Bimekizumab for the Treatment of Moderate to Severe Plaque Psoriasis with Scalp, Nail and Palmoplantar Involvement Through 52 Weeks: Post-Hoc Analysis from the BE VIVID Phase 3 Trial

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Objective

To compare the efficacy of bimekizumab with ustekinumab and placebo in patients with moderate to severe plaque psoriasis with scalp, palmoplantar, and nail involvement.

Background

- Psoriasis is the archetypal Th17-driven disease, for which both interleukin (IL)-17A and IL-17F have emerged as pivotal drivers of inflammation.[2]
- Bimekizumab is a monoclonal IgG1 antibody that selectively inhibits IL-17F in addition to IL-17A.[3,4]
- In the BE VIVID phase 3 trial (NCT03370133) bimekizumab demonstrated superior clinical efficacy versus ustekinumab and placebo over 16 weeks of treatment (PASI 90: 85.0% versus 49.7% and 4.8%, respectively; p<0.001). This rapid initial response was durable over one year.[5]
- Here, we report efficacy of bimekizumab for patients with scalp, palmoplantar (palms and soles) or nail psoriasis; psoriasis localized in these areas can restrict activities of daily living and negatively impact quality of life, and continues to pose a challenge for both physicians and patients.[6]

Methods

- Patients were enrolled in BE VIVID, a randomized, double-blinded, placebo- and active comparator (ustekinumab)-controlled study **(Figure 1)**.
- These post-hoc analyses include patient subsets with scalp Investigator's Global Assessment (IGA) ≥3, palmoplantar (pp)-IGA ≥3, or modified Nail Psoriasis Severity Index (mNAPSI) >10 at baseline.
- Proportions of patients achieving complete clearance in each region (scalp IGA 0, pp-IGA 0, mNAPSI 0) are reported through Week 52.
- Missing data were imputed using non-responder imputation (NRI).

Results

Patient Population

- Baseline characteristics for all randomized patients are shown in **Table 1**.

Scalp, Palmoplantar and Nail Outcomes

- Among patients with baseline scalp IGA ≥3 treated with bimekizumab, scalp response was rapid, with a higher proportion of patients achieving scalp IGA 0 at Week 16, compared with ustekinumab or placebo; response rates remained high through Week 52 **(Figure 2A)**.
- Similar trends were observed in the pp-IGA 0 response rates among patients with baseline pp-IGA ≥3 **(Figure 2B)**.
- Among those with baseline mNAPSI >10, a higher proportion of bimekizumab- versus ustekinumab-treated patients achieved nail clearance by Week 52 **(Figure 2C)**.

Conclusions

Bimekizumab demonstrated high levels of efficacy in high-impact areas in patients with moderate to severe plaque psoriasis.

Complete clearance of scalp, palmoplantar, and nail psoriasis was observed in a higher proportion of patients after 16 weeks of treatment with bimekizumab, compared with ustekinumab or placebo.

Initial responses were durable through Week 52 for bimekizumab-treated patients with scalp and palmoplantar symptoms, and further increased for those with nail symptoms, reflecting the longer timescale required for nail growth.

Synopsis

Scalp IGA

- Range of 0 to 4
- Analysis includes patients scoring 3 (moderate) or 4 (severe) at baseline
- Score of 0 = clear scalp

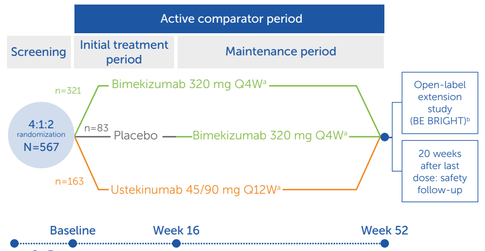
pp-IGA

- Range of 0 to 4
- Analysis includes patients scoring 3 (moderate) or 4 (severe) at baseline
- Score of 0 = clear hands and feet

mNAPSI

- Range of 0 to 130 (0 to 13 per fingernail)
- Analysis includes patients scoring >10 at baseline
- Score of 0 = clear nails

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. Enrolled patients were adults with moderate to severe plaque psoriasis (Psoriasis Area Severity Index ≥12, ≥10% body surface area affected and IGA score ≥3 on a 5 point scale).

