



BE RADIANT

Bimekizumab in patients with moderate-to-severe plaque psoriasis

Summary of results from the Phase 3b BE RADIANT study

BE RADIANT assessed different maintenance dosing regimens for bimekizumab.
Only the Q8W maintenance dosing regimen after week 16 was licensed for use.
Please always read the Bimzelx SmPC before prescribing.

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Study overview¹

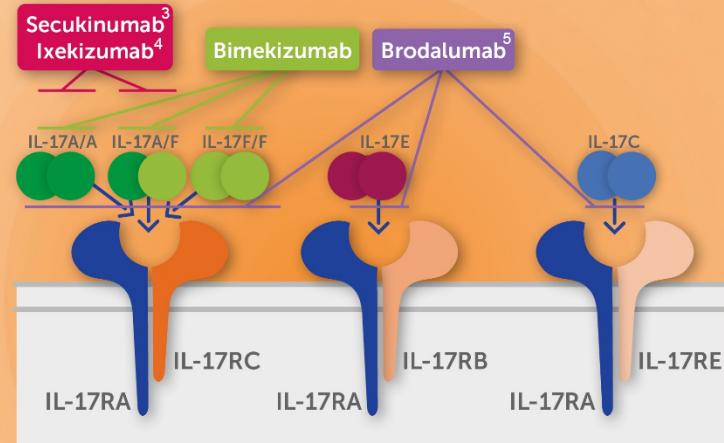


A 48-week, phase 3b, multicentre, randomised, double-blinded, secukinumab-controlled study investigating the efficacy and safety of bimekizumab in patients with moderate-to-severe chronic plaque psoriasis

Study objective

To compare the clinical benefit for patients with psoriasis of inhibiting both IL-17A and IL-17F, with bimekizumab, with the inhibition of IL-17A alone, with secukinumab

IL-17 inhibitors²



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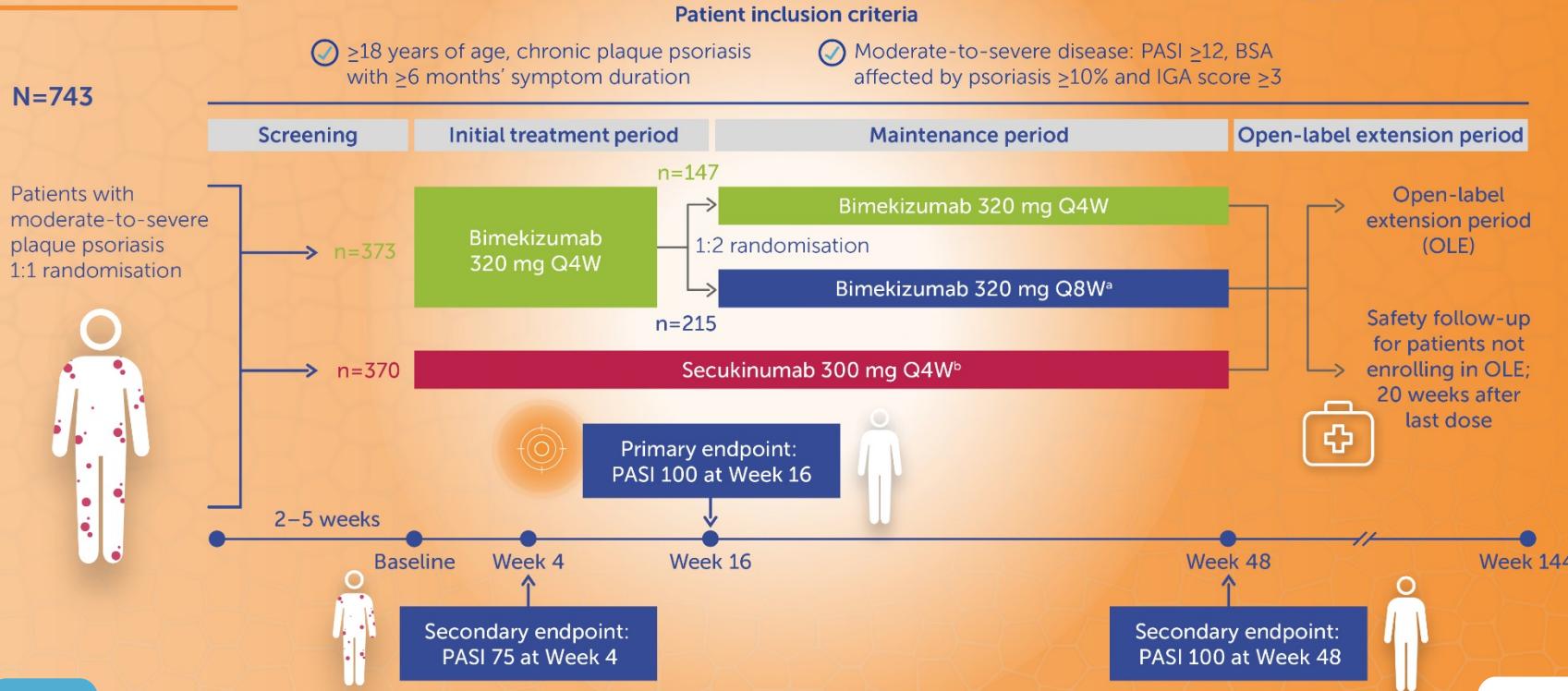
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1. Reich K, et al. N Engl J Med 2021;385:142–152; 2. Adapted from: Patel D et al. Ann Rheum Dis 2013;72(Suppl 2):ii116–23. Abbreviations: IL: interleukin.; 3. Cosentyx SmPC, www.fass.se. 4. Taltz SmPC, www.fass.se. 5. Kyntheum SmPC, www.fass.se

Study design¹

BE RADIANT 

N=743



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Note: Q4W dosing after week 16 is an unlicensed dosing regimen. Bimekizumab is approved for use in moderate to severe psoriasis at Q4W dosing until week 16, followed by Q8W maintenance dosing. Only if the patient is >120kg, maintenance dosing may be Q4W. 1. Reich K, et al. N Engl J Med 2021;385:142–152. ^aThe Q8W maintenance dosing regimen was added via protocol amendment, with the first re-randomisation occurring approximately 7 months after the trial began, after 82 patients had completed Week 16. ^bSecukinumab was administered weekly to Week 4 and then Q4W. Abbreviations: BSA: Body Surface Area; IGA: Investigator's Global Assessment; OLE: open-label extension; PASI75/100: ≥75%/100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks.

