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Bimekizumab Impact on Lesion Count by Anatomical Region in Moderate to Severe Hidradenitis Suppurativa: Results to Week 48 from BE HEARD I & II

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Objective

To report the impact of bimekizumab (BKZ) on hidradenitis suppurativa (HS) lesions by anatomical region up to Week 48 in patients with moderate to severe HS in two phase 3 trials.

Background

- HS is a chronic and debilitating inflammatory skin condition which is characterised by painful deep-seated lesions, such as abscesses (AB) and draining tunnels (DT), which can lead to scarring and disfigurement.[1]
- These lesions are generally intertriginous and occur at various anatomical areas such as the axillary and inguinal regions.[1]
- Other, more visible regions including the head, can also be affected.[2]
- BKZ is a monoclonal IgG1 antibody which selectively inhibits interleukin (IL)-17F in addition to IL-17A, and has demonstrated clinical efficacy in patients with HS.[3–5]

Methods

- We report pooled data from the randomised, double-blind, placebo (PBO)-controlled, multicentre BE HEARD I & II trials which included initial (Weeks 0–16) and maintenance (Weeks 16–48) treatment periods.[4,5]
- Patients with moderate to severe HS were randomised 2:2:2:1 to BKZ 320 mg every 2 weeks (Q2W) to Week 48, BKZ 320 mg every 4 weeks (Q4W) to Week 48, BKZ 320 mg Q2W to Week 16 then BKZ 320 mg Q4W to Week 48, or PBO to Week 16 then BKZ 320 mg Q2W to Week 48 (PBO/BKZ Q2W).
- Data were pooled for all patients randomised to BKZ from baseline (BKZ Total).
- Presented here are change from baseline (CfB) and percentage CfB lesion data from five anatomical regions: axilla, inguinal, gluteal, head and mammary. Clearance data (whereby lesion count was equal to 0 at Weeks 16 and 48) are presented for axilla and inguinal regions.
- We report BKZ's impact on three lesion types: AB, inflammatory nodules (IN) and DT.
- All data are reported as observed case (OC), data analysed as observed.

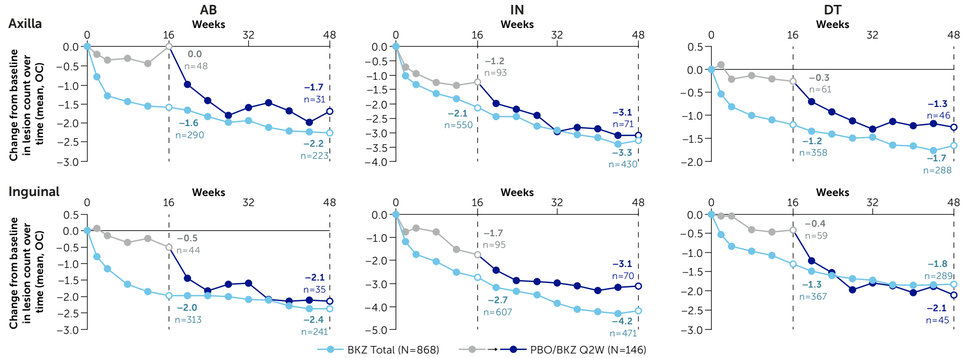
Results

- At baseline, 1,014 patients were randomised to BKZ Total (N=868) or PBO/BKZ Q2W (N=146). Baseline mean lesion counts for all lesion types and anatomical regions were balanced between the two treatment groups (data not shown).
- At Week 16, larger reductions in lesion counts, as shown by negative mean CfB, were observed across all five anatomical regions and lesion types in the BKZ-treated group vs the PBO-treated group (**Figure 1** and **Table 1**). This trend is also observed in percentage CfB data for the axilla and inguinal regions (**Figure 2**) and the gluteal, head and mammary regions (**Table 1**).
- Overall, greater lesion clearance was achieved at Week 16 in the BKZ-treated group vs the PBO group in the axilla and inguinal regions (**Figure 3**).
- At Week 48, sustained or further reductions in lesion count were observed across all lesion types in the BKZ Total group (**Figures 1–2** and **Table 1**). The PBO/BKZ Q2W group demonstrated overall comparable reductions (**Figures 1–2** and **Table 1**).
- In the axilla and inguinal regions, at Week 48, lesion clearance was comparable between the two groups (**Figure 3**). Generally similar lesion clearance results were seen in lesions located in the gluteal, head and mammary regions (data not shown).

