

# EULAR Recommendations for the Management of Psoriatic Arthritis With Pharmacological Therapies: 2023 Update

For proactive use by medical affairs personnel



Inspired by patients.  
Driven by science.



# Disclaimer

BIMZELX® (bimekizumab-bkzx) is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. The recommended dosage of BIMZELX is 320 mg (given as 2 subcutaneous injections of 160 mg each) at Weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter. For patients weighing  $\geq 120$  kg, consider a dosage of 320 mg every 4 weeks after Week 16.

BIMZELX is indicated for the treatment of adult patients with active psoriatic arthritis. The recommended dosage is 160 mg by subcutaneous injection every 4 weeks. For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing regimen for adult patients with plaque psoriasis.

BIMZELX is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation. The recommended dosage is 160 mg by subcutaneous injection every 4 weeks.

BIMZELX is indicated for the treatment of adult patients with active ankylosing spondylitis. The recommended dosage is 160 mg by subcutaneous injection every 4 weeks.



BIMZELX® [prescribing information]. Smyrna, GA: UCB, Inc.

# Supporting Publication

*Gossec, et al. (2024)*

EULAR Recommendations for the Management of Psoriatic Arthritis With Pharmacological Therapies: 2023 Update



# New Therapeutics Have Been Approved, Necessitating an Update of EULAR Recommendations

- Since the 2019 EULAR recommendations for pharmacological management of PsA, new treatment options have been approved for the treatment of patients with PsA. Therefore, an update of the EULAR recommendations was needed
- The 2023 update considered new non-topical, pharmacological agents approved for the treatment of patients with PsA. This update specifically focused on musculoskeletal manifestations, while also addressing the spectrum of PsA, including how skin psoriasis, extra-musculoskeletal manifestations, and comorbidities should influence treatment choices

## Disease-modifying treatment options for PsA as of December 2023

Type of DMARD	Target	Name of Drug	
csDMARD		➤ Methotrexate ➤ Leflunomide	➤ Sulfasalazine
	TNF	➤ Adalimumab ➤ Certolizumab ➤ Etanercept	➤ Infliximab ➤ Golimumab
bDMARD	IL-12/23	➤ Ustekinumab	
	IL-17A	➤ Ixekizumab	➤ Secukinumab
	IL-17A/F	➤ Bimekizumab	
	IL-23-p19	➤ Guselkumab	➤ Risankizumab
	CTLA-4	➤ Abatacept	
tsDMARD	PDE4	➤ Apremilast	
	JAK	➤ Tofacitinib	➤ Upadacitinib

# Methods



The convenor and methodologist  
**identified members for the  
task force**



## Steering Committee

- 6 rheumatologists\*
- 1 dermatologist
- 1 infectious disease specialist
- 1 experienced fellow rheumatologist
- 1 patient research partner
- 2 health professionals



Questions were defined, and a systematic literature review was conducted to identify publications pertaining to pharmacologic treatments for patients with PsA since the 2019 EULAR recommendations



## Task Force<sup>†</sup>

- 27 rheumatologists
- 2 dermatologists
- 1 infectious disease specialist
- 2 patient research partners
- 2 health professionals
- 3 rheumatology/epidemiology fellows/trainees



The task force discussed the systematic literature review to update the 2019 EULAR recommendations

**47%** of the members were not involved in the 2019 EULAR recommendations  
Members were from **19** countries, of which 15 were EULAR countries. Experts from **Australia, Japan, and North America** were included for the first time

The process was evidence-based and experience-based and included consideration of safety, efficacy, cost, and long-term data  
The levels of evidence and grades of recommendation were determined using the Oxford Evidence Based System<sup>‡</sup>  
The task force members voted on the level of agreement for each recommendation by using a 0-10 scale, via an anonymized email



Inspired by patients.  
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\*Included the convenor and methodologist. <sup>†</sup>The task force included members of the steering committee. <sup>‡</sup>The limit for acceptance of individual recommendations was set at  $\geq 75\%$  majority among the task force for the first voting round; then (after discussions and potential reformulations), at  $\geq 67\%$  majority; and finally, if required, the last round of votes was accepted with  $>50\%$  acceptance or else a proposal was rejected.

# Overarching Principles: 2023 Update

- Overarching principles set the stage for EULAR recommendations—to help delineate highly obvious and relevant clinical observations and provide context for the recommendations that appear in the following slides

Overarching principle*	Changes
A Psoriatic arthritis is a heterogeneous and potentially severe disease, which may require multidisciplinary treatment	Unchanged
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, <b>patient preferences</b> and costs	Reformulated
C Rheumatologists are the specialists who should primarily care for the musculoskeletal manifestations of patients with psoriatic arthritis; in the presence of <b>clinically relevant</b> skin involvement, a rheumatologist and a dermatologist should collaborate in diagnosis and management	Reformulated
D The primary goal of treating patients with psoriatic arthritis is to maximize health-related quality of life, through control of symptoms, prevention of structural damage, normalization of function and social participation; abrogation of inflammation is an important component to achieve these goals	Unchanged
E In managing patients with psoriatic arthritis, consideration should be given to each musculoskeletal manifestation and treatment decisions made accordingly	Unchanged
F When managing patients with psoriatic arthritis, non-musculoskeletal manifestations (particularly skin, eye and gastrointestinal tract) should be taken into account; comorbidities such <b>as obesity</b> , metabolic syndrome, cardiovascular disease or depression should also be considered	Reformulated
<b>G The choice of treatment should take account of safety considerations regarding individual modes of action to optimize the benefit–risk profile</b>	New

# Recommendations: 2023 Update (1/2)

	Recommendations*	Changes
1	Treatment should be aimed at reaching the target of remission or, alternatively, minimal/low disease activity, by regular monitoring and appropriate adjustment of therapy	Unchanged
2	Non-steroidal anti-inflammatory drugs may be used to relieve musculoskeletal signs and symptoms; local injections of glucocorticoids may be considered as adjunctive therapy	Previous recommendations 2 and 3 were merged and modified. "Systemic glucocorticoids may be used with caution at the lowest effective dose" was removed from the recommendation
3	In patients with polyarthritis, or those with monoarthritis/oligoarthritis and poor prognostic factors (e.g., structural damage, elevated acute phase reactants, dactylitis, or nail involvement), a csDMARD should be initiated rapidly, with methotrexate preferred in those with clinically relevant skin involvement	Previous recommendations 4 and 5 were merged for clarity
4	In patients with peripheral arthritis and an inadequate response to at least one csDMARD, therapy with a bDMARD should be commenced	Previous recommendation 6 was separated into 2 recommendations. Given the worldwide cautionary statement issued from the FDA and EMA based on the increased risk of CVDs and malignancies observed in older patients with RA treated with tofacitinib, task force members updated the recommendation for the use of a JAKi emphasizing usage with caution
5	In patients with peripheral arthritis and an inadequate response to at least one bDMARD, or when a bDMARD is not appropriate, a JAKi may be considered, taking safety considerations into account	

Link to the table with level of evidence, grade of recommendation, and level of agreement

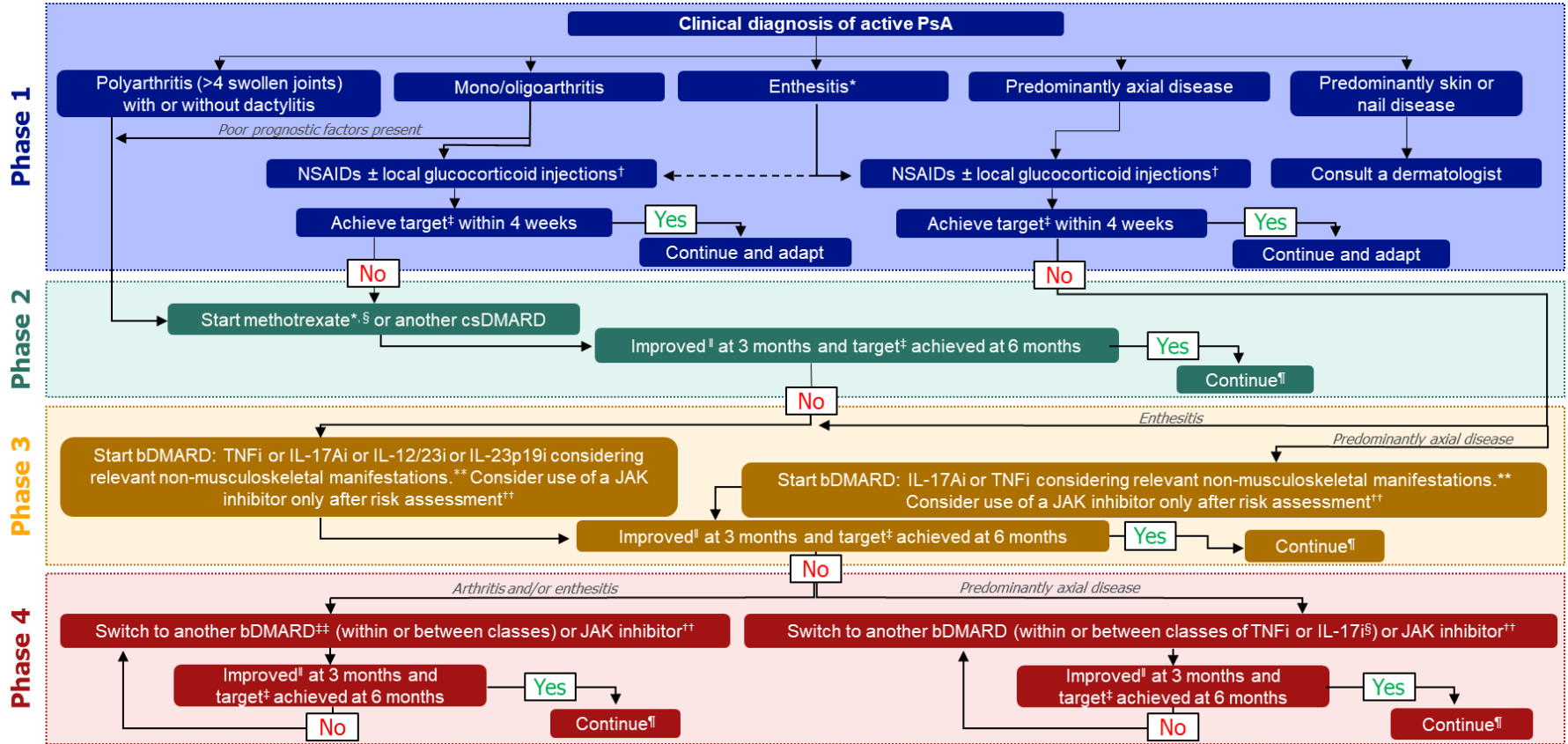
# Recommendations: 2023 Update (2/2)

