BE VIVID

Bimekizumab in patients with moderate-to-severe psoriasis

Summary of results from the Phase 3 BE VIVID study

NEXT →

 Date of preparation: November 2021 SE-P-BK-PSO-2100067

Study overview

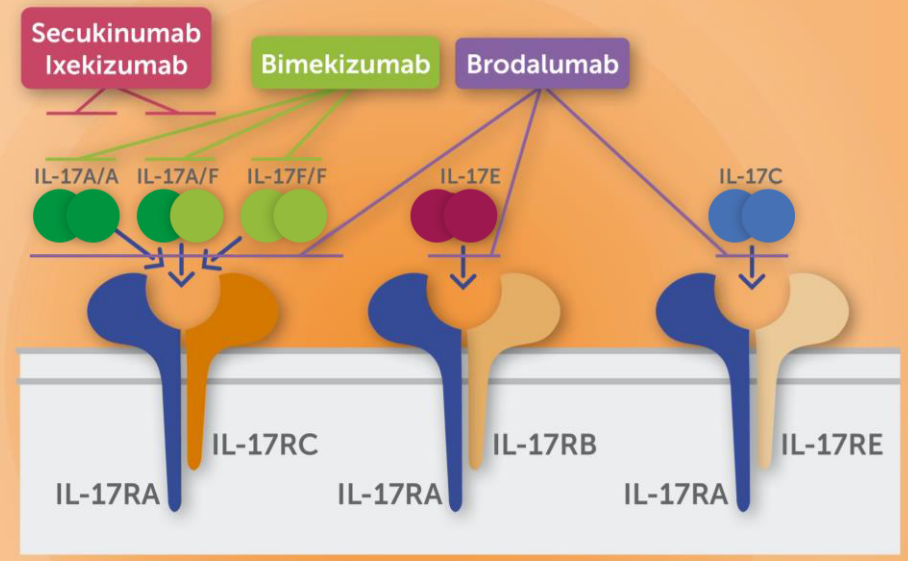
BE VIVID

A 52-week, Phase 3, randomised, double-blinded, ustekinumab- and placebo-controlled study investigating bimekizumab in patients with moderate-to-severe plaque psoriasis[1]

Study objective

To compare the efficacy and safety of bimekizumab with ustekinumab and placebo in patients with psoriasis treated for one year[1]

Bimekizumab is the only monoclonal IgG1 antibody that **selectively inhibits IL-17A and IL-17F, which are pivotal proinflammatory cytokines that drive pathophysiology across a number of chronic diseases, including psoriasis**[2]



