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-blind, 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).1-3
- Scalp and nail psoriasis are considered difficult-to-treat areas and can be challenging to manage effectively with current therapies.1-4
- Interleukin (IL)-17A and IL-17F are expressed in psoriasis lesional skin and synergize with other cytokines to amplify inflammation; precise 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 (NCT02995006) 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 20% reduction in Psoriasis Area Severity Index [PASI90] at Week 12).9

Methods

- In BE ABLE 1, patients were randomized to placebo or bimekizumab 44 mg, 160 mg, 160 mg with a 320 mg loading dose (LD), 320 mg or 480 mg.10 (Figure 1)
- In BE ABLE 2, BE ABLE 1 PAS90 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 1210 (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 PAS90 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)

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, PASI, Psoriasis Area Severity Index.

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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 PAS90 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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References


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