Demographics and baseline characteristics¹

	Bimekizumab N=373	Secukinumab N=370
Age (years), mean \pm SD	45.9 \pm 14.2	44.0 \pm 14.7
Male, n (%)	251 (67.3)	235 (63.5)
Caucasian, n (%)	347 (93.0)	348 (94.1)
Weight (kg), mean \pm SD	90.1 \pm 21.3	88.8 \pm 20.0
Duration of PSO (years), mean \pm SD	18.4 \pm 13.1	17.2 \pm 12.3
PASI, mean \pm SD	20.2 \pm 7.5	19.7 \pm 6.7
BSA (%), mean \pm SD	24.8 \pm 15.5	23.8 \pm 14.3
IGA, n (%)		
3: moderate	240 (64.3)	268 (72.4)
4: severe	131 (35.1)	102 (27.6)
DLQI total, mean \pm SD	10.8 \pm 6.6	11.3 \pm 7.2
Any prior systemic therapy, n (%)	267 (71.6)	272 (73.5)
Prior biologic therapy, n (%) ^a		
anti-TNF	125 (33.5)	119 (32.2)
anti-IL-17	71 (19.0)	69 (18.6)
anti-IL-23	39 (10.5)	50 (13.5)
anti-IL-12/23	24 (6.4)	23 (6.2)
	23 (6.2)	17 (4.6)

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Adapted from Reich K, et al. 2021.

1. Reich K, et al. N Engl J Med 2021;385:142–152. ^a Included are patients with previous use of one or multiple biologic agents. Abbreviations: BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; IL: interleukin; PASI: Psoriasis Area and Severity Index; PSO: psoriasis; SD: standard deviation; TNF: tumour necrosis factor.

Results¹ (1/2)

● BKZ 320 mg Q4W

● SEC 300 mg Q4W



Short-term data

Primary endpoint: PASI 100 at Week 16 for BKZ vs SEC

At Week 16

61.7%*

of patients on BKZ
achieved clear skin (PASI 100)
compared to

48.9%

of patients on SEC¹



n=373, 370

[VIEW FULL GRAPH](#)

[VIEW PASI 100 AT 48 WEEKS](#)

Key secondary endpoint:^a PASI 75 at Week 4 for BKZ vs SEC

At Week 4

71.0%*

of patients on BKZ
achieved PASI 75
compared to

47.3%

of patients on SEC¹



n=373, 370

[VIEW FULL GRAPH](#)

At Week 16

85.5%

of patients on BKZ
achieved PASI 90
compared to

74.3%

of patients on SEC¹



n=373, 370

[VIEW FULL GRAPH](#)

[VIEW PASI 90 AT 48 WEEKS](#)

At Week 16

85.5%

of patients on BKZ
achieved IGA 0/1
compared to

78.6%

of patients on SEC¹



n=373, 370

[VIEW FULL GRAPH](#)

[VIEW IGA 0/1 AT 48 WEEKS](#)

*p<0.001 vs SEC; p values are based on the stratified Cochran-Mantel-Haenszel test for the general association, with prior biologic exposure and geographic region as stratification factors

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1. Reich K, et al. N Engl J Med 2021;385:142–152. ^a Other key secondary endpoints include PASI 100 at Week 48 for BKZ vs SEC, presented on the following slide.

Abbreviations: BKZ: bimekizumab; IGA 0/1: score of 0 (clear) or 1 (almost clear) with ≥2-category improvement relative to baseline in Investigator's Global Assessment, scored on a 5-point scale; PASI 75/90/100: ≥75%/≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; SEC: secukinumab.

Results¹ (2/2)

● BKZ 320 mg Q4W or Q4W/Q8W

● SEC 300 mg Q4W



Long-term data

Key secondary endpoint:^a PASI 100 at Week 48 for BKZ vs SEC

At Week 48

67.0%*

of patients on BKZ Q4W or Q4W/Q8W

achieved clear
skin (PASI 100)

compared to

46.2%

of patients on SEC¹



n=373, 370

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At Week 48

83.6%

of patients on BKZ Q4W or Q4W/Q8W

achieved
PASI 90

compared to

70.5%

of patients on SEC¹



n=373, 370

[VIEW FULL GRAPH](#)

At Week 48

83.9%

of patients on BKZ Q4W or Q4W/Q8W

achieved
IGA 0/1

compared to

73.8%

of patients on SEC¹



n=373, 370

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*p<0.001 vs SEC; p values are based on the stratified Cochran-Mantel-Haenszel test for the general association, with prior biologic exposure and geographic region as stratification factors

