BE SURE

Bimekizumab in patients with moderate-to-severe plaque psoriasis

Summary of results from the Phase 3 BE SURE study

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Study overview

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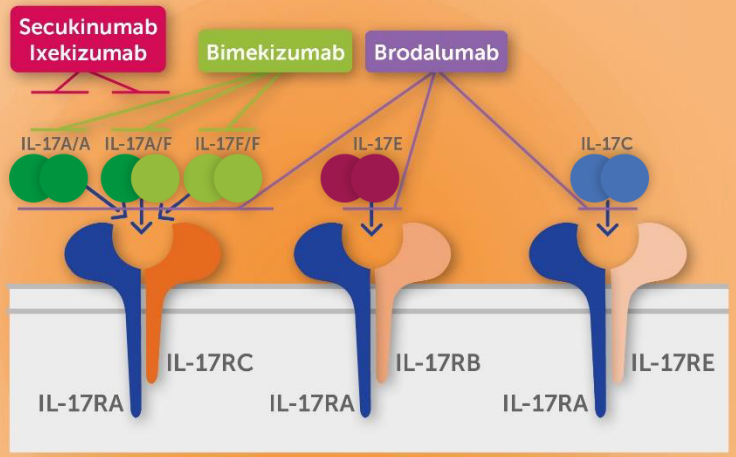
A 56-week, phase 3, randomised, double-blinded, adalimumab-controlled study investigating bimekizumab in patients with moderate-to-severe plaque psoriasis[1]

Study objective

To compare the efficacy and safety of bimekizumab versus adalimumab in patients with moderate-to-severe plaque psoriasis[1]

To assess the maintenance of efficacy of bimekizumab dosed Q4W versus Q8W[1]

Bimekizumab led to substantial **clinical improvements** in patients with moderate-to-severe plaque psoriasis in phase 3 studies **BE VIVID** and **BE READY**, with no unexpected safety findings[2,3]



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1. Warren RB, et al. N Engl J Med 2021;385:130–141; 2. Reich K, et al. Lancet 2021;397:487–498; 3. Gordon KB, et al. Lancet 2021;397:475–486; 4. Adapted from: Patel D, et al. Ann Rheum Dis 2013;72(Suppl 2):ii116–23. **Abbreviations:** IL: interleukin; Q4W: every four weeks; Q8W: every eight weeks.

Study design[1]

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Patient inclusion criteria:

- ≥18 years of age, chronic plaque psoriasis with ≥6 months' symptom duration
- Moderate to severe disease: PASI ≥ 12, BSA affected by psoriasis ≥10% and IGA score ≥3

N=478

Patients with moderate-to-severe plaque psoriasis 1:1:1 randomisation

Screening	Initial treatment period	Maintenance period
n=158	Bimekizumab 320 mg Q4W	
n=161	Bimekizumab 320 mg Q4W	Bimekizumab 320 mg Q8W
n=159	Adalimumab 40 mg Q2W[a]	Bimekizumab 320 mg Q4W

- Open-label extension study (BE BRIGHT)
- Safety follow-up for patients not enrolling in extension study; 20 weeks after last dose

2–5 weeks

Baseline — Week 16 — Week 24 — Week 56

Co-primary endpoints PASI 90 and IGA 0/1

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Note: bimekizumab is approved for use in moderate-to-severe psoriasis at Q4W dosing till week 16 followed by Q8W maintenance dosing. If the patient is ≥120 kg, maintenance dosing may be Q4W. 1. Warren RB, et al. N Engl J Med 2021;385:130–141. [a]Adalimumab was dosed 80 mg at Week 0 and 40 mg at Week 1, then every 2 weeks until Week 24 where the patient was switched to bimekizumab. **Abbreviations:** BSA: Body Surface Area; 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: ≥90% improvement from baseline in Psoriasis Area and Severity Index; Q2W/Q4W/Q8W: every two/four/eight weeks.

Baseline characteristics[1]

	BKZ 320 mg Q4W N=158	BKZ 320 mg Q4W ⟶ Q8W N=161	ADA 40 mg Q2W ⟶ BKZ 320 mg Q4W N=159
Age (years), mean ± SD	45.3 ± 13.2	44.0 ± 13.5	45.5 ± 14.3
Male, n (%)	102 (64.6)	112 (69.6)	114 (71.7)
Caucasian, n (%)	140 (88.6)	140 (87.0)	141 (88.7)
Weight (kg), mean ± SD	89.6 ± 21.4	93.2 ± 24.4	90.5 ± 22.1
Duration of PSO (years), mean ± SD	20.4 ± 13.2	17.3 ± 10.9	16.2 ± 11.9
PASI, mean ± SD	20.5 ± 6.9	19.9 ± 6.1	19.0 +/- 5.9
BSA (%), mean ± SD	26.5 ± 15.9	25.2 ± 12.4	25.0 ± 14.4
IGA, n (%)			
3: moderate	102 (64.6)	111 (68.9)	114 (71.7)
4: severe	56 (35.4)	50 (31.1)	45 (28.3)
DLQI total, mean ± SD	11.1 ± 6.5	10.8 ± 6.2	10.5 ± 7.4
Any prior systemic therapy, n (%)	112 (70.9)	116 (72.0)	110 (69.2)
Prior biologic therapy, n (%)[a]	50 (31.6)	50 (31.1)	53 (33.3)
anti-TNF	14 (8.9)	10 (6.2)	14 (8.8)
anti-IL-17	33 (20.9)	37 (23.0)	35 (22.0)
anti-IL-12/23	11 (7.0)	9 (5.6)	15 (9.4)
anti-IL-23	3 (1.9)	2 (1.2)	2 (1.3)

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Note: bimekizumab is approved for use in moderate-to-severe psoriasis at Q4W dosing till week 16 followed by Q8W maintenance dosing. If the patient is ≥120 kg, maintenance dosing may be Q4W. Adapted from Warren RB, et al. 2021. 1. Warren RB, et al. N Engl J Med 2021;385:130–141. aPatients with multiple prior biologics use included in n (%).
Abbreviations: ADA: adalimumab; BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; IL: interleukin; PASI: Psoriasis Area and Severity Index; PSO: plaque psoriasis; Q4W: every four weeks; Q8W: every eight weeks; SD: standard deviation; TNF: tumour necrosis factor.