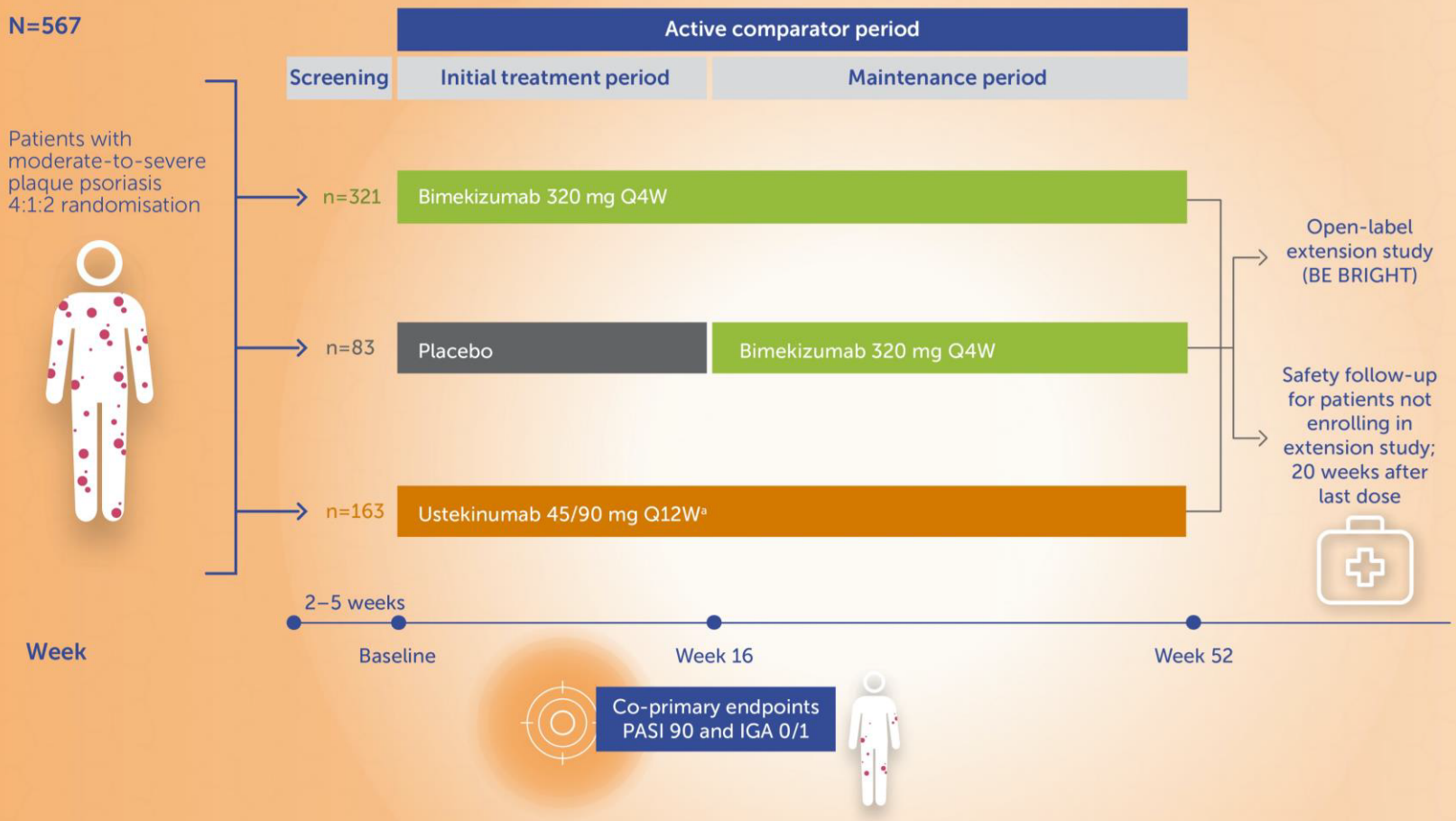
← BACK

NEXT →

1. Reich K, et al, Lancet 2021;397:487–498; 2. Diagram modified from Patel D et al. Ann Rheum Dis. 2013;72(Suppl 2):ii116–23
Abbreviations: IgG1, immunoglobulin G1; IL, interleukin.

Study design[1]

BE VIVID



[a]Ustekinumab dosing was based on weight: patients ≤100 kg at Baseline received one ustekinumab 45 mg injection, patients >100 kg at Baseline received two ustekinumab 45 mg injections

← BACK

NEXT →

Note: bimekizumab is approved for use in moderate-to-severe psoriasis at Q4W dosing until week 16 followed by Q8W maintenance dosing. If the patient is ≥120 kg, maintenance dosing may be Q4W. Adapted from Reich K, et al. 2021. 1. Reich K, et al, Lancet 2021; 397:487–498. **Abbreviations:** IGA, investigator's global assessment; PASI 90, ≥90% improvement from baseline in Psoriasis Area and Severity Index; Q4W, every 4 weeks; Q12W, every 12 weeks.

Baseline characteristics[1]

	PBO/bimekizumab 320 mg Q4W (N=83)	Bimekizumab 320 mg Q4W (N=321)	Ustekinumab[a] (N=163)
Age (years), mean ± SD	49.7 ± 13.6	45.2 ± 14.0	46.0 ± 13.6
Male, n (%)	60 (72.3)	229 (71.3)	117 (71.8)
Caucasian, n (%)	63 (75.9)	237 (73.8)	120 (73.6)
Weight (kg), mean ± SD	89.1 ± 26.4	88.7 ± 23.1	87.2 ± 21.1
Duration of PSO (years), mean ± SD	19.7 ± 13.8	16.0 ± 11.6	17.8 ± 11.6
PASI, mean ± SD	20.1 ± 6.8	22.0 ± 8.6	21.3 ± 8.3
BSA (%), mean ± SD	27.0 ± 16.3	29.0 ± 17.1	27.3 ±16.7
IGA, n (%)			
3: moderate	54 (65.1)	201 (62.6)	96 (58.9)
4: severe	28 (33.7)	119 (37.1)	66 (40.5)
DLQI total, mean ± SD	10.0 ± 6.8	9.9 ± 6.3	11.0 ± 6.9
Any prior systemic therapy, n (%)	64 (77.1)	267 (83.2)	132 (81.0)
Prior biologic therapy, n (%)	33 (39.8)	125 (38.9)	63 (38.7)
anti-TNF	16 (19.3)	51 (15.9)	24 (14.7)
anti-IL-17	18 (21.7)	76 (23.7)	38 (23.3)
anti-IL-23	5 (6.0)	16 (5.0)	6 (3.7)

[a]Ustekinumab dosing was based on weight: patients ≤100 kg at Baseline received one ustekinumab 45 mg injection, patients >100 kg at Baseline received two ustekinumab 45 mg injections

← BACK

NEXT →

Note: bimekizumab is approved for use in moderate-to-severe psoriasis at Q4W dosing until week 16 followed by Q8W maintenance dosing. If the patient is ≥120 kg, maintenance dosing may be Q4W. 1. Reich K, et al, Lancet 2021;397:487–498. **Abbreviations:** BSA, body surface area; DLQI, dermatology life quality index; IGA, investigator's global assessment; IL, interleukin; PASI, Psoriasis Area and Severity Index; PBO, placebo; PSO, psoriasis; Q4W, every 4 weeks; SD, standard deviation; TNF, tumour necrosis factor.

