BE READY

Bimekizumab in patients with moderate-to-severe psoriasis

Summary of results from the Phase 3 BE READY study

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Study overview

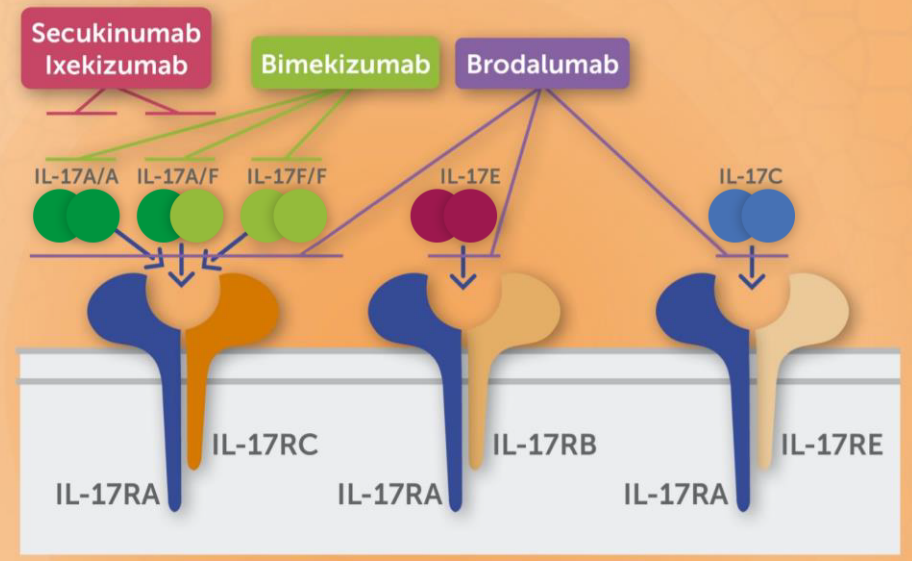
BE READY

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

Study objective

To compare the efficacy and safety of bimekizumab versus placebo at 16 weeks, evaluate the effects of treatment withdrawal and look at the effect of two maintenance dosing schedules on the efficacy and safety of bimekizumab over 56 weeks[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]



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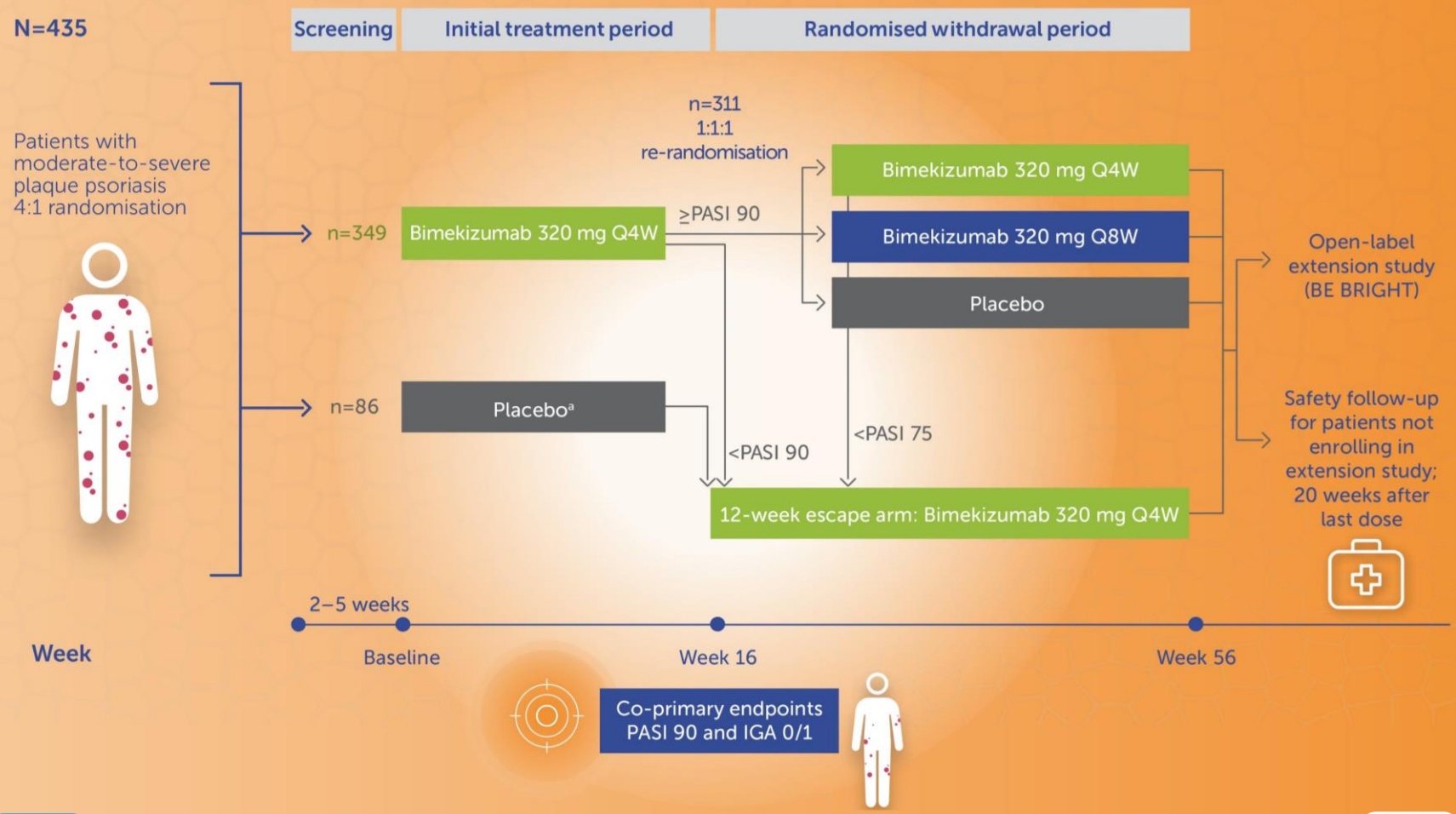
1. Gordon KB, et al. Lancet 2021;397:475–486; 2. Diagram modified from Patel D et al. Ann Rheum Dis. 2013;72(Suppl 2):ii116–23.
Abbreviations: IgG1, immunoglobulin G1; IL, interleukin.