Results[1] (1/2)

● BKZ 320 mg Q4W ● ADA 40 mg Q2W

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Short-term data

Co-primary endpoints: PASI 90 and IGA 0/1 at Week 16 for BKZ vs ADA

At Week 16

86.2%*

of patients on BKZ[a]

achieved PASI 90

compared to

47.2%

of patients on ADA[1]

n=319, 159

VIEW FULL GRAPH

VIEW PASI 90 OVER 16 WEEKS

At Week 16

85.3%*

of patients on BKZ[a]

achieved IGA 0/1

compared to

57.2%

of patients on ADA[1]

n=319, 159

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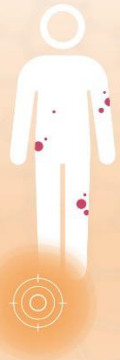


Secondary endpoints: PASI 75 at Week 4 for BKZ vs ADA, and PASI 100 at Week 16 for BKZ vs ADA

At Week 4

76.5%*

of patients on BKZ[a]

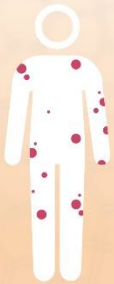
achieved PASI 75

compared to

31.4%

of patients on ADA[1]

n=319, 159



At Week 16

60.8%*

of patients on BKZ[a]

achieved clear skin (PASI 100)

compared to

23.9%

of patients on ADA[1]

n=319, 159

VIEW PASI 100 OVER 16 WEEKS

*p<0.001 vs ADA; p values for the comparison of treatment groups are based on the Cochran-Mantel-Haenszel test from the general association. Data shown include all randomised patients.

[a]Data were pooled from both bimekizumab arms as all patients received the same dose regimen through Week 16 (pre-specified)

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1. Warren RB, et al. N Engl J Med 2021;385:130–141. **Abbreviations**: ADA: adalimumab; 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; PASI 75: ≥75% improvement from baseline in Psoriasis Area and Severity Index; PASI 90: ≥90% improvement from baseline in Psoriasis Area and Severity Index; PASI 100: ≥100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every four weeks.

Results[1] (2/2)

● ADA 40 mg Q2W ● BKZ 320 mg Q4W→Q8W ● ADA→BKZ Q4W

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Long-term data

At Week 24

85.1%

of patients on BKZ Q4W → Q8W **achieved PASI 90** compared to

51.6%

of patients on ADA[1]

n=161, 159

VIEW FULL GRAPH

At Week 24

65.8%

of patients on BKZ Q4W → Q8W **achieved clear skin (PASI 100)** compared to

29.6%

of patients on ADA[1]

n=161, 159

VIEW FULL GRAPH

At Week 56

82.6%

of patients on BKZ Q4W → Q8W **achieved PASI 90** compared to

81.8%

of patients on ADA[1] → BKZ Q4W[1]

n=161, 159

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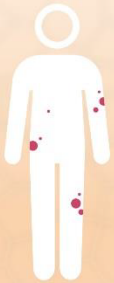

At Week 56

70.2%

of patients on BKZ Q4W → Q8W **achieved clear skin (PASI 100)** compared to

66.7%

of patients on ADA[1] → BKZ Q4W[1]

n=161, 159

VIEW FULL GRAPH

*p<0.001 vs ADA; p values for the comparison of treatment groups are based on the Cochran-Mantel-Haenszel test from the general association. Data shown include all randomised patients.