	Recommendations*	Changes
6	In patients with mild disease <sup>†</sup> and an inadequate response to at least one csDMARD, in whom neither a bDMARD nor a JAKi is appropriate, a PDE4 inhibitor may be considered	Unchanged
7	In patients with unequivocal enthesitis and an insufficient response to NSAIDs or local glucocorticoid injections, therapy with a bDMARD should be considered	Unchanged
8	In patients with clinically relevant axial disease with an insufficient response to NSAIDs, therapy with an IL-17Ai, a TNFi, <b>an IL-17A/Fi</b> , or a JAKi should be considered	This recommendation was updated to emphasize the choice of drugs rather than a combination of the drugs. In addition, the list of drugs was updated, and the order of the drugs listed reflect the order in which each treatment should be considered
9	<b>The choice of the mode of action should reflect non-musculoskeletal manifestations related to psoriatic arthritis; with clinically relevant skin involvement, preference should be given to an IL-17A or IL-17A/F or IL-23 or IL-12/23 inhibitor; with uveitis to an anti-TNF monoclonal antibody; and with IBD to an anti-TNF monoclonal antibody or an IL-23i or IL-12/23i or a JAKi</b>	New
10	In patients with an inadequate response or intolerance to a bDMARD or a JAKi, switching to another bDMARD or <b>JAKi</b> should be considered, including one switch within a class	This recommendation was updated to specifically indicate JAKi instead of tsDMARD
11	In patients in sustained remission, tapering of DMARDs may be considered	Reformulated

Link to the table with level of evidence, grade of recommendation, and level of agreement



# 2023 EULAR Recommendations Algorithm for the Management of PsA



\*Some studies suggest that enthesitis may respond to methotrexate, but the level of evidence is low. <sup>†</sup>No glucocorticoids for axial disease. <sup>‡</sup>The target is remission or low disease activity (especially with long-standing disease) in accordance with the target-to-treat recommendations. <sup>§</sup>Preferred in the presence of relevant skin involvement; however, in case of concomitant inflammatory bowel disease or uveitis, a TNF monoclonal antibody or (for IBD) IL-23i or 12/23i or JAKi is recommended. <sup>¶</sup>Improvement means at least 50% reduction in disease activity. <sup>¶¶</sup>Consider tapering in sustained remission. <sup>\*\*</sup>Arthritis/enthesitis: TNFi or IL-17i or IL-12/23i or IL-23p19i; Skin: IL-17i or IL-12/23i or IL-23p19i; Uveitis: anti-TNF monoclonal antibody; IBD: anti-TNF monoclonal antibody or IL-12/23i or IL-23p19i or JAKi; Consider using PDE4i in mild disease if bDMARD and JAKi is inappropriate. <sup>††</sup>For JAK inhibitors, caution is needed for patients aged 65 years or above, current, or past long-time smokers, with a history of atherosclerotic cardiovascular disease or other cardiovascular risk factors or with other malignancy risk factors; with known risk factors for venous thromboembolism. <sup>‡‡</sup>Including abatacept.

# Research Agenda Indicating Priorities for Future Research in PsA (1/2)

Theme	Question
Responsibility	<ul style="list-style-type: none"> <li>➤ Role of the rheumatologist vs other specialists in the management of PsA</li> </ul>
Pathogenesis	<ul style="list-style-type: none"> <li>➤ Pathogenesis of different tissue involvements in PsA</li> <li>➤ Pathogenesis of axial disease</li> <li>➤ Microbiome relationship to disease onset and progression</li> <li>➤ Prediction markers of response on synovial histopathology</li> <li>➤ Identification of new therapeutic targets</li> <li>➤ Understanding the biopathology of treatment-refractory PsA</li> <li>➤ Genetics of PsA</li> </ul>
Very Early PsA	<ul style="list-style-type: none"> <li>➤ Biomarkers for pre-PsA</li> <li>➤ Defining screening strategies for PsA among patients with psoriasis: is screening needed, and if so, in which populations, how and when?</li> <li>➤ Criteria for early diagnosis of PsA and role of imaging</li> <li>➤ Prevention of progression from psoriasis to PsA: pre-PsA therapy/interception (efficacy of DMARDs in preventing progression from PSO to PsA)</li> <li>➤ Window of opportunity studies</li> </ul>
Drug ordering/response prediction and biomarkers	<ul style="list-style-type: none"> <li>➤ Research on the effect of sex on treatment choices, treatment efficacy and treatment maintenance</li> <li>➤ Incorporating ultrasonography in decision-making</li> <li>➤ Biomarkers for prediction of disease and response</li> <li>➤ Prediction of response with genetics and polygenetics</li> </ul>
Prognosis	<ul style="list-style-type: none"> <li>➤ Prognostic factors of progressive disease, structural damage and unfavorable functional outcomes</li> <li>➤ Predicting response to treatment (predicting response to NSAIDs, to csDMARDs, to the different bDMARDs, to tsDMARDs)</li> <li>➤ Prognosis of early-onset (juvenile) PsA</li> </ul>
First DMARD choices	<ul style="list-style-type: none"> <li>➤ Biosimilars vs methotrexate as first choice—strategy trials</li> <li>➤ Comparing direct and indirect costs, efficacy, side effects in employed, early, severe, bio-naïve PsA patient groups treated with methotrexate or biosimilars. Is there any advantage of using methotrexate over biosimilars in this group?</li> </ul>

# Research Agenda Indicating Priorities for Future Research in PsA (2/2)

Theme	Question
Outcomes in PsA	<ul style="list-style-type: none"> <li>➤ Development/validation of composite scores of disease activity in PsA</li> <li>➤ Consensus on core outcomes in PsA trials</li> <li>➤ Coprimary outcomes for skin and joints</li> </ul>
Treatments	<ul style="list-style-type: none"> <li>➤ Efficacy of csDMARDs for dactylitis</li> <li>➤ Assessing combinations of csDMARDs with biologics compared with biologic monotherapy</li> <li>➤ Associations of bDMARDs</li> </ul>
Contextual factors in PsA	<ul style="list-style-type: none"> <li>➤ Sex and gender</li> <li>➤ Age</li> </ul>
Safety	<ul style="list-style-type: none"> <li>➤ Differential JAKi safety in PsA and across drugs</li> <li>➤ Tyrosine-kinase inhibition safety in PsA</li> </ul>
Axial PsA	<ul style="list-style-type: none"> <li>➤ Pathogenesis of axial PsA vs axSpA</li> <li>➤ Criteria for differentiation and overlap between axSpA and PsA</li> </ul>
Comorbidities	<ul style="list-style-type: none"> <li>➤ Impact of comorbidities on drug choice</li> <li>➤ Effect of metabolic intervention on disease activity</li> <li>➤ Effect of different DMARDs on cardiovascular risk</li> <li>➤ Influence of non-pharmacological interventions on multimorbidity</li> <li>➤ Enteseal PsA: overlap with widespread pain syndrome and role of imaging in the diagnosis</li> </ul>
Switches	<ul style="list-style-type: none"> <li>➤ Repeat switching within a DMARD class</li> <li>➤ Switching and cycling between drugs</li> </ul>

# Strengths and Limitations of the Study



## Strengths

- EULAR standardized the voting procedure to avoid minor modification and rewording
- Since 2019, additional therapeutics were approved, and longer efficacy and safety data were available to refine the 2019 recommendations



## Limitations

- The 2023 EULAR recommendations only considered treatments for patients with PsA that were approved during the systematic literature review. Therefore, the recommendations do not consider therapeutics that were approved for psoriasis only (e.g., brodalumab) or therapeutics that were in development (e.g., TYK2i, izokibep)
- The task force recognized that cost is an important factor to consider when deciding on the treatment for patients with PsA. The task force noted that a few originators (e.g., tofacitinib) will soon become generic, which will allow a wider application, especially in less-affluent countries

# EULAR Recommendations for the Management of Psoriatic Arthritis With Pharmacological Therapies: 2023 Update

Laure Gossec, Andreas Kerschbaumer, Ricardo J O Ferreira, Daniel Aletaha, Xenofon Baraliakos, Heidi Bertheussen, Wolf-Henning Boehncke, Bente Appel Esbensen, Iain B McInnes, Dennis McGonagle, Kevin L Winthrop, Andra Balanescu, Peter V Balint, Gerd R Burmester, Juan D Cañete, Pascal Claudepierre, Lih Eder, Merete Lund Hetland, Annamaria Iagnocco, Lars Erik Kristensen, Rik Lories, Rubén Queiro, Daniele Mauro, Helena Marzo-Ortega, Philip J Mease, Peter Nash, Wendy Wagenaar, Laura Savage, Georg Schett, Stephanie J W Shoop-Worrall, Yoshiya Tanaka, Filip E Van den Bosch, Annette van der Helm-van Mil, Alen Zabotti, Désirée van der Heijde, Josef S Smolen

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**AK:** Speakers bureau, consultant for **UCB Pharma**

**RJOF:** Consultant for **UCB Pharma**

**XB:** Consultant for **UCB Pharma**

**W-HB:** Honoraria fees from **UCB Pharma**, advisory board for **UCB Pharma**

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**KLW:** Research grants from **UCB Pharma**

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**DvdH:** Consulting fees **UCB Pharma**