Conclusions

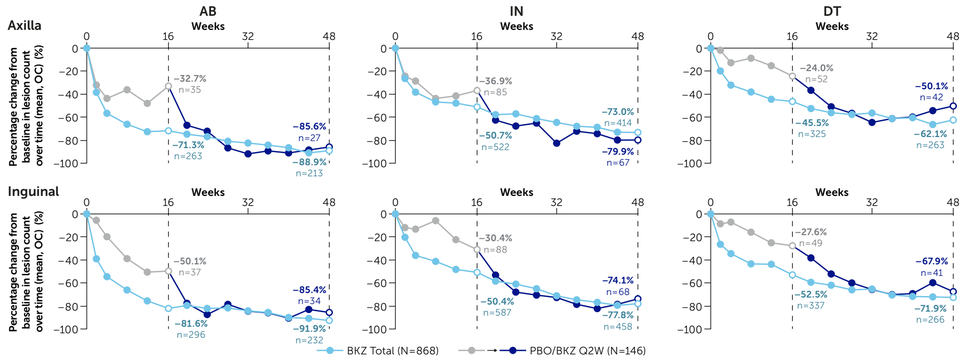
Improvements in the presented lesion types and anatomical regions were higher in BKZ vs PBO-treated patients at Week 16. Results with BKZ were sustained or improved across 48 weeks of treatment, with PBO to BKZ switchers achieving similar improvements at Week 48 as patients on continuous BKZ from baseline. These data demonstrate BKZ's effectiveness across different lesion locations and types in patients with moderate to severe HS.

Figure 1 Change from baseline in lesion count for patients with axilla and/or inguinal region involvement over time to Week 48 (OC)



Statistics are reported for patients with lesions in a given region at baseline.

Figure 2 Percentage change from baseline in lesion count for patients with axilla and/or inguinal region involvement over time to Week 48 (OC)



Statistics are reported for patients with lesions in a given region at baseline.

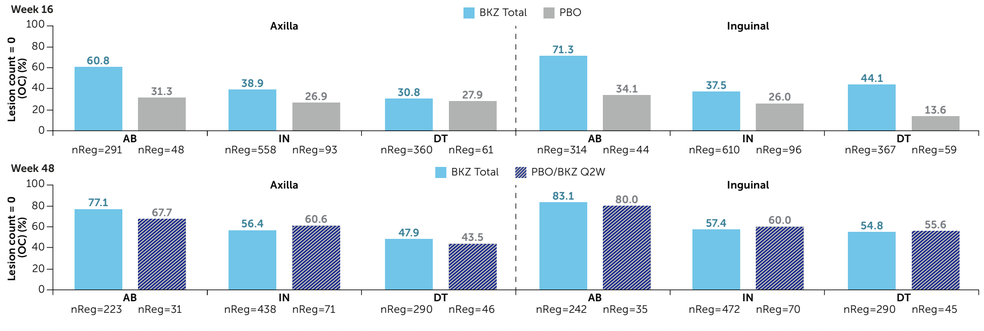
AB: abscesses; **BKZ:** bimekizumab; **CfB:** change from baseline; **DT:** draining tunnels; **HS:** hidradenitis suppurativa; **IL:** interleukin; **IN:** inflammatory nodules; **OC:** observed case; **PBO:** placebo; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation.