Results[1] (1/2)

● BKZ 320 mg Q4W ● UST 45/90 mg Q12W[a] ● Placebo

BE VIVID Short-term data

Co-primary endpoints: PASI 90 and IGA 0/1 at Week 16 for BKZ vs PBO; Key secondary endpoints: PASI 90 and IGA 0/1 at Week 16 for BKZ vs UST

At Week 16

85%*

of patients on BKZ **achieved PASI 90** compared to

5%

of patients on PBO and

50%

of patients on UST[1]

n=321,163,83

VIEW FULL GRAPH

and

84%*

of patients on BKZ **achieved IGA 0/1** compared to

5%

of patients on PBO and

53%

of patients on UST[1]

n=321,163,83

VIEW FULL GRAPH

Secondary endpoints: PASI 75 response at Week 4 for BKZ vs UST and PBO, and PASI 100 response at Week 16 for BKZ vs UST and PBO

At Week 4

77%*

of patients on BKZ **achieved PASI 75** compared to

2%

of patients on PBO and

15%

of patients on UST[1]

n=321,163,83

VIEW FULL GRAPH

At Week 16

59%*§

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

0%

of patients on PBO and

21%

of patients on UST[1]

n=321,163,83

VIEW FULL GRAPH

*p<0.0001 vs ustekinumab. §The p value for a general association was based on a stratified Cochran-Mantel-Haenszel test where region and prior biologic exposure were used as stratification variables, is considered nominal, and was not controlled for multiplicity.

[a]Ustekinumab dosing was based on weight: patients ≤100 kg at Baseline received one ustekinumab 45 mg injection, patients >100 kg at Baseline received two ustekinumab 45 mg injections

← BACK NEXT →

1. Reich K, et al, Lancet 2021;397:487–498.

Abbreviations: BKZ, bimekizumab; IGA, investigator's global assessment; PASI 75/90/100, ≥75%/≥90%/100% improvement in Psoriasis Area and Severity Index; Q4W, every 4 weeks; UST, ustekinumab.

Results[1] (2/2)

● BKZ 320 mg Q4W ● UST 45/90 mg Q12W[a]

BE VIVID Long-term data

At Week 52

82%*

of patients on BKZ **achieved PASI 90** compared to

56%

of patients on UST[1]

n=321,163,83

VIEW FULL GRAPH

and

78%*

of patients on BKZ **achieved IGA 0/1** compared to

61%

of patients on UST[1]

n=321,163,83

VIEW FULL GRAPH

and

65%*§

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

38%

of patients on UST[1]

n=321,163,83

VIEW FULL GRAPH

*p<0.0001 vs ustekinumab. §The p value for a general association was based on a stratified Cochran-Mantel-Haenszel test where region and prior biologic exposure were used as stratification variables, is considered nominal, and was not controlled for multiplicity.

[a]Ustekinumab dosing was based on weight: patients ≤100 kg at Baseline received one ustekinumab 45 mg injection, patients >100 kg at Baseline received two ustekinumab 45 mg injections

← BACK NEXT →

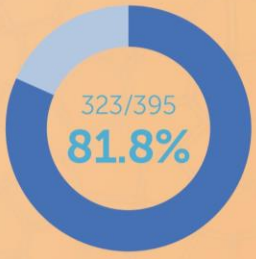
Note: bimekizumab is approved for use in moderate-to-severe psoriasis at Q4W dosing till week 16 followed by Q8W maintenance dosing. If the patient is ≥120 kg, maintenance dosing may be Q4W. 1. Reich K, et al, Lancet 2021;397:487–498. **Abbreviations:** BKZ, bimekizumab; IGA, investigator's global assessment; PASI 90/100, ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; PBO, placebo; Q4W, every 4 weeks; Q12W, every 12 weeks; UST, ustekinumab.

Safety profile[1]

The safety profile of bimekizumab was consistent with previous studies

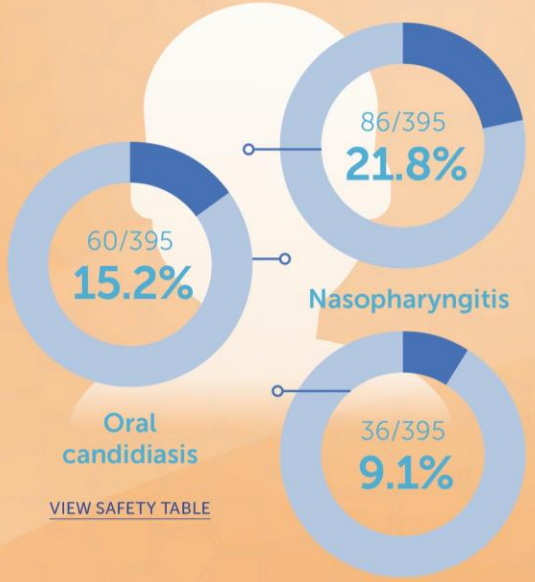
These safety data were taken from the initial and maintenance treatment period (Week 0-52)