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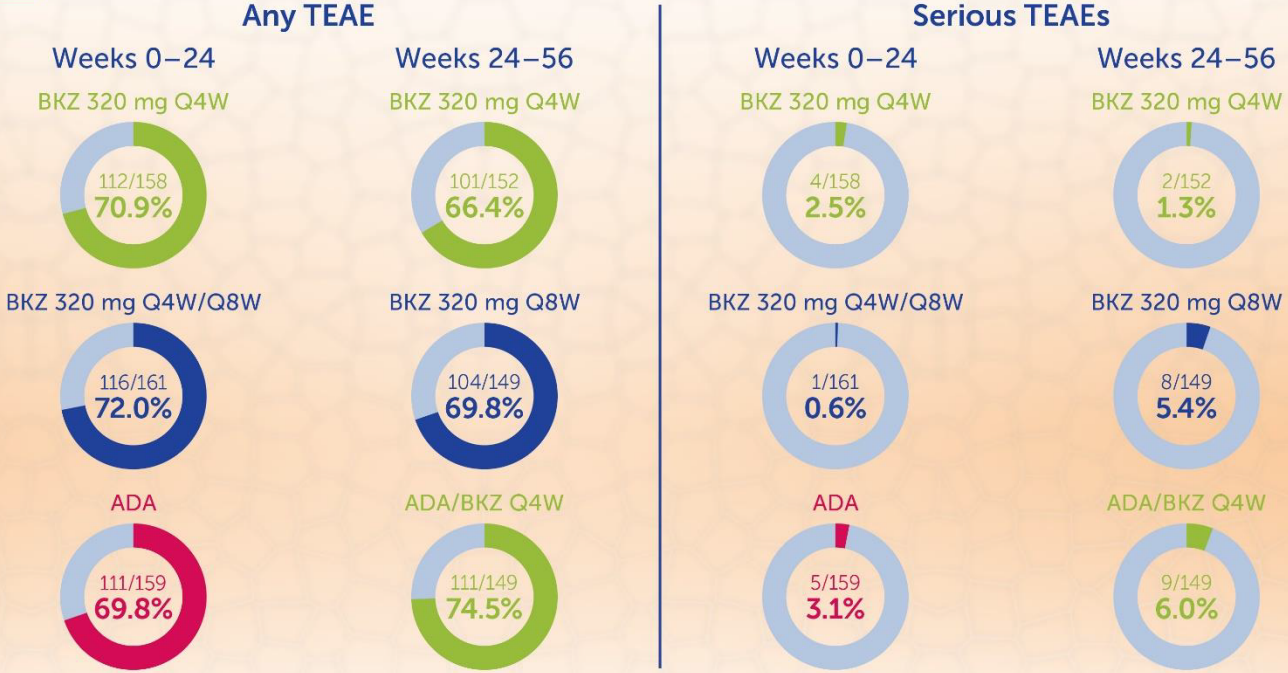
Note: bimekizumab is approved for use in moderate-to-severe psoriasis at Q4W dosing till week 16 followed by Q8W maintenance dosing. If the patient is ≥120 kg, maintenance dosing may be Q4W. 1. Warren RB, et al. N Engl J Med 2021;385:130–141. **Abbreviations:** ADA: adalimumab; BKZ: bimekizumab; PASI 90: ≥90% improvement from baseline in Psoriasis Area and Severity Index; PASI 100: ≥100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every four weeks; Q8W: every eight weeks.

Safety profile[1] (1/2)

BKZ 320 mg Q4W · ADA 40 mg Q2W · BKZ 320 mg Q4W→Q8W · ADA→BKZ Q4W

The proportions of TEAEs, severe TEAEs and discontinuations due to TEAEs were similar between treatment groups



VIEW SAFETY TABLE

Data for Weeks 0–24 are from the full safety set; data for Weeks 24–56 include only BKZ-treated patients. One death reported in the ADA Weeks 0–24 treatment group: a 50-year-old male was diagnosed with squamous cell carcinoma of the tongue 6 weeks after the start of ADA treatment, which led to a fatal outcome 5 months later.

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Note: bimekizumab is approved for use in moderate-to-severe psoriasis at Q4W dosing till week 16 followed by Q8W maintenance dosing. If the patient is ≥120 kg, maintenance dosing may be Q4W. 1. Warren RB, et al. N Engl J Med 2021;385:130–141. **Abbreviations:** ADA: adalimumab; BKZ: bimekizumab; TEAE, treatment-emergent adverse event; Q4W: every four weeks; Q8W: every eight weeks.

Safety profile[1] (2/2)

- The most common TEAEs* (>5% of patients) were upper respiratory tract infection, oral candidiasis, hypertension and diarrhoea
- The vast majority of oral candidiasis cases were mild or moderate and there were no patient discontinuations due to candidiasis infection

VIEW COMMON TEAES

VIEW SAFETY TOPICS OF INTEREST

*The most common TEAEs occurred in >5% of patients in any treatment group through Weeks 0–24 or 24–56.

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1. Warren RB, et al. N Engl J Med 2021;385:130–141. **Abbreviations:** TEAE: treatment-emergent adverse event.

