Bimekizumab long-term incidence of psoriatic arthritis symptoms and psoriatic arthritis adverse events in patients with psoriasis and risk factors for disease progression

P2785

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Objectives

To evaluate psoriatic arthritis (PsA) symptom development in bimekizumab (BKZ)-treated patients from BE RADIANT with psoriasis only, who have risk factors at baseline for disease progression to PsA, using the Psoriatic Arthritis Screening and Evaluation (PASE) questionnaire.

To assess the 4-year incidence of PsA treatment-emergent adverse events (TEAEs) among BKZ-treated patients with psoriasis only, who have risk factors at baseline for disease progression to PsA, from three phase 3/3b trials and two open-label extension (OLE) trials.

Introduction

- For patients with psoriasis, the incidence of PsA has been reported to range from 0.23 to 7.4/100 patient-years (PY), depending on study population and follow-up duration.[1] Up to a third of patients with psoriasis develop PsA,[2] highlighting the importance of early detection and intervention.
- The PASE questionnaire aids early detection of PsA,[3] and early intervention, to delay or halt disease progression.
- BKZ inhibits both interleukin (IL)-17A and IL-17F,[4] and has demonstrated superior efficacy versus comparators,[5–8] as well as long-term efficacy,[9,10] in the treatment of moderate to severe plaque psoriasis.
- BKZ has also shown a high level of efficacy in the short and long term for patients with active PsA.[11,12]

Methods

- Patients with moderate to severe plaque psoriasis only (no PsA) at baseline from the BE SURE, BE VIVID, and BE READY phase 3 trials,[5–7] their OLE BE BRIGHT,[9] and BE RADIANT,[8] were analysed by number of risk factors at baseline.
  - Patients with presence of PsA at baseline, defined as PASE ≥47[3] and/or a reported medical history of PsA, were excluded.
- PsA risk factors, based on availability of data, were Psoriasis Area and Severity Index (PASI) ≥12, type 2 diabetes mellitus (based on reported medical history), body mass index (BMI) ≥30 kg/m^2, scalp Investigator's Global Assessment >0, and modified Nail Psoriasis Severity Index (mNAPSI) >0.[2,14]
- The proportions of patients maintaining PASE <47 (no PsA symptoms)[3] over 3 years are reported from the BE RADIANT phase 3b trial (data only available from this study),[8] using modified non-responder imputation.
  - Included patients were randomised to receive BKZ 320 mg every 4 weeks (Q4W) to Week 16, then received BKZ Q4W or Q8W into the OLE (BKZ Total); the subset who received BKZ Q4W to Week 16 then Q8W thereafter were also analysed (BKZ Q4W/Q8W; the approved dosing regimen for the majority of patients with psoriasis).[13]
  - Patients discontinuing due to lack of efficacy or treatment-related AEs were considered non-responders; multiple imputation was used for other missing data.
- In patients with psoriasis only at baseline, exposure-adjusted incidence rates (EAIRs) of reported PsA TEAEs are presented over 4 years, and by year, across all included trials.[5–9]
  - TEAE data are reported for patients who received ≥1 BKZ dose and the BKZ Q4W/Q8W subgroup.

Results

- Some numerical differences in baseline characteristics were seen between risk factor subgroups, with a trend of higher disease severity in groups with more PsA risk factors.
  - In the ≥4 risk factors subgroup, patients typically had higher BMI, and greater proportions had mNAPSI >0 and arthralgia.

PsA symptoms (BE RADIANT)

- Among BKZ Total patients with psoriasis only at baseline in BE RADIANT, 266 had ≥1 baseline PsA risk factor, 260 had ≥2, 183 had ≥3, and 68 had ≥4.
- For patients with ≥1, ≥2, ≥3, and ≥4 baseline risk factors, the vast majority maintained absence of PsA symptoms (PASE <47) through 3 years (96.0–98.1%; **Figure 1A–D**).
  - Results were similar in the BKZ Q4W/Q8W subgroup (**Figure 1A–D**).