Any TEAE



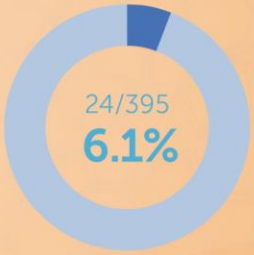
VIEW SAFETY TABLE

Most common TEAEs



VIEW SAFETY TABLE

Serious TEAEs



VIEW SAFETY TOPICS OF INTEREST

Deaths

2 deaths*

*One death was from a fatal cardiac arrest during the initial treatment period and one from unknown causes three months after the last dose of treatment. Both were assessed as unrelated to study treatment

← BACK

NEXT →

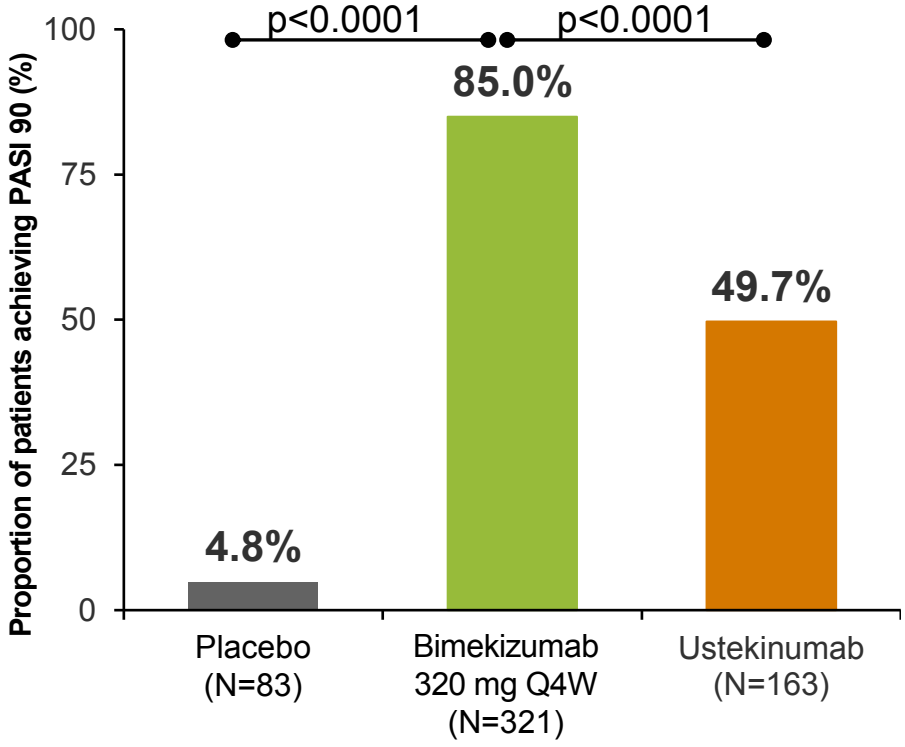
1. Reich K, et al, Lancet 2021;397:487–498. **Abbreviations:** MACE, major adverse cardiovascular events; TEAE, treatment-emergent adverse event.

BACK

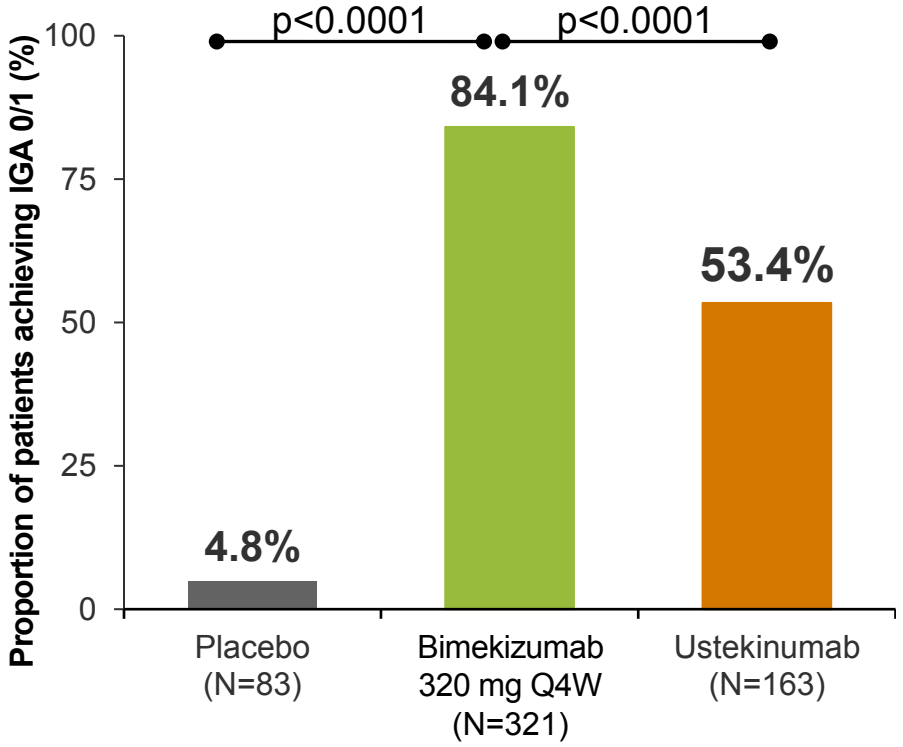
BE VIVID PASI 90 and IGA 0/1 at Week 16 (ITT, NRI)[1]

Co-primary endpoints: superiority with bimekizumab versus placebo
Key secondary endpoints: superiority with bimekizumab versus ustekinumab

Week 16 PASI 90



Week 16 IGA 0/1



p values for the comparison of treatment groups were based on the Cochran–Mantel–Haenszel test from the general association. Proportions were calculated using non-responder imputation (NRI). 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.

