	BKZ 160 mg Q4W	BKZ 160 mg Q4W
nr-AxSpA (BE MOBILE 1)	n = 126 (38.1 PYAR)	n = 128 (40.4 PYAR)	n = 242 (167.8 PYAR)	n = 244 (208.2 PYAR)
r-AxSpA (BE MOBILE 2)	n = 111 (34.6 PYAR)	n = 221 (68.3 PYAR)	n = 319 (220.0 PYAR)	n = 330 (290.9 PYAR)

AS = ankylosing spondylitis; ASAS40 = Assessment of SpondyloArthritis international Society 40% response; BKZ = bimekizumab; EAIR = exposure-adjusted incidence rate; nr-axSpA = non-radiographic axial spondyloarthritis; NRI = nonresponder imputation; PYAR = patient-years at risk; Q4W = every 4 weeks; r-axSpA = radiographic axSpA.
Baraliakos X, et al. *Ann Rheum Dis*. 2024;83:199-213. van der Heijde D, et al. *Ann Rheum Dis*. 2022;82:515-526.

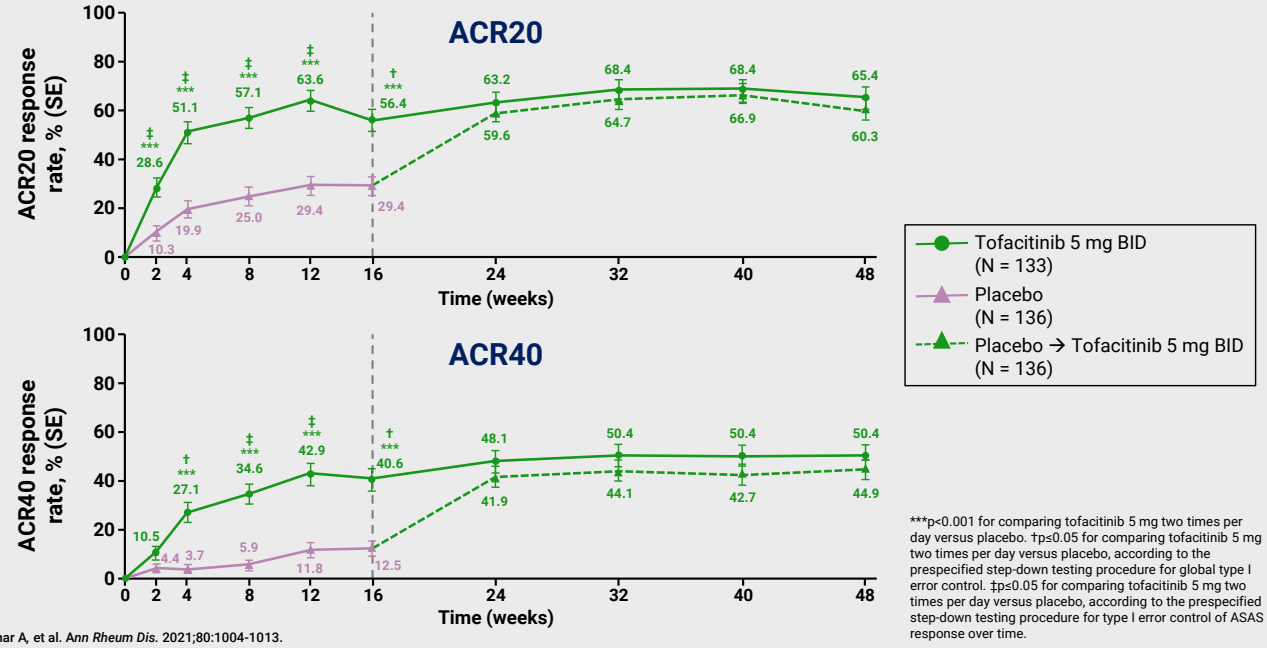
Tofacitinib Clinical Data in PsA (OPAL Broaden Trial)



(*) unadjusted P value of 0.05 or less, (**) unadjusted P value of less than 0.01, (***) unadjusted P value of less than 0.001. (†) P value was 0.05 or less for the comparison with placebo for global type I error control, according to the prespecified step-down testing procedure. (‡) P value was 0.05 or less, according to the prespecified step-down testing procedure for type I error control within the ACR20 response time course.

Mease PJ, et al. *N Engl J Med*. 2017;377:1537-1550.

Tofacitinib Clinical Trial Data in AS (NCT03502616)



***p<0.001 for comparing tofacitinib 5 mg two times per day versus placebo. †p≤0.05 for comparing tofacitinib 5 mg two times per day versus placebo, according to the prespecified step-down testing procedure for global type I error control. ‡p≤0.05 for comparing tofacitinib 5 mg two times per day versus placebo, according to the prespecified step-down testing procedure for type I error control of ASAS response over time.