Study design[1]



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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 Gordon KB, et al. 2021. 1. Gordon KB, et al. Lancet 2021; 397:475–486. **Abbreviations:** IGA, investigator's global assessment; PASI 75/90, ≥75/≥90% improvement from baseline in Psoriasis Area and Severity Index; Q4W, every 4 weeks; Q8W, every 8 weeks.

Baseline characteristics[1]

	Placebo N=86	Bimekizumab 320 mg Q4W N=349	All patients N=435
Age (years), mean ± SD	43.5 ± 13.1	44.5 ± 12.9	44.3 ± 12.9
Male, n (%)	58 (67)	255 (73)	313 (72)
Caucasian, n (%)	79 (92)	324 (93)	403 (93)
Weight (kg), mean ± SD	91.7 ± 22.2	88.7 ± 20.6	89.3 ± 20.9
Duration of PSO (years), mean ± SD	19.1 ± 12.8	19.6 ± 13.3	19.5 ± 13.2
PASI, mean ± SD	20.1 ± 7.6	20.4 ± 7.6	20.3 ± 7.6
BSA (%), mean ± SD	24.4 ± 16.0	24.6 ± 15.2	24.5 ± 15.4
IGA, n (%)			
3: moderate	62 (72)	242 (69)	304 (70)
4: severe	24 (28)	107 (31)	131 (30)
DLQI total, mean ± SD	11.3 ± 6.9	10.4 ± 6.3	10.6 ± 6.4
Any prior systemic therapy, n (%)	71 (83)	276 (79)	347 (80)
Prior biologic therapy, n (%)	37 (43)	154 (44)	192 (44)
anti-TNF	12 (14)	62 (18)	74 (17)
anti-IL-17	18 (21)	85 (24)	103 (24)
anti-IL-23	5 (6)	28 (8)	33 (8)
anti-IL-12/23	11 (13)	40 (12)	51 (12)

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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 Gordon KB, et al. 2021. 1. Gordon KB, et al. Lancet 2021; 397:475–486. **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 ● BKZ 320 mg Q8W ● Placebo

BE READY Week 16

At Week 16

91%*

of patients on BKZ **achieved PASI 90 (Primary Endpoint)[1]**

n=349,86

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and

93%*

of patients on BKZ **achieved IGA 0/1 (Primary Endpoint)[1]**

n=349,86

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and

95%†§

of patients on BKZ **achieved PASI 75[1]**

n=349,86

VIEW FULL GRAPH

and

68%*

of patients on BKZ **achieved clear skin (PASI 100)[1]**

n=349,86

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BE READY Week 4

At Week 4

76%*

of patients on BKZ **achieved PASI 75[1]**

n=349,86

VIEW FULL GRAPH

and

45%†§

of patients on BKZ **achieved PASI 90[1]**

n=349,86

VIEW FULL GRAPH

and

19%†§

of patients on BKZ **achieved clear skin (PASI 100)[1]**

n=349,86

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*p<0.0001 vs placebo. §The p values for a general association were based on a stratified Cochran–Mantel–Haenszel test, where region and prior biologic exposure were used as stratification variables, are considered nominal, and were not controlled for multiplicity. †Nominal p<0.0001 vs placebo.

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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. Gordon KB, et al. Lancet 2021;397:475–486. **Abbreviations:** BKZ, bimekizumab; IGA, investigator's global assessment; PASI 75/90/100, ≥75%/≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; Q4W, every 4 weeks; Q8W, every 8 weeks.

Results[1] (2/2)

● BKZ 320 mg Q4W ● BKZ 320 mg Q8W ● Placebo

BE READY Week 56

PASI 90 responders in maintenance and withdrawal arms

In Week 16 PASI 90 responders,

91%*

of patients on BKZ 320 mg Q8W

and **87%†§**

of patients on BKZ 320 mg Q4W

maintained PASI 90 at Week 56[1]

n=106,100,105

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In Week 16 PASI 90 responders,

83%

of patients on BKZ 320 mg Q8W

and **71%**

of patients on BKZ 320 mg Q4W

maintained clear skin (PASI 100) at Week 56[1]

n=106,100,105

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Time to relapse in Week 16 PASI 90 responders

Median **time to relapse** (< PASI 75) after re-randomisation to placebo was

~28 weeks

(32 weeks after last BKZ dose)

n=106,100,105

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*Nominal p<0.0001 vs placebo.

†The p values for a general association were based on a stratified Cochran–Mantel–Haenszel test, where region and prior biologic exposure were used as stratification variables, are considered nominal, and were not controlled for multiplicity.

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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. Gordon KB, et al. Lancet 2021;397:475–486.
Abbreviations: BKZ, bimekizumab; PASI 75/90/100, ≥75%/≥90%/ 00% improvement from baseline in Psoriasis Area and Severity Index; PBO, placebo; Q4W, every 4 weeks; Q8W, every 8 weeks.