# **Bimekizumab Data Informing the 2023 Update of EULAR Recommendations**

# BE OPTIMAL Study Design

## Key inclusion criteria<sup>1</sup>

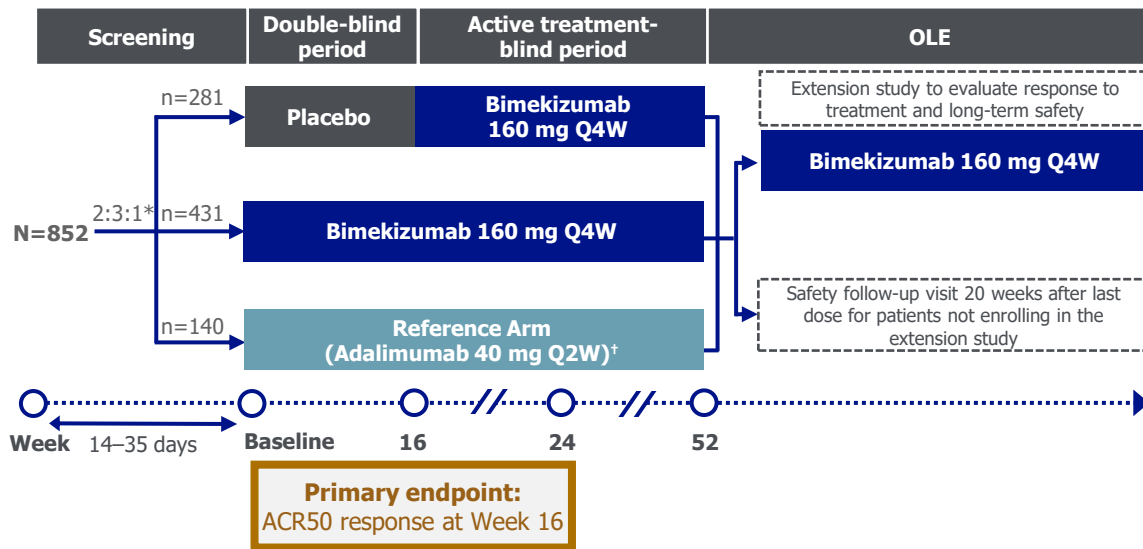
- ≥18 years of age with adult-onset PsA fulfilling CASPAR criteria for ≥6 months before screening
- TJC of ≥3 of 68 joints and SJC of ≥3 of 66 joints
- ≥1 active psoriatic lesion and/or a documented history of PSO

## Key exclusion criteria<sup>1,2</sup>

- Current or prior exposure to any biologics for treatment of PsA or PSO
- Active symptomatic IBD at baseline or screening (prior history was not an exclusion criterion)

Patients were allowed concomitant NSAIDs, analgesics, oral corticosteroids, or conventional synthetic DMARDs at stable doses<sup>1</sup>

## BE OPTIMAL (bDMARD-naïve patients)<sup>1,2</sup>



# BE COMPLETE Study Design

## Key inclusion criteria<sup>1</sup>

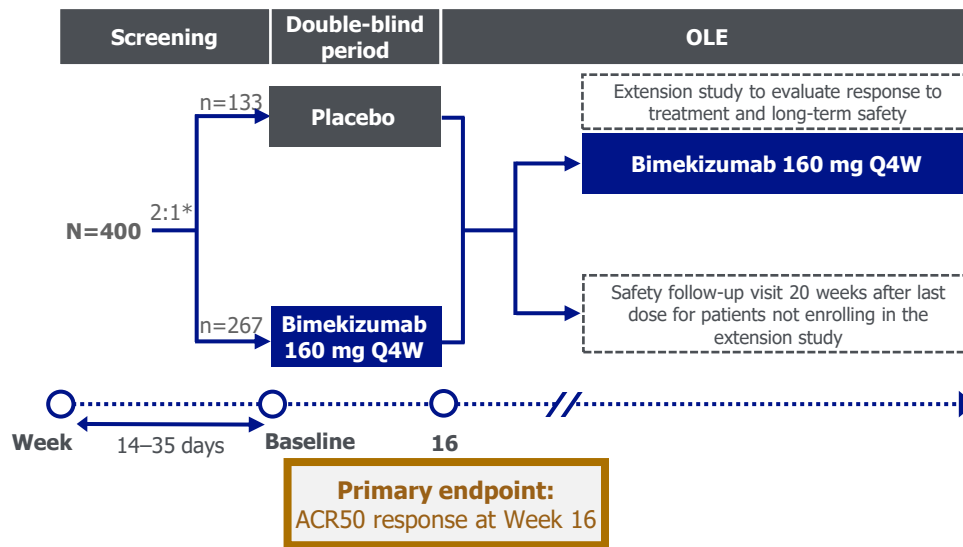
- ≥18 years of age with adult-onset PsA fulfilling CASPAR criteria for ≥6 months before screening
- TJC of ≥3 of 68 joints and SJC of ≥3 of 66 joints
- ≥1 active psoriatic lesion and/or a documented history of PSO
- Inadequate response or intolerance to 1 or 2 TNFis for either PsA or PSO

## Key exclusion criteria<sup>1,2</sup>

- Current or prior exposure to any biologics other than TNFis for treatment of PsA or PSO
- Active symptomatic IBD at baseline or screening (prior history was not an exclusion criterion)

Patients were allowed concomitant NSAIDs, analgesics, oral corticosteroids, or conventional synthetic DMARDs at stable doses<sup>1</sup>

## BE COMPLETE (TNFi-IR patients)<sup>1,2</sup>

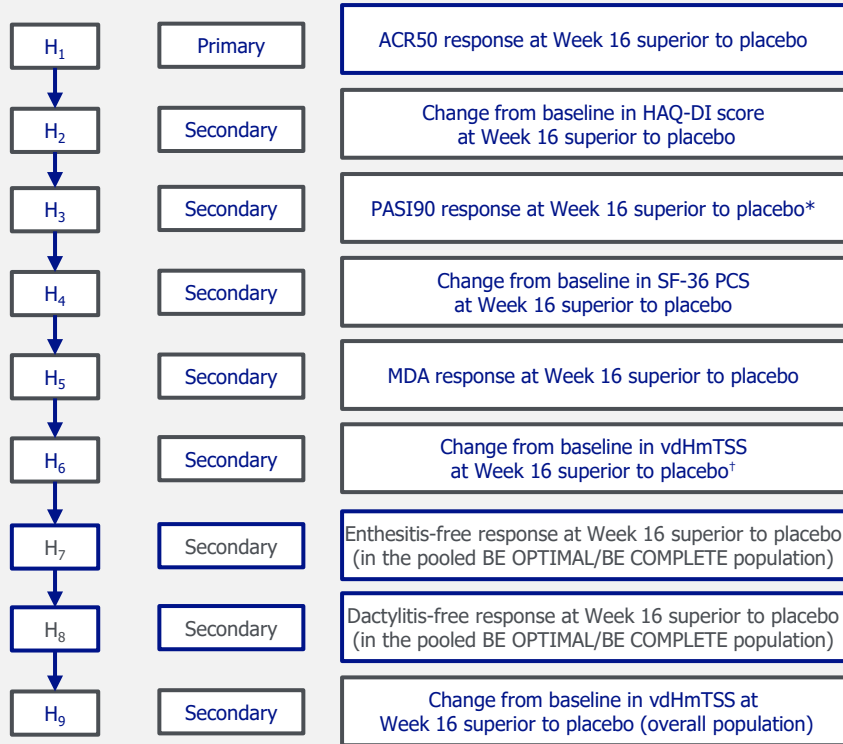




# Statistical Testing Hierarchy

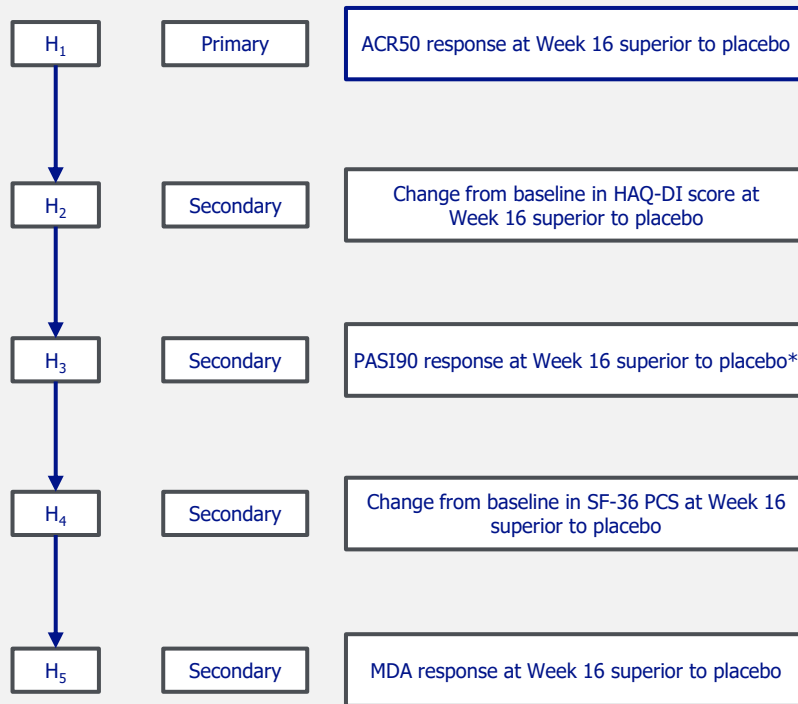
## BE OPTIMAL (bDMARD-naïve patients)<sup>1</sup>