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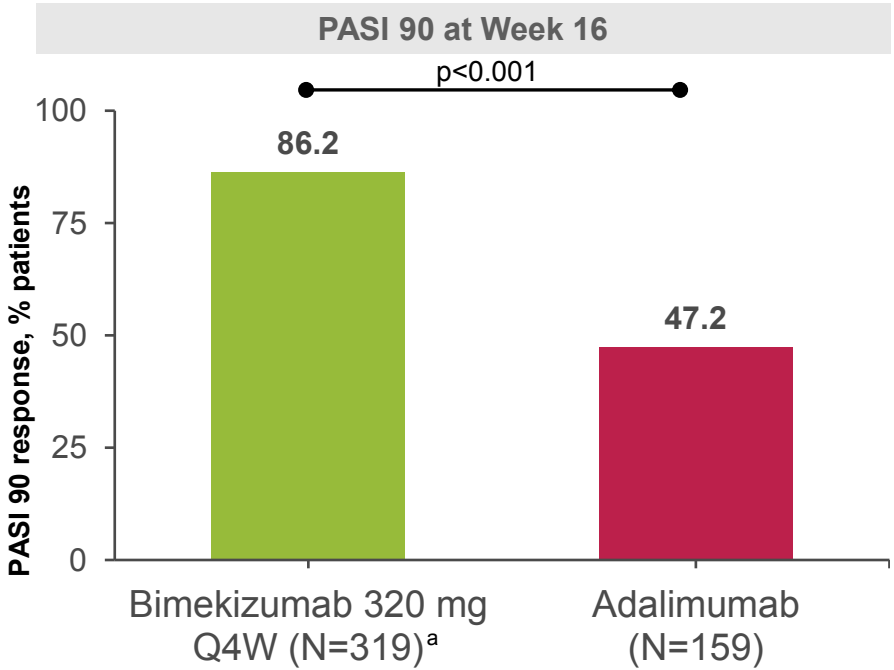
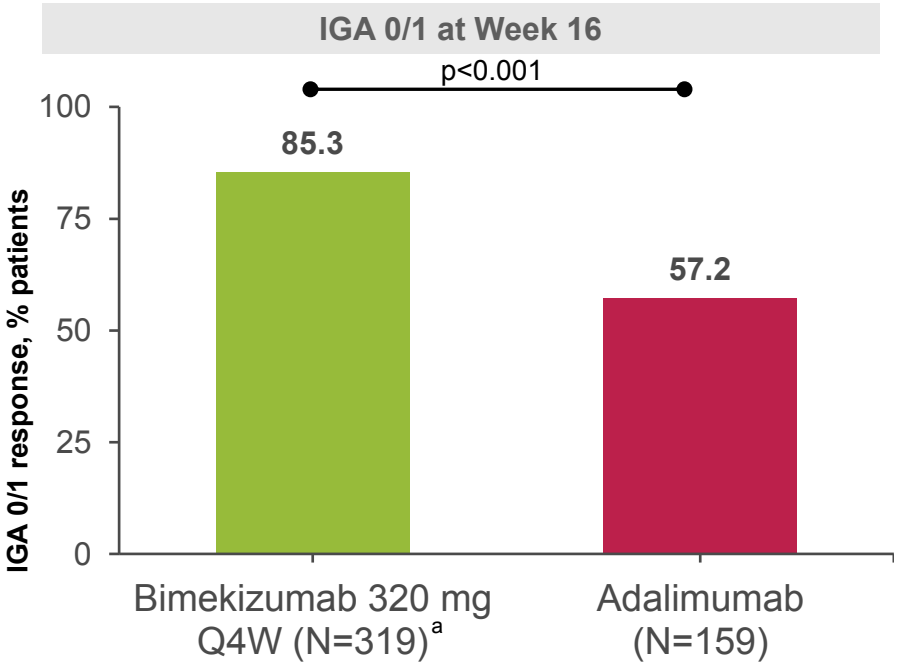
BE SURE PASI 90 and IGA 0/1 at Week 16 (ITT, NRI)[1]

Co-primary endpoints: superiority with bimekizumab versus adalimumab at Week 16





[a]Data were pooled from both bimekizumab arms as all patients received the same dose regimen through Week 16 (pre-specified).
p values for the comparison of treatment groups are based on the Cochran-Mantel-Haenszel test from the general association.
Data shown include all randomized patients.

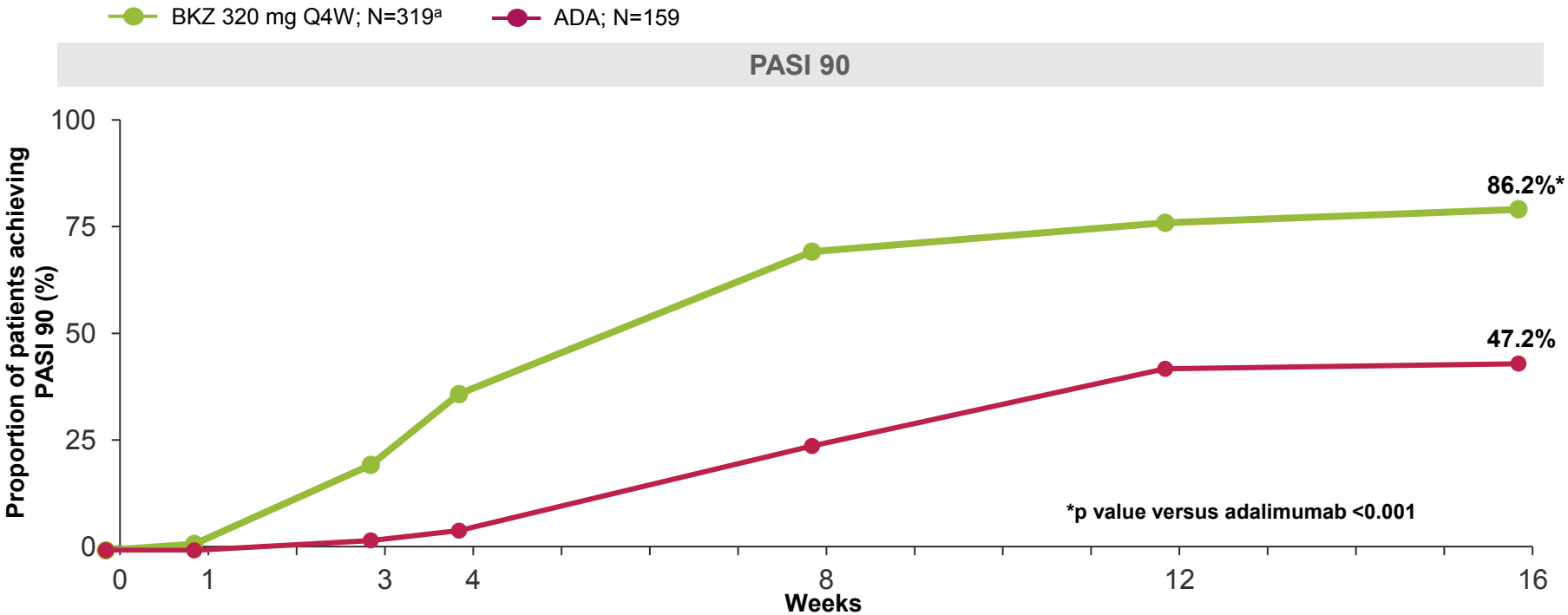
Return to short-term results

Adapted from Warren RB, et al. 2021.