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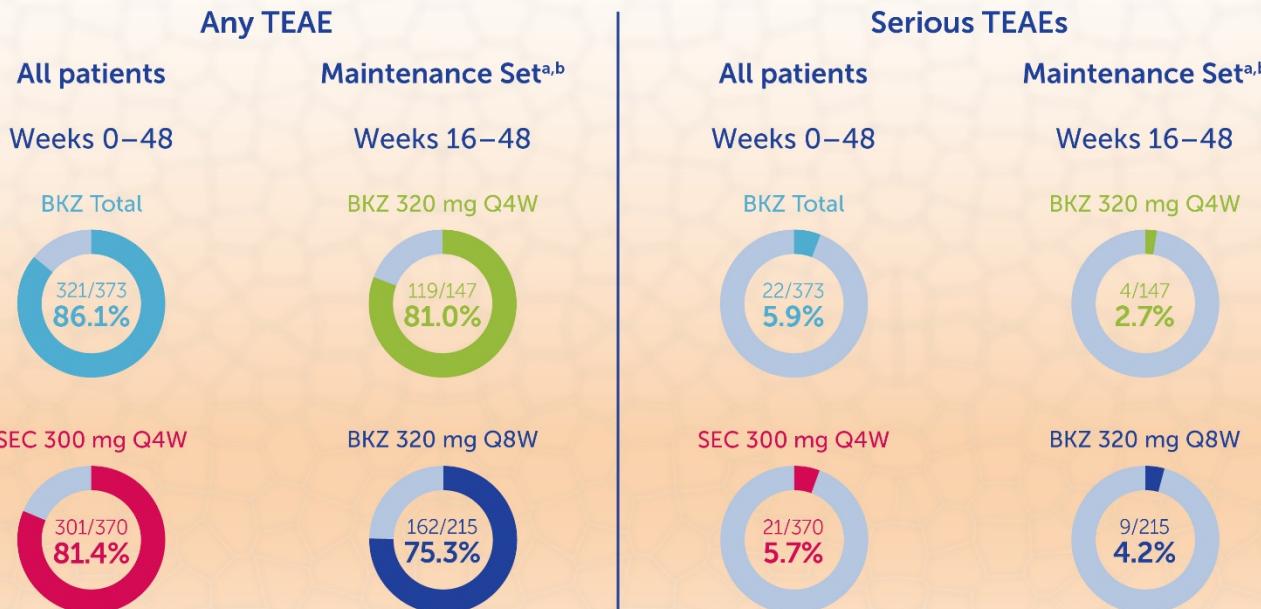
Note: Q4W dosing after week 16 is an unlicensed dosing regimen. Bimekizumab is approved for use in moderate to severe psoriasis at Q4W dosing until week 16, followed by Q8W maintenance dosing. Only if the patient is >120kg, maintenance dosing may be Q4W. 1. Reich K, et al. N Engl J Med 2021;385:142–152. ^a Other key secondary endpoints include PASI 75 at Week 4 for BKZ vs SEC, presented on the previous slide. Abbreviations: BKZ: bimekizumab; IGA 0/1: score of 0 (clear) or 1 (almost clear) with ≥2-category improvement relative to baseline in Investigator's Global Assessment, scored on a 5-point scale; PASI 90/100: ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC: secukinumab.

Safety profile¹ (1/2)

● BKZ 320 mg Q4W ● BKZ Total ● BKZ 320 mg Q8W ● SEC 300 mg Q4W

The incidence of TEAEs, severe TEAEs and discontinuations due to TEAEs was comparable between treatment groups

Deaths: one pedestrian vehicular accident in the BKZ Q8W group and one fatal asphyxia adjudicated as MACE in the SEC group.



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Note: Q4W dosing after week 16 is an unlicensed dosing regimen. Bimekizumab is approved for use in moderate to severe psoriasis at Q4W dosing until week 16, followed by Q8W maintenance dosing. Only if the patient is >120kg, maintenance dosing may be Q4W. 1. Reich K, et al. N Engl J Med 2021;385:142–152. ^a Patients are summarised by maintenance treatment, this includes patients who received at least one dose of study treatment at Week 16 or later. ^b Only events with a start date during the maintenance treatment period are included. Abbreviations: BKZ: bimekizumab; MACE: major adverse cardiovascular event; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC: secukinumab; TEAE: treatment-emergent adverse event.

Safety profile¹ (2/2)

Overall, the safety profile of bimekizumab was in line with secukinumab

- Incidence of serious infections, IBD, SIB, and death was low for both bimekizumab and secukinumab

There was an increased incidence of oral candidiasis with bimekizumab compared with secukinumab

- 97.2% of cases of oral candidiasis were mild or moderate with bimekizumab, none were serious and none led to discontinuation

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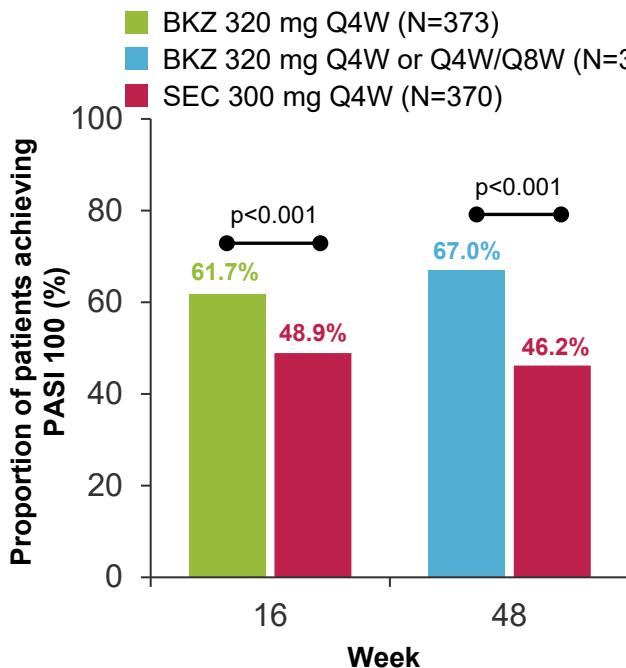
BE RADIANT PASI 100 over 48 Weeks (NRI)¹