PsA TEAEs (pooled trials)

- Among patients with psoriasis only at baseline who received ≥1 BKZ dose, 1,630 had ≥1 baseline PsA risk factor, 1,599 had ≥2, 1,144 had ≥3, and 417 had ≥4.
- In those with ≥1, ≥2, ≥3, and ≥4 baseline risk factors, EAIRs of PsA TEAEs were low (0.4, 0.4, 0.5, 0.9/100 PY, respectively) through 4 years (**Table 1**).
  - EAIRs were also consistently low during each year of treatment (**Table 1**)
  - 4-year data were similar in the subset of patients who received BKZ Q4W/Q8W (**Table 1**).

Conclusions

In BE RADIANT, the vast majority of bimekizumab-treated patients did not report psoriatic arthritis symptoms over 3 years, independently of number of risk factors at baseline for progression to psoriatic arthritis. A low incidence rate of psoriatic arthritis treatment-emergent adverse events were reported over 4 years from five trials, regardless of the number of risk factors at baseline.

These findings support long-term bimekizumab use to manage psoriasis and reduce the risk of progression to psoriatic arthritis, as well as demonstrating the importance of early detection and intervention.

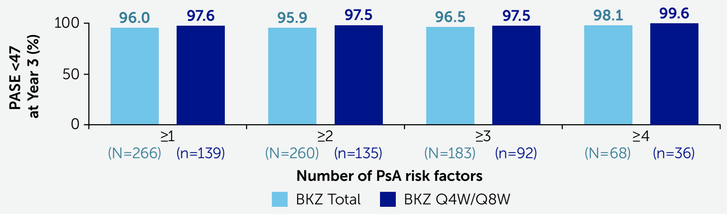
Summary

The PASE questionnaire is a tool designed to help **identify** patients with psoriasis who would benefit from **early referral** to a clinician.[3] It was continuously used throughout BE RADIANT to monitor the **severity of musculoskeletal symptoms indicating PsA**

7 Symptom Questions + 8 Function Questions = PASE Questionnaire

Each rated on a 1–5 scale | ≥47/75 = high likelihood of PsA

The vast majority of patients in BE RADIANT with psoriasis only **did not report symptoms of PsA through 3 years (PASE <47)**, regardless of the number of PsA risk factors that they had at baseline