1. Warren RB, et al. N Engl J Med 2021;385:130–141. **Abbreviations:** IGA 0/1: score of 0 (clear) or 1 (almost clear) with ≥2-category improvement relative to baseline in Investigator's Global Assessment; ITT: intent-to-treat; NRI: non-responder imputation; PASI 90: ≥90% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every four weeks.

BE SURE PASI 90 Over 16 Weeks (ITT, NRI)[1,2]

Co-primary endpoint: PASI 90 response with bimekizumab versus adalimumab at Week 16



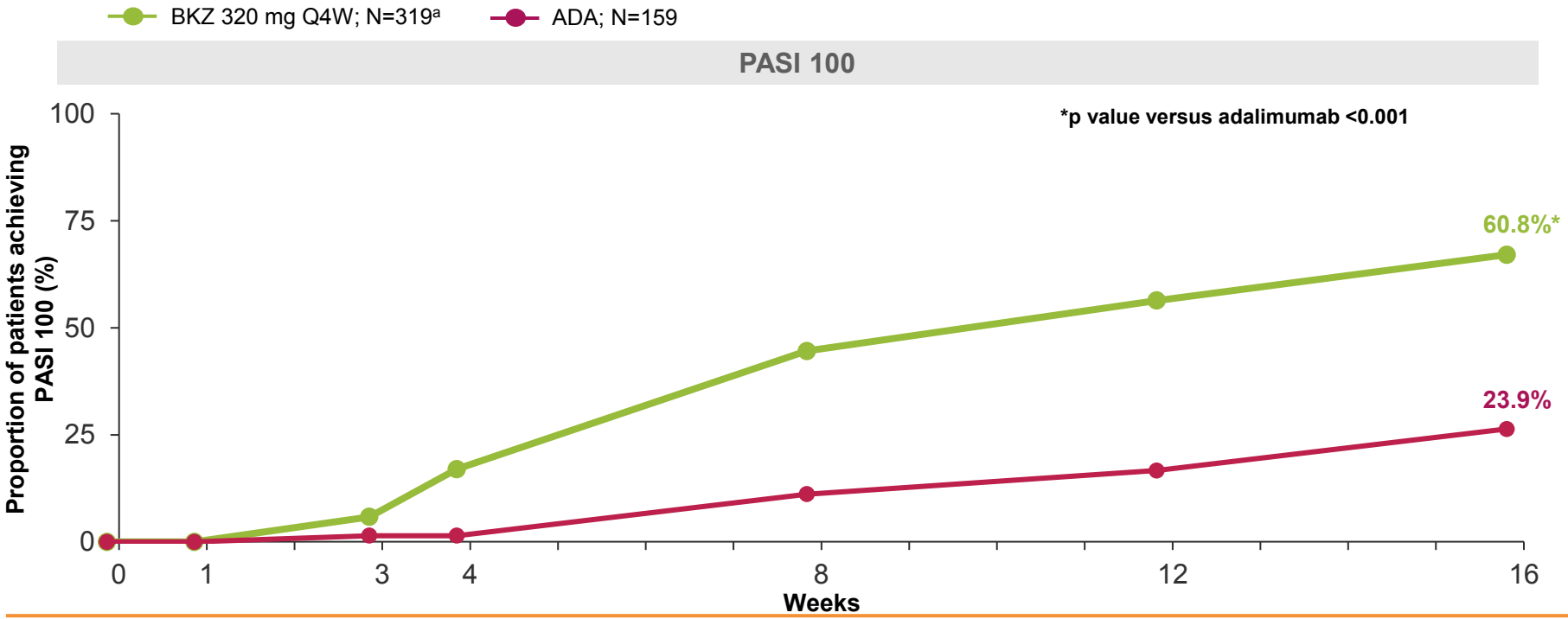
[a]Data were pooled from both bimekizumab arms as all patients received the same dose regimen through Week 16 (pre-specified).
Data shown include all randomized patients. p values for the comparison of treatment groups are based on the Cochran-Mantel-Haenszel test from the general association.

Return to short-term results

Adapted from Warren RB, et al. 2021. 1. Warren RB, et al. N Engl J Med 2021;385:130–141. 2. Warren RB, et al. AAD 2020;oral presentation.
Abbreviations: ADA: adalimumab; 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.

BE SURE PASI 100 Over 16 Weeks (ITT, NRI)[1,2]

Secondary endpoint: PASI 100 response with bimekizumab versus adalimumab at Week 16

