Bimekizumab provides rapid and sustained improvements in quality of life that correlate with clinical 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

- Bimekizumab, a monoclonal IgG1 antibody that potently and selectively binds, and neutralizes, both IL-17A and IL-17F,[1] provided rapid, substantial and sustainable clinical improvements in patients with moderate-to-severe plaque psoriasis in the 12-week BE ABLE 1 (NCT02905006) and the 48-week BE ABLE 2 extension (NCT03010527) studies, with no unexpected safety findings[2–4]
- The disease burden of psoriasis extends beyond physical manifestations and can have a profound negative impact on quality of life (QoL)
- A substantial proportion of patients with moderate to severe psoriasis experience impaired QoL, including negative effects on emotional well-being and ability to perform everyday activities[5–8]
- Approximately 50% of patients with moderate-to-severe psoriasis have a Dermatology Life Quality Index (DLQI) score >10, indicating a very large effect on patient QoL[9]

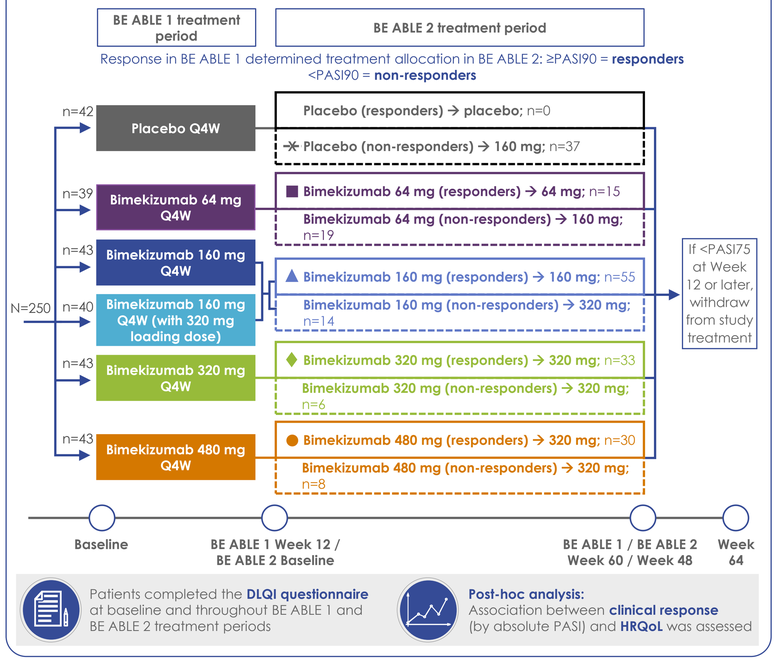
Objective

- **In this post-hoc QoL analysis we evaluated the effect of bimekizumab on health-related QoL (HRQoL) in patients with moderate-to-severe psoriasis and correlation with clinical response over the 60-week treatment period**

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[1]
- BE ABLE 1 responders (≥90% reduction in Psoriasis Area and Severity Index [PASI90] at Week 12) randomized to placebo or bimekizumab every 4 weeks (Q4W) 64 mg, 160 mg, or 160 mg (320 mg LD), continued the same treatment to Week 60 (**Figure 1**)
- Patients completed the DLQI questionnaire throughout the treatment period
  - A DLQI score of 0/1 indicated no impact of psoriasis on disease-specific HRQoL
- To evaluate a possible correlation between clinical response and HRQoL, patients achieving DLQI of 0/1 were grouped by absolute PASI (0, >0–<2, ≥2–<5, ≥5) at Weeks 12 and 60
- Non-responder imputation (NRI) and observed data are presented

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



Results

- Patient demographics and baseline disease characteristics were balanced across treatment groups (**Table 1**)