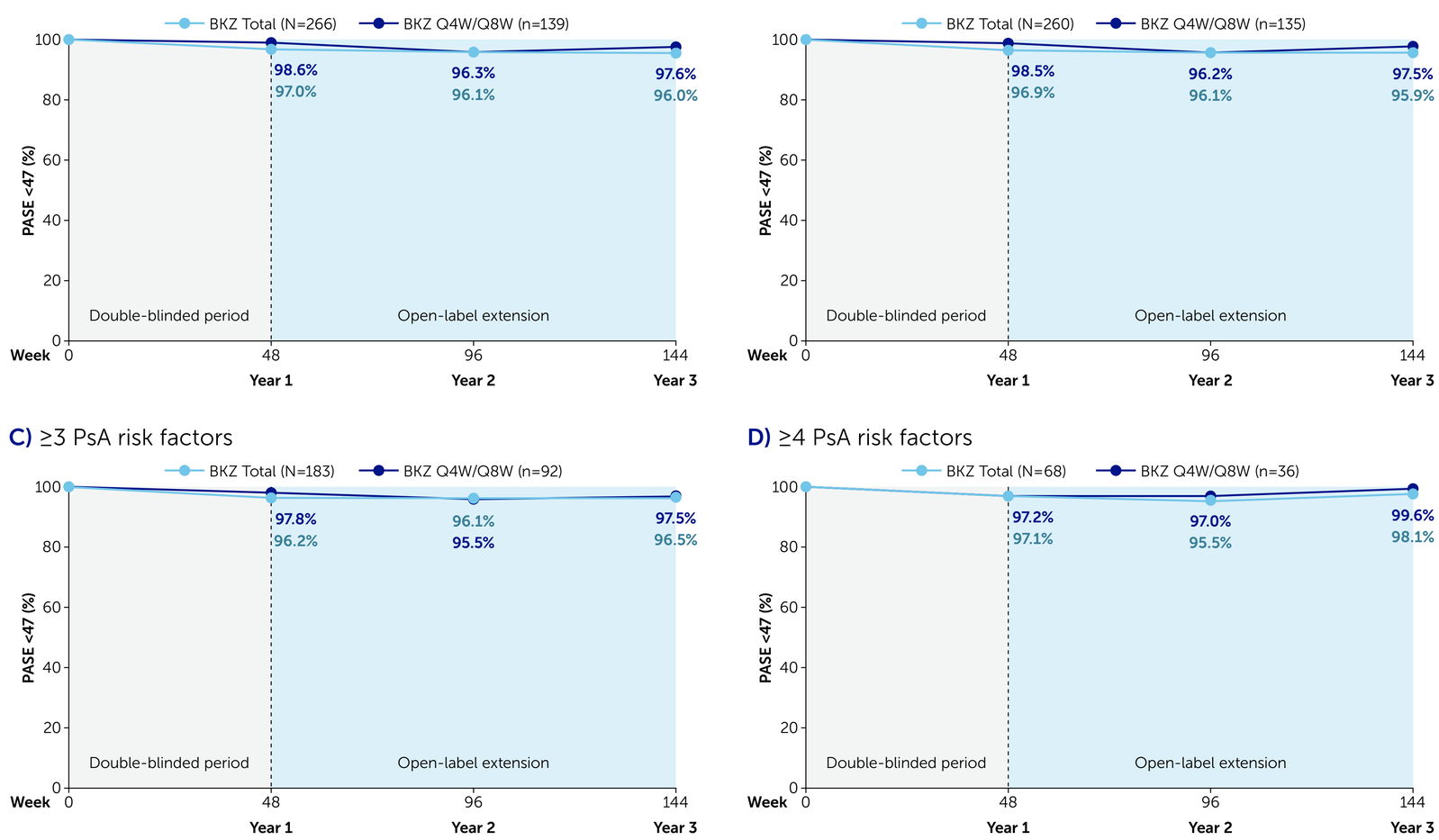
Patients with psoriasis only (i.e. excluding those with PsA at baseline) were grouped by number of **baseline PsA risk factors**; these risk factors included:[2,14]

- PASI ≥12
- BMI ≥30 kg/m^2
- Nail involvement (mNAPSI >0)
- Type 2 diabetes mellitus (based on reported medical history)
- Scalp involvement (scalp IGA >0)

The EAIR of **PsA TEAEs was low through 4 years** of BKZ treatment across pooled studies, regardless of the number of PsA risk factors at baseline

≥1 risk factor (N=1,630)	≥2 risk factors (N=1,599)	≥3 risk factors (N=1,144)	≥4 risk factors (N=417)
0.4/100 PY	0.4/100 PY	0.5/100 PY	0.9/100 PY

Figure 1 PASE <47 over 3 years in patients from BE RADIANT with psoriasis only at baseline and ≥1, ≥2, ≥3, or ≥4 PsA risk factors at baseline (mNRI)



Included PsA risk factors were PASI ≥12, type 2 diabetes mellitus (based on reported medical history), BMI ≥30 kg/m^2, scalp IGA >0, and mNAPSI >0. PASE data were only available from BE RADIANT.