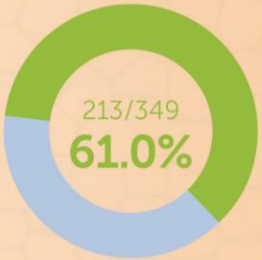
Safety profile[1] (1/2)

The safety profile of bimekizumab was consistent with previous studies[2–5]

BE READY Initial period (Weeks 0–16)[1]

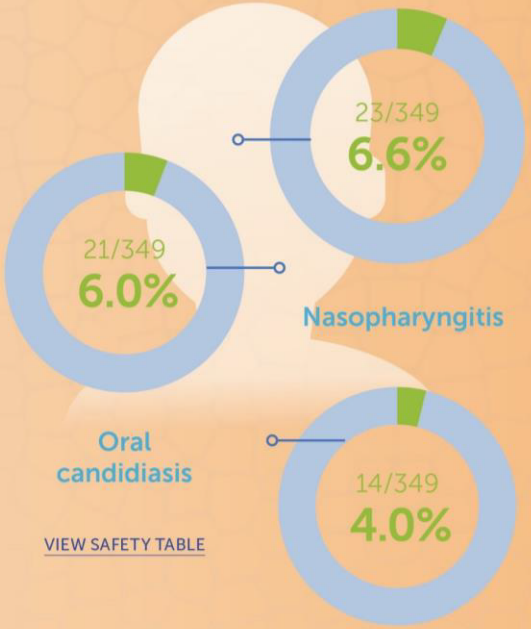
Initial treatment period

Any TEAE



VIEW SAFETY TABLE

Most common TEAEs



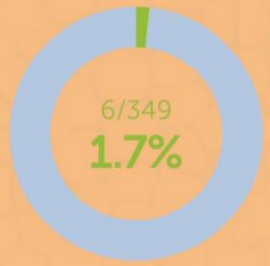
Nasopharyngitis

Oral candidiasis

VIEW SAFETY TABLE

Upper respiratory tract infection

Serious TEAEs



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Deaths

BKZ 320 mg Q4W

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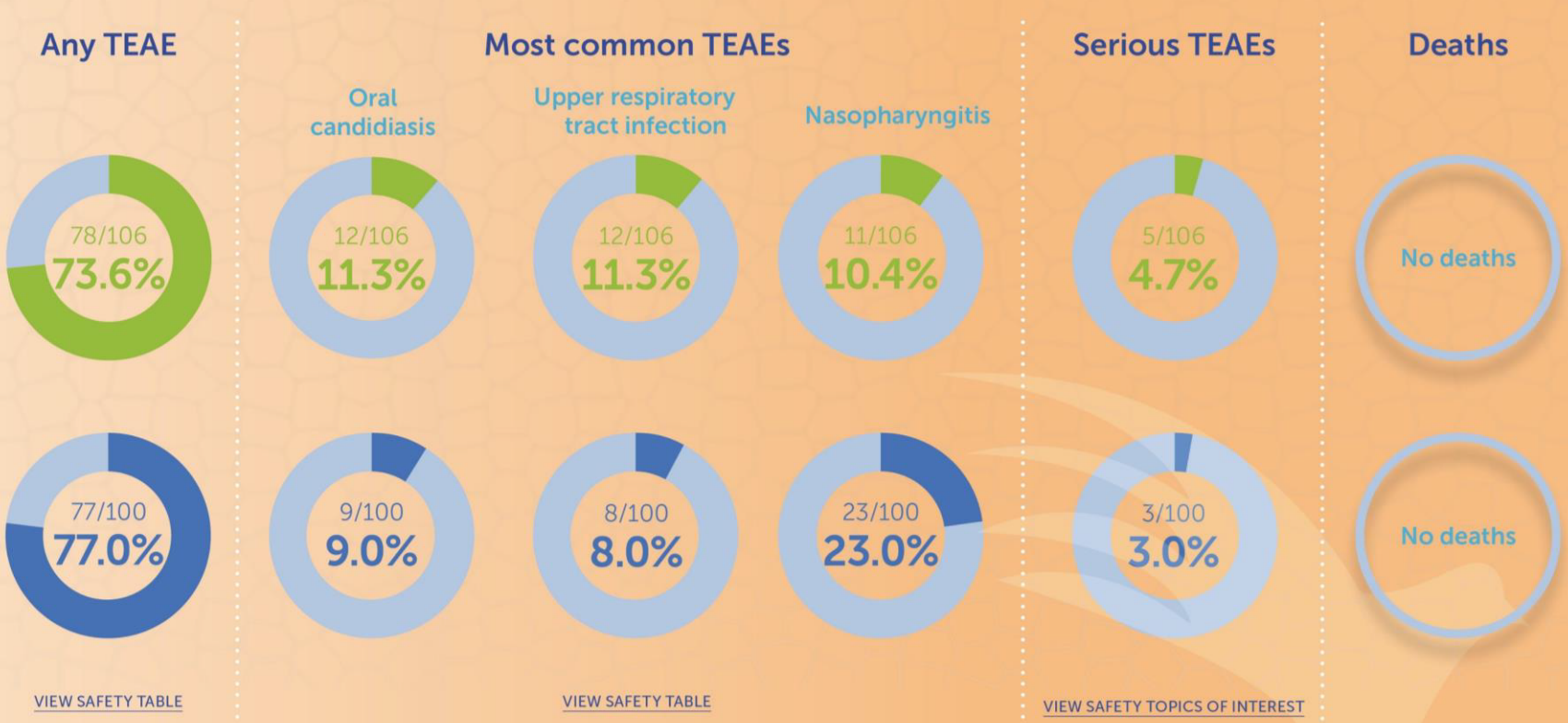
Note: bimekizumab is approved for use in moderate-to-severe psoriasis at Q4W dosing until week 16 followed by Q8W maintenance dosing. If the patient is ≥120 kg, maintenance dosing may be Q4W. 1. Gordon KB, et al. Lancet 2021;397:475–486; 2. Glatt et al. Ann Rheum Dis. 2018;77:523–32; 3. Papp et al. J Am Acad Dermatol. 2018;79(2):277–286; 4. Blauvelt A et al. AAD 2019 (OP11180); 5. Glatt et al. Br J Clin Pharm. 2017;83(5):991–1001. **Abbreviation:** TEAE, treatment-emergent adverse event.

