Inhibition of Radiographic Progression with Bimekizumab Treatment Observed in bDMARD-Naïve Patients with Active Psoriatic Arthritis at 2 Years: Results from a Phase 3 Study and Its Open-Label Extension

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Objective

To assess radiographic progression at 2 years with bimekizumab (BKZ) treatment in patients with active psoriatic arthritis (PsA) who were biologic disease-modifying antirheumatic drug (bDMARD)-naïve.

Background

- BKZ is a humanised IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.
- Persistent inflammation in patients with PsA can lead to irreversible structural damage and negative impacts on physical function and quality of life.[1]
- Prevention of structural damage is a key treatment goal in PsA.[2]
- BKZ treatment has shown significantly greater inhibition of radiographic progression compared with placebo (PBO) at 16 weeks in patients with active PsA;[3] minimal changes in radiographic progression have been observed in those treated with BKZ as early as 16 weeks and sustained up to 1 year.[4]

Methods

- BE OPTIMAL (NCT03895203), PBO-controlled to Week 16, assessed subcutaneous BKZ 160 mg every 4 weeks (Q4W) in bDMARD-naïve patients with PsA, and included a reference arm (adalimumab [ADA] 40 mg Q2W).
- PBO patients switched to BKZ at Week 16 (PBO/BKZ); ADA patients switched to BKZ at Week 52 with no washout between treatments (ADA/BKZ).
- Week 52 completers could enter BE VITAL (NCT04009499), an ongoing open-label extension, in which all patients received BKZ 160 mg Q4W.
- At Week 104, PBO/BKZ, BKZ-randomised and ADA/BKZ patients had received 88, 104 and 52 weeks of BKZ treatment, respectively.
- Radiographic progression was assessed on plain radiographs of the hands and feet using the van der Heijde modified Total Sharp Score (vdHmTSS; score range: 0–528, with higher scores representing greater damage), quantifying the extent of joint damage based on erosions and joint space narrowing (JSN).
- Radiographs taken at baseline and Week 104 were read centrally and independently by two experienced readers, blind to treatment assignment and time course of the films; readings were adjudicated by a third reader in the event of disagreement.
- Data are reported as observed case for patients with radiographs available at Week 104, in the overall radiographic set and at-risk set (subgroup of patients at higher risk of progression; high-sensitivity C-reactive protein levels [hs-CRP] ≥6 mg/L and/or ≥1 bone erosion at baseline):
  - Mean change from baseline (CfB) in vdHmTSS, vdH JSN sub-score and vdH Erosions sub-score
  - Cumulative probability of vdHmTSS CfB
  - Proportion of patients with no radiographic progression, defined as vdHmTSS CfB ≤0.5 and ≤0.0

Results

- Of 852 patients randomised at baseline, 664 patients in the overall radiographic set (221 PBO/BKZ, 343 BKZ, 100 ADA/BKZ) had radiographs taken at baseline and at Week 104; of these, 566 (85.2%) patients were in the at-risk set (186 PBO/BKZ, 296 BKZ, 84 ADA/BKZ).
- Patients had similar vdHmTSS scores at baseline across treatment arms (**Table 1**).
- Most patients had minimal changes in vdHmTSS score at Week 104 (**Figure 1**).
- Radiographic progression to Week 104 was minimal, with negligible changes in mean vdH Erosions and JSN sub-scores at 2 years across all treatment arms and in both sets (**Table 2**).
- High proportions of patients experienced no radiographic progression at Week 104, both in the overall radiographic and at-risk set (**Figure 2**).

Conclusions

Inhibition of radiographic progression was observed at 2 years with bimekizumab treatment in bDMARD-naive patients with active PsA, including those in the at-risk set. Most patients experienced no radiographic progression, regardless of original randomisation group.

Summary

Persistent inflammation in patients with **PsA** can lead to irreversible structural damage; preventing structural damage is a key treatment goal.

Radiographic progression was assessed at **2 years** with **bimekizumab** treatment in **bDMARD-naïve patients** with active **PsA** using the vdHmTSS, in:

Overall radiographic set
Patients with radiographs available to 2 years

At-risk set
Patients with hs-CRP ≥6 mg/L and/or ≥1 bone erosion at baseline with radiographs available to 2 years

In both sets, most patients experienced no radiographic progression[a] at Week 104 (OC):

Inhibition of radiographic progression was observed at **2 years** with **bimekizumab** treatment in **bDMARD-naïve** patients with **active PsA**.

