Supplementary Material

Bimekizumab Efficacy and Safety in Japanese Patients with Plaque Psoriasis in BE VIVID – Phase 3, Ustekinumab and Placebo Controlled Study

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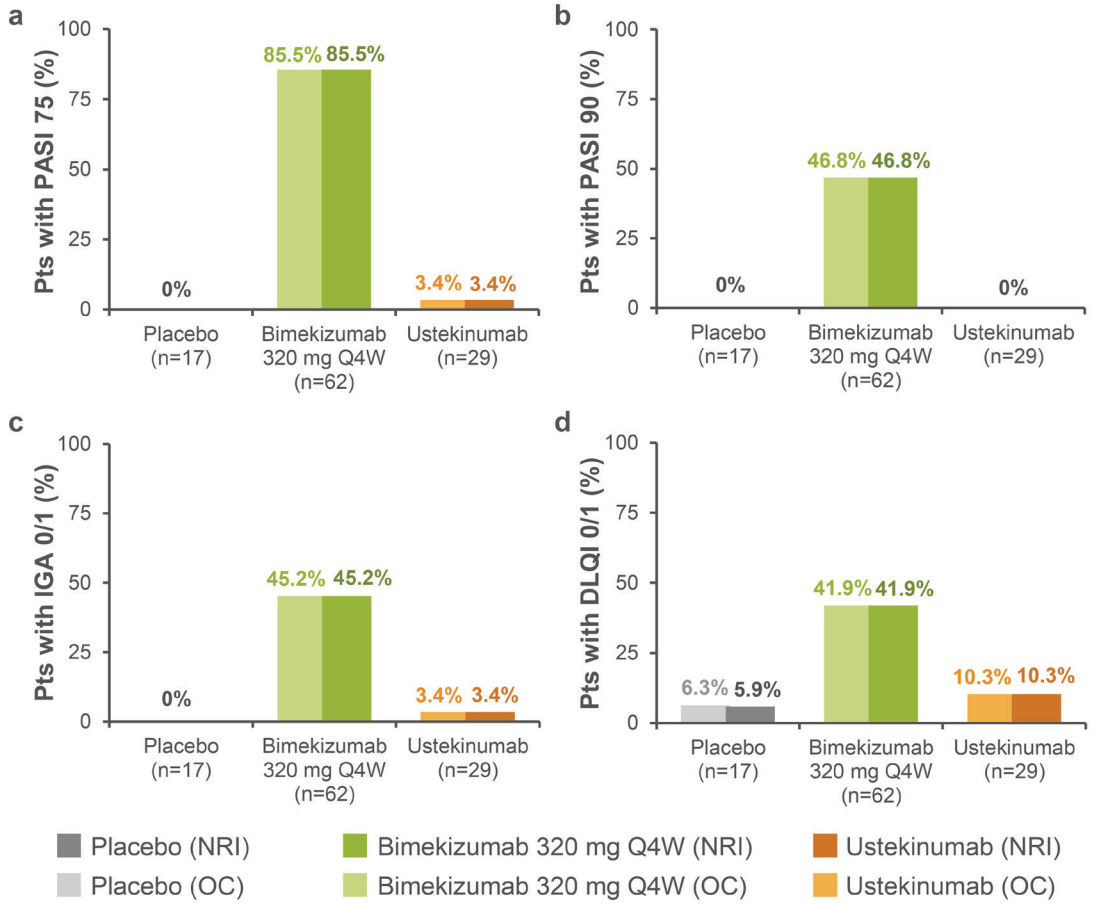
Supplementary Table S1. Summary of selected efficacy endpoints.

Endpoint[a]	Placebo (n=17)		Bimekizumab 320 mg Q4W (n=62)		Ustekinumab (n=29)		Odds ratio versus placebo (95% CI)	Odds ratio versus ustekinumab (95% CI)
	NRI	OC	NRI	OC	NRI	OC		
PASI 90 at Week 16	1 (5.9%)	1/15 (6.7%)	53 (85.5%)	53/61 (86.9%)	15 (51.7%)	15/27 (55.6%)	94.9 (10.9–822.7)	5.4 (1.9–14.9)
IGA 0/1 at Week 16	0 (0%)	0/15 (0%)	51 (82.3%)	51/61 (83.6%)	14 (48.3%)	14/27 (51.9%)	61.2 (7.1–527.3)	5.1 (1.9–13.6)
PASI 100 at Week 16	0 (0%)	0/15 (0%)	32 (51.6%)	32/61 (52.5%)	4 (13.8%)	4/27 (14.8%)	14.6 (1.8–121.8)	6.6 (2.1–20.9)
IGA 0 at Week 16	0 (0%)	0/15 (0%)	32 (51.6%)	32/61 (52.5%)	5 (17.2%)	5/27 (18.5%)	14.6 (1.8–121.8)	5.1 (1.7–15.2)
PASI 90 at Week 12	0 (0%)	0/15 (0%)	53 (85.5%)	53/61 (86.9%)	12 (41.4%)	12/26 (46.2%)	72.2 (8.3–627.4)	8.5 (3.0–24.0)
IGA 0/1 at Week 12	0 (0%)	0/15 (0%)	48 (77.4%)	48/61 (78.7%)	13 (44.8%)	13/26 (50.0%)	41.8 (4.9–353.0)	4.4 (1.7–11.6)
PASI 75 at Week 4	0 (0%)	0/16 (0%)	53 (85.5%)	53/62 (85.5%)	1 (3.4%)	1/29 (3.4%)	66.9 (7.7–579.8)	73.8 (11.7–462.3)
P-SIM Pain response at Week 16 (patients with baseline score ≥1.98)	1/8 (12.5%)	1/6 (16.7%)	40/51 (78.4%)	40/46 (87.0%)	12/20 (60.0%)	12/18 (66.7%)	21.3 (2.5–182.1)	2.3 (0.7–7.0)
P-SIM Itch response at Week 16 (patients with baseline score ≥2.39)	1/12 (8.3%)	1/9 (11.1%)	40/54 (74.1%)	40/49 (81.6%)	16/25 (64.0%)	16/23 (69.6%)	27.0 (3.5–211.8)	1.6 (0.6–4.2)
P-SIM Scaling response at Week 16 (patients with baseline score ≥2.86)	1/13 (7.7%)	1/10 (10.0%)	42/53 (79.2%)	42/48 (87.5%)	17/24 (70.8%)	17/22 (77.3%)	44.8 (5.2–383.5)	1.5 (0.5–4.6)
Scalp IGA 0/1 at Week 16 (patients with scalp psoriasis, baseline scalp IGA score ≥2)	2/17 (11.8%)	2/15 (13.3%)	49/59 (83.1%)	49/58 (84.5%)	17/26 (65.4%)	17/24 (70.8%)	48.4 (8.3–281.4)	3.2 (1.0–9.7)
PASI 90 at Week 52	-	-	50 (80.6%)	50/53 (94.3%)	14 (48.3%)	14/25 (56.0%)	-	4.2 (1.6–11.0)
IGA 0/1 at Week 52	-	-	46 (74.2%)	46/53 (86.8%)	13 (44.8%)	13/25 (52.0%)	-	3.5 (1.4–8.9)