Return to short-term results

Adapted from Reich K, et al. 2021.

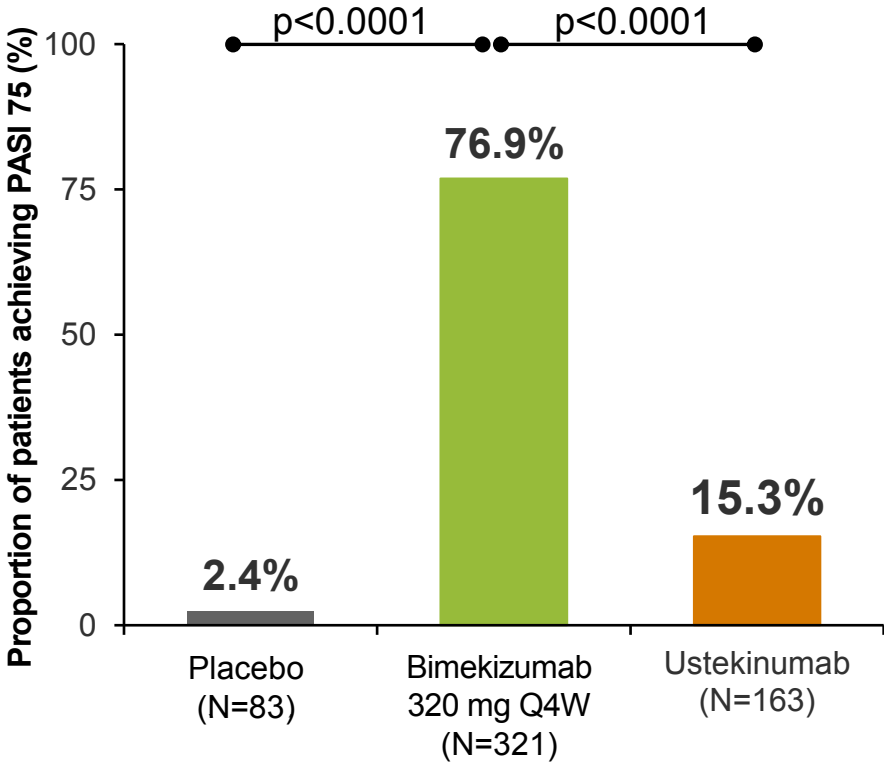
1. Reich K, et al, Lancet 2021;397:487–498.

Abbreviations: IGA, 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 4 weeks.

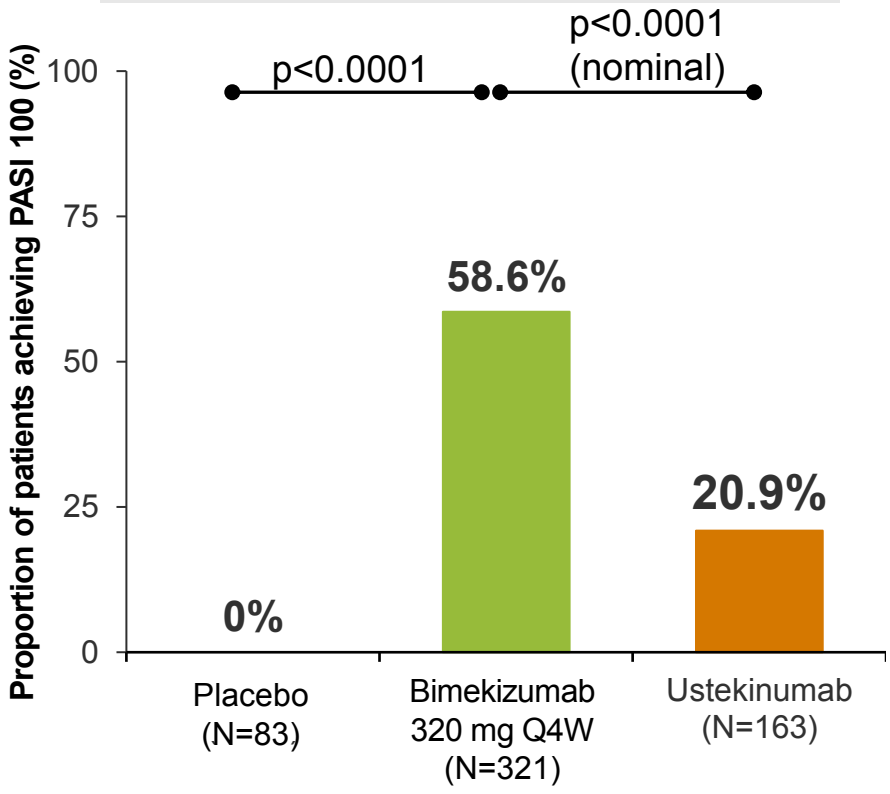
BE VIVID PASI 75 at Week 4 and PASI 100 at Week 16 (ITT, NRI)[1]