Safety profile[1] (2/2)

The safety profile of bimekizumab was consistent with previous studies[2–5]

BE READY — Randomised withdrawal period (Weeks 16–56)



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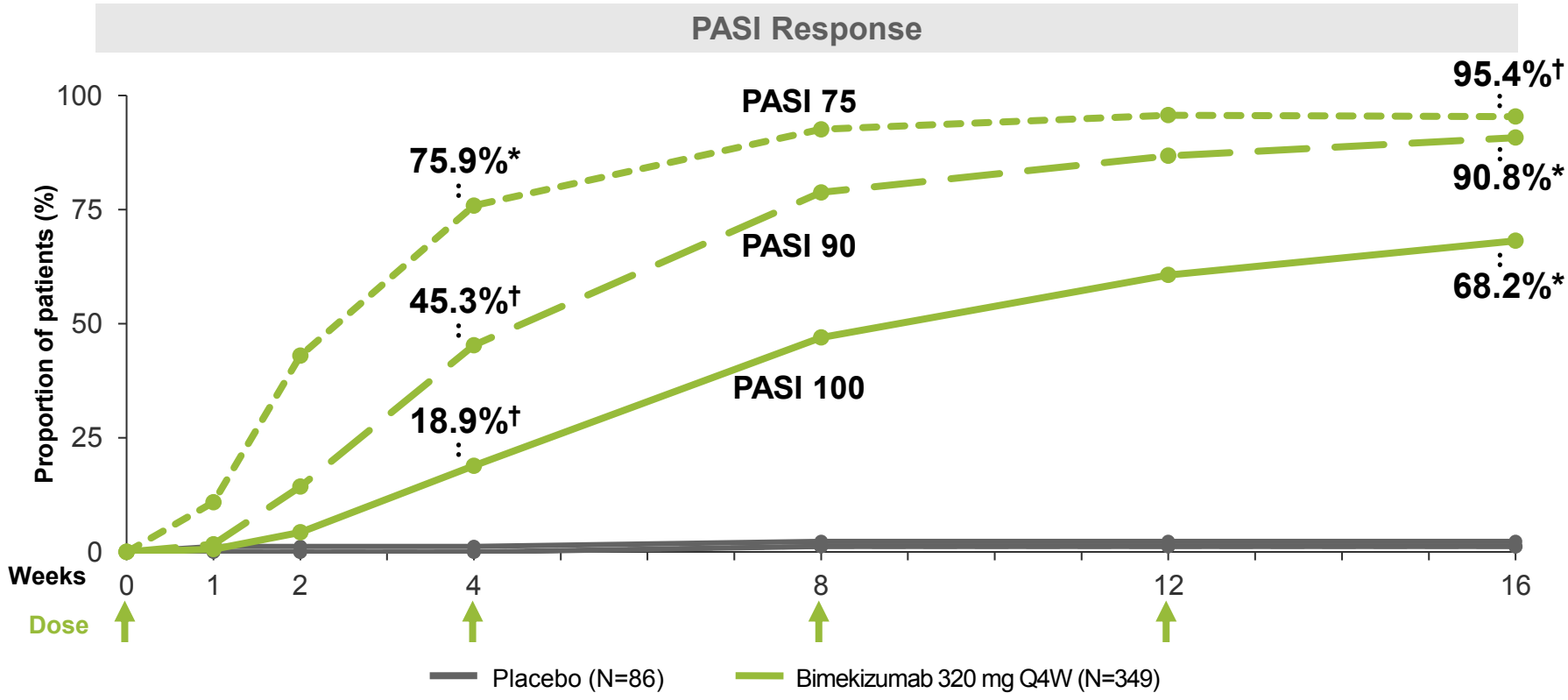
BE READY PASI 75, PASI 90, and PASI 100 over 16 Weeks (ITT, NRI)[1]



*p<0.0001 versus placebo. †Nominal p<0.0001 vs placebo. For PASI 75 at Week 4, and PASI 90/PASI 100 at Week 16, p values for the comparison of treatment groups were based on the Cochran–Mantel–Haenszel test from the general association; for other comparisons, p values for a general association were based on a stratified Cochran–Mantel–Haenszel test, where region and prior biologic exposure were used as stratification variables, are considered nominal, and were not controlled for multiplicity. Missing data were imputed with non-responder imputation (NRI).