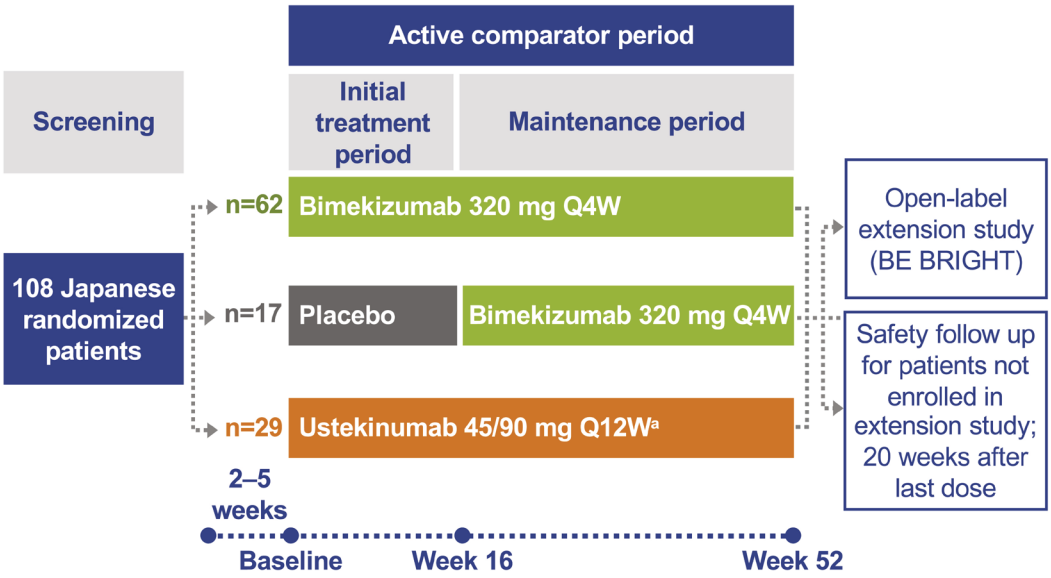
[a]Results are from the randomized set. Odds ratio of bimekizumab/placebo calculated using Cochran–Mantel–Haenszel test with region and prior biologic exposure as stratification variables (logit method used where Cochran–Mantel–Haenszel test was not possible due to very low response). Odds ratio of bimekizumab/ustekinumab calculated using Cochran–Mantel–Haenszel test with region and prior biologic exposure as stratification variables. CI: confidence interval; IGA 0/1: Investigator's Global Assessment 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; NRI: non-responder imputation; OC: observed case; PASI XX: ≥XX% improvement in Psoriasis Area and Severity Index score; PRO: patient-reported outcome; P-SIM: Psoriasis Symptoms and Impacts Measure, a 14-item PRO measure assessing severity of key signs, symptoms, and effects of psoriasis, where items were scored daily (0–10; no–very severe) using a handheld electronic device and averaged weekly through Week 16; Q4W: every 4 weeks.

Supplementary Figure S1. Week 4 efficacy in the Japan patient subpopulation.



(a) PASI 75 response; (b) PASI 90 response; (c) IGA 0/1 response; (d) DLQI 0/1 response. DLQI 0/1: Dermatology Life Quality Index score of 0 or 1, indicating 'no effect of psoriasis on patient's life'; IGA 0/1: Investigator's Global Assessment 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; NRI: non-responder imputation; OC: observed case; PASI XX: ≥XX% improvement from baseline in Psoriasis Area and Severity Index score; Pts: patients; Q4W: every 4 weeks.

Supplementary Figure S2. Study design.



In the BE VIVID study, the coprimary endpoints were the proportion of patients with a PASI 90 or IGA 0/1 response at Week 16. [a]Patients received ustekinumab at baseline and Week 4, then Q12W thereafter; ustekinumab dosing was based on weight: patients ≤100 kg at baseline received one ustekinumab 45 mg injection and one placebo injection, patients >100 kg at baseline received two ustekinumab 45 mg injections. IGA 0/1: Investigator's Global Assessment 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; Q4W: every 4 weeks; Q12W: every 12 weeks.