Bimekizumab  
160 mg Q4W  
 $\alpha=0.05$



## BE COMPLETE (TNFi-IR patients)<sup>2</sup>

Bimekizumab  
160 mg Q4W  
 $\alpha=0.05$



# BE OPTIMAL and BE COMPLETE: Baseline Characteristics (1/2)

	BE OPTIMAL <sup>1</sup>			BE COMPLETE <sup>2</sup>	
	Placebo (n=281)	BKZ 160 mg Q4W (n=431)	Reference Arm (ADA 40 mg Q2W) (n=140)	Placebo (n=133)	BKZ 160 mg Q4W (n=267)
Age, mean (SD), y	48.7 (11.7)	48.5 (12.6)	49.0 (12.8)	51.3 (12.9)	50.1 (12.4)
Sex, male, n (%)	127 (45)	201 (47)	71 (51)	60 (45)	130 (49)
BMI, mean (SD), kg/m <sup>2</sup>	29.6 (6.1)	29.2 (6.8)	28.4 (5.9)	29.0 (5.4)	30.1 (6.5)
Time since PsA diagnosis,* mean (SD), y	5.6 (6.5)	6.0 (7.3)	6.1 (6.8)	9.2 (8.1)	9.6 (9.9)
csDMARDs at baseline, n (%)	192 (68)	301 (70)	99 (71)	63 (47)	139 (52)
Concomitant methotrexate, n (%)	162 (58)	252 (59)	82 (59)	51 (38)	119 (45)
Prior TNFi exposure, n (%)					
Inadequate response to 1 TNFi	-	-	-	103 (77)	204 (76)
Inadequate response to 2 TNFi	-	-	-	15 (11)	29 (11)
Intolerance to TNFi	-	-	-	15 (11)	34 (13)
TJC (of 68 joints), mean (SD)	17.1 (12.5)	16.8 (11.8)	17.5 (13.1)	19.3 (14.2)	18.4 (13.5)
SJC (of 66 joints), mean (SD)	9.5 (7.3)	9.0 (6.2)	9.7 (7.1)	10.3 (8.2)	9.7 (7.5)
hs-CRP ≥6 mg/L, n (%)	121 (43)	158 (37)	44 (31)	59 (44)	118 (44)

# BE OPTIMAL and BE COMPLETE: Baseline Characteristics (2/2)

	BE OPTIMAL <sup>1</sup>			BE COMPLETE <sup>2</sup>	
	Placebo (n=281)	BKZ 160 mg Q4W (n=431)	Reference Arm (ADA 40 mg Q2W) (n=140)	Placebo (n=133)	BKZ 160 mg Q4W (n=267)
Affected BSA ≥3%, n (%)	140 (50)	217 (50)	68 (49)	88 (66)	176 (66)
PASI score,* mean (SD)	7.9 (5.6)	8.2 (6.8)	8.6 (7.6)	8.5 (6.6)	10.1 (9.1)
HAQ-DI score, <sup>†</sup> mean (SD)	0.89 (0.61)	0.82 (0.59)	0.86 (0.54)	1.0 (0.69)	1.0 (0.59)
SF-36 PCS, <sup>†</sup> mean (SD)	36.9 (9.7)	38.1 (9.4)	37.6 (8.8)	35.9 (10.2)	36.4 (9.0)
PtAAP, <sup>†</sup> mean (SD)	56.8 (23.2)	53.6 (24.3)	56.7 (23.9)	61.7 (24.6)	58.3 (24.2)
Nail psoriasis, <sup>‡</sup> n (%)	-	-	-	83 (62)	159 (60)
mNAPSI score, <sup>§</sup> mean (SD)	-	-	-	4.5 (2.8)	4.3 (2.8)
Enthesitis, <sup>  </sup> n (%)	70 (25)	143 (33)	36 (26)	36 (27)	106 (40)
LEI score, <sup>  </sup> mean (SD)	2.9 (1.5)	2.5 (1.5)	2.3 (1.6)	2.9 (1.6)	2.6 (1.5)
Dactylitis,** n (%)	33 (12)	56 (13)	11 (8)	14 (11)	34 (13)
LDI score, <sup>††</sup> mean (SD)	47.3 (41.1)	46.7 (54.3)	49.7 (31.9)	66.4 (127.6)	72.7 (114.4)

Randomized set.<sup>1,2</sup> \*In patients with ≥3% BSA with PSO at baseline (BE OPTIMAL: placebo, n=140; BKZ 160 mg Q4W, n=217; reference group [ADA 40 mg Q2W], n=68; BE COMPLETE: placebo, n=83; BKZ 160 mg Q4W, n=176).<sup>1,2</sup> †BE OPTIMAL: data missing for 1 patient receiving BKZ.<sup>1</sup> ‡mNAPSI score >0.<sup>1,2</sup> §BE COMPLETE: data missing for 1 patient receiving placebo.<sup>2</sup> ¶In patients with nail psoriasis at baseline (BE COMPLETE; placebo, n=83; BKZ, n=159).<sup>2</sup> ||The presence of enthesitis was defined by a score greater than 0 on the LEI.<sup>1,2</sup> BE OPTIMAL: data missing for 6 patients receiving BKZ and for 1 patient receiving ADA.<sup>1</sup> ††In patients with enthesitis at baseline (BE COMPLETE: placebo, n=36; BKZ, n=106).<sup>2</sup> \*\*Leeds Dactylitis Index >0; BE OPTIMAL: data missing for 1 patient receiving placebo, 7 patients receiving BKZ, and 1 patient receiving ADA.<sup>1,2</sup> †††In patients with dactylitis at baseline (BE COMPLETE: placebo, n=14; BKZ, n=34).<sup>1,2</sup>

1. McInnes IB, et al. *Lancet*. 2023;401(10370):25-37. 2. Merola JF, et al. *Lancet*. 2023;401(10370):38-48.

# BE OPTIMAL Met the Primary and All Ranked Secondary Endpoints at Week 16

	BE OPTIMAL			
	Placebo (n=281)	BKZ 160 mg Q4W (n=431)	BKZ vs placebo p value*	Reference Arm (ADA 40 mg Q2W) (n=140) <sup>†</sup>
ACR50 response <sup>‡</sup>	<b>28 (10%)</b>	<b>189 (44%)</b>	<b>&lt;0.0001</b>	<b>64 (46%)</b>
HAQ-DI score CFB	-0.09 (0.03)	-0.26 (0.02)	<0.0001	-0.33 (0.04)
PASI90 response <sup>§</sup>	4 of 140 (3%)	133 of 217 (61%)	<0.0001	28 of 68 (41%)
SF-36 PCS CFB	2.3 (0.5)	6.3 (0.4)	<0.0001	6.8 (0.8)
MDA response	37 (13%)	194 (45%)	<0.0001	63 (45%)
vdHmTSS CFB (at-risk subgroup); No. of patients	0.36 (0.10); 227	0.01 (0.04); 361	0.0012	-0.06 (0.08); 112
Complete resolution of enthesitis (pooled) <sup>  </sup>	37 (35%) of 106	124 (50%) of 249	0.0083	18 (50%) of 36
Complete resolution of dactylitis (pooled) <sup>  </sup>	24 (51%) of 47	68 (76%) of 90	0.0022	9 (82%) of 11
vdHmTSS CFB (overall population); No. of patients	0.31 (0.09); 269	0.01 (0.04); 420	0.0012	-0.03 (0.07); 135

**Missing data were imputed using RBMI for continuous variables and NRI for proportions.** Randomized set. Data are n (%) or mean CFB (SE) unless indicated. \*For binary values, ORs, CIs, and p values were generated using logistic regression with treatment, bone erosion, and region as factors. For enthesitis and dactylitis resolution, where data were pooled from BE OPTIMAL and BE COMPLETE, the study was also included as a factor in the model, and bone erosion at baseline was excluded. For continuous variables, least squares mean, SE, difference in least squares means, and p values were generated using ANCOVA with treatment, bone erosion at baseline, and region as fixed effects and the baseline value as covariate. <sup>†</sup>The adalimumab 40-mg every-2-weeks treatment group served as an active reference, and the study was not powered for statistical comparisons of adalimumab to bimekizumab or placebo. <sup>‡</sup>Primary endpoint. <sup>§</sup>In patients with psoriasis affecting 3% or more BSA at baseline. <sup>||</sup>Resolution of enthesitis and dactylitis data are reported for patients with enthesitis or dactylitis at baseline. Data for the placebo and bimekizumab groups are pooled from the BE OPTIMAL and BE COMPLETE trials; data for patients in the reference group are reported from BE OPTIMAL only. McInnes IB, et al. *Lancet*. 2023;401(10370):25-37.

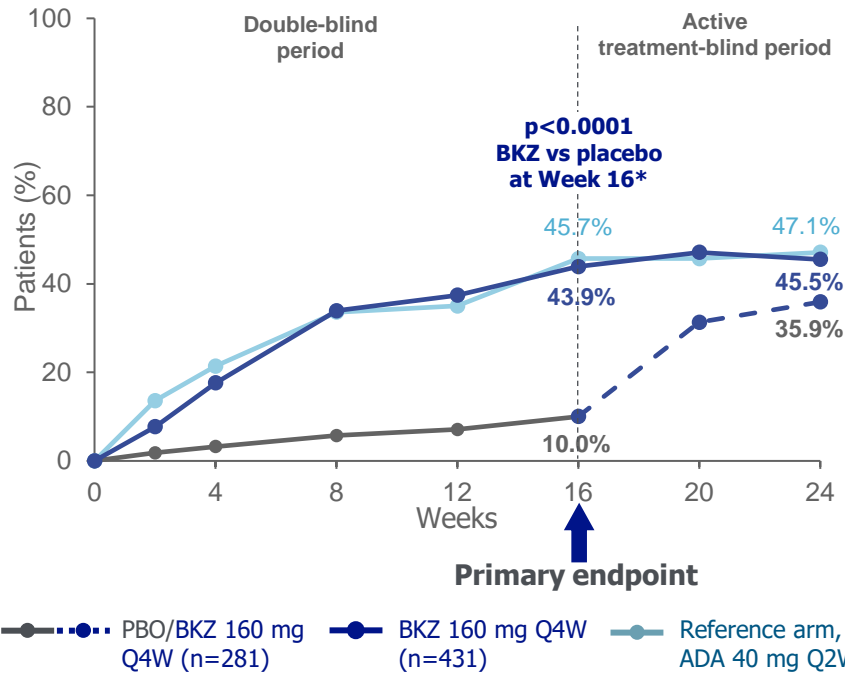
# BE COMPLETE Met the Primary and All Ranked Secondary Endpoints at Week 16

	BE COMPLETE		
	Placebo (n=133)	BKZ 160 mg Q4W (n=267)	BKZ vs placebo p value*
ACR50 response <sup>†</sup>	9 (7%)	116 (43%)	<0.0001
HAQ-DI score Cfb	-0.07 (0.04)	-0.38 (0.03)	<0.0001
PASI90 response <sup>‡</sup>	6 (7%) of 88	121 (69%) of 176	<0.0001
SF-36 PCS Cfb	1.4 (0.7)	7.3 (0.5)	<0.0001
MDA response	8 (6%)	118 (44%)	<0.0001