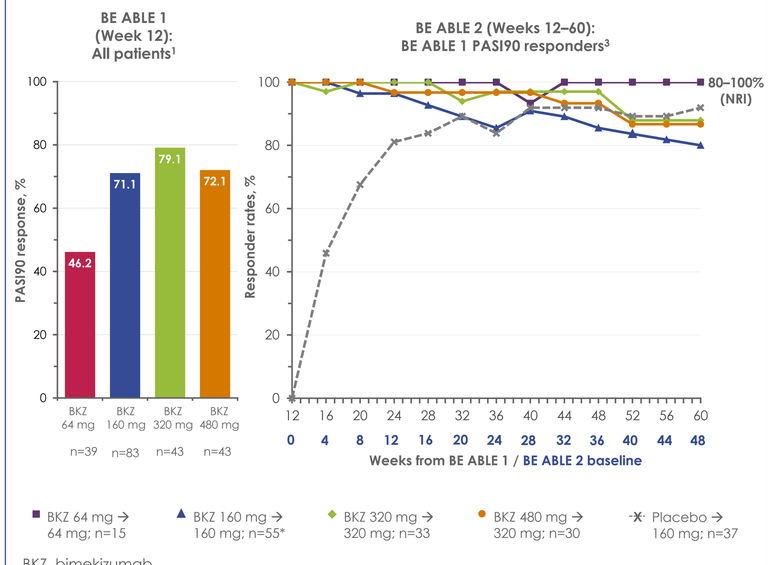
Table 1. Demographics and baseline disease characteristics[3]

	Bimekizumab 64 mg Q4W N=15	Bimekizumab 160 mg Q4W N=111	Bimekizumab 320 mg Q4W N=91	All patients N=217
Age, years, mean (±SD)	44.5 (14.7)	44.5 (12.8)	43.5 (14.7)	44.1 (13.7)
Sex, male, n (%)	9 (60.0)	71 (64.0)	60 (65.9)	140 (64.5)
Weight, kg, mean (±SD)	85.2 (16.8)	88.4 (19.1)	90.3 (23.5)	89.0 (20.9)
Race, Caucasian, n (%)	13 (86.7)	99 (89.2)	83 (91.2)	195 (89.9)
Prior systemic therapy, n (%)	13 (86.7)	77 (69.4)	67 (73.6)	157 (72.4)
Prior non-biologic systemic therapy	6 (40.0)	37 (33.3)	41 (45.1)	84 (38.7)
Prior biologic therapy	6 (40.0)	23 (20.7)	21 (23.1)	50 (23.0)
Prior anti-TNF therapy, n (%)	2 (13.3)	13 (11.7)	13 (14.3)	28 (12.9)
Disease duration, years, median (range)	13.9 (6.0–53.4)	15.0 (0–58.7)	15.0 (0.7–50.0)	15.0 (0–58.7)
PASI, mean (±SD)	**17.1 (4.5)**	**19.8 (7.0)**	**19.3 (6.6)**	**19.4 (6.7)**
IGA score, n (%)				
3 (Moderate)	**11 (73.3)**	**84 (75.7)**	**71 (78.0)**	**166 (76.5)**
4 (Severe)	**4 (26.7)**	**27 (24.3)**	**20 (22.0)**	**51 (23.5)**
Percentage BSA involvement, mean (±SD)	**21.8 (9.5)**	**26.5 (14.8)**	**24.8 (12.7)**	**25.4 (13.6)**

BSA, body surface area; IGA, Investigator's Global Assessment; SD, standard deviation; TNF, tumour necrosis factor; safety set