Secondary endpoints: PASI 75 response superiority with bimekizumab versus ustekinumab and placebo at Week 4, and PASI 100 response superiority with bimekizumab versus placebo at Week 16

Week 4 PASI 75



Week 16 PASI 100



For PASI 75 at Week 4, the p value for the comparison of treatment groups was based on the Cochran–Mantel–Haenszel test from the general association; for PASI 100 at Week 16, the p value for a general association was based on a stratified Cochran–Mantel–Haenszel test where region and prior biologic exposure were used as stratification variables, is considered nominal, and was not controlled for multiplicity. Proportions were calculated using non-responder imputation (NRI).

Return to short-term results

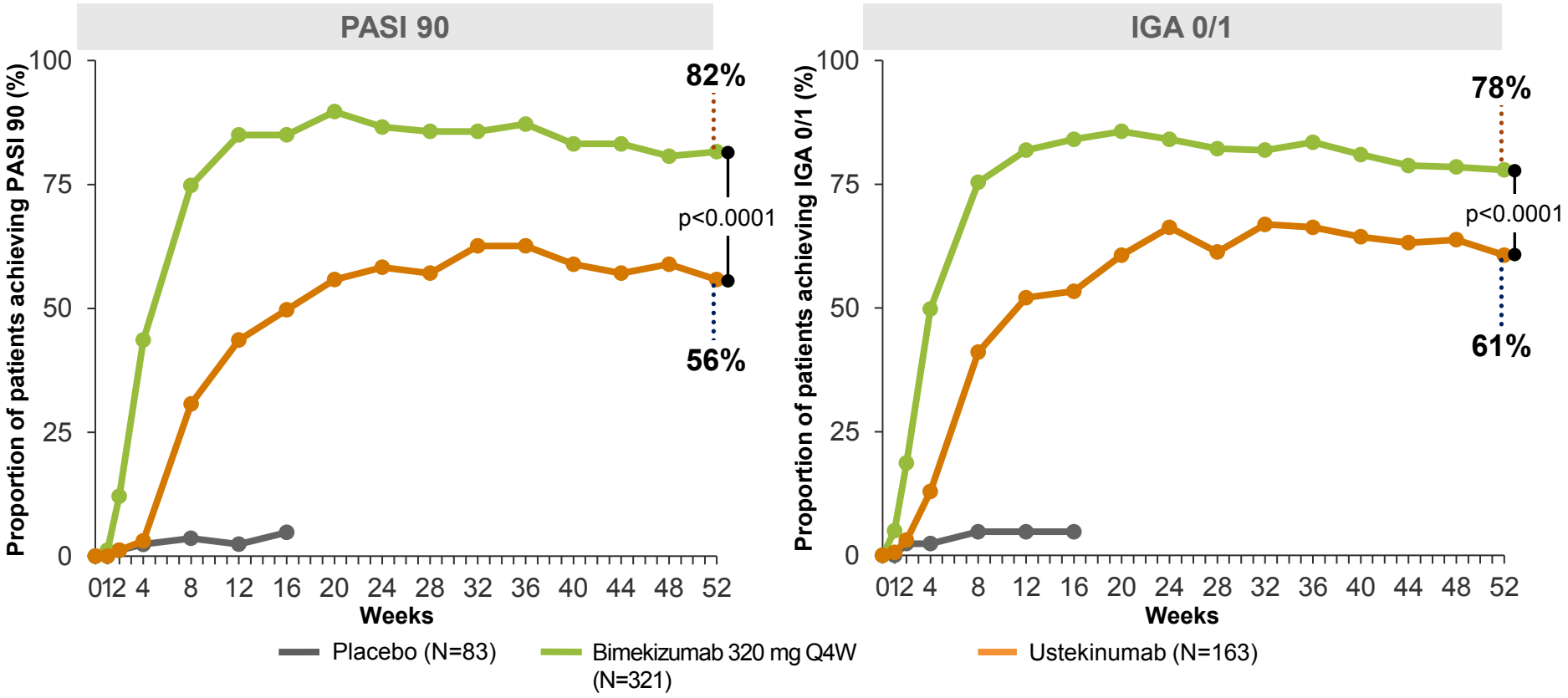
Adapted from Reich K, et al. 2021.

1. Reich K, et al, Lancet 2021;397:487–498.

Abbreviations: ITT, intent-to-treat; NRI, non-responder imputation; PASI 75/100, ≥75%/100% improvement from baseline in Psoriasis Area and Severity Index; Q4W, every 4 weeks.