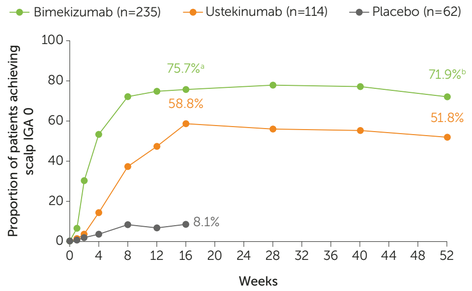
Table 1 Baseline characteristics

	Bimekizumab 320 mg Q4W (n=321)	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 PSO (years), mean ± SD	16.0 ± 11.6	17.8 ± 11.6	19.7 ± 13.8
Scalp IGA ≥3, n (%)	**235 (73.2)**	**114 (69.9)**	**62 (74.7)**
pp-IGA ≥3, n (%)	**61 (19.0)**	**28 (17.2)**	**14 (16.9)**
mNAPSI >10, n (%)	**113 (35.2)**	**62 (38.0)**	**30 (36.1)**
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)
anti-TNF	51 (15.9)	24 (14.7)	16 (19.3)
anti-IL-17	76 (23.7)	38 (23.3)	18 (21.7)
anti-IL-23	16 (5.0)	6 (3.7)	5 (6.0)

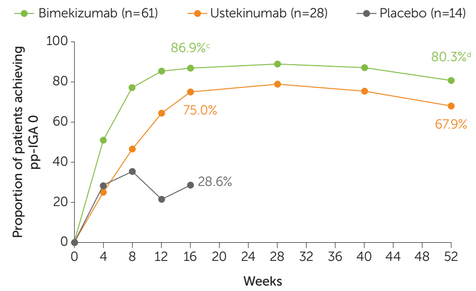
[a]Ustekinumab dosing was based on weight: patients ≤100 kg at baseline received one ustekinumab 45 mg injection and one placebo injection, patients >100 kg at baseline received two ustekinumab 45 mg injections.

Figure 2 Scalp, nail, and palmoplantar clearance through Week 52 (NRI)

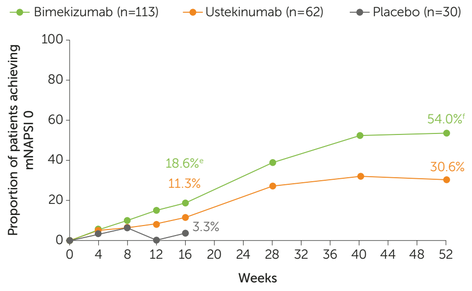
A) Scalp IGA 0 in patients with scalp IGA ≥3 at baseline



B) pp-IGA 0 in patients with pp-IGA ≥3 at baseline



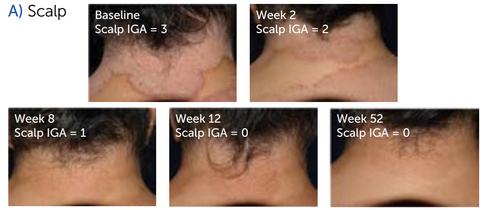
C) mNAPSI 0 in patients with mNAPSI >10 at baseline



[a]Nominal p<0.001 versus ustekinumab and placebo; [b]Nominal p<0.001 versus ustekinumab; [c]Nominal p=0.087 versus ustekinumab and p<0.001 versus placebo; [d]Nominal p=0.052 versus ustekinumab; [e]Nominal p=0.261 versus ustekinumab and p=0.035 versus placebo; [f]Nominal p=0.001 versus ustekinumab.

Figure 3 Bimekizumab treatment examples over 52 weeks

A) Scalp



B) Nail

Scalp IGA and mNAPSI data shown are total scores for that region in the patient shown. Photos are representative of part of that region: back of the scalp and left hand fingers.

IGA: Investigator's Global Assessment; IL: interleukin; mNAPSI: modified Nail Psoriasis Severity Index; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; pp: palmoplantar; PSO: plaque psoriasis; Q4W: every 4 weeks; Q12W: every 12 weeks; SD: standard deviation; TNF: tumor necrosis factor.

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