Deodhar A, et al. *Ann Rheum Dis*. 2021;80:1004-1013.

Safety Data Tofacitinib (OPAL Broaden Trial)

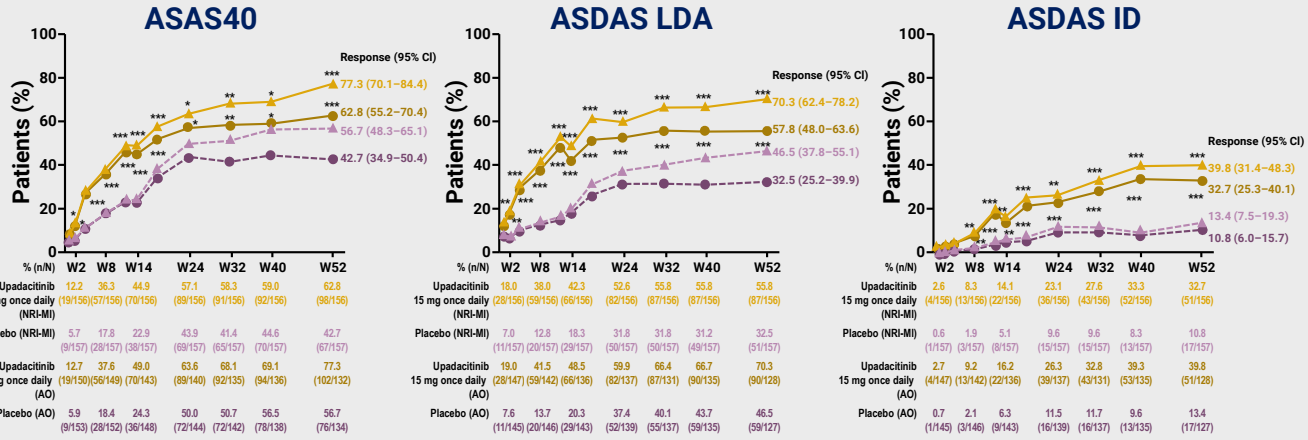
Summary of Safety Events*

Event	Up to 3 Months				Up to 12 Months				
	Pooled Placebo (N = 105)	Tofacitinib 5 mg (N = 107)	Tofacitinib 10 mg (N = 104)	Adalimumab (N = 106)	Placebo to Tofacitinib 5 mg (N = 52)	Placebo to Tofacitinib 10 mg (N = 53)	Tofacitinib 5 mg (N = 107)	Tofacitinib 10 mg (N = 104)	Adalimumab (N = 106)
Any adverse event — no. (%)	37 (35)	42 (39)	47 (45)	49 (46)	36 (69)	34 (64)	71 (66)	74 (71)	76 (72)
Serious adverse event — no. (%)	1 (1)	3 (3)	1 (1)	1 (1)	3 (6)	4 (8)	8 (7)	4 (4)	9 (8)
Discontinuation due to adverse event — no. (%)	1 (1)	3 (3)	0	2 (2)	2 (4)	2 (4)	6 (6)	3 (3)	4 (4)
Adverse event of special interest — no. (%) [day of onset]†									
Serious infection	0	0	0	0	2 (4) [days 102, 331]	0	0	1 (1) [day 132]	1 (1) [day 170]
Herpes zoster infection	0	1 (1) [day 61]	0	0	0	0	2 (2) [days 61, 173]	2 (2) [days 221, 317]	0
Opportunistic infection	0	1 (1) [day 61]	0	0	0	0	1 (1) [day 61]	0	0
Cancer, excluding nonmelanoma skin cancer	0	2 (2) [days 1, 11]	0	0	0	0	3 (3) [days 1, 11, 232]	0	0
Nonmelanoma skin cancer	0	0	1 (1) [day 103]	0	0	0	0	1 (1) [day 103]	0
Cardiovascular event	0	0	0	0	1 (2) [day 139]	0	0	0	2 (2) [days 263, 345]
Gastrointestinal perforation	0	0	0	0	1 (2) [day 102]	0	0	0	0

*Analyses were performed with data from safety analysis set, which was the same as full analysis set and included all patients who received ≥1 dose of tofacitinib, adalimumab, or placebo. AEs from any cause were included in analyses. †Among AEs of special interest, cases of herpes zoster infection were not judged to be serious, and events of opportunistic infection, cancer, cardiovascular event, and gastrointestinal perforation were all adjudicated.

Mease PJ, et al. *N Engl J Med*. 2017;377:1537-1550.