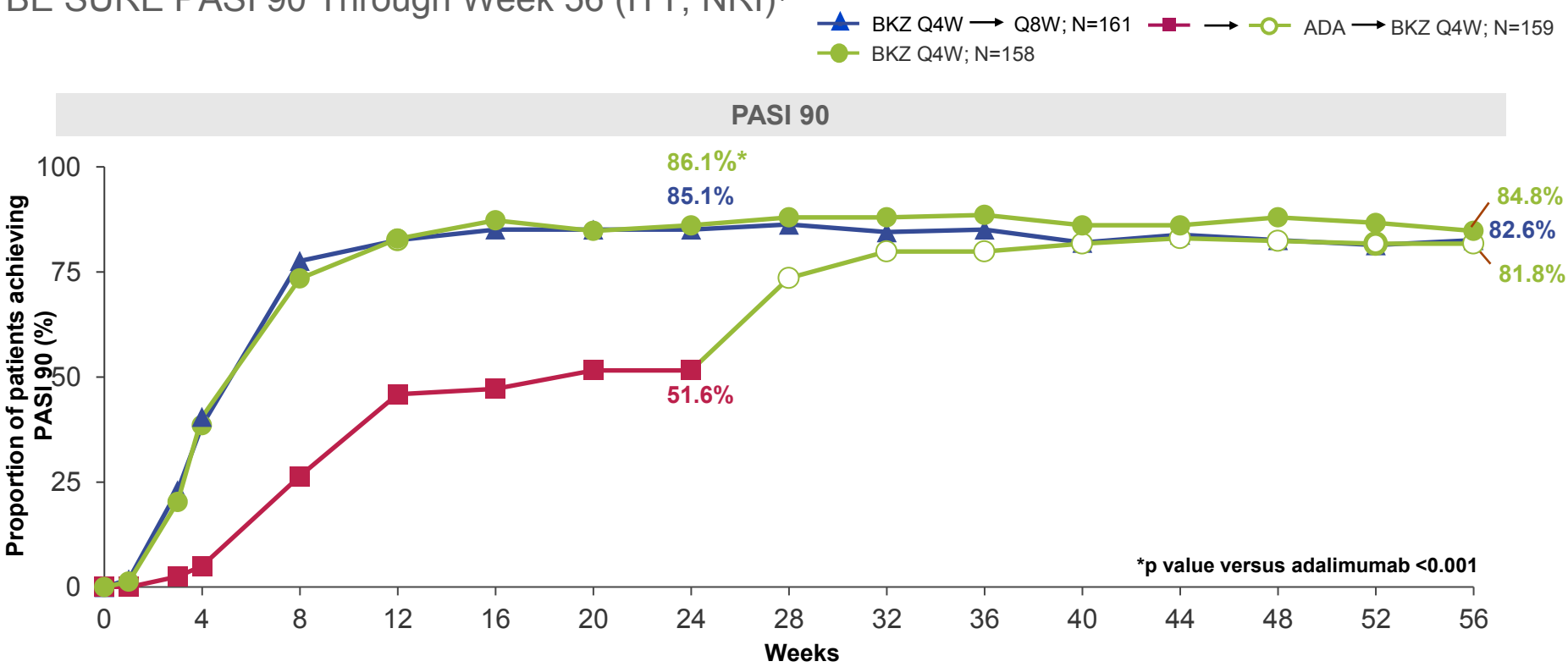


[a]Data were pooled from both bimekizumab arms as all patients received the same dose regimen through Week 16 (pre-specified).
Data shown include all randomized patients. p values for the comparison of treatment groups are based on the Cochran-Mantel-Haenszel test from the general association.

Return to short-term results

Adapted from Warren RB, et al. 2021. 1. Warren RB, et al. N Engl J Med 2021;385:130–141. 2. Warren RB, et al. AAD 2020;oral presentation.
Abbreviations: ADA: adalimumab; 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.

BE SURE PASI 90 Through Week 56 (ITT, NRI)[1]



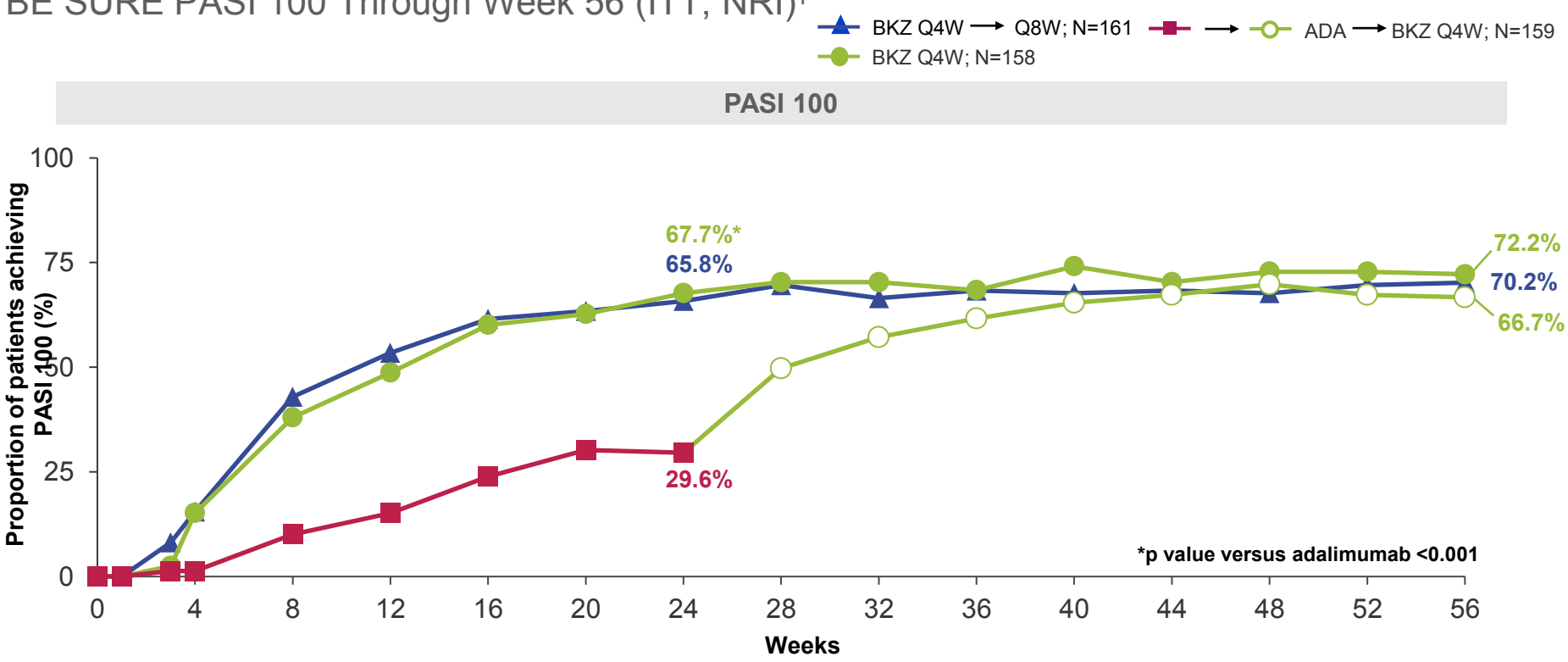
Data shown include all randomized patients. p values for the comparison of treatment groups are based on the Cochran-Mantel-Haenszel test from the general association.