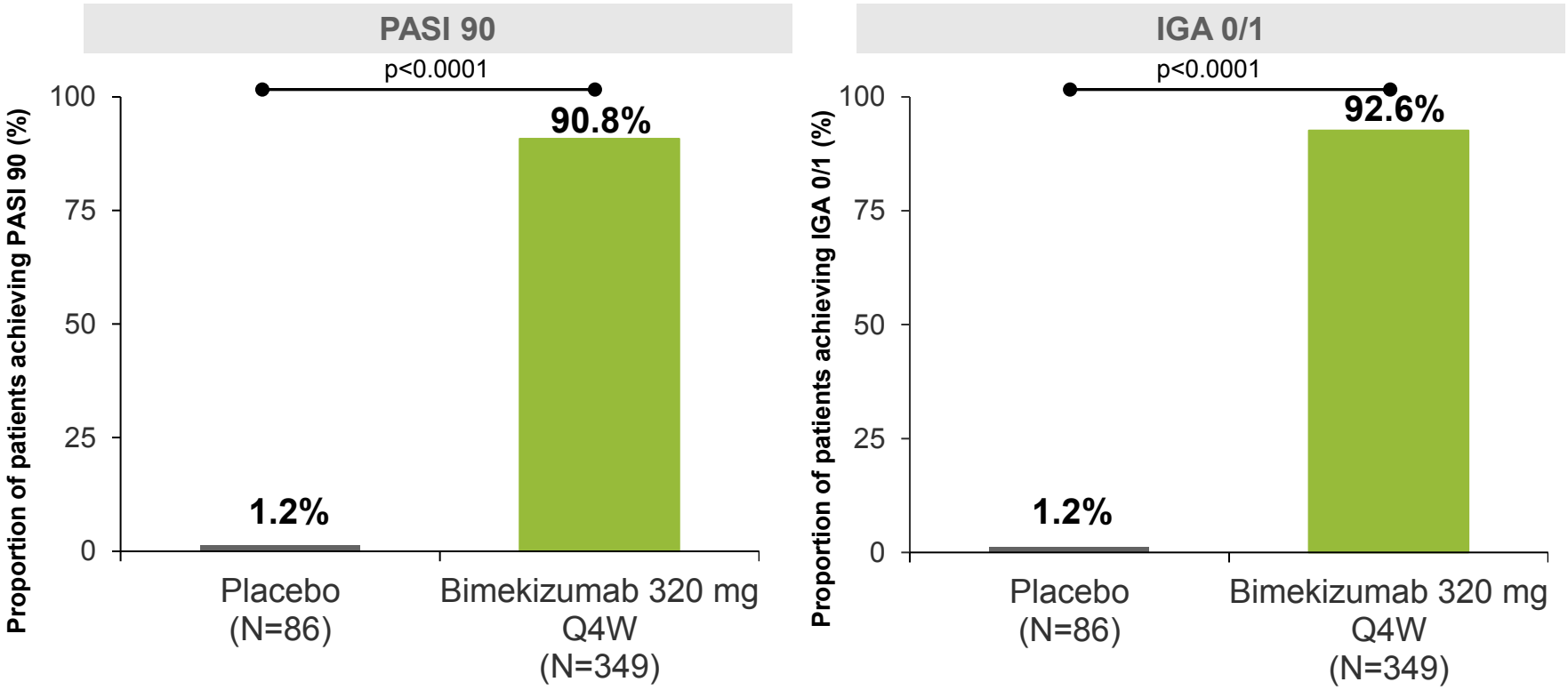
Return to short-term results

Adapted from Gordon KB, et al. 2021.

1. Gordon KB, et al. Lancet 2021;397:475–486.

Abbreviations: 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 READY PASI 90 and IGA 0/1 at Week 16 (ITT, NRI)[1]



Missing data were imputed with non-responder imputation (NRI); p values for the comparison of treatment groups were based on the Cochran–Mantel–Haenszel test from the general association. 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.

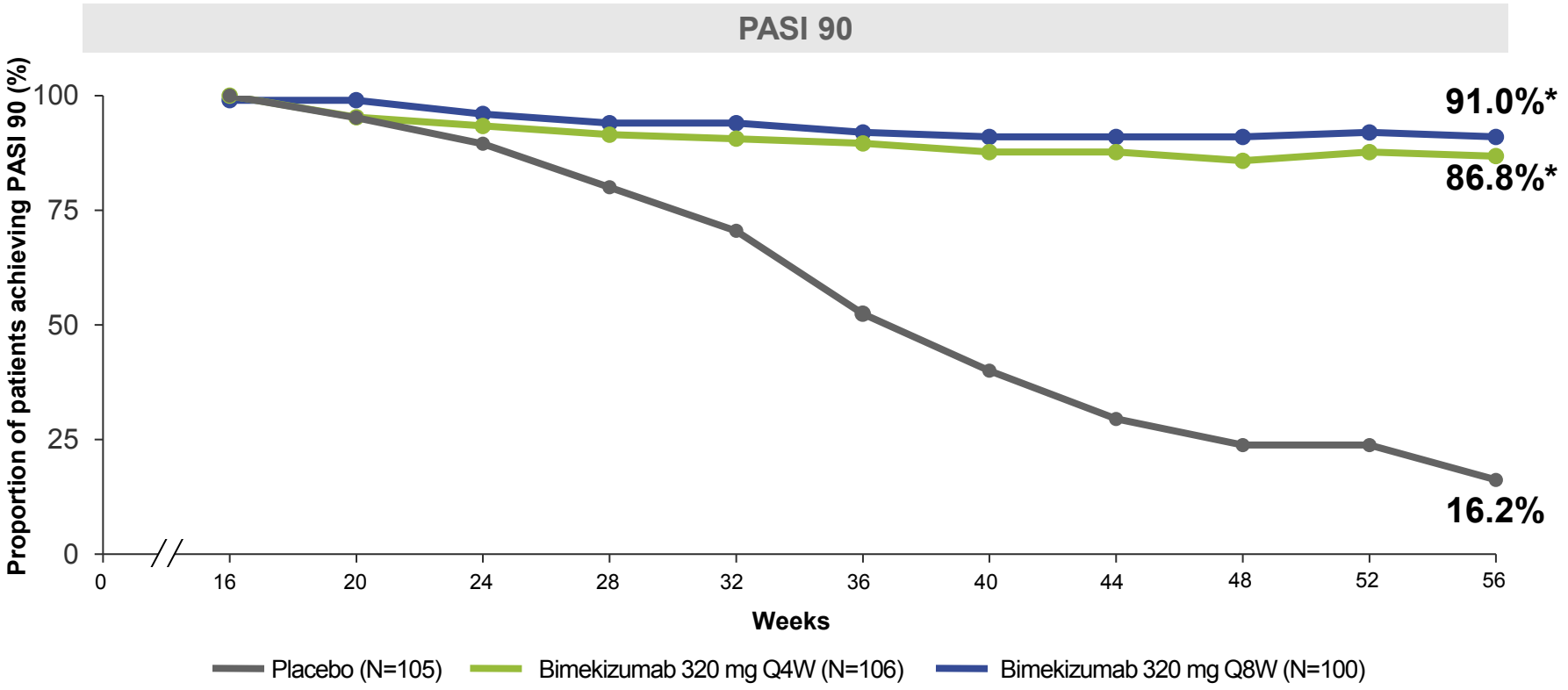
Return to short-term results

Adapted from Gordon KB, et al. 2021.

1. Gordon KB, et al. Lancet 2021;397:475–486.

Abbreviations: 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 READY PASI 90 in Maintenance and Withdrawal Arms (Week 16 PASI 90 Responders, NRI)[1]



*Nominal p<0.0001 versus placebo. p values for the comparison of treatment groups were based on stratified Cochran. Mantel–Haenszel test, where region and prior biologic exposure were used as stratification variables. Patients randomized to bimekizumab 320 mg Q4W who achieved PASI 90 at Week 16 were re-randomized for maintenance treatment; for patients re-randomized to placebo, the last dose of bimekizumab was at Week 12; missing data were imputed with non-responder imputation (NRI).