[a] Defined as vdHmTSS change from baseline ≤0.5.

Table 1 Baseline characteristics

	Overall radiographic set			At-risk radiographic set (hs-CRP ≥6 mg/L and/or ≥1 bone erosion at baseline)		
	PBO/BKZ 160 mg Q4W n=221	BKZ 160 mg Q4W n=343	Reference (ADA 40 mg Q2W)/ BKZ 160 mg Q4W n=100	PBO/BKZ 160 mg Q4W n=186	BKZ 160 mg Q4W n=296	Reference (ADA 40 mg Q2W)/ BKZ 160 mg Q4W n=84
Age, years, mean (SD)	48.5 (11.4)	48.2 (12.4)	48.6 (12.5)	50.0 (11.3)	48.9 (12.2)	50.2 (12.2)
Male, n (%)	106 (48.0)	159 (46.4)	55 (55.0)	91 (48.9)	146 (49.3)	49 (58.3)
BMI, kg/m^2, mean (SD)	29.1 (5.4)	29.1 (6.5)	27.6 (5.2)	29.4 (5.5)	29.4 (6.5)	27.5 (5.2)
Time since first PsA diagnosis, years, mean (SD)	5.4 (6.0)	6.2 (7.6)[a]	6.3 (7.1)[b]	6.0 (6.3)	6.6 (8.0)[a]	6.9 (7.4)
TJC (of 68 joints), mean (SD)	16.3 (11.6)	16.7 (11.8)	16.3 (12.5)	16.3 (11.7)	17.1 (11.8)	15.9 (12.5)
SJC (of 66 joints), mean (SD)	9.3 (7.4)	8.9 (6.1)	9.6 (7.4)	9.6 (7.7)	9.1 (6.2)	9.5 (7.6)
hs-CRP ≥6 mg/L, n (%)	94 (42.5)	131 (38.2)	28 (28.0)	94 (50.5)	131 (44.3)	28 (33.3)
vdHmTSS						
vdHmTSS score, mean (SD)	13.36 (23.81)	13.03 (31.92)	12.77 (21.36)	15.76 (25.24)	14.91 (33.99)	15.10 (22.57)
Baseline score >0, n (%)	186 (84.2)	299 (87.2)	84 (84.0)	179 (96.2)	286 (96.6)	80 (95.2)
Mean score (SD) in patients with score >0	15.20 (26.20)	14.75 (31.52)	14.84 (22.49)	15.73 (26.57)	15.31 (32.12)	15.38 (22.91)
vdH JSN						
vdH JSN sub-score, mean (SD)	7.58 (12.97)	7.31 (15.93)	8.12 (14.94)	8.93 (13.72)	8.32 (16.91)	9.58 (15.89)
Baseline score >0, n (%)	143 (64.7)	235 (68.5)	71 (71.0)	136 (73.1)	222 (75.0)	67 (79.8)
Mean score (SD) in patients with score >0	11.19 (16.43)	10.81 (17.99)	10.62 (14.71)	11.68 (16.70)	11.30 (18.39)	11.01 (15.04)
vdH Erosions sub-score, mean (SD)	5.79 (11.96)	5.71 (16.74)	4.65 (7.39)	6.85 (12.77)	6.58 (17.87)	5.52 (7.77)
Bone erosions						
Bone erosion ≥1, n (%)	165 (74.7)	270 (78.7)	79 (79.0)	158 (84.9)	257 (86.8)	77 (91.7)
Mean number of bone erosions (SD) in patients with ≥1 erosion	7.3 (11.5)	6.9 (17.1)	6.2 (7.9)	7.6 (11.6)	7.2 (17.5)	6.3 (7.9)

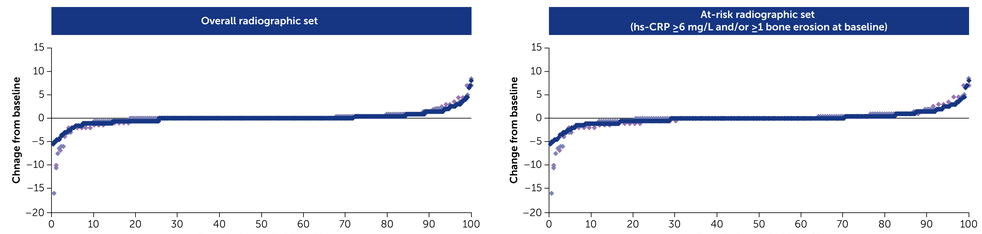
Radiographic set. Baseline scores are reported for patients who were assessed at both baseline and 2 years. PBO/BKZ patients switched from PBO to BKZ at Week 16. ADA/BKZ patients switched from ADA to BKZ at Week 52. **[a]** Data missing for 6 patients; **[b]** Data missing for 1 patient.

