Bimekizumab provides rapid and sustained improvements in scalp and nail outcomes in patients with moderate-to-severe plaque psoriasis: 60-week results from a randomized, double-blinded, Phase 2b extension study

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Synopsis

- Psoriasis of the scalp and nails are associated with substantial physical, psychosocial and functional impairments affecting patients' quality of life (QoL)[1,2]
- Scalp and nail psoriasis are considered difficult-to-treat areas and can be challenging to manage effectively with current therapies[3,4]
- Interleukin (IL)-17A and IL-17F are expressed in psoriasis lesional skin and synergize with other cytokines to amplify inflammation; preclinical data support neutralization of both IL-17A and IL-17F as a novel targeting approach in psoriasis[5]
- Bimekizumab is a monoclonal IgG1 antibody that potently and selectively neutralizes both IL-17A and IL-17F[6]
- Bimekizumab was associated with rapid, substantial and durable clinical responses in patients with moderate-to-severe plaque psoriasis in the 12-week BE ABLE 1 (NCT02905006) and 48-week BE ABLE 2 extension (NCT03010527) Phase 2 studies, with no unexpected safety findings[7,8]

Objective

- **This post-hoc analysis evaluated scalp and nail outcomes over the 60-week treatment period in BE ABLE 1 responders (defined as patients who achieved a ≥90% reduction in Psoriasis Area Severity Index [PASI90] at Week 12)**

Methods

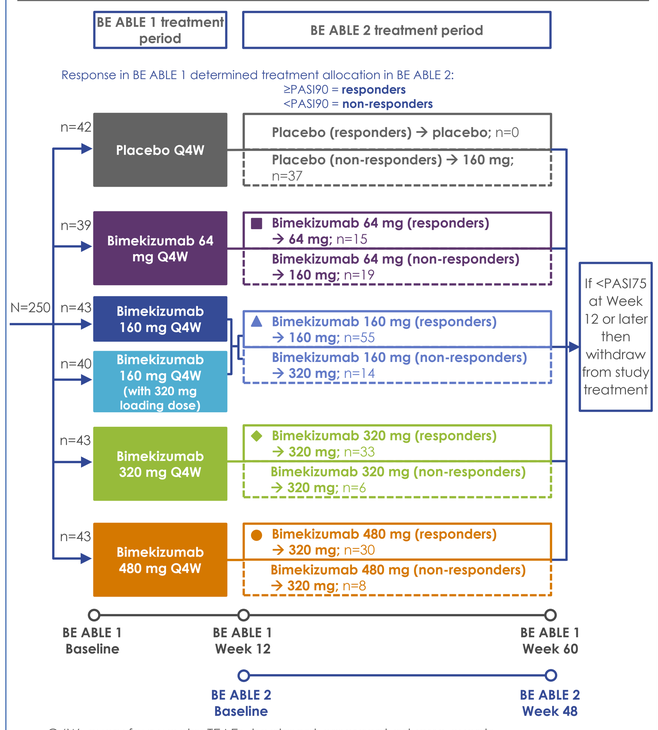
- In BE ABLE 1, patients were randomized to placebo or bimekizumab 64 mg, 160 mg, 160 mg with a 320 mg loading dose (LD), 320 mg or 480 mg[7] (**Figure 1**)
- In BE ABLE 2, BE ABLE 1 PASI90 responders remained on the same dose up to Week 60, except for those previously randomized to bimekizumab 480 mg, who received 320 mg from Week 12[8] (**Figure 1**)
- Presence of scalp or nail psoriasis at baseline (Week 0) was defined as a Psoriasis Scalp Severity Index (PSSI) score >0 or a modified Nail Psoriasis Severity Index (mNAPSI) score of >0, respectively
- The following outcomes were assessed in Week 12 responders:
  - Resolution of scalp psoriasis (defined as PSSI of 0)
  - Resolution of nail psoriasis (defined as mNAPSI of 0)
  - Complete skin clearance (defined as a score of 0 on both absolute PASI and the Investigator's Global Assessment [IGA])
  - Dermatology Life Quality Index (DLQI) of 0 or 1 (representing no impact of psoriasis on health-related QoL)
- Non-responder imputation and observed data are presented

Results

PATIENTS

- At the start of BE ABLE 2 (Week 12), across all treatment groups, 133 of 217 patients (61.3%) were PASI90 responders
- Of these 133 BE ABLE 1 responders, 125 (94.0%) had scalp psoriasis and 80 (60.2%) had nail psoriasis at baseline (Week 0)

Figure 1. BE ABLE 1 and BE ABLE 2 study design



Q4W, every four weeks; TEAEs, treatment-emergent adverse events.

Figure 2A. Percentage of BE ABLE 1 responders with scalp psoriasis at baseline achieving resolution of scalp psoriasis over time (NRI)