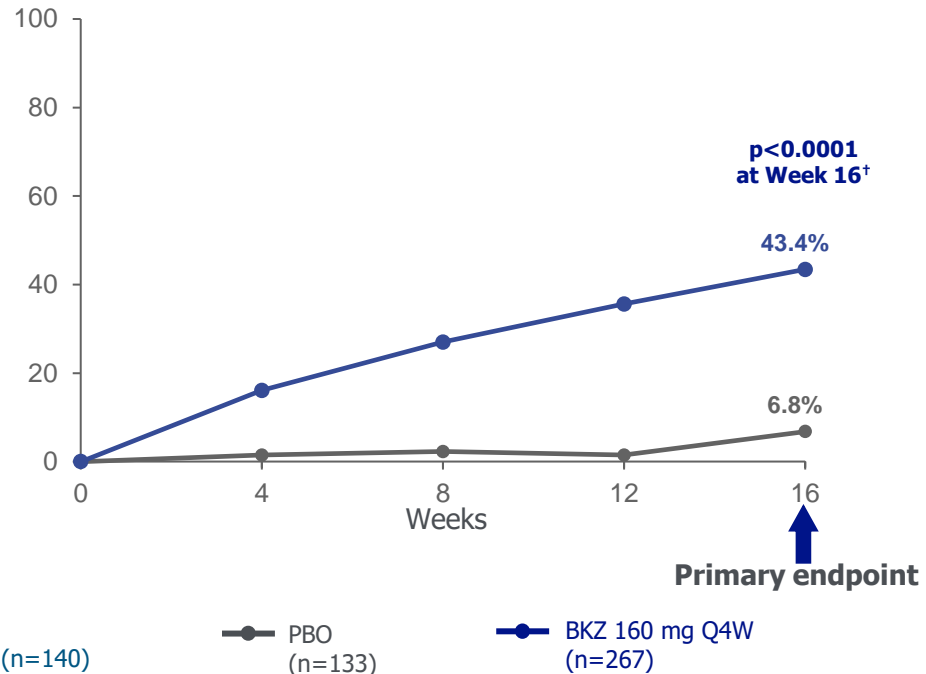
**Missing data were imputed using RBMI for continuous variables and NRI for binary variables.** Randomized set. Data are n (%) or mean Cfb (SE) unless indicated. \*For binary variables, ORs, CIs, and p values were generated using logistic regression with treatment, previous exposure to TNF $\alpha$  inhibitors, and region as factors. For continuous variables, least squares means, SEs, difference in least squares means, and p values were generated using ANCOVA with treatment, previous exposure to TNF $\alpha$  inhibitors, and region as fixed effects and the baseline value of the outcome as covariate. <sup>†</sup>Primary endpoint. <sup>‡</sup>In patients with psoriasis affecting 3% or more BSA at baseline. Merola JF, et al. *Lancet*. 2023;401(10370):38-48.

# ACR50 Response With BKZ to Week 16 or Week 24 in bDMARD-Naïve and TNFi-IR Patients (NRI)

**BE OPTIMAL (bDMARD-naïve patients)<sup>1</sup>**

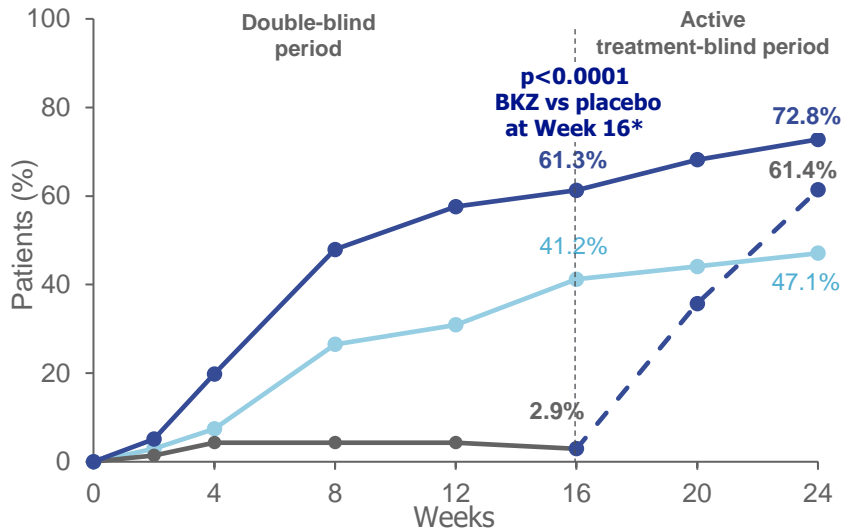


**BE COMPLETE (TNFi-IR patients)<sup>2</sup>**

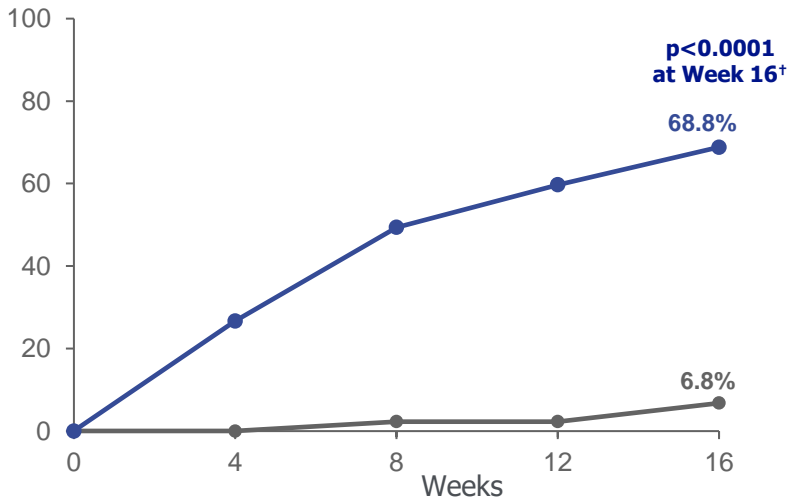


# PASI90 Response With BKZ to Week 16 or Week 24 in bDMARD-Naïve and TNFi-IR Patients (NRI)

BE OPTIMAL (bDMARD-naïve patients)<sup>1</sup>



BE COMPLETE (TNFi-IR patients)<sup>2</sup>



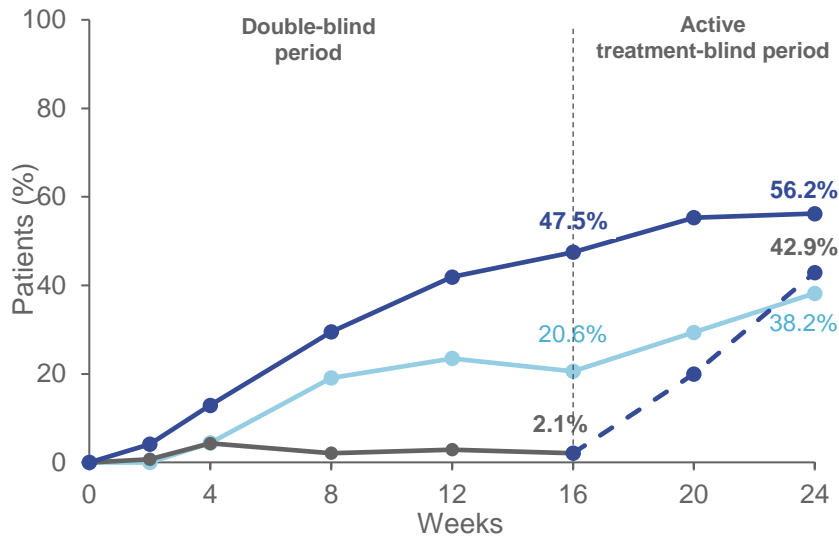
● PBO/BKZ 160 mg Q4W (n=140)
 ● BKZ 160 mg Q4W (n=217)
 ● Reference arm, ADA 40 mg Q2W (n=68)

● PBO (n=88)

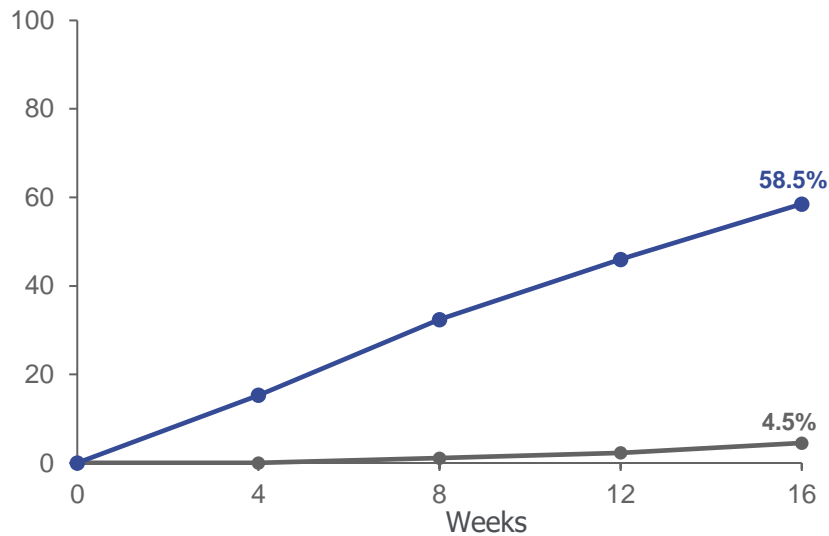
● BKZ 160 mg Q4W (n=176)

# PASI100 Response With BKZ to Week 16 or Week 24 in bDMARD-Naïve and TNFi-IR Patients (NRI)

**BE OPTIMAL (bDMARD-naïve patients)<sup>1</sup>**



**BE COMPLETE (TNFi-IR patients)<sup>2</sup>**



●●● PBO/BKZ 160 mg Q4W (n=140)

● BKZ 160 mg Q4W (n=217)

● Reference arm, ADA 40 mg Q2W (n=68)

● PBO (n=88)