Return to long-term results

Note: bimekizumab is approved for use in moderate-to-severe psoriasis at Q4W dosing till week 16 followed by Q8W maintenance dosing. If the patient is ≥120 kg, maintenance dosing may be Q4W.

Adapted from Warren RB, et al. 2021. 1. Warren RB, et al. N Engl J Med 2021;385:130–141. **Abbreviations:** ADA: adalimumab; BKZ: bimekizumab; ITT: intent-to-treat; NRI: non-responder imputation; PASI 90: ≥90% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every four weeks; Q8W: every eight weeks.

BE SURE PASI 100 Through Week 56 (ITT, NRI)[1]



Data shown include all randomized patients. p values for the comparison of treatment groups are based on the Cochran-Mantel-Haenszel test from the general association.

Return to long-term results

Note: bimekizumab is approved for use in moderate-to-severe psoriasis at Q4W dosing till week 16 followed by Q8W maintenance dosing. If the patient is ≥120 kg, maintenance dosing may be Q4W.

Adapted from Warren RB, et al. 2021. 1. Warren RB, et al. N Engl J Med 2021;385:130–141. **Abbreviations**: ADA: adalimumab; BKZ: bimekizumab; ITT: intent-to-treat; NRI: non-responder imputation; PASI 100: 100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every four weeks; Q8W: every eight weeks.

BE SURE Incidence of TEAEs[1]

	Weeks 0–24[a]			Weeks 24–56[b]		
	BKZ 320 mg Q4W (N=158) n (%)	BKZ 320 mg Q4W/Q8W (N=161) n (%)	ADA (N=159) n (%)	BKZ 320 mg Q4W (N=152) n (%)	BKZ 320 mg Q4W/Q8W (N=149) n (%)	ADA/ BKZ Q4W (N=149) n (%)
Any TEAE	112 (70.9)	116 (72.0)	111 (69.8)	101 (66.4)	104 (69.8)	111 (74.5)
Serious TEAEs	4 (2.5)	1 (0.6)	5 (3.1)	2 (1.3)	8 (5.4)	9 (6.0)
Discontinuation due to TEAEs	3 (1.9)	6 (3.7)	5 (3.1)	3 (2.0)	2 (1.3)	5 (3.4)
Drug-related TEAEs	41 (25.9)	46 (28.6)	38 (23.9)	40 (26.3)	35 (23.5)	45 (30.2)
Severe TEAEs	3 (1.9)	2 (1.2)	5 (3.1)	5 (3.3)	8 (5.4)	7 (4.7)
Deaths	0 (0.0)	0 (0.0)	1 (0.6)[c]	0 (0.0)	0 (0.0)	0 (0.0)

Proportions of TEAEs, severe TEAEs and discontinuations due to TEAEs were similar between treatment groups

[a]Data for weeks 0 to 24 include all the patients who received at least one dose of bimekizumab or adalimumab (full safety set). [b]Data for weeks 24 to 56 include all the patients who had received at least one dose of bimekizumab at week 24 or beyond (bimekizumab week-24 set). [c]A 50-year-old male patient received a diagnosis of squamous-cell carcinoma of the tongue 6 weeks after the start of adalimumab treatment and died 5 months later. Mouth ulcerations were noted on screening; he had no history of tobacco use.

Return to safety overview (1/2)

Note: bimekizumab is approved for use in moderate-to-severe psoriasis at Q4W dosing till week 16 followed by Q8W maintenance dosing. If the patient is ≥120 kg, maintenance dosing may be Q4W.

Adapted from Warren RB, et al. 2021. 1. Warren RB, et al. N Engl J Med 2021;385:130–141. **Abbreviations:** ADA: adalimumab; BKZ: bimekizumab; Q4W: every four weeks; Q8W: every eight weeks; TEAE, treatment-emergent adverse event.