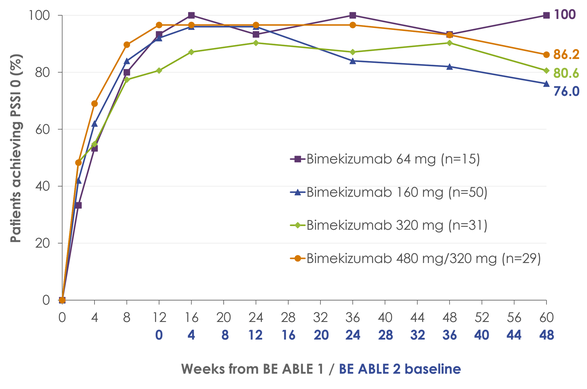
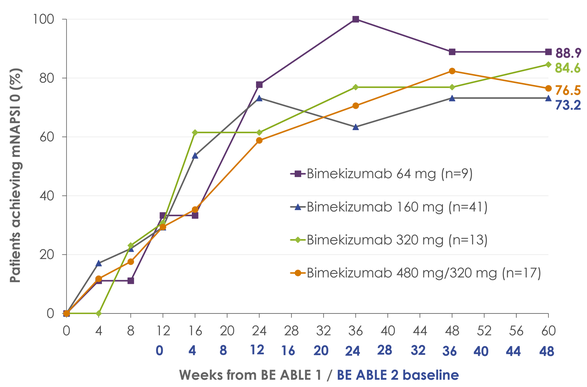
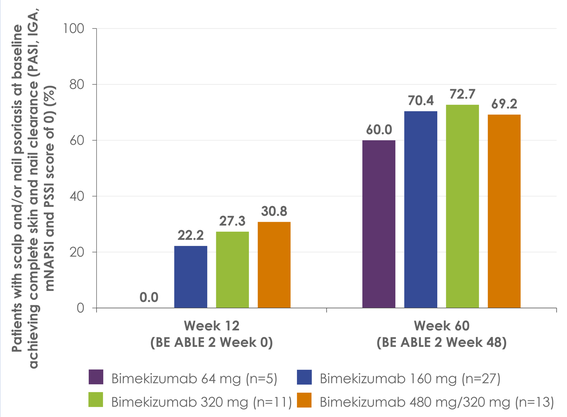


Figure 2B. Percentage of BE ABLE 1 responders with nail psoriasis at baseline achieving resolution of nail psoriasis over time (NRI)



The 160 mg treatment group includes patients who received 160 mg plus 320 mg loading dose. Non-responder imputation. mNAPSI, modified Nail Psoriasis Severity Index; PSSI, Psoriasis Scalp Severity Index.

Figure 3. BE ABLE 1 responders with both scalp and nail psoriasis at baseline achieving complete skin and nail clearance (absolute PASI, IGA, mNAPSI and PSSI scores of 0) at Week 12 and Week 60 (NRI)



The 160 mg treatment group includes patients who received 160 mg plus 320 mg loading dose. Non-responder imputation. IGA, Investigators Global Assessment; mNAPSI, modified Nail Psoriasis Severity Index; PASI, Psoriasis Area and Severity Index; PSSI, Psoriasis Scalp Severity Index.

Figure 4A. BE ABLE 1 responders with scalp psoriasis at baseline (n=125) achieving resolution of scalp psoriasis (PSSI=0) and DLQI score of 0 or 1 at Weeks 12, 24 and 60 (pooled bimekizumab groups, observed data)

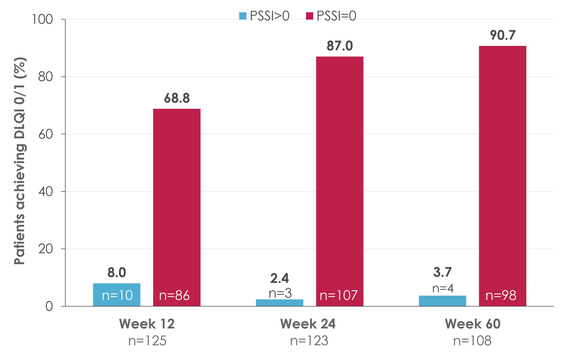
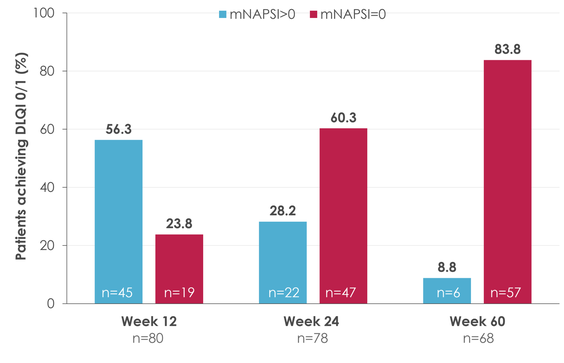


Figure 4B. BE ABLE 1 responders with nail psoriasis at baseline (n=80) achieving resolution of nail psoriasis (mNAPSI=0) and DLQI score of 0 or 1 at Weeks 12, 24 and 60 (pooled bimekizumab groups, observed data)



Observed data. DLQI, Dermatology Life Quality Index; mNAPSI, modified Nail Psoriasis Severity Index; PSSI, Psoriasis Scalp Severity Index.

SCALP AND NAIL OUTCOMES

- Bimekizumab treatment provided considerable improvements in both scalp and nail psoriasis
  - The proportion of patients with scalp psoriasis at baseline who achieved resolution increased rapidly with bimekizumab treatment; responses were generally maintained up to Week 60 (**Figure 2A**)
  - The percentage of BE ABLE 1 responders with nail psoriasis at baseline achieving resolution increased over time across all bimekizumab dose groups, reaching 73–89% at Week 60 (**Figure 2B**)
- Among PASI90 responders with both scalp and nail psoriasis at baseline, the majority (60–73%) achieved complete skin and nail clearance by Week 60 (**Figure 3**)
- Resolution of scalp and nail psoriasis was associated with improved health-related QoL, with 91% and 84% of patients, respectively, achieving DLQI of 0 or 1 by Week 60 (**Figure 4**)

Conclusions

- **In BE ABLE 1 responders with scalp and/or nail psoriasis at baseline, bimekizumab provided rapid and substantial clinical benefit that was maintained for up to 60 weeks**
- **The majority of these patients achieved resolution of their scalp and/or nail psoriasis during the treatment period**
- **Resolution of scalp and nail psoriasis was associated with improved health-related QoL**
- **These results provide further support for dual neutralization of IL-17A and IL-17F with bimekizumab as a novel approach for the treatment of patients with moderate-to-severe psoriasis, including difficult-to-treat areas**

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