Table 1 EAIRs of PsA TEAEs in patients from pooled trials with psoriasis only at baseline and ≥1, ≥2, ≥3, or ≥4 PsA risk factors at baseline

	Year 1 (>0–52 weeks of BKZ exposure)	Year 2 (>52–104 weeks of BKZ exposure)	Year 3 (>104–156 weeks of BKZ exposure)	Year 4 (>156–208 weeks of BKZ exposure)	Overall through 4 years of BKZ exposure	
n (%) EAIR (95% CI)	BKZ Total	BKZ Total	BKZ Total	BKZ Total	BKZ Total	BKZ Q4W/Q8W
≥1 PsA Risk Factor	**N=1,630**	**N=1,501**	**N=1,360**	**N=1,006**	**N=1,630**	**n=297**
Any PsA TEAE	2 (0.1) 0.1 (0.0, 0.5)	6 (0.4) 0.4 (0.2, 0.9)	7 (0.5) 0.6 (0.2, 1.3)	4 (0.4) 0.6 (0.2, 1.6)	19 (1.2) 0.4 (0.2, 0.6)	4 (1.3) 0.4 (0.1, 1.0)
≥2 PsA Risk Factors	**N=1,599**	**N=1,474**	**N=1,336**	**N=990**	**N=1,599**	**n=292**
Any PsA TEAE	2 (0.1) 0.1 (0.0, 0.5)	6 (0.4) 0.4 (0.2, 0.9)	7 (0.5) 0.6 (0.2, 1.3)	4 (0.4) 0.6 (0.2, 1.7)	19 (1.2) 0.4 (0.2, 0.6)	4 (1.4) 0.4 (0.1, 1.0)
≥3 PsA Risk Factors	**N=1,144**	**N=1,056**	**N=957**	**N=722**	**N=1,144**	**n=209**
Any PsA TEAE	2 (0.2) 0.2 (0.0, 0.7)	6 (0.6) 0.6 (0.2, 1,3)	5 (0.5) 0.6 (0.2, 1.4)	4 (0.6) 0.9 (0.2, 2.3)	17 (1.5) 0.5 (0.3, 0.8)	4 (1.9) 0.6 (0.2, 1.5)
≥4 PsA Risk Factors	**N=417**	**N=386**	**N=355**	**N=265**	**N=417**	**n=76**
Any PsA TEAE	2 (0.5) 0.5 (0.1, 1.9)	4 (1.0) 1.1 (0.3, 2.8)	4 (1.1) 1.3 (0.4, 3.4)	1 (0.4) 0.6 (0.0, 3.4)	11 (2.6) 0.9 (0.4, 1.6)	3 (3.9) 1.2 (0.2, 3.5)

Pooled trials included BE SURE,[5] BE VIVID,[6] BE READY,[7] their OLE BE BRIGHT,[9] and BE RADIANT.[8] All reported PsA TEAEs were reported under the MedDRA preferred term 'psoriatic arthropathy'.

BKZ: bimekizumab; **BMI:** body mass index; **CI:** confidence interval; **EAIR:** exposure-adjusted incidence rate; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **mNAPSI:** modified Nail Psoriasis Severity Index; **mNRI:** modified non-responder imputation; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **PASE:** Psoriatic Arthritis Screening and Evaluation; **PsA:** psoriatic arthritis; **PY:** patient-year; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **TEAE:** treatment-emergent adverse event.

