Bimekizumab Versus Ustekinumab in Plaque Psoriasis: Lasting Efficacy Translates to Rapid and Sustained Improvements in Quality of Life in the BE VIVID Multicenter, Randomized, Double-Blinded Phase 3 Trial

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Objective

To examine how improved disease control translates to greater quality of life in patients with moderate to severe plaque psoriasis receiving bimekizumab compared with ustekinumab and placebo.

Background

- Psoriasis negatively impacts patients' quality of life,[1] and therefore it is important to determine whether improvements in disease control achieved with treatment may also be reflected in greater quality of life.
- Bimekizumab is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, both of which have a pivotal role in psoriasis immunopathogenesis.[2–5]
- Absolute Psoriasis Area and Severity Index (PASI) and Dermatology Life Quality Index (DLQI) were assessed in patients with moderate to severe plaque psoriasis being treated with bimekizumab versus (vs) ustekinumab and placebo.

Methods

- In BE VIVID (NCT03370133) patients were randomized to bimekizumab through Week 52, ustekinumab through Week 52 or placebo; patients randomized to placebo switched to bimekizumab at Week 16 **(Figure 1)**.
- Psoriasis severity was assessed by PASI, where PASI=0 indicated complete skin clearance and PASI≤2, a relevant disease endpoint for a treat to target approach in psoriasis,[6] indicated disease control.
- Patients completed the DLQI questionnaire throughout treatment; DLQI of 0 or 1 indicated no impact on quality of life.[7]
- To evaluate how clinical response translates into health-related quality of life in these post hoc analyses, patients achieving DLQI 0/1 were grouped by PASI=0, PASI≤2, 2<PASI<5, and PASI≥5 responses at the same timepoint.
- Weeks 4 and 16 data for all patients, and Week 52 data for bimekizumab- and ustekinumab-randomized patients, are presented here.

Results

Patient Population

- In BE VIVID, 321 patients were randomized to bimekizumab, 163 to ustekinumab, and 83 to placebo **(Table 1)**.

PASI and DLQI Outcomes

- At Week 4, after one dose, a greater proportion of bimekizumab-treated patients rapidly achieved superior rates of PASI=0 and PASI≤2 as compared to ustekinumab (nominal p<0.0001 for both) and placebo (nominal p=0.0019 and nominal p<0.0001, respectively); this was further improved and sustained through Week 16 to Week 52 **(Table 2)**.
- Similarly, rapid improvements in quality of life were seen with bimekizumab; DLQI 0/1 achievement by Week 4 was greater with bimekizumab as compared to ustekinumab and placebo (nominal p<0.0001 for both). Quality of life continued to improve through to Week 52, and remained greater in bimekizumab patients vs ustekinumab (nominal p=0.0007) **(Table 2)**.
- Across all treatment arms, higher disease control translated into greater improvements in quality of life. This was more pronounced in bimekizumab than ustekinumab with 44.6% vs 17.3% achieving both PASI=0 and DLQI 0/1 at Week 16, increasing to 68.6% vs 40.3% at Week 52 **(Figure 2)**. Similar trends were seen when considering PASI≤2; 65.1% of patients treated with bimekizumab vs 34.6% with ustekinumab achieved both PASI≤2 and DLQI 0/1 at Week 16, increasing to 83.8% vs 59.7% at Week 52 **(Figure 3)**.

Conclusions

Greater levels of disease control seen with bimekizumab treatment, as compared to ustekinumab, translated to greater quality of life as measured by DLQI.

After one year of treatment with bimekizumab, almost 70% of patients achieved complete skin clearance and reported that psoriasis had no impact on their quality of life, compared to 40% with ustekinumab.

Synopsis

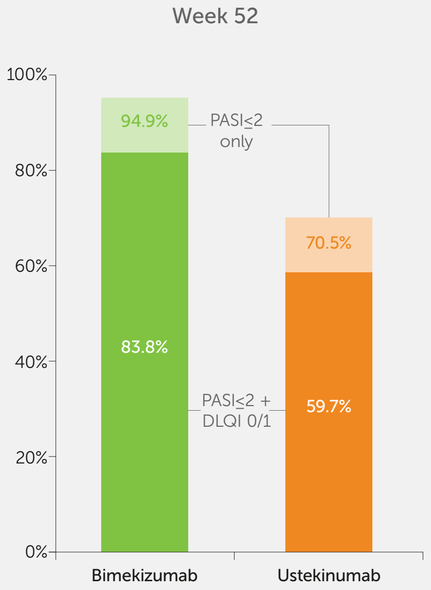
Objective

To determine whether increased disease control in psoriasis with treatment translates into improvements in quality of life.

Methods

Patients reaching different absolute PASI thresholds were assessed for simultaneous achievement of DLQI 0/1.