BE VIVID PASI 90 and IGA 0/1 over 52 weeks (ITT, NRI)[1]

Secondary endpoints: PASI 90 and IGA 0/1 response superiority with bimekizumab versus ustekinumab at Week 52



p values for the comparison of treatment groups were based on the Cochran–Mantel–Haenszel test from the general association. Proportions were calculated using non-responder imputation (NRI). At Week 16, patients receiving placebo were switched to bimekizumab 320 mg Q4W. 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.

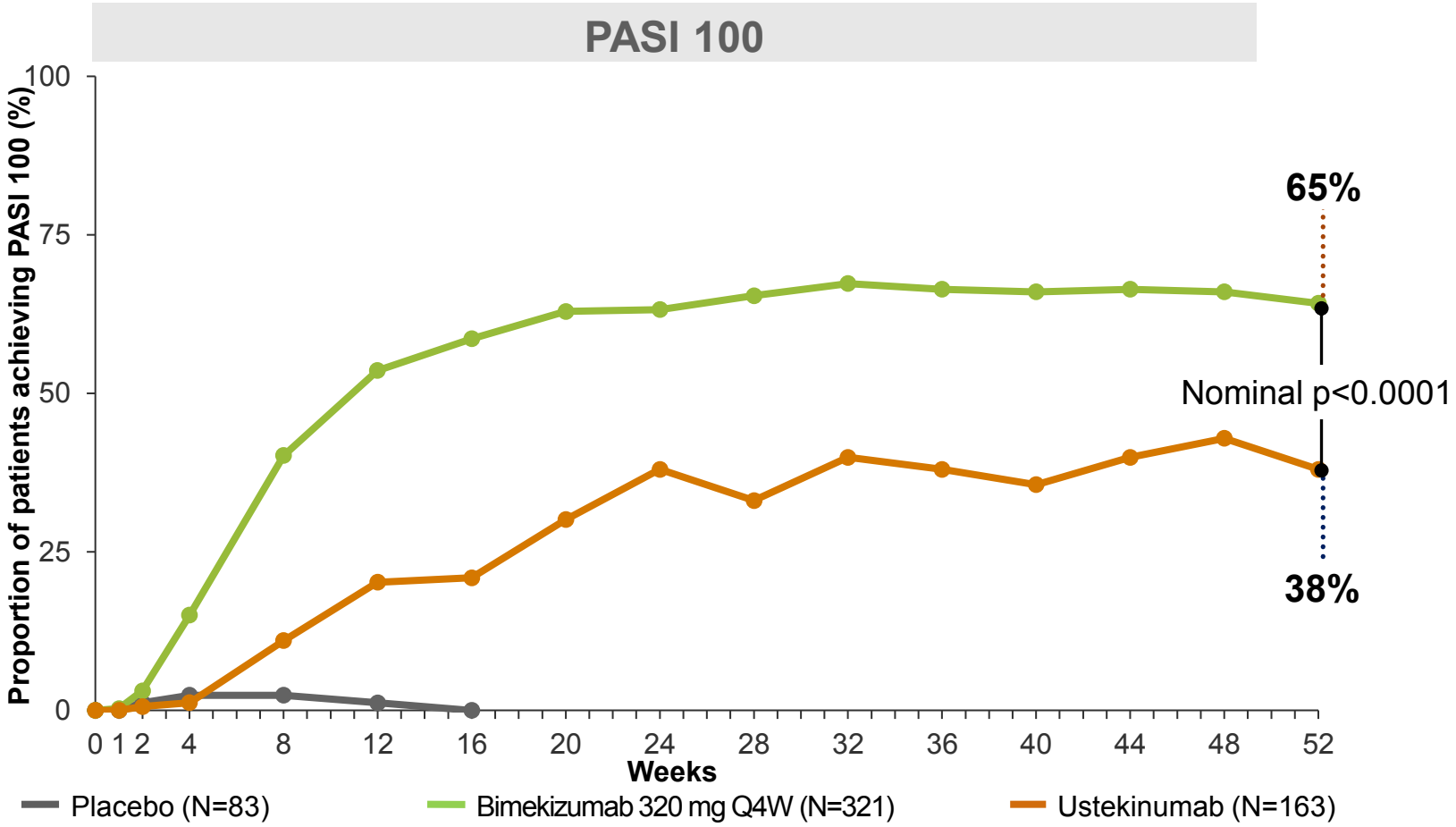
Return to long-term results

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 Reich K, et al. 2021. 1. Reich K, et al, Lancet 2021;397:487–498.

Abbreviations: IGA, 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 4 weeks.

BE VIVID PASI 100 over 52 weeks (ITT, NRI)[1]



The p value for a general association was based on a stratified Cochran–Mantel–Haenszel test where region and prior biologic exposure were used as stratification variables, is considered nominal, and was not controlled for multiplicity. Proportions were calculated using non-responder imputation (NRI). At Week 16, patients receiving placebo were switched to bimekizumab 320 mg Q4W.

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 Reich K, et al. 2021. 1. Reich K, et al, Lancet 2021;397:487–498.