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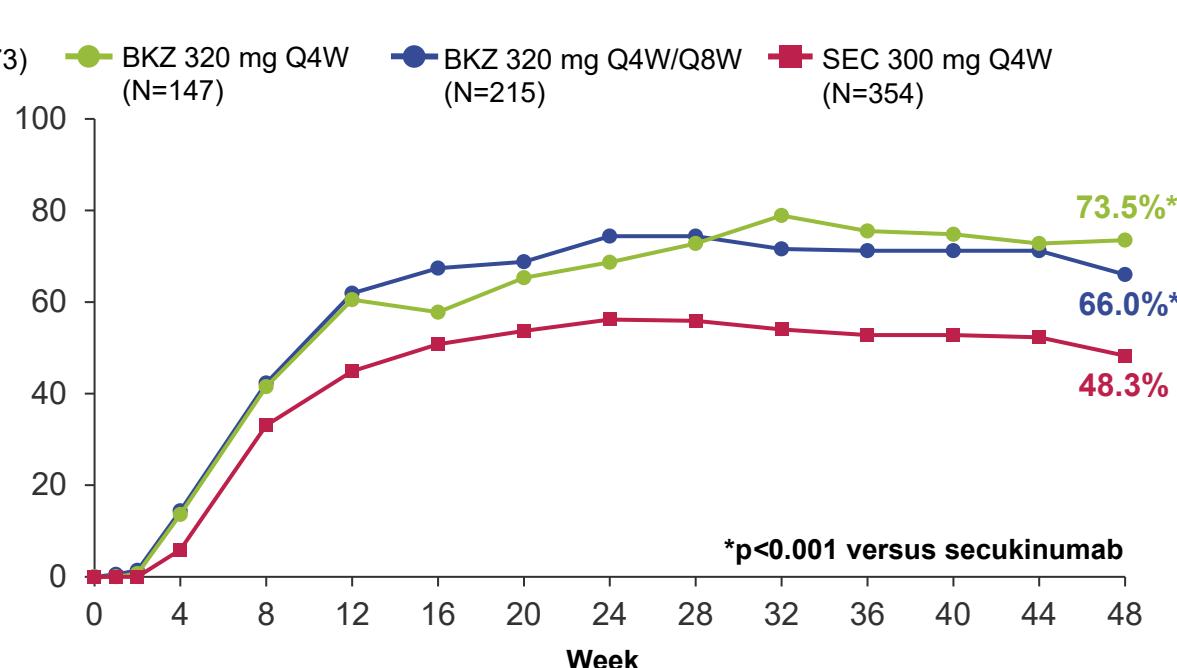
Primary endpoint: PASI 100 response with bimekizumab versus secukinumab at Week 16

Secondary endpoint: PASI 100 response with bimekizumab versus secukinumab at Week 48

PASI 100 at Weeks 16 and 48 (ITT, NRI)



PASI 100 to Week 48 (Maintenance Set, NRI)

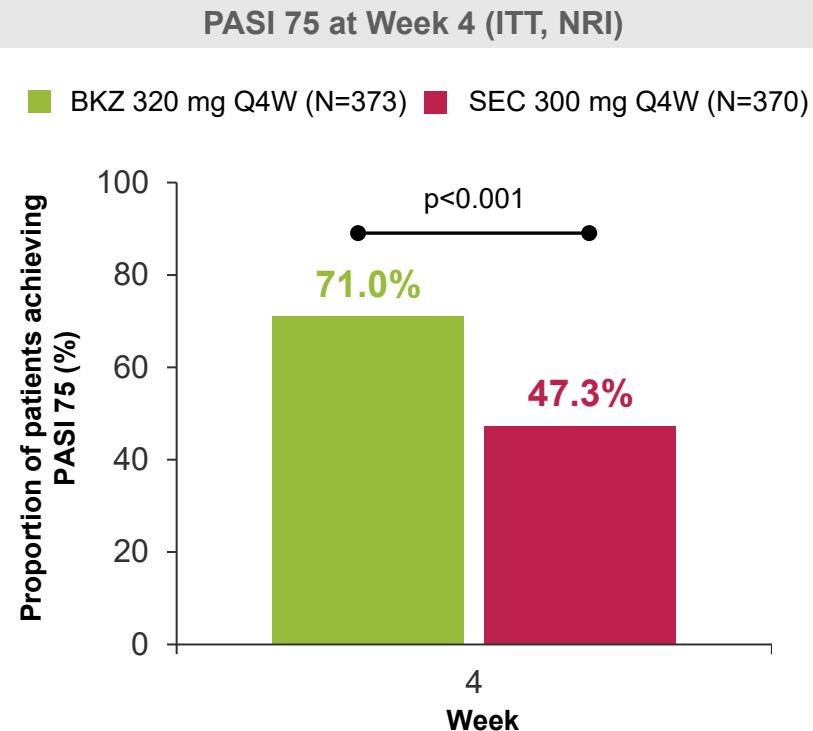


Note: Q4W dosing after week 16 is an unlicensed dosing regimen. Bimekizumab is approved for use in moderate to severe psoriasis at Q4W dosing until week 16, followed by Q8W maintenance dosing. Only if the patient is >120kg, maintenance dosing may be Q4W. Adapted from Reich K, et al. 2021. 1. Reich K, et al. N Engl J Med 2021;385:142–152. p values are based on the stratified Cochran-Mantel-Haenszel test for the general association, with prior biologic exposure and geographic region as stratification factors. Abbreviations: BKZ: bimekizumab; ITT: intent-to-treat; NRI: non-responder imputation; PASI 100: 100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC: secukinumab.