Upadacitinib in nr-AxSpA (SELECT-AXIS 2)

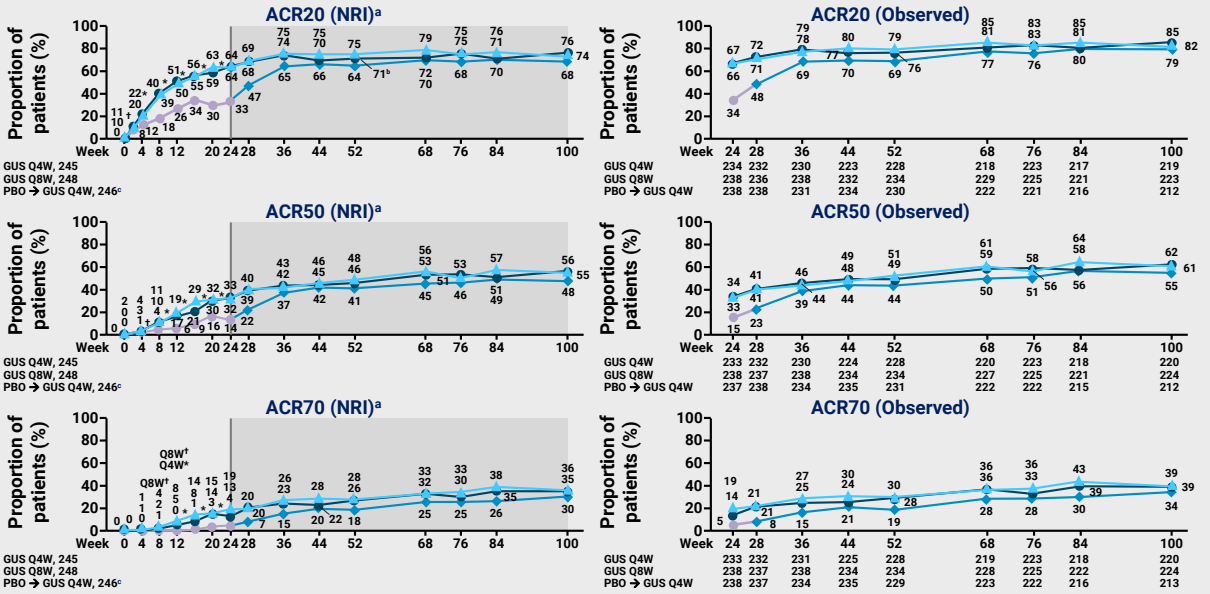


*P < 0.05; **P < 0.01; ***P < 0.001 versus placebo (all P values are nominal).

AO = as observed; ID = inactive disease; LDA = low disease activity; MI = multiple imputation; NRI = nonresponder imputation; W = week.

Van den Bosch F, et al. *ACR Open Rheumatol*. 2024;6:470-480.

Guselkumab in PsA (DISCOVER2)



*$P \leq .001$; †$P < .05$

[a] Includes patients randomized to Q4W and Q8W at Week 0 who received ≥1 dose of study agent. [b] One patient's Week 52 visit, which was not captured in the interim data base lock, was included in the final data base lock. [c] 238 crossed over to O4W at Week 24 and eight received placebo only before study agent discontinuation.

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

Guselkumab Safety Data (Pooled DISCOVER 1 and 2)

Adverse reactions reported by ≥ 1% of patients through week 24 in DISCOVER 1 and DISCOVER 2

	Placebo N = 372 n (%)	Guselkumab Q8W[a] N = 375 n (%)	Guselkumab Q4W[b] N = 373 n (%)
Gastrointestinal disorders Diarrhea	3 (0.8%)	6 (1.6%)	4 (1.1%)
General disorders and administration site conditions Injection site reactions[c]	1 (0.3%)	5 (1.3%)	3 (0.8%)
Infections and infestations Respiratory tract infections[d]	45 (12.1%)	46 (12.3%)	52 (13.9%)
Investigations • Transaminases increased[e] • Neutrophil count decreased	17 (4.6%) 0	31 (8.3%) 1 (0.3%)	32 (8.6%) 6 (1.6%)
Nervous system disorders Headache/tension headache	3 (0.8%)	8 (2.1%)	7 (1.9%)

[a] Subjects received 100 mg of guselkumab at week 0, week 4, and every 8 weeks thereafter. [b] Subjects received 100 mg of guselkumab at week 0, and every 4 weeks thereafter.
[c] Injection site reactions include injection site erythema, bruising, hematoma, hemorrhage, swelling, edema, pruritus, pain, discoloration, induration, inflammation, and urticaria.
[d] Respiratory tract infections include nasopharyngitis, upper respiratory tract infection (URTI), bronchitis, pharyngitis, and viral URTI. [e] Transaminases increased includes: alanine aminotransferase increased, aspartate aminotransferase increased, hepatic enzyme increased, transaminases increased, liver function test abnormal, hypertransaminasemia.

NPS Medicinewise. Consumer medicine information. Guselkumab (Tremfya®). https://www.nps.org.au/medicine-finder/Tremfya.