BE SURE Common TEAEs (>5% Patients[a])[1]

	Weeks 0–24[b]			Weeks 24–56[c]		
	BKZ 320 mg Q4W (N=158) n (%)	BKZ 320 mg Q4W/Q8W (N=161) n (%)	ADA (N=159) n (%)	BKZ 320 mg Q4W (N=152) n (%)	BKZ 320 mg Q4W/Q8W (N=149) n (%)	ADA/ BKZ Q4W (N=149) n (%)
Upper respiratory tract infection[d]	48 (30.4)	45 (28.0)	55 (34.6)	36 (23.7)	36 (24.2)	42 (28.2)
Oral candidiasis	15 (9.5)	19 (11.8)	0	20 (13.2)	13 (8.7)	26 (17.4)
Hypertension	6 (3.8)	9 (5.6)	13 (8.2)	2 (1.3)	3 (2.0)	3 (2.0)
Diarrhea	8 (5.1)	5 (3.1)	4 (2.5)	2 (1.3)	3 (2.0)	2 (1.3)

From weeks 0 to 56, there were 76 cases of oral candidiasis with bimekizumab, 36 of which were rated by investigators as moderate and 2 of which were rated as severe; none of the cases of oral candidiasis resulted in trial discontinuation.

[a]Shown are adverse events that occurred in more than 5% of the patients in any treatment group from weeks 0 to 24 or from weeks 24 to 56. [b]Data for weeks 0 to 24 include all the patients who received at least one dose of bimekizumab or adalimumab (full safety set). [c]Data for weeks 24 to 56 include all the patients who had received at least one dose of bimekizumab at week 24 or beyond (bimekizumab week-24 set). [d]Upper respiratory tract infections included nasopharyngitis, upper respiratory tract infection, pharyngitis, rhinitis, tonsillitis, sinusitis, acute sinusitis, chronic sinusitis, laryngitis, peritonsillar abscess, and sinobronchitis.

Return to safety overview (2/2)

Note: bimekizumab is approved for use in moderate-to-severe psoriasis at Q4W dosing till week 16 followed by Q8W maintenance dosing. If the patient is ≥120 kg, maintenance dosing may be Q4W.

Adapted from Warren RB, et al. 2021. 1. Warren RB, et al. N Engl J Med 2021;385:130–141. **Abbreviations**: ADA: adalimumab; BKZ: bimekizumab; Q4W: every four weeks; Q8W: every eight weeks; TEAE, treatment-emergent adverse event.

BE SURE Safety Topics of Interest[1]

Return to safety overview (2/2)

	Weeks 0–24[a]			Weeks 24–56[b]		
	BKZ 320 mg Q4W (N=158) n (%)	BKZ 320 mg Q4W/Q8W (N=161) n (%)	ADA (N=159) n (%)	BKZ 320 mg Q4W (N=152) n (%)	BKZ 320 mg Q4W/Q8W (N=149) n (%)	ADA/ BKZ Q4W (N=149) n (%)
Inflammatory bowel disease	0	0	0	0	0	0
Adjudicated SIB	0	0	0	0	0	0
Cancer[c]	0	4 (2.5)	1 (0.6)	0	2 (1.3)	1 (0.7)
NMSC	0	3 (1.9)	0	0	0	1 (0.7)
Active tuberculosis	0	0	0	0	0	0
Latent tuberculosis	0	0	0	1 (0.7)	3 (2.0)	1 (0.7)
Serious hypersensitivity reaction	0	0	0	0	0	0
Adjudicated MACE	0	0	0	0	0	0
Elevated level of liver enzymes[d]	3 (1.9)	4 (2.5)	11 (6.9)	1 (0.7)	2 (1.3)	6 (4.0)
Serious infection[e]	0	1 (0.6)	1 (0.6)	1 (0.7)	2 (1.3)	4 (2.7)

[a]Data for weeks 0 to 24 include all the patients who received at least one dose of bimekizumab or adalimumab (full safety set). [b]Data for weeks 24 to 56 include all the patients who had received at least one dose of bimekizumab at week 24 or beyond (bimekizumab week-24 set). [c]From weeks 0 to 24, three cases of basal-cell carcinoma and one case of anal squamous-cell carcinoma were reported in the group receiving bimekizumab every 4 weeks and then every 8 weeks, and one case of squamous-cell carcinoma of the tongue was reported in the group receiving adalimumab. From weeks 24 to 56, one case each of colon cancer and squamous-cell carcinoma was reported in the group receiving bimekizumab every 4 weeks and then every 8 weeks, and one case of basal-cell carcinoma was reported in the group that switched from adalimumab to bimekizumab every 4 weeks at week 24. [d]Liver-function tests included the following terms reported as adverse events: elevated levels of hepatic enzymes, aspartate aminotransferase, blood bilirubin, γ-glutamyltransferase, alanine aminotransferase, or aminotransferases or increased liver-function test findings. [e]From weeks 0 to 24, one case of cellulitis was reported in the group receiving bimekizumab every 4 weeks and then every 8 weeks, and one case of infected dermal cyst was reported in the group receiving adalimumab. From weeks 24 to 56, one case of subcutaneous abscess was reported in the group receiving bimekizumab every 4 weeks, one case each of appendicitis and erysipelas was reported in the group receiving bimekizumab every 4 weeks and then every 8 weeks, and two cases of cellulitis and one case each of anal abscess and helicobacter infection were reported in the group that switched from adalimumab to bimekizumab every 4 weeks at week 24.

Note: bimekizumab is approved for use in moderate-to-severe psoriasis at Q4W dosing till week 16 followed by Q8W maintenance dosing. If the patient is ≥120 kg, maintenance dosing may be Q4W. Adapted from Warren RB, et al. 2021. 1. Warren RB, et al. N Engl J Med 2021;385:130–141. **Abbreviations:** ADA: adalimumab; BKZ: bimekizumab; LFT: liver function test; MACE: major adverse cardiovascular event; NMSC: non-melanoma skin cancer; SIB: suicidal ideation and behaviour; Q4W: every 4 weeks; Q8W: every 8 weeks.