BE RADIANT PASI 75 at Week 4 (NRI)¹

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Secondary endpoint: PASI 75 response with bimekizumab versus secukinumab at Week 4



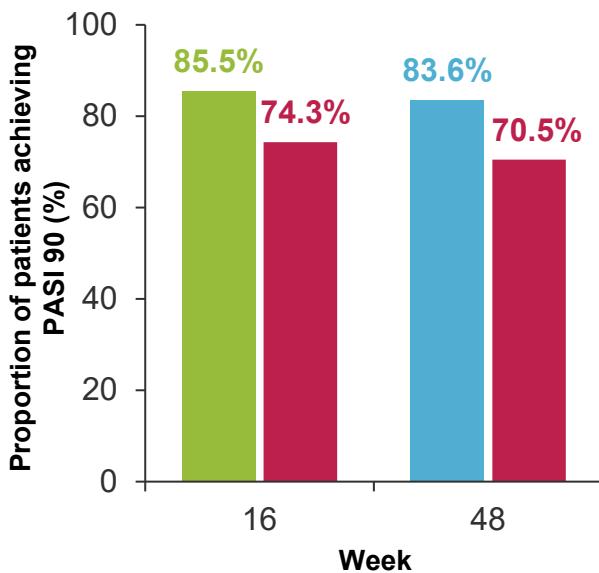
Adapted from Reich K, et al. 2021. 1. Reich K, et al. N Engl J Med 2021;385:142–152. p values are based on the stratified Cochran-Mantel-Haenszel test for the general association, with prior biologic exposure and geographic region as stratification factors. Abbreviations: BKZ: bimekizumab; ITT: intent-to-treat; NRI: non-responder imputation; PASI 75/90: ≥75%/≥90% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; SEC: secukinumab.

BE RADIANT PASI 90 over 48 Weeks (NRI)¹

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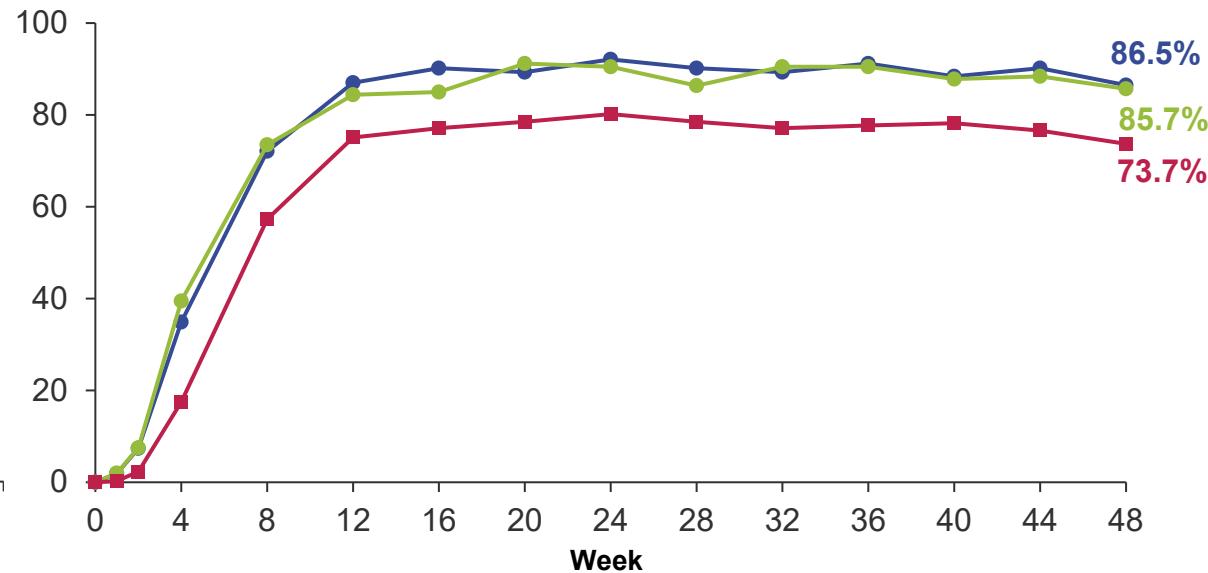
PASI 90 at Weeks 16 and 48 (ITT, NRI)

- BKZ 320 mg Q4W (N=373)
- BKZ 320 mg Q4W or Q4W/Q8W (N=373)
- SEC 300 mg Q4W (N=370)



PASI 90 to Week 48 (Maintenance Set, NRI)

- BKZ 320 mg Q4W (N=147)
- BKZ 320 mg Q4W/Q8W (N=215)
- SEC 300 mg Q4W (N=354)