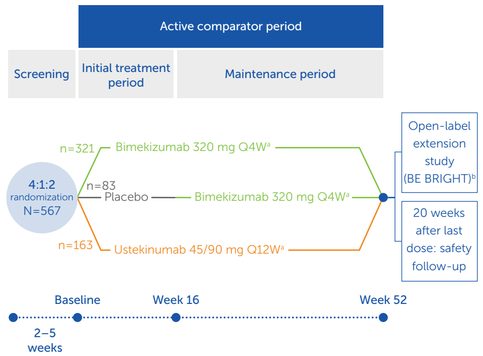
Results



Conclusion

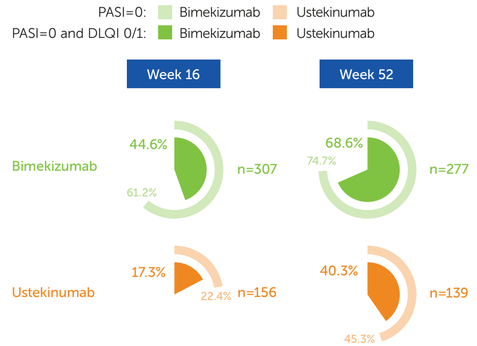
Patients treated with bimekizumab more frequently achieved PASI≤2 by Week 52, with the majority of these patients also achieving DLQI 0/1.

Figure 1 Study design



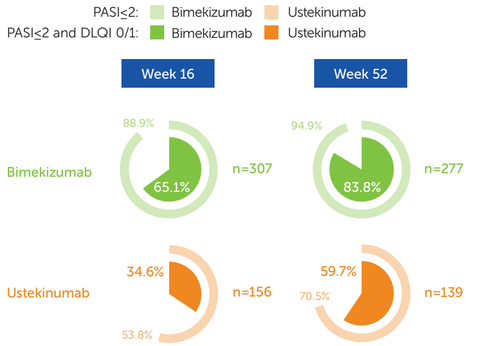
[a]Bimekizumab dosing was 320 mg regardless of weight, while ustekinumab dosing was based on weight: patients ≤100 kg at baseline received one ustekinumab 45 mg injection and one placebo injection, patients >100 kg at baseline received two ustekinumab 45 mg injections; [b]BE BRIGHT: NCT03598790.

Figure 2 Simultaneous achievement of PASI=0 and DLQI 0/1 at Weeks 16 and 52 (OC)[a]



N numbers represent the number of patients with *both* a PASI and DLQI assessment at that time point. [a]Patients randomized to placebo not shown.

Figure 3 Simultaneous achievement of PASI≤2 and DLQI 0/1 at Weeks 16 and 52 (OC)[a]



N numbers represent the number of patients with *both* a PASI and DLQI assessment at that time point. [a]Patients randomized to placebo not shown.

Table 1 Baseline characteristics

	Bimekizumab 320 mg Q4W (n=321)[a]	Ustekinumab 45/90 mg Q12W (n=163)[a]	Placebo (n=83)
Age (years), mean ± SD	45.2 ± 14.0	46.0 ± 13.6	49.7 ± 13.6
Male, n (%)	229 (71.3)	117 (71.8)	60 (72.3)
Caucasian, n (%)	237 (73.8)	120 (73.6)	63 (75.9)
Weight (kg), mean ± SD	88.7 ± 23.1	87.2 ± 21.1	89.1 ± 26.4
Duration of psoriasis (years), mean ± SD	16.0 ± 11.6	17.8 ± 11.6	19.7 ± 13.8
PASI, mean ± SD	22.0 ± 8.6	21.3 ± 8.3	20.1 (6.8)
BSA (%), mean ± SD	29.0 ± 17.1	27.3 ± 16.7	27.0 ± 16.3
IGA, n (%)[b]			
3: moderate	201 (62.6)	96 (58.9)	54 (65.1)
4: severe	119 (37.1)	66 (40.5)	28 (33.7)
DLQI total, mean ± SD	9.9 ± 6.3	11.0 ± 6.9	10.0 ± 6.8
Any prior systemic therapy, n (%)	267 (83.2)	132 (81.0)	64 (77.1)
Prior biologic therapy, n (%)	125 (38.9)	63 (38.7)	33 (39.8)

[a]Bimekizumab dosing was 320 mg regardless of weight, while 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; [b]In each treatment group, one patient with mild IGA score was mistakenly enrolled.

BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; OC: observed case; PASI: Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q12W: every 12 weeks; SD: standard deviation; vs: versus.

Table 2 Number (%) of patients achieving absolute PASI scores and DLQI 0/1 (OC)

		Absolute PASI		DLQI 0/1
		PASI=0	PASI≤2	
Week 4	Bimekizumab	48/318 (15.1)	148/318 (46.5)	120/320 (37.5)
	Ustekinumab	2/161 (1.2)	10/161 (6.2)	18/161 (11.2)
	Placebo	2/81 (2.5)	2/81 (2.5)	5/80 (6.3)
Week 16	Bimekizumab	188/307 (61.2)	273/307 (88.9)	216/308 (70.1)
	Ustekinumab	35/156 (22.4)	84/156 (53.8)	69/156 (44.2)
	Placebo	0/76 (0.0)	3/76 (3.9)	10/76 (13.2)
Week 52[a]	Bimekizumab	207/277 (74.7)	263/277 (94.9)	240/277 (86.6)
	Ustekinumab	63/139 (45.3)	98/139 (70.5)	103/141 (73.0)

[a]Week 52 data not shown for patients randomized to placebo as they switched to bimekizumab treatment at Week 16. Denominators used represent the number of patients in that treatment group with an assessment at that time point for each type of measure (PASI or DLQI). Of all patients, 283 randomized to bimekizumab, 141 to ustekinumab and 69 to placebo completed the study to Week 52.

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