Table 2 Mean change from baseline in radiographic endpoints at Week 104 (OC)

	Overall radiographic set			At-risk radiographic set (hs-CRP ≥6 mg/L and/or ≥1 bone erosion at baseline)		
	PBO/BKZ 160 mg Q4W n=221	BKZ 160 mg Q4W n=343	Reference (ADA 40 mg Q2W)/ BKZ 160 mg Q4W n=100	PBO/BKZ 160 mg Q4W n=186	BKZ 160 mg Q4W n=296	Reference (ADA 40 mg Q2W)/ BKZ 160 mg Q4W n=84
vdHmTSS, mean (SD)	0.08 (2.05) (n=218)	0.07 (1.43) (n=335)	0.06 (2.01) (n=99)	0.08 (2.23) (n=184)	0.07 (1.53) (n=289)	0.02 (2.19) (n=83)
vdH JSN sub-score, mean (SD)	0.01 (0.98) (n=218)	0.09 (0.67) (n=335)	0.14 (0.78) (n=99)	0.02 (1.07) (n=184)	0.11 (0.72) (n=289)	0.16 (0.84) (n=83)
vdH Erosions sub-score, mean (SD)	0.03 (1.39) (n=218)	−0.03 (1.07) (n=335)	−0.08 (1.49) (n=99)	0.03 (1.51) (n=184)	−0.05 (1.14) (n=289)	−0.13 (1.61) (n=83)

Radiographic set. Data are reported as observed case for all patients with radiographs available at Week 104. PBO/BKZ patients switched from PBO to BKZ at Week 16. ADA/BKZ patients switched from ADA to BKZ at Week 52.

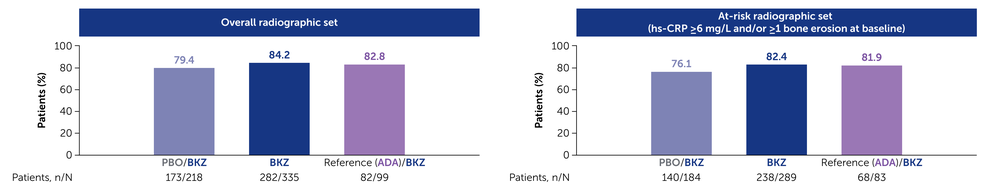
Figure 1 Cumulative probability of vdHmTSS change from baseline by patient at Week 104 (OC)



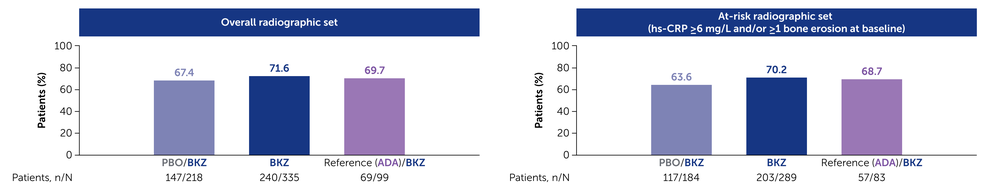
Radiographic set. Data are reported as observed case for all patients with radiographs available at Week 104. PBO/BKZ patients switched from PBO to BKZ at Week 16. ADA/BKZ patients switched from ADA to BKZ at Week 52.

Figure 2 Proportion of patients with no radiographic progression at Week 104 (OC)

A) Proportion of patients with vdHmTSS change from baseline ≤0.5



B) Proportion of patients with vdHmTSS change from baseline ≤0.0



Radiographic set. Data are reported as observed case for all patients with radiographs available at Week 104. PBO/BKZ patients switched from PBO to BKZ at Week 16. ADA/BKZ patients switched from ADA to BKZ at Week 52.

ADA: adalimumab; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BMI:** body mass index; **CfB:** change from baseline; **hs-CRP:** high-sensitivity C-reactive protein; **IL:** interleukin; **JSN:** joint space narrowing; **OC:** observed case; **PASI:** Psoriasis Area and Severity Index; **PBO:** placebo; **PsA:** psoriatic arthritis; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation; **SJC:** swollen joint count; **TJC:** tender joint count; **vdHmTSS:** van der Heijde modified Total Sharp Score.

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