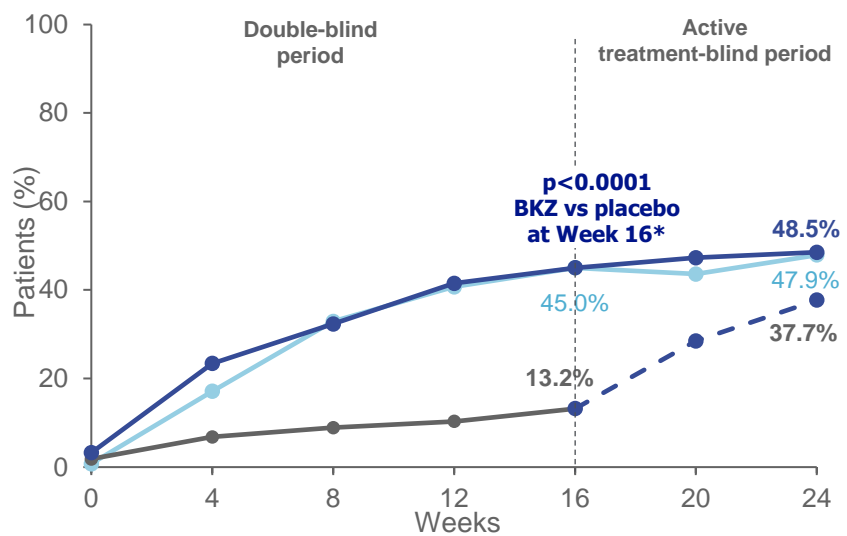
● BKZ 160 mg Q4W (n=176)



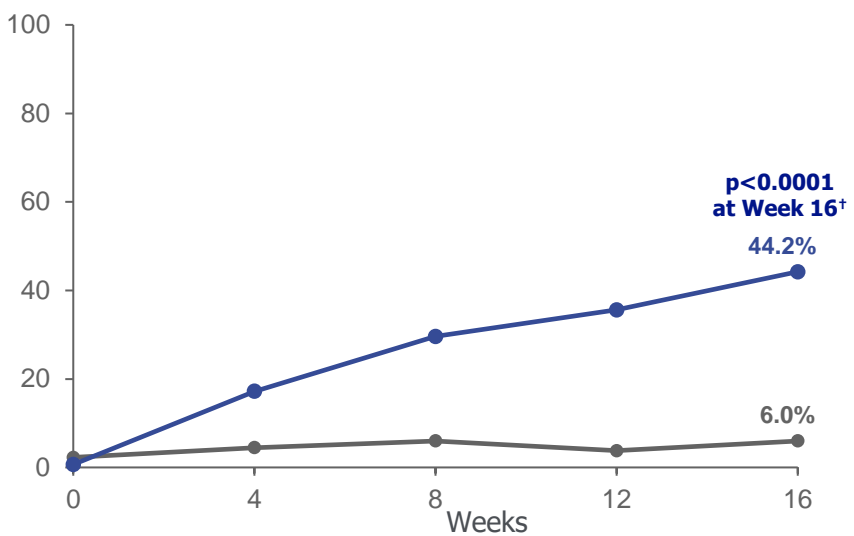
# Minimal Disease Activity (MDA) Response With BKZ to Week 16 or Week 24 in bDMARD-Naïve and TNFi-IR Patients (NRI)

**MDA response defined as achievement of at least 5 of the following 7 criteria:**  
 TJC of  $\leq 1$ , SJC of  $\leq 1$ , PASI  $\leq 1$  or BSA  $\leq 3\%$ , patient assessment of arthritis pain (VAS)  $\leq 15$ , patient global assessment for PsA (VAS)  $\leq 20$ , HAQ-DI  $\leq 0.5$ , and tender entheses points (LEI)  $\leq 1^{1,2}$

**BE OPTIMAL (bDMARD-naïve patients)<sup>1</sup>**



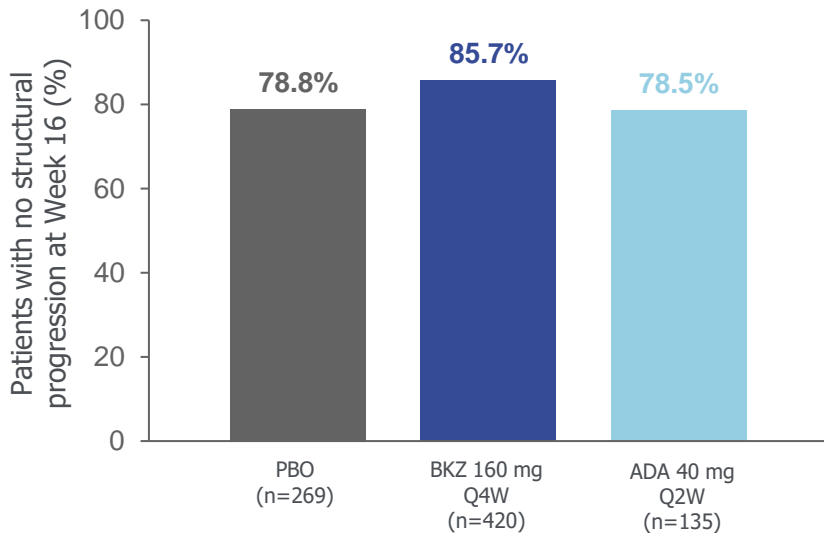
**BE COMPLETE (TNFi-IR patients)<sup>2</sup>**



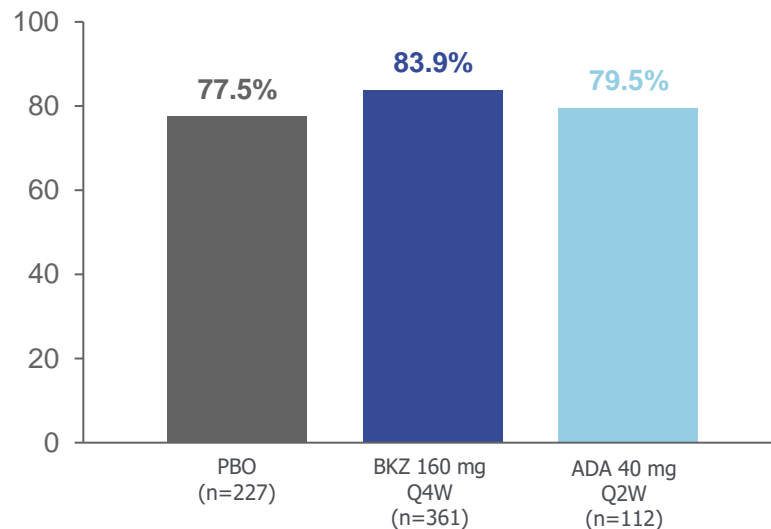
PBO/BKZ 160 mg Q4W (n=281)   
  BKZ 160 mg Q4W (n=431)   
  Reference arm, ADA 40 mg Q2W (n=140)   
  PBO (n=133)   
  BKZ 160 mg Q4W (n=267)

# BE OPTIMAL: Inhibition of Structural Progression With BKZ at Week 16 in bDMARD-Naïve Patients (NRI)

Overall Population<sup>1</sup>

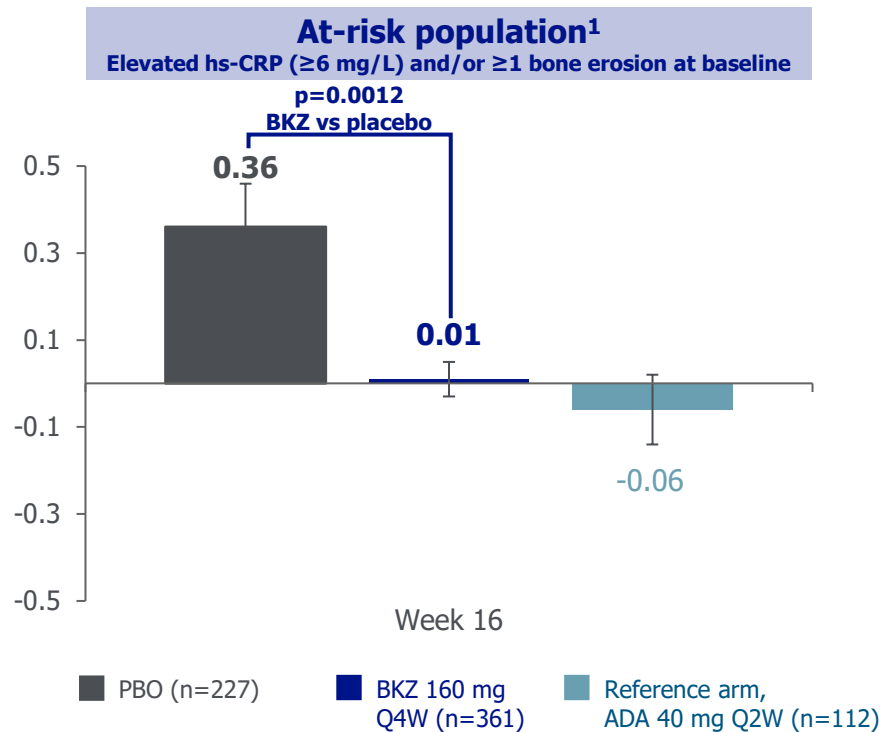
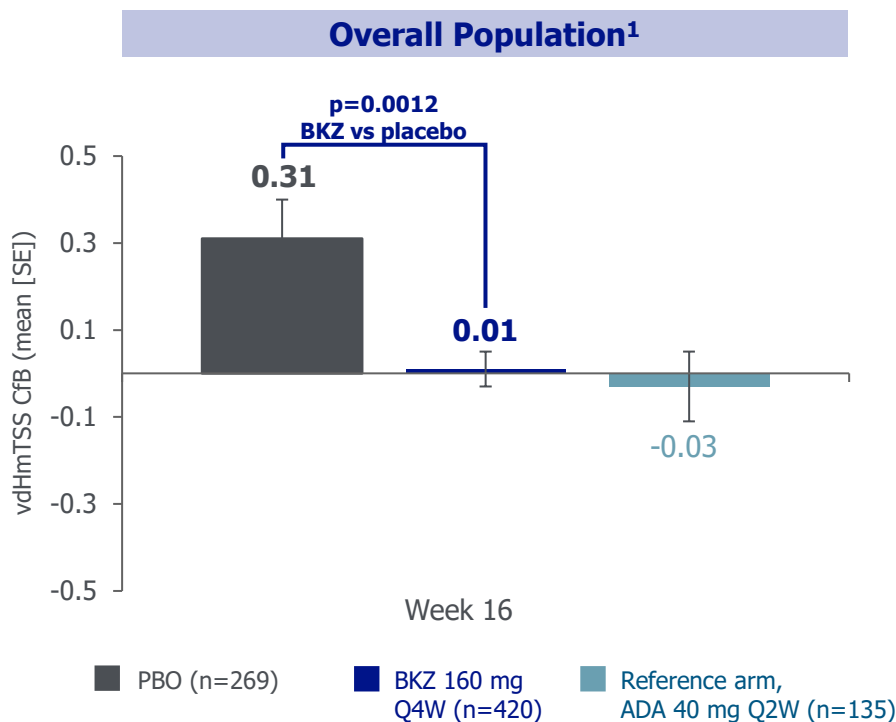