Abbreviations: 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 VIVID Incidence of TEAEs[1]

	Initial Period (Weeks 0–16)			Initial and Maintenance Periods (Weeks 0–52)	
	Placebo (N=83) n (%)	Bimekizumab 320 mg Q4W (N=321) n (%)	Ustekinumab (N=163) n (%)	Bimekizumab 320 mg Q4W[a] (N=395) n (%)	Ustekinumab (N=163) n (%)
Any TEAE	39 (47)	181 (56)	83 (51)	323 (82)	130 (80)
Serious TEAEs	2 (2)	5 (2)	5 (3.1)	24 (6)	13 (8)
Discontinuation due to TEAEs	6 (7)	6 (2)	3 (2)	21 (5)	7 (4)
Severe TEAEs	3 (4)	5 (2)	3 (2)	21 (5)	9 (6)
Deaths	1 (1)	1 (<1)	1 (1)	2 (1)	1 (1)

Bimekizumab was well-tolerated, and discontinuation due to TEAEs was low

There were four deaths overall, all assessed as unrelated to study treatment:

- One patient receiving placebo had a fatal TEAE of esophageal adenocarcinoma during the initial treatment period
- One patient receiving ustekinumab experienced TEAEs of heart injury, followed by fatal cardiac arrest seven days later, during the initial treatment period
- One patient receiving bimekizumab had a fatal TEAE of cardiac arrest during the initial treatment period
- One patient receiving bimekizumab died from unknown causes three months after last dose, during the safety follow-up period

[a] Includes patients switching from placebo to bimekizumab 320 mg Q4W at Week 16; only events occurring after switching are included in this column.

Return to safety overview

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

Adapted from Reich K, et al. 2021. 1. Reich K, et al, Lancet 2021;397:487–498.

Abbreviations: Q4W, every 4 weeks; TEAE, treatment-emergent adverse event.

BE VIVID Common TEAEs (>5% of Patients)[1]

	Initial Period (Weeks 0–16)			Initial and Maintenance Periods (Weeks 0–52)	
	Placebo (N=83) n (%)	Bimekizumab 320 mg Q4W (N=321) n (%)	Ustekinumab (N=163) n (%)	Bimekizumab 320 mg Q4W[a] (N=395) n (%)	Ustekinumab (N=163) n (%)
Nasopharyngitis	7 (8)	30 (9)	14 (9)	86 (22)	36 (22)
Oral candidiasis	0	28 (9)	0	60 (15)	1 (2)
Upper respiratory tract infection	2 (2)	9 (3)	5 (3)	36 (9)	18 (11)

The most common TEAEs with bimekizumab were nasopharyngitis, oral candidiasis, and upper respiratory tract infection

The vast majority of the oral candidiasis cases were mild or moderate, and did not lead to discontinuation

Three patients had oral candidiasis leading to discontinuation

[a] Includes patients switching from placebo to bimekizumab 320 mg Q4W at Week 16; only events occurring after switching are included in this column.

Return to safety overview

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

Adapted from Reich K, et al. 2021. 1. Reich K, et al, Lancet 2021;397:487–498.

Abbreviations: Q4W, every 4 weeks; TEAE, treatment-emergent adverse event.

BE VIVID Safety Topics of Interest[1]

	Initial Period (Weeks 0–16)			Initial and Maintenance Periods (Weeks 0–52)	
	Placebo (N=83) n (%)	Bimekizumab 320 mg Q4W (N=321) n (%)	Ustekinumab (N=163) n (%)	Bimekizumab 320 mg Q4W[a] (N=395) n (%)	Ustekinumab (N=163) n (%)
Serious infections	0	0	2 (1)	5 (1)	4 (3)
Active tuberculosis	0	0	0	0	0
Latent tuberculosis	0	0	0	0	0
Inflammatory bowel disease	0	1 (<1)[b]	0	1 (<1)	0
Adjudicated SIB	0	0	0	1 (<1)	1 (1)
Malignancies	1 (1)[c]	0	0	1 (<1)[d]	1 (1)[e]
Non-melanoma skin cancer	0	0	0	0	1 (1)[e]
Serious hypersensitivity reactions	0	0	0	0	0
Adjudicated MACE	0	1 (<1)	0	5 (1)	0
Hepatic events[f]	1 (1)	4 (1)	0	10 (3)	4 (3)

All incidences of MACE occurred in patients with ≥2 pre-existing cardiovascular risk factors

[a]Includes patients switching from placebo to bimekizumab 320 mg every 4 weeks at week 16; only events occurring after switching are included in this column. [b]Ulcerative colitis. [c]Oesophageal adenocarcinoma. [d]Gastric cancer. [e]Basal cell carcinoma. [f]The majority of hepatic events were elevated liver function tests (including liver aminotransferases, γ-glutamyltransferase, alkaline phosphatase, and bilirubin), which were transient and resolved by the end of the study without dose adjustment.

Return to safety overview

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

Adapted from Reich K, et al. 2021. 1. Reich K, et al, Lancet 2021;397:487–498.

Abbreviations: MACE, major adverse cardiovascular events; NEC, not elsewhere classified; OLE, open-label extension; PSO, psoriasis; PY, patient years; Q4W, every 4 weeks; TEAE, treatment-emergent adverse event; SIB, suicidal ideation and behavior.