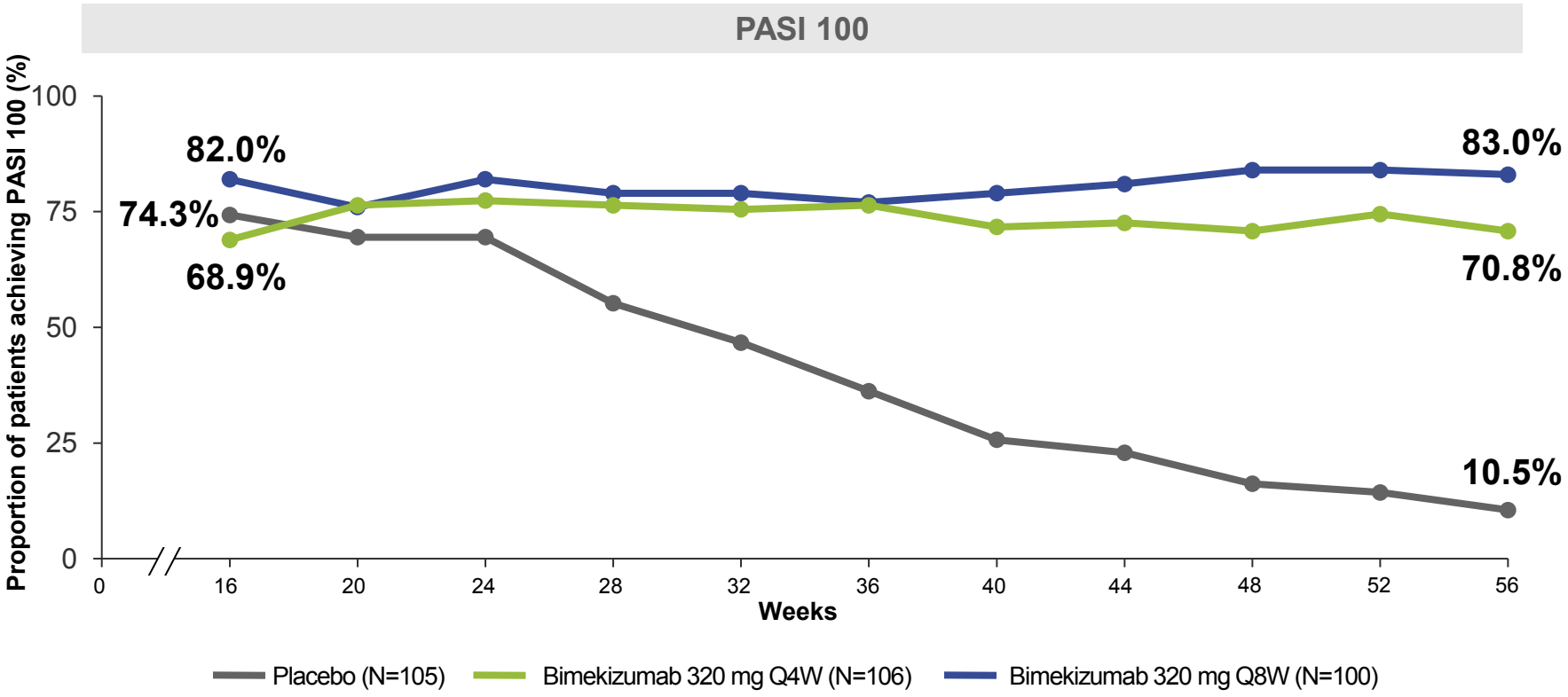
Return to long-term results

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 Gordon KB, et al. 2021. 1. Gordon KB, et al. Lancet 2021;397:475–486.

Abbreviations: NRI, non-responder imputation; PASI 90, ≥90% improvement from baseline in Psoriasis Area and Severity Index; PBO, placebo; Q4W, every 4 weeks; Q8W, every 8 weeks.

BE READY PASI 100 in Maintenance and Withdrawal Arms (Week 16 PASI 90 Responders, NRI)[1]



Patient randomized to bimekizumab 320 mg Q4W who achieved PASI 90 at Week 16 were re-randomized for maintenance treatment; missing data were imputed with non-responder imputation (NRI).