At-risk population<sup>1,2,\*</sup>  
Elevated hs-CRP ( $\geq 6$  mg/L) and/or  $\geq 1$  bone erosion at baseline



**Non-responder imputation (Week 16).**<sup>1</sup> Radiographic set.<sup>1</sup> No structural progression defined as vdHmTSS score CFB  $\leq 0.5$ .<sup>2</sup> This analysis was not performed for the BE COMPLETE study.<sup>3</sup> \*Patients were stratified by bone erosion number at baseline (0 or  $\geq 1$ ) and region (North America, western Europe, eastern Europe, or Asia).<sup>1</sup>  
1. McInnes IB, et al. Supplementary appendix. *Lancet*. 2023;401(10370):25-37. 2. McInnes IB, et al. *Lancet*. 2023;401(10370):25-37. 3. Merola JF, et al. *Lancet*. 2023;401(10370):38-48.

# BE OPTIMAL: Inhibition of Structural Progression With BKZ at Week 16 in bDMARD-Naïve Patients (MI)



# BE OPTIMAL: Adverse Event Summary to Week 16 and Week 24 (1/4)

n (%)	Weeks 0–16			Weeks 0–24		
	Placebo n=281	BKZ 160 mg Q4W n=431	Reference Arm (ADA 40 mg Q2W) n=140	Placebo to BKZ 160 mg Q4W n=271*	BKZ 160 mg Q4W n=431	Reference Arm (ADA 40 mg Q2W) n=140
Any TEAE	139 (49)	258 (60)	83 (59)	95 (35)	300 (70)	96 (69)
Serious TEAE	3 (1)	7 (2)	2 (1)	3 (1)	17 (4)	5 (4)
Discontinuation due to TEAE	3 (1)	8 (2)	3 (2)	0	12 (3)	7 (5)
Drug-related TEAE	35 (12)	101 (23)	34 (24)	27 (10)	122 (28)	43 (31)
Severe TEAE	0	4 (1)	3 (2)	1 (<1)	9 (2)	3 (2)
Deaths	0	0	0	0	0	0

# BE OPTIMAL: Adverse Event Summary to Week 16 and Week 24 (2/4)

n (%)	Weeks 0–16			Weeks 0–24		
	Placebo n=281	BKZ 160 mg Q4W n=431	Reference Arm (ADA 40 mg Q2W) n=140	Placebo to BKZ 160 mg Q4W n=271*	BKZ 160 mg Q4W n=431	Reference Arm (ADA 40 mg Q2W) n=140
<b>Most frequent TEAEs†</b>						
Nasopharyngitis	13 (5)	40 (9)	7 (5)	8 (3)	50 (12)	12 (9)
Upper respiratory tract infection	18 (6)	21 (5)	3 (2)	5 (2)	26 (6)	5 (4)
Headache	7 (2)	20 (5)	2 (1)	6 (2)	20 (5)	3 (2)
Diarrhea	7 (2)	16 (4)	5 (4)	1 (<1)	20 (5)	5 (4)
Oral candidiasis	0	9 (2)	0	1 (<1)	15 (3)	0
Pharyngitis	4 (1)	11 (3)	2 (1)	3 (1)	15 (3)	2 (1)
Hypertension	11 (4)	12 (3)	4 (3)	5 (2)	14 (3)	4 (3)
Urinary tract infection	4 (1)	9 (2)	3 (2)	4 (1)	14 (3)	3 (2)
Oral herpes	3 (1)	5 (1)	3 (2)	0	7 (2)	6 (4)
Increased ALT	2 (1)	3 (1)	7 (5)	1 (<1)	4 (1)	8 (6)
Injection site erythema	0	1 (<1)	4 (3)	0	2 (<1)	5 (4)

# BE OPTIMAL: Adverse Event Summary to Week 16 and Week 24 (3/4)

n (%)	Weeks 0–16			Weeks 0–24		
	Placebo n=281	BKZ 160 mg Q4W n=431	Reference Arm (ADA 40 mg Q2W) n=140	Placebo to BKZ 160 mg Q4W n=271*	BKZ 160 mg Q4W n=431	Reference Arm (ADA 40 mg Q2W) n=140
<b>Infections</b>	56 (20)	131 (30)	35 (25)	41 (15)	170 (39)	41 (29)
Serious	0	1 (<1)	1 (1)	0	3 (1)	2 (1)
Opportunistic	0	0	1 (1)	3 (1)	1 (<1)	1 (1)
Active tuberculosis	0	0	0	0	0	0
SARS-CoV-2	0	0	0	1 (<1)	1 (<1)	0
Neutropenia	1 (<1)	5 (1)	1 (1)	1 (<1)	5 (1)	2 (1)
Serious hypersensitivity	0	0	0	0	0	0
Injection site reactions	3 (1)	5 (1)	7 (5)	1 (<1)	6 (1)	11 (8)
Adjudicated SI/B	0	0	0	0	0	0
Adjudicated MACE	0	0	0	0	1 (<1)	0
<b>Liver function test changes or enzyme concentration increases<sup>†</sup></b>						
ALT >3 ULN	0	5 (1)	2 (1)	0	6 (1)	5 (4)
AST >3 ULN	0	5 (1)	3 (2)	0	7 (2)	6 (4)
Adjudicated IBD	0	0	0	0 <sup>‡</sup>	1 (<1) <sup>§</sup>	0
<b>Malignancies</b>						
Breast cancer stage I	1 (<1)	0	0	0	0	0
Non-melanoma skin cancers	0	1 (<1)	0	1 (<1)	2 (<1)	0

# BE OPTIMAL: Adverse Event Summary to Week 16 and Week 24 (4/4)

n (%)	Weeks 0–16			Weeks 0–24		
	Placebo n=281	BKZ 160 mg Q4W n=431	Reference Arm (ADA 40 mg Q2W) n=140	Placebo to BKZ 160 mg Q4W n=271*	BKZ 160 mg Q4W n=431	Reference Arm (ADA 40 mg Q2W) n=140
<b>Fungal infections</b>	4 (1)	20 (5)	1 (1)	7 (3)	33 (8)	1 (1)
<i>Candida</i> infections	2 (1)	11 (3)	0	4 (1)	18 (4)	0
Oral candidiasis	0	9 (2)	0	1 (<1)	15 (3)	0
Vulvovaginal candidiasis	2 (1)	1 (<1)	0	2 (1)	1 (<1)	0
Esophageal candidiasis	0	0	0	1 (<1)	1 (<1)	0
Skin candida	0	1 (<1)	0	0	2 (<1)	0
Fungal infections NEC	2 (1)	9 (2)	0	2 (1)	15 (3)	0
Fungal skin infection	0	3 (1)	0	0	5 (1)	0
Tongue fungal infection	0	3 (1)	0	0	3 (1)	0
Oral fungal infection	0	2 (<1)	0	0	4 (1)	0
Onychomycosis	0	1 (<1)	0	0	1 (<1)	0
Fungal esophagitis	0	0	0	1 (<1)	0	0
Laryngitis fungal	0	0	0	1 (<1)	0	0
Vulvovaginal mycotic infection	2 (1)	0	0	0	3 (1)	0
Tinea infections	0	0	1 (1)	1 (<1)	1 (<1)	1 (1)
Tinea pedis	0	0	0	0	1 (<1)	0
Tinea versicolor	0	0	1 (1)	1 (<1)	0	1 (1)
Serious <i>Candida</i> infections	0	0	0	0	0	0
Systemic fungal infections	0	0	0	0	0	0
<i>Candida</i> infections leading to study discontinuation	0	1 (<1)	0	0	1 (<1)	0

# BE COMPLETE: Adverse Event Summary to Week 16 (1/3)

n (%)	Weeks 0–16	
	Placebo n=132*	BKZ 160 mg Q4W n=267
Any TEAE	44 (33)	108 (40)
Serious TEAEs <sup>†</sup>	0	5 (2)
Discontinuation due to TEAEs <sup>†</sup>	0	2 (1)
Drug-related TEAEs	4 (3)	35 (13)
Severe TEAEs <sup>§</sup>	0	5 (2)
Deaths	0	0
<b>Most frequently reported TEAEs in the BKZ group<sup>  </sup></b>		
Nasopharyngitis	1 (1)	10 (4)
Oral candidiasis	0	7 (3)
Upper respiratory tract infection	2 (2)	6 (2)



# BE COMPLETE: Adverse Event Summary to Week 16 (2/3)

n (%)	Weeks 0–16	
	Placebo n=132*	BKZ 160 mg Q4W n=267
<b>Infections<sup>†</sup></b>		
Serious <sup>‡</sup>	0	2 (1)
Opportunistic	0	0
Active tuberculosis	0	0
SARS-CoV-2	6 (5)	5 (2)
<b>Fungal infections</b>	0	12 (4)
<i>Candida</i> infections <sup>§</sup>	0	7 (3)
Oral candidiasis <sup>§</sup>	0	7 (3)
Fungal infections NEC	0	4 (1)
Fungal skin infection	0	1 (<1)
Tongue fungal infection	0	1 (<1)
Vulvovaginal mycotic infection	0	2 (1)
Tinea infections	0	1 (<1)
Tinea pedis	0	1 (<1)
Serious fungal infections	0	0
Systemic fungal infections	0	0
Fungal infections leading to discontinuation	0	1 (<1)
<i>Candida</i> infections leading to discontinuation	0	1 (<1)