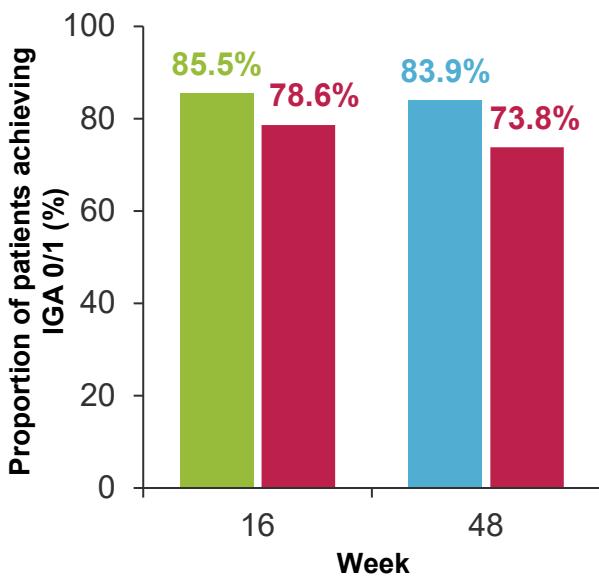
Note: Q4W dosing after week 16 is an unlicensed dosing regimen. Bimekizumab is approved for use in moderate to severe psoriasis at Q4W dosing until week 16, followed by Q8W maintenance dosing. Only if the patient is >120kg, maintenance dosing may be Q4W. Adapted from Reich K, et al. 2021. 1. Reich K, et al. N Engl J Med 2021;385:142–152. Non-ranked secondary endpoint: PASI 90 at Week 16 for BKZ vs SEC. p values are based on the stratified Cochran-Mantel-Haenszel test for the general association, with prior biologic exposure and geographic region as stratification factors. Abbreviations: BKZ: bimekizumab; ITT: intent-to-treat; NRI: non-responder imputation; PASI 90: ≥90% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC: secukinumab.

BE RADIANT IGA 0/1 over 48 Weeks (NRI)¹

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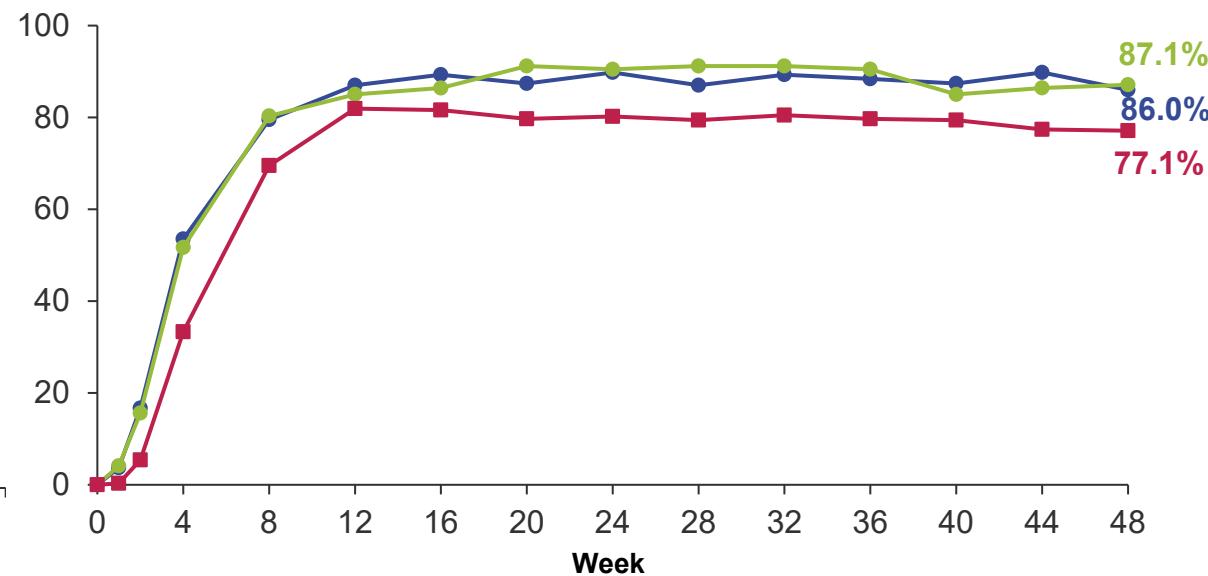
IGA 0/1 at Weeks 16 and 48 (ITT, NRI)

- █ BKZ 320 mg Q4W (N=373)
- █ BKZ 320 mg Q4W or Q4W/Q8W (N=373)
- █ SEC 300 mg Q4W (N=370)



IGA 0/1 to Week 48 (Maintenance Set, NRI)

- BKZ 320 mg Q4W (N=147)
- BKZ 320 mg Q4W/Q8W (N=215)
- SEC 300 mg Q4W (N=354)



Note: Q4W dosing after week 16 is an unlicensed dosing regimen. Bimekizumab is approved for use in moderate to severe psoriasis at Q4W dosing until week 16, followed by Q8W maintenance dosing. Only if the patient is >120kg, maintenance dosing may be Q4W. Adapted from Reich K, et al. 2021. 1. Reich K, et al. N Engl J Med 2021;385:142–152. Non-ranked secondary endpoint: IGA 0/1 at Week 16 for BKZ vs SEC. p values are based on the stratified Cochran-Mantel-Haenszel test for the general association, with prior biologic exposure and geographic region as stratification factors. Abbreviations: BKZ: bimekizumab; ITT: intent-to-treat; NRI: non-responder imputation; IGA 0/1: score of 0 (clear) or 1 (almost clear) with ≥2-category improvement relative to baseline in the Investigator's Global Assessment; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC: secukinumab.

BE RADIANT Incidence of TEAEs and Common TEAEs¹

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	Weeks 0–48 (All Patients)		Weeks 16–48 (Maintenance Set) ^{a,b}	
	BKZ Total (N=373) n (%)	SEC 300 mg Q4W (N=370) n (%)	BKZ 320 mg Q4W (N=147) n (%)	BKZ 320 mg Q8W (N=215) n (%)
Any TEAE	321 (86.1)	301 (81.4)	119 (81.0)	162 (75.3)
Serious TEAEs	22 (5.9)	21 (5.7)	4 (2.7)	9 (4.2)
Discontinuation due to TEAEs	13 (3.5)	10 (2.7)	3 (2.0)	1 (0.5)
Drug-related TEAEs	160 (42.9)	117 (31.6)	46 (31.3)	72 (33.5)
Severe TEAEs	26 (7.0)	15 (4.1)	5 (3.4)	11 (5.1)
Deaths	1 (0.3)	1 (0.3)	0 (0.0)	1 (0.5)
Most common TEAEs (>5% of patients^c)				
Upper respiratory tract infections ^d	145 (38.9)	154 (41.6)	35 (23.8)	62 (28.8)
Oral candidiasis	72 (19.3)	11 (3.0)	19 (12.9)	36 (16.7)
Urinary tract infection	25 (6.7)	22 (5.9)	11 (7.5)	10 (4.7)