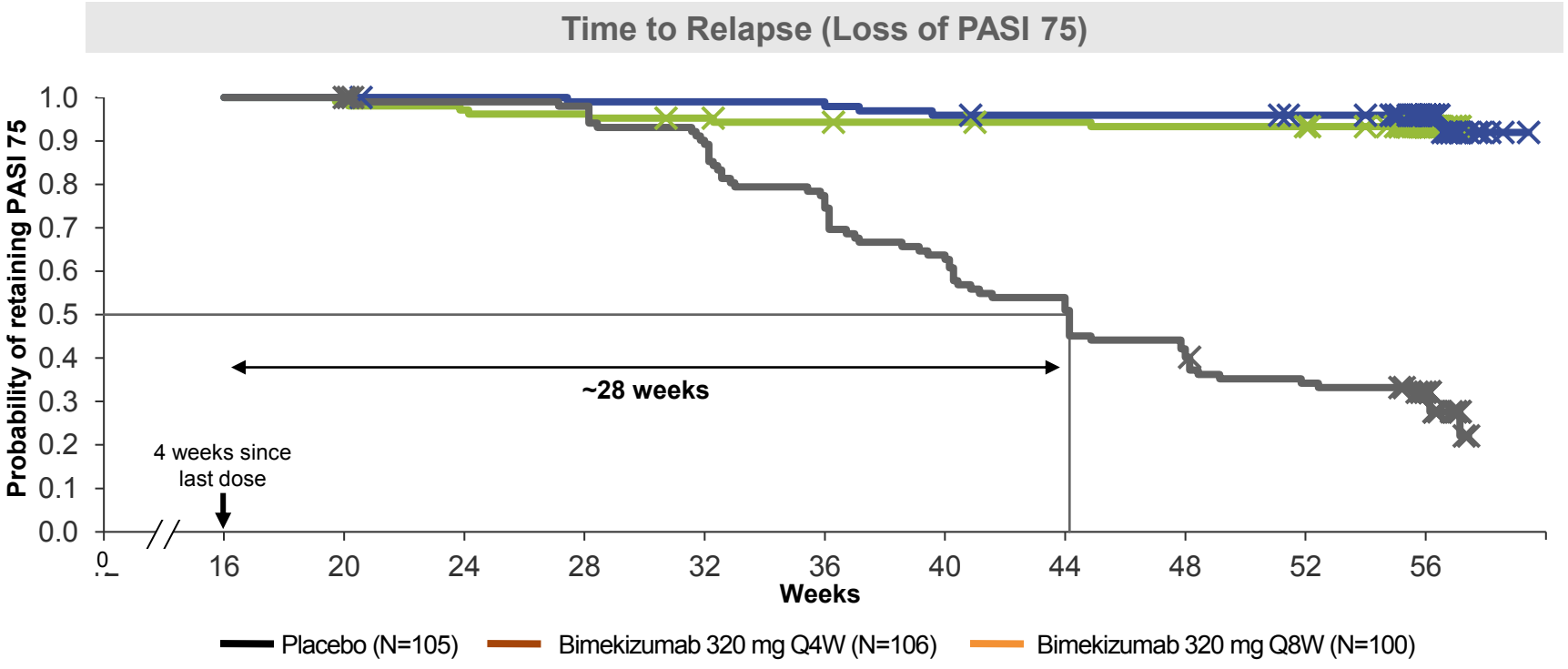
Return to long-term results

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 Gordon KB, et al. 2021. 1. Gordon KB, et al. Lancet 2021;397:475–486.

Abbreviations: NRI, non-responder imputation; PASI 90/100, ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; Q4W, every 4 weeks; Q8W, every 8 weeks.

BE READY Time to Relapse in Week 16 PASI 90 Responders[1]



Median time to relapse after re-randomization to placebo was ~28 weeks

Patients randomized to bimekizumab 320 mg Q4W who achieved PASI 90 at Week 16 were re-randomized for maintenance treatment; relapse was defined as not achieving PASI 75 at Week 20 or later. Crosses represent patients who were censored at that timepoint. Patients who completed the randomized withdrawal period without relapsing are censored at the date of the Week 56 visit. For patients re-randomized to placebo, the last dose of bimekizumab was at Week 12, and Week 32 marks the timepoint anticipated to be 5 half-lives after the last dose of bimekizumab [Papp K. *et al.* JAAD 2018;79:279–86].

Return to long-term results

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 Gordon KB, et al. 2021. 1. Gordon KB, et al. Lancet 2021;397:475–486.

Abbreviations: PASI 75/90, ≥75%/≥90% improvement from baseline in Psoriasis Area and Severity Index; Q4W, every 4 weeks; Q8W, every 8 weeks.

BE READY Incidence of TEAEs[1]

	Initial Period (Weeks 0–16)		Randomized Withdrawal Period (Weeks 16–56)		
			Bimekizumab 320 mg Q4W →		
	Placebo (N=86) n (%)	Bimekizumab 320 mg Q4W (N=349) n (%)	Placebo N=105 n (%)	Bimekizumab 320 mg Q8W N=100 n (%)	Bimekizumab 320 mg Q4W N=106 n (%)
Any TEAE	35 (40.7)	213 (61.0)	72 (68.6)	77 (77.0)	78 (73.6)
Serious TEAEs	2 (2.3)	6 (1.7)	4 (3.8)	3 (3.0)	5 (4.7)
Discontinuation due to TEAEs	0	3 (1.0)	3 (2.9)	2 (2.0)	0
Severe TEAEs	1 (1.2)	3 (0.9)	4 (3.8)	1 (1.0)	4 (3.8)
Deaths	0	0	0	0	0

Bimekizumab was well-tolerated

Discontinuation due to TEAEs was low

No deaths

Return to Weeks 0-16 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 Gordon KB, et al. 2021. 1. Gordon KB, et al. Lancet 2021;397:475–486.

Abbreviations: TEAE, treatment-emergent adverse event; Q4W, every 4 weeks; Q8W, every 8 weeks.

BE READY Common TEAEs (>5% of patients)[1]

	Initial Period (Weeks 0–16)		Randomized Withdrawal Period (Weeks 16–56)		
			Bimekizumab 320 mg Q4W →		
	Placebo (N=86) n (%)	Bimekizumab 320 mg Q4W (N=349) n (%)	Placebo N=105 n (%)	Bimekizumab 320 mg Q8W N=100 n (%)	Bimekizumab 320 mg Q4W N=106 n (%)
Nasopharyngitis	4 (4.7)	23 (6.6)	20 (19.0)	23 (23.0)	11 (10.4)
Oral candidiasis	0	21 (6.0)	6 (5.7)	9 (9.0)	12 (11.3)
Upper respiratory tract infection	7 (8.1)	14 (4.0)	5 (4.8)	8 (8.0)	12 (11.3)

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

All cases of oral candidiasis were non-serious, mild, or moderate infections, and no cases led to discontinuation

Return to Weeks 0-16 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 Gordon KB, et al. 2021. 1. Gordon KB, et al. Lancet 2021;397:475–486.

Abbreviations: TEAE, treatment-emergent adverse event; Q4W, every 4 weeks; Q8W, every 8 weeks.