# BE COMPLETE: Adverse Event Summary to Week 16 (3/3)

n (%)	Weeks 0–16	
	Placebo n=132*	BKZ 160 mg Q4W n=267
Neutropenia <sup>†</sup>	0	4 (1)
Serious hypersensitivity	0	0
Injection site reactions	0	3 (1)
Adjudicated SI/B	0	0
Adjudicated MACE	0	0
<b>Liver function test changes or enzyme concentration increases<sup>†</sup></b>		
ALT >3 ULN	0	2 (1)
AST >3 ULN	0	4 (1)
Adjudicated IBD	0	0
<b>Malignancies</b>		
Basal cell carcinoma	1 (1)	0

# Appendix

# Overarching Principles: 2023 Update

	Overarching principle	Level of agreement, mean (SD)
A	Psoriatic arthritis is a heterogeneous and potentially severe disease, which may require multidisciplinary treatment	10.0 (0.1)
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 (0.6)
C	Rheumatologists are the specialists who should primarily care for the musculoskeletal manifestations of patients with psoriatic arthritis; in the presence of clinically relevant skin involvement, a rheumatologist and a dermatologist should collaborate in diagnosis and management	9.7 (0.5)
D	The primary goal of treating patients with psoriatic arthritis is to maximize health-related quality of life, through control of symptoms, prevention of structural damage, normalization of function and social participation; abrogation of inflammation is an important component to achieve these goals	9.9 (0.3)
E	In managing patients with psoriatic arthritis, consideration should be given to each musculoskeletal manifestation and treatment decisions made accordingly	9.8 (0.4)
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 (0.7)
G	The choice of treatment should take account of safety considerations regarding individual modes of action to optimize the benefit–risk profile	9.9 (0.4)

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# Recommendations: 2023 Update (1/2)

	Recommendations	Level of evidence	Grade of recommendation	Level of agreement, mean (SD)
1	Treatment should be aimed at reaching the target of remission or, alternatively, minimal/low disease activity, by regular monitoring and appropriate adjustment of therapy	1b	A	9.5 (1.0)
2	Non-steroidal anti-inflammatory drugs may be used to relieve musculoskeletal signs and symptoms <sup>a</sup> ; local injections of glucocorticoids may be considered as adjunctive therapy <sup>b</sup>	1b <sup>a</sup> , 3b <sup>b</sup>	A, C	9.5 (0.7)
3	In patients with polyarthritis, or those with monoarthritis/oligoarthritis and poor prognostic factors <sup>a</sup> (e.g., structural damage, elevated acute phase reactants, dactylitis or nail involvement), a csDMARD should be initiated rapidly, with methotrexate preferred in those with clinically relevant skin involvement	1b, 4 <sup>a</sup>	B, C	9.3 (0.8)
4	In patients with peripheral arthritis and an inadequate response to at least one csDMARD, therapy with a bDMARD should be commenced	1a	A	9.5 (1.3)
5	In patients with peripheral arthritis and an inadequate response to at least one bDMARD, or when a bDMARD is not appropriate <sup>a</sup> , a JAKi may be considered*, taking safety considerations into account	1b, 4 <sup>a</sup>	B, D	9.1 (1.5)

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The level of evidence is an estimate of the extent to which a bullet-point is supported by the availability of properly weighed scientific publications on a 1-5 level (1=most supported, 4=least supported). The grade of recommendation is determined by qualitative assessment and expert opinion. The level of agreement was recorded on a scale ranging from 0 (no agreement) to 10 (full agreement). \*For JAKi, caution is needed for patients aged 65 years or above, those who are current or past long-time smokers, with a history of atherosclerotic cardiovascular disease or other cardiovascular risk factors or with other malignancy risk factors, and with known risk factors for venous thromboembolism. The superscript letters 'a' and 'b' are used to link a part of the recommendation to a level of evidence.

# Recommendations: 2023 Update (2/2)

	Recommendations	Level of evidence	Grade of recommendation	Level of agreement, mean (SD)
6	In patients with mild disease* and an inadequate response to at least one csDMARD, in whom neither a bDMARD nor a JAKi is appropriate <sup>†</sup> , a PDE4 inhibitor may be considered	1b	B	8.7 (1.1)
7	In patients with unequivocal enthesitis and an insufficient response to NSAIDs or local glucocorticoid injections, therapy with a bDMARD should be considered	1b	B	9.5 (0.9)
8	In patients with clinically relevant axial disease with an insufficient response to NSAIDs, therapy with an IL-17Ai, a TNFi, an IL-17A/Fi or a JAKi should be considered <sup>†</sup>	1b	B	9.4 (1.3)
9	The choice of the mode of action should reflect non-musculoskeletal manifestations related to psoriatic arthritis; with clinically relevant skin involvement, preference should be given to an IL-17A or IL-17A/F or IL-23 or IL-12/23 inhibitor; with uveitis to an anti-TNF monoclonal antibody; and with IBD to an anti-TNF monoclonal antibody or an IL-23i or IL-12/23i or a JAKi <sup>†</sup>	1b	B	9.6 (0.7)
10	In patients with an inadequate response or intolerance to a bDMARD or a JAKi, switching to another bDMARD or JAKi should be considered <sup>†,a</sup> , including one switch within a class <sup>b</sup>	1b <sup>a</sup> , 4 <sup>b</sup>	C	9.5 (0.7)
11	In patients in sustained remission, tapering of DMARDs may be considered	2b	B	9.4 (1.2)

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The level of evidence is an estimate of the extent to which a bullet-point is supported by the availability of properly weighed scientific publications on a 1-5 level (1=most supported, 4=least supported). The grade of recommendation is determined by qualitative assessment and expert opinion. The level of agreement was recorded on a scale ranging from 0 (no agreement) to 10 (full agreement). \*Mild disease is defined as oligoarticular or enthesal disease without poor prognostic factors and limited skin involvement. <sup>†</sup>For JAKis, caution is needed for patients aged 65 years or above, those who are current or past long-time smokers, with a history of atherosclerotic cardiovascular disease or other cardiovascular risk factors or with other malignancy risk factors, and with known risk factors for venous thromboembolism. The superscript letters 'a' and 'b' are used to link a part of the recommendation to a level of evidence.

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# Abbreviations

# Abbreviations

	Description
<b>ACR50</b>	≥50% improvement in American College of Rheumatology criteria
<b>ADA</b>	Adalimumab
<b>ALT</b>	Alanine aminotransferase
<b>ANCOVA</b>	Analysis of covariance
<b>AST</b>	Aspartate aminotransferase
<b>axSpA</b>	Axial spondyloarthritis
<b>bDMARD</b>	Biologic disease-modifying antirheumatic drug
<b>BKZ</b>	Bimekizumab
<b>BMI</b>	Body mass index
<b>BSA</b>	Body surface area
<b>CASPAR</b>	Classification criteria for psoriatic arthritis
<b>CfB</b>	Change from baseline
<b>csDMARD</b>	Conventional synthetic disease-modifying antirheumatic drug
<b>CVDs</b>	Cardiovascular diseases
<b>CTLA-4</b>	Cytotoxic T-lymphocyte protein 4
<b>DMARD</b>	Disease-modifying antirheumatic drug
<b>EAIR</b>	Exposure-adjusted incidence rate
<b>EMA</b>	European Medicines Agency
<b>EULAR</b>	European Alliance of Associations for Rheumatology
<b>FDA</b>	Food and Drug Administration
<b>HAQ-DI</b>	Health Assessment Questionnaire – Disability Index
<b>hs-CRP</b>	High-sensitivity C-reactive protein

	Description
<b>IBD</b>	Inflammatory bowel disease
<b>IL</b>	Interleukin
<b>IL-Xi</b>	Interleukin X inhibitor
<b>IR</b>	Inadequate response
<b>JAKi</b>	Janus kinase inhibitor
<b>LDI</b>	Leeds dactylitis index
<b>LEI</b>	Leeds enthesitis index
<b>MACE</b>	Major adverse cardiovascular event
<b>MDA</b>	Minimal disease activity
<b>MI</b>	Multiple imputation
<b>mNAPSI</b>	Modified Nail Psoriasis Severity Index
<b>NEC</b>	Not elsewhere classified
<b>NRI</b>	Nonresponder imputation
<b>NSAIDs</b>	Nonsteroidal anti-inflammatory drugs
<b>OLE</b>	Open-label extension
<b>OR</b>	Odd ratio
<b>PASI90/100</b>	≥90%/100% improvement in Psoriasis Area and Severity Index
<b>PBO</b>	Placebo
<b>PCS</b>	Physical Component Summary
<b>PDE4i</b>	3',5'-Cyclic-AMP phosphodiesterase 4A inhibitor
<b>PsA</b>	Psoriatic arthritis
<b>PSO</b>	Psoriasis
<b>PtAAP</b>	Patient Assessment of Arthritis Pain

	Description
<b>PY</b>	Patient-years
<b>Q2/4W</b>	Every 2/4 weeks
<b>RA</b>	Rheumatoid arthritis
<b>RBMI</b>	Reference based multiple imputation
<b>SARS-CoV-2</b>	Severe acute respiratory syndrome coronavirus 2
<b>SF-36</b>	36-Item Short-Form Health Survey
<b>SI/B</b>	Suicide ideation and behavior
<b>SJC</b>	Swollen joint count
<b>TEAE</b>	Treatment-emergent adverse event
<b>TNF</b>	Tumor necrosis factor
<b>TJC</b>	Tender joint count
<b>TNFi</b>	Tumor necrosis factor inhibitor
<b>tsDMARD</b>	Targeted synthetic disease-modifying antirheumatic drug
<b>TYK2i</b>	Tyrosine kinase 2 inhibitor
<b>ULN</b>	Upper limit of normal
<b>VAS</b>	Visual analogue scale
<b>vdHmTSS</b>	van der Heijde-modified total Sharp score