The incidence of TEAEs, severe TEAEs, and discontinuations due to TEAEs was comparable between treatment groups

Deaths: one pedestrian vehicular accident (bimekizumab Q8W); one fatal asphyxia adjudicated as MACE (secukinumab)

Note: Q4W dosing after week 16 is an unlicensed dosing regimen. Bimekizumab is approved for use in moderate to severe psoriasis at Q4W dosing until week 16, followed by Q8W maintenance dosing. Only if the patient is >120kg, maintenance dosing may be Q4W. Adapted from Reich K, et al. 2021. 1. Reich K, et al. N Engl J Med 2021;385:142–152. ^aPatients are summarised by maintenance treatment (patients who received at least one dose of study treatment at Week 16 or later). ^bOnly events with a start date during the maintenance treatment period are included. ^c>5% occurring in any group. ^dUpper respiratory tract infections include laryngitis, nasopharyngitis, pharyngeal abscess, pharyngitis, rhinitis, sinusitis, tonsillitis, tracheitis, and upper respiratory tract infection.

Abbreviations: BKZ: bimekizumab; MACE: major adverse cardiovascular event; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC: secukinumab; TEAE: treatment-emergent adverse event.

BE RADIANT Safety Topics of Interest (1/2)¹

	Weeks 0–48 (All Patients)		Weeks 16–48 (Maintenance Set) ^{a,b}	
	BKZ Total (N=373) n (%)	SEC 300 mg Q4W (N=370) n (%)	BKZ 320 mg Q4W (N=147) n (%)	BKZ 320 mg Q8W (N=215) n (%)
Serious infections	8 (2.1)	8 (2.2)	1 (0.7)	6 (2.8)
Active TB	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Latent TB	5 (1.3)	4 (1.1)	4 (2.7)	1 (0.5)
Inflammatory bowel disease	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)
Ulcerative colitis	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)
Candida infections	79 (21.2)	17 (4.6)	21 (14.3)	38 (17.7)
Genital candidiasis ^c	3 (0.8)	5 (1.4)	0 (0.0)	2 (0.9)
Oral candidiasis	72 (19.3)	11 (3.0)	19 (12.9)	36 (16.7)
Oropharyngeal candidiasis	2 (0.5)	1 (0.3)	1 (0.7)	0 (0.0)
Skin candida	4 (1.1)	2 (0.5)	1 (0.7)	1 (0.5)

97.2% of oral candidiasis cases were mild or moderate with bimekizumab; none were serious and none led to discontinuation

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Note: Q4W dosing after week 16 is an unlicensed dosing regimen. Bimekizumab is approved for use in moderate to severe psoriasis at Q4W dosing until week 16, followed by Q8W maintenance dosing. Only if the patient is >120kg, maintenance dosing may be Q4W. Adapted from Reich K, et al. 2021. 1. Reich K, et al. N Engl J Med 2021;385:142–152. aPatients are summarised by maintenance treatment (patients who received at least one dose of study treatment at Week 16 or later). bOnly events with a start date during the maintenance treatment period are included. cIn weeks 0 through 48, there were 3 cases of vulvovaginal candidiasis in the bimekizumab group; and 3 cases of vulvovaginal candidiasis, 1 case of genital candidiasis, and 1 case of balanitis candida in the secukinumab group. In weeks 16 through 48, there were 2 cases of vulvovaginal candidiasis in the group receiving bimekizumab every 8 weeks. Abbreviations: BKZ: bimekizumab; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC: secukinumab; TB: tuberculosis.

BE RADIANT Safety Topics of Interest (2/2)¹

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	Weeks 0–48 (All Patients)		Weeks 16–48 (Maintenance Set) ^{a,b}	
	BKZ Total (N=373) n (%)	SEC 300 mg Q4W (N=370) n (%)	BKZ 320 mg Q4W (N=147) n (%)	BKZ 320 mg Q8W (N=215) n (%)
Adjudicated SIB Suicide attempt	1 (0.3) 1 (0.3)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
Cancer^c NMSC	5 (1.3) 3 (0.8)	3 (0.8) 3 (0.8)	1 (0.7) 1 (0.7)	2 (0.9) 1 (0.5)
Serious hypersensitivity reactions	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Adjudicated MACE	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)
Elevated liver enzymes^d	21 (5.6)	19 (5.1)	3 (2.0)	7 (3.3)

There were no cases of adjudicated MACE in bimekizumab-treated patients; there were two cases of adjudicated MACE in secukinumab-treated patients

Note: Q4W dosing after week 16 is an unlicensed dosing regimen. Bimekizumab is approved for use in moderate to severe psoriasis at Q4W dosing until week 16, followed by Q8W maintenance dosing. Only if the patient is >120kg, maintenance dosing may be Q4W. Adapted from Reich K, et al. 2021. 1. Reich K, et al. N Engl J Med 2021;385:142–152. ^aPatients are summarised by maintenance treatment (patients who received at least one dose of study treatment at Week 16 or later). ^bOnly events with a start date during the maintenance treatment period are included. ^cIn weeks 0 through 48, there was 1 squamous cell carcinoma, 1 malignant melanoma in situ, and 3 basal cell carcinomas in the bimekizumab group, and 3 basal cell carcinomas in the secukinumab group. In weeks 16 through 48, there was 1 basal cell carcinoma in the group receiving bimekizumab every 4 weeks and 1 squamous cell carcinoma and 1 basal cell carcinoma in the group receiving bimekizumab very 8 weeks. All cases of nonmelanoma skin cancer were basal cell carcinomas. ^dLiver function tests included the following reported as adverse events: elevated levels of alanine aminotransferase, aspartate aminotransferase, blood bilirubin, γ-glutamyltransferase, hepatic enzymes, and liver aminotransferase or an elevated liver-function test. **Abbreviations:** BKZ: bimekizumab; MACE: major adverse cardiovascular event; NMSC: non-melanoma skin cancer; Q4W: every 4 weeks; Q8W: every 8 weeks; SIB: suicidal ideation and behaviour; SEC: secukinumab; TB: tuberculosis.