BE READY Safety Topics of Interest[1]

	Initial Period (Weeks 0–16)		Randomized Withdrawal Period (Weeks 16–56)		
			Bimekizumab 320 mg Q4W →		
	Placebo (N=86) n (%)	Bimekizumab 320 mg Q4W (N=349) n (%)	Placebo N=105 n (%)	Bimekizumab 320 mg Q8W N=100 n (%)	Bimekizumab 320 mg Q4W N=106 n (%)
Treatment-emergent AEs					
Serious infections	0	2 (1)*	0	0	1 (1)†
Active tuberculosis	0	0	0	0	0
Latent tuberculosis	0	0	0	0	1(1)
Inflammatory bowel disease	0	0	0	0	0
Adjudicated suicidal ideation and behavior	0	0	0	0	0
Malignancies	0	1 (<1)‡	1 (1) §	0	0
Non-melanoma skin cancer	0	1 (<1) ‡	0	0	0
Serious hypersensitivity reactions	0	0	0	0	0
Adjudicated MACE¶	0	0	0	1 (1)	0
Hepatic events‖	1 (1)	10 (3)	0	3 (3)	8 (8)

There were no incidences of inflammatory bowel disease or adjudicated suicide ideation and behavior among patients treated with bimekizumab

*One case of enterovirus infection and one case of pneumonia. †One case of otitis media chronic. ‡One case of basal cell carcinoma. §One case of prostate cancer. ¶A non-fatal myocardial infarction in a male patient aged 53 years with six pre-existing cardiovascular risk factors, which was not attributed to the study drug. ‖The majority of hepatic events were elevated liver function tests (including liver transaminases, gamma-glutamyltransferase, alkaline phosphatase, and bilirubin), which were transient and resolved by the end of the study without dose adjustment.

Return to Weeks 0-16 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 Gordon KB, et al. 2021. 1. Gordon KB, et al. Lancet 2021;397:475–486.

Abbreviations: MACE, major adverse cardiovascular events; Q4W, every 4 weeks; Q8W, every 8 weeks.

BE READY Incidence of TEAEs[1]

	Initial Period (Weeks 0–16)		Randomized Withdrawal Period (Weeks 16–56)		
			Bimekizumab 320 mg Q4W →		
	Placebo (N=86) n (%)	Bimekizumab 320 mg Q4W (N=349) n (%)	Placebo N=105 n (%)	Bimekizumab 320 mg Q8W N=100 n (%)	Bimekizumab 320 mg Q4W N=106 n (%)
Any TEAE	35 (40.7)	213 (61.0)	72 (68.6)	77 (77.0)	78 (73.6)
Serious TEAEs	2 (2.3)	6 (1.7)	4 (3.8)	3 (3.0)	5 (4.7)
Discontinuation due to TEAEs	0	3 (1.0)	3 (2.9)	2 (2.0)	0
Severe TEAEs	1 (1.2)	3 (0.9)	4 (3.8)	1 (1.0)	4 (3.8)
Deaths	0	0	0	0	0

Bimekizumab was well-tolerated

Discontinuation due to TEAEs was low

No deaths

Return to Weeks 16-56 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 Gordon KB, et al. 2021. 1. Gordon KB, et al. Lancet 2021;397:475–486.

Abbreviations: TEAE, treatment-emergent adverse event; Q4W, every 4 weeks; Q8W, every 8 weeks.

BE READY Common TEAEs (>5% of patients)[1]

	Initial Period (Weeks 0–16)		Randomized Withdrawal Period (Weeks 16–56)		
			Bimekizumab 320 mg Q4W →		
	Placebo (N=86) n (%)	Bimekizumab 320 mg Q4W (N=349) n (%)	Placebo N=105 n (%)	Bimekizumab 320 mg Q8W N=100 n (%)	Bimekizumab 320 mg Q4W N=106 n (%)
Nasopharyngitis	4 (4.7)	23 (6.6)	20 (19.0)	23 (23.0)	11 (10.4)
Oral candidiasis	0	21 (6.0)	6 (5.7)	9 (9.0)	12 (11.3)
Upper respiratory tract infection	7 (8.1)	14 (4.0)	5 (4.8)	8 (8.0)	12 (11.3)

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

All cases of oral candidiasis were non-serious, mild, or moderate infections, and no cases led to discontinuation

Return to Weeks 16-56 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.

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BE READY Safety Topics of Interest[1]

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	Placebo (N=86) n (%)	Bimekizumab 320 mg Q4W (N=349) n (%)	Placebo N=105 n (%)	Bimekizumab 320 mg Q8W N=100 n (%)	Bimekizumab 320 mg Q4W N=106 n (%)
Treatment-emergent AEs					
Serious infections	0	2 (1)*	0	0	1 (1)†
Active tuberculosis	0	0	0	0	0
Latent tuberculosis	0	0	0	0	1(1)
Inflammatory bowel disease	0	0	0	0	0
Adjudicated suicidal ideation and behavior	0	0	0	0	0
Malignancies	0	1 (<1)‡	1 (1) §	0	0
Non-melanoma skin cancer	0	1 (<1) ‡	0	0	0
Serious hypersensitivity reactions	0	0	0	0	0
Adjudicated MACE¶	0	0	0	1 (1)	0
Hepatic events‖	1 (1)	10 (3)	0	3 (3)	8 (8)

There were no incidences of inflammatory bowel disease or adjudicated suicide ideation and behavior among patients treated with bimekizumab

*One case of enterovirus infection and one case of pneumonia. †One case of otitis media chronic. ‡One case of basal cell carcinoma. §One case of prostate cancer. ¶A non-fatal myocardial infarction in a male patient aged 53 years with six pre-existing cardiovascular risk factors, which was not attributed to the study drug. ‖The majority of hepatic events were elevated liver function tests (including liver transaminases, gamma-glutamyltransferase, alkaline phosphatase, and bilirubin), which were transient and resolved by the end of the study without dose adjustment.

Return to Weeks 16-56 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 Gordon KB, et al. 2021. 1. Gordon KB, et al. Lancet 2021;397:475–486.

Abbreviations: MACE, major adverse cardiovascular events; Q4W, every 4 weeks; Q8W, every 8 weeks.