Table 1 Change from baseline and percentage change from baseline in lesion count for patients with gluteal, head and/or mammary region involvement at Week 16 and Week 48 (OC)

Anatomical Region	Change from baseline: Week 16 Mean ± SD			Change from baseline: Week 48 Mean ± SD			Percentage change from baseline (%): Week 16 Mean ± SD			Percentage change from baseline (%): Week 48 Mean ± SD		
	AB	IN	DT	AB	IN	DT	AB	IN	DT	AB	IN	DT
	BKZ Total (N=868)						BKZ Total (N=868)					
Gluteal	−1.6 ± 3.3 (n=180)	−2.1 ± 3.5 (n=398)	−1.1 ± 2.0 (n=196)	−2.3 ± 3.6 (n=133)	−3.0 ± 4.0 (n=304)	−1.5 ± 2.4 (n=157)	−58.8 ± 120.9 (n=172)	−58.3 ± 85.5 (n=371)	−54.3 ± 88.8 (n=181)	−84.1 ± 36.1 (n=127)	−77.1 ± 56.6 (n=293)	−65.4 ± 81.5 (n=144)
Head	−1.2 ± 2.5 (n=56)	−1.8 ± 3.9 (n=137)	−0.6 ± 2.2 (n=46)	−2.0 ± 1.8 (n=43)	−3.1 ± 4.2 (n=107)	−1.1 ± 1.8 (n=33)	−68.7 ± 44.8 (n=46)	−48.1 ± 63.7 (n=129)	−70.3 ± 50.3 (n=37)	−87.7 ± 28.5 (n=40)	−78.0 ± 34.8 (n=100)	−67.7 ± 52.7 (n=28)
Mammary[a]	−1.1 ± 2.1 (n=82)	−1.6 ± 3.8 (n=207)	−0.6 ± 2.2 (n=71)	−1.5 ± 1.5 (n=57)	−2.6 ± 3.7 (n=145)	−1.2 ± 1.9 (n=51)	−76.2 ± 56.7 (n=71)	−49.5 ± 111.7 (n=195)	−54.2 ± 77.1 (n=58)	−94.7 ± 18.3 (n=51)	−71.1 ± 72.3 (n=141)	−69.6 ± 57.9 (n=42)
	PBO/BKZ Q2W (N=146)						PBO/BKZ Q2W (N=146)					
Gluteal	−0.5 ± 2.0 (n=25)	−1.5 ± 4.1 (n=65)	−0.1 ± 2.4 (n=34)	−1.4 ± 1.5 (n=20)	−3.1 ± 3.1 (n=47)	−1.5 ± 2.3 (n=26)	−16.7 ± 127.9 (n=22)	−48.7 ± 62.5 (n=60)	−21.1 ± 63.8 (n=30)	−74.6 ± 56.8 (n=20)	−87.0 ± 27.2 (n=45)	−68.3 ± 54.6 (n=25)
Head	−0.6 ± 1.8 (n=19)	−1.1 ± 3.2 (n=41)	−0.5 ± 1.3 (n=8)	−2.4 ± 2.3 (n=13)	−2.7 ± 3.3 (n=31)	−1.3 ± 2.1 (n=10)	−61.5 ± 56.1 (n=14)	−23.0 ± 130.5 (n=37)	−31.9 ± 36.7 (n=7)	−100.0 ± 0.0 (n=11)	−75.7 ± 43.8 (n=30)	−95.2 ± 12.6 (n=7)
Mammary[a]	−0.3 ± 1.6 (n=15)	−0.6 ± 2.5 (n=34)	0.2 ± 1.4 (n=10)	−1.8 ± 2.0 (n=10)	−2.3 ± 2.1 (n=26)	0.4 ± 1.3 (n=8)	−62.5 ± 88.2 (n=12)	−8.3 ± 135.6 (n=31)	−57.1 ± 78.7 (n=7)	−90.0 ± 31.6 (n=10)	−79.2 ± 40.1 (n=25)	−40.0 ± 89.4 (n=5)

[a] Mammary anatomical region includes lesions recorded in the following regions for females only, left breast, right breast, left sub-mammary, right sub-mammary and intermammary (BKZ Total: N=501; PBO/BKZ Q2W: N=75). Statistics are reported for patients with lesions in a given region at baseline.

Figure 3 Proportion of patients achieving lesion clearance in axilla and inguinal regions at Week 16 and Week 48 (OC)



nReg represents the number of patients with at least one lesion present in the affected body region(s) for the given lesion type either at the given visit or at baseline, and percentages are calculated out of N. The proportion of patients with count equal to 0 are based on the nReg subset.

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