BIMZELX▼ Solution for injection in pre-filled syringe or pre-filled pen.

ABBREVIATED PRODUCT INFORMATION

▼ Detta läkemedel är föremål för utökad övervakning. Detta möjliggör snabb identifiering av ny säkerhetsinformation. Vårdgivare uppmanas att rapportera misstänkta biverkningar.

Förkortad förskrivningsinformation Bimzelx® (bimekizumab).

Beredningsform: 160 mg lösning i förfylld spruta och förfylld injektionspenna. Varje förfylld spruta eller förfylld penna innehåller 160 mg bimekizumab i 1 mL Rx, (F), L04AC21.

Indikation: Bimzelx® är indicerat för behandling av: 1. Måttlig till svår plackpsoriasis hos vuxna som behöver systemisk behandling, 2. Aktiv ankyloserande spondylit (AS) hos vuxna med tidigare otillräcklig respons på eller intolerans mot konventionell behandling, 3. Aktiv icke-radiografisk axial spondylartrit (nr-axSpA) med objektiva tecken på inflammation påvisat genom förhöjt C-reaktivt protein och/eller magnetkameraundersökning hos vuxna med tidigare otillräcklig respons på eller intolerans mot icke-steroida antiinflammatoriska läkemedel (NSAID) samt 4. Aktiv psoriasisartrit hos vuxna med tidigare otillräckligt svar eller intolerans mot ett eller flera sjukdomsmodifierande antireumatiska läkemedel (DMARDs) där bimekizumab kan ges i monoterapi eller i kombination med metotrexat.

Dosering och administreringssätt: Den rekommenderade dosen för vuxna patienter med plackpsoriasis är 320 mg (som ges som 2 subkutana injektioner på 160 mg vardera) vid vecka 0, 4, 8, 12, 16 och därefter var 8:e vecka. Den rekommenderade dosen för patienter med AS, nr-axSpA och psoriasisartrit är 160 mg (ges som 1 subkutan injektion på 160 mg) var 4:e vecka. För patienter med psoriasisartrit och samtidig måttlig till svår plackpsoriasis är den rekommenderade dosen densamma som för plackpsoriasis och baserat på kliniskt svar i lederna kan efter vecka 16 behandling med 160 mg var 4:e vecka övervägas. Ingen dosjustering krävs för patienter över 65 års ålder. Bimekizumab har inte studerats i patientpopulationer med nedsatt njur- eller leverfunktion. Säkerhet och effekt för bimekizumab hos barn och ungdomar yngre än 18 år har inte fastställts.

Kontraindikationer: Överkänslighet mot den aktiva substansen eller mot något hjälvpämne. Kliniskt betydelsefull aktiv infektion (t.ex. aktiv tuberkulos (TB)).

Varng och försiktighet: Bimekizumab kan öka risken för infektioner såsom övre luftvägsinfektioner och oral kandidos. Försiktighet bör iakttas då man överväger att använda bimekizumab till patienter med kronisk infektion eller anamnes på återkommande infektion. Bimekizumab ska inte ges till patienter med aktiv TB. Patienter som får bimekizumab bör övervakas avseende tecken och symptom på aktiv TB. Behandling mot TB bör övervägas innan behandling med bimekizumab påbörjas hos patienter med anamnes på latent eller aktiv TB för vilka en adekvat behandlingskur inte kan bekräftas. Bimekizumab rekommenderas inte till patienter med inflammatorisk tarmsjukdom. Allvarliga överkänslighetsreaktioner inklusive anafylaktiska reaktioner har observerats med IL-17-hämmare. Överväg att slutföra alla lämpliga vaccinationer enligt aktuella riktlinjer för åldersgruppen innan behandling med bimekizumab påbörjas. Levande vacciner ska inte ges till patienter som behandlas med bimekizumab. Fertila kvinnor ska använda en effektiv preventivmetod under pågående behandling och i minst 17 veckor efter avslutad behandling.

Biverkningar: mycket vanliga ($\geq 1/10$): övre luftvägsinfektioner; vanliga ($\geq 1/100, < 1/10$): oral kandidos, tineainfektioner, öroninfektioner, herpes simplex-infektion, orofaryngeal kandidos, gastroenterit, follikulit, huvudvärk, dermatit och eksem, akne, reaktioner på injektionsstället, trötthet; mindre vanliga ($\geq 1/1\,000, < 1/100$): mukös och kutan kandidos (inklusive esophageal kandidos), konjunktivit, neutropeni, inflammatorisk tarmsjukdom.

Läkemedelsförmån: Subventioneras endast för patienter som har behandlats med TNF-hämmare eller där detta inte är lämpligt. **Datum för översyn av produktresumén:** Juni 2023. **För fullständig produktinformation och pris** se www.fass.se. UCB Pharma AB, Olof Palmes gata 29, 111 22 Stockholm. Tel 040-294900.



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