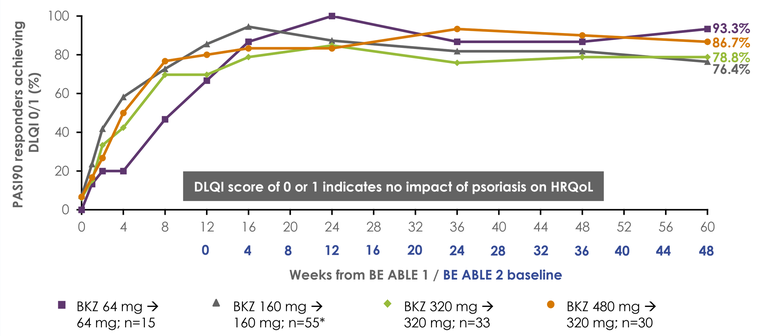
- Substantial proportions of patients achieved PASI90 at Week 12, which was maintained to Week 60 (**Figure 2**)
- In BE ABLE 1 PASI90 responders, bimekizumab provided rapid improvements in QoL (achieving DLQI of 0 or 1) at Week 8 (**Figure 3**)
  - The majority achieved DLQI 1 or 0 by Week 12
  - DLQI responses were maintained to Week 60 (76–93%)
- In PASI90 non-responders, rapid improvements in QoL were observed and maintained in patients re-assigned from placebo to bimekizumab 160 mg, with 84% of patients achieving DLQI of 0/1 at Week 60
  - Across the other bimekizumab dose groups, DLQI of 0/1 was achieved by 50–71% of non-responders at Week 60
- In the pooled bimekizumab group, patients with an absolute PASI of 0 were most frequently associated with higher QoL, with 79% and 95% achieving DLQI of 0/1 at Weeks 12 and 60, respectively (**Figure 4**)

Figure 2. Phase 2 BE ABLE study: Substantial proportions of patients achieved PASI90 at Week 12, which was maintained to Week 60 (NRI)



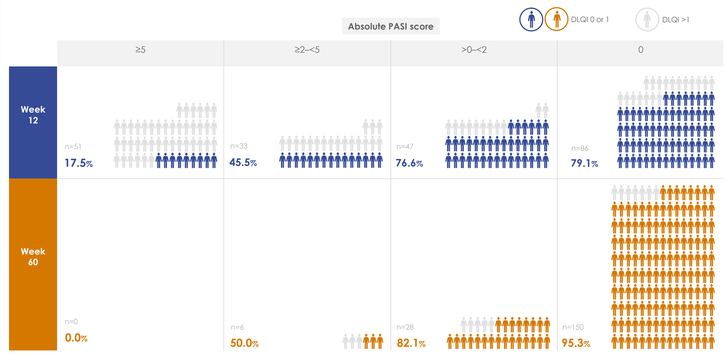
BKZ, bimekizumab
*Bimekizumab 160 mg group includes bimekizumab 160 mg and 160 mg with 320 mg loading dose in BE ABLE 1; full analysis set NRI

Figure 3. DLQI scores in PASI90 responders: Bimekizumab provided rapid improvements in QoL that were sustained to Week 60 (NRI)



*Bimekizumab 160 mg group includes bimekizumab 160 mg and 160 mg with 320 mg loading dose in BE ABLE 1
DLQI was assessed throughout BE ABLE 1 and BE ABLE 2 treatment periods; full analysis set NRI

Figure 4. Percentage of patients achieving DLQI of 0 or 1 by absolute PASI at Weeks 12 and 60 (pooled; observed)



DLQI was assessed throughout BE ABLE 1 and BE ABLE 2 treatment periods; full analysis set observed data

Conclusions

- Bimekizumab treatment resulted in rapid, substantial and sustained improvements in QoL in patients with moderate-to-severe psoriasis
  - The majority of BE ABLE 1 responders achieved DLQI of 0 or 1 by Week 12 and maintained responses up to Week 60
- Improvements in QoL was associated with clinical response
  - Patients with an absolute PASI of 0 were most frequently associated with high QoL, with 79% and 95% achieving DLQI of 0 or 1 at Weeks 12 and 60, respectively

References

1. Glatt S et al. *Br J Clin Pharmacol* 2017;83:991–1001
2. Papp KA et al. *J Am Acad Dermatol* 2018;79:279–286
3. Papp KA et al. EADV 2018 [e-poster P1978]
4. Blauvelt A et al. AAD 2019 (oral presentation OP11180)
5. Armstrong AW et al. *PLoS One* 2012;7(12):e52935
6. Strober B et al. *BMJ Open* 2019;9(4):e027535
7. Griffiths CEM et al. Br J Dermatol 2018;179:173–181
8. Korman NJ et al. *Dermatol Online J* 2015;21(10):pii: 13030/qt1x16v3dg
9. Augustin M et al. *Br J Dermatol* 2018;179:1385–1391.

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