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Dermatol Ther (Heidelb) 2018;8:593–604. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **JFM**, **AP**, **KY**, **BS**, **RRD**, **LS**, **JMLP**, **DD**, **SK**, **PG**; Drafting of the publication, or reviewing it critically for important intellectual content: **JFM**, **AP**, **KY**, **BS**, **RRD**, **LS**, **JMLP**, **DD**, **SK**, **PG**; Final approval of the publication: **JFM**, **AP**, **KY**, **BS**, **RRD**, **LS**, **JMLP**, **DD**, **SK**, **PG**. **Author Disclosures:** **JFM:** Consultant and/or investigator for AbbVie, Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, Incyte, Janssen, LEO Pharma, MoonLake Immunotherapeutics, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma, and UCB. **AP:** Investigator, speaker and/or advisor for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Galderma, GSK, Hexal, Janssen, LEO Pharma, MC2 Therapeutics, Medac, Merck Serono, Mitsubishi Pharma, MSD, MoonLake Immunotherapeutics, Novartis, Pfizer, Regeneron, Roche, Sandoz, Schering-Plough, Tigercat Pharma, UCB, and Zuellig Pharma. **KY:** Received grants from AbbVie, Bayer Yakuhin, Eisai, Eli Lilly and Company, Kaken Pharmaceutical, Kyowa Kirin, Maruho, Maruho Takagi Dermatology Foundation, Nihon Pharmaceutical, Nippon Kayaku, Sasaki Chemical, Taiho Pharmaceutical, Torii Pharmaceutical, and Sun Pharma; speaker for AbbVie, Celgene, Daiichi Sankyo, Eisai, Eli Lilly and Company, Janssen, Kaken Pharmaceutical, Kyowa Kirin, LEO Pharma, Maruho, Mitsubishi-Tanabe Pharmaceutical, Nippon Kayaku, Nobelpharma, Novartis, Sanofi, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, and UCB. **BS:** Consultant (honoraria) for AbbVie, Almirall, Alumis, Amgen, Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Capital One, PPD CorEvitas, LLC, Dermavant, Eli Lilly and Company, Janssen, LEO Pharma, Maruho, Meiji Seika Pharma, Novartis, Oruka, Pfizer, Protagonist, Rapt, Regeneron, Sanofi-Genzyme, Takeda, UCB, and Union Therapeutics; stock options from Connect Biopharma and Mindera Health; speaker for AbbVie, Arcutis, Dermavant, Eli Lilly and Company, Incyte, Janssen, Regeneron, and Sanofi-Genzyme; scientific co-director (consulting fee): CorEvitas Psoriasis Registry; investigator for CorEvitas Psoriasis Registry; editor-in-chief (honorarium): Journal of Psoriasis and Psoriatic Arthritis. **RRD:** Consultant, investigator and/or speaker for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Incyte, Johnson & Johnson, LEO Pharma, Novartis, Pfizer, and UCB. **LS:** Consultant, scientific adviser, investigator, scientific officer, and/or speaker for AbbVie, Akesobio, Alphyn Biologics, Amgen, Anacor, Ascend, Aslan, Astellas, AstraZeneca, Blaze Bioscience, Bristol Myers Squibb, Boehringer Ingelheim, Botanix, Celgene, Connect Biopharmaceuticals Australia, Dermira, Eli Lilly and Company, Evelo Biosciences, Galderma, Genentech, GSK, Hexima, Immunic Therapeutics, Invion, Janssen, Kiniksa Pharmaceuticals, Kobiolabs, LEO Pharma, Lipidio, Mayne, MedImmune, Merck-Serono, MSD, Novartis, Otsuka, Pfizer, Phosphagenics, Photon MD, Regeneron, Reistone, Roche, Samumed, Sanofi-Genzyme, SHR, Sun Pharma ANZ, Trius, UCB, Vyne Therapeutics, and Zai Lab. **JMLP, DD:** Employees and shareholders of UCB. **SK:** Consultant for Aclipse Therapeutics, Aliada Therapeutics, Allay Therapeutics, Autobahn Therapeutics, Cognition Therapeutics, Colorado Prevention Center, Karuna Therapeutics, Kisbee Therapeutics, LB Pharmaceuticals, Nesos, Novartis, Onward Medical, PharPoint Research, Summit Analytical, Therini Bio, Tonix Pharmaceuticals, Tornado Therapeutics, UCB, Whitsell Innovations, Worldwide Clinical Trials, and Zosano Pharma. **PG:** Consultant for AbbVie, Abiogen, Almirall, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Merck, MSD, Novartis, Otsuka, Pfizer, Pierre Fabre, Sanofi, and UCB. **Acknowledgements:** These studies were funded by UCB. 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