Bimekizumab efficacy in high-impact areas for patients with moderate to severe plaque psoriasis: Pooled results through two years from the BE SURE and BE RADIANT phase 3 trials

**Objectives**

To evaluate scalp, nail, and palmoplantar (pp) outcomes over 2 years in patients with moderate to severe plaque psoriasis treated with two different bimekizumab (BKZ) maintenance dosing regimens.

**Introduction**

- Plateau psoriasis affecting the scalp, nails, palms, and soles can cause significant physical impairment and negatively impact quality of life, therefore, clearance of psoriasis in these high-impact areas is of substantial clinical interest.
- High levels of clearance in high-impact areas after 1 year of BKZ treatment have been reported.

**Materials and Methods**

- Data were pooled from two years over the 1-year BE SURE phase 3 trial (NCT03412747) with the ongoing open-label extension (OLE; BE BRIGHT; NCT03538890), and the BE RADIANT phase 3 trial (NCT03536884), including the first year of its ongoing OLE (Figure 1).
- Patients included in the analyses had moderate to severe regional involvement at baseline (defined as scalp Investigator’s Global Assessment (IGA) ≥3, modified Nail Psoriasis Severity Index [mNAPSI] ≥10, pp-IGA ≥3; Figure 2).
- Proportions of patients who achieved complete regional clearance (scalp IGA 0, mNAPSI 0, pp-IGA 0) are reported through Year 2 (OLE Week 48).
- Data are presented for patients who received BKZ every 4 weeks (Q4W) through Week 16 followed by continuous BKZ Q4W or every 8 weeks (Q4W/Q8W) for 96 weeks.
- Data are not presented for patients who received BKZ Q4W/Q4W or Q8W/Q8W/Q8W due to low patient numbers.
- Data are reported using modified non-responder imputation (mNRI; not reported for pp-IGA due lack of convergence of the statistical model), in which patients who discontinued treatment due to lack of efficacy were considered non-responders and multiple imputation was used for all other missing data, NRI, and observed case (OC).

**Results**

- Baseline characteristics for patients included in this analysis are presented in Table 1.
- Among patients with scalp IGA ≥3 at baseline, complete clearance was achieved rapidly by a large proportion of patients; high levels of response were achieved through the end of Year 2 (Figure 3).
- Among patients with mNAPSI ≥10 at baseline, levels of complete clearance increased through to the end of Year 1 and response rates were sustained to the end of Year 2 (Figure 3).

**Conclusions**

Complete and sustained clearance of scalp and palmoplantar psoriasis was achieved in a high percentage of BKZ-treated patients over two years, regardless of dosing regimen.

**Baseline characteristics**

<table>
<thead>
<tr>
<th>Age (years), mean ± SD</th>
<th>Male, n (%)</th>
<th>Caucaisan, n (%)</th>
<th>Weight (kg), mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>46.5 ± 13.5</td>
<td>210 (69.9)</td>
<td>225 (69.7)</td>
<td>85.8 ± 12.8</td>
</tr>
</tbody>
</table>

**Table 1**

<table>
<thead>
<tr>
<th>BKZ 320 mg Q4W/Q4W (N=351)</th>
<th>BKZ 320 mg Q4W/Q8W/Q8W (N=323)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean ± SD</td>
<td>45.0 ± 14.3</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>210 (69.9)</td>
</tr>
<tr>
<td>Caucaisan, n (%)</td>
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<tr>
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**Figure 3**

- **Figure 3A:** Complete regional clearance of scalp, nail, or palmoplantar psoriasis over 2 years in patients with scalp IGA ≥3.
- **Figure 3B:** Complete regional clearance of scalp and palmoplantar psoriasis over 2 years in patients with scalp IGA ≥3.
- **Figure 3C:** Complete regional clearance of scalp and palmoplantar psoriasis over 2 years in patients with mNAPSI ≥10.

**Figure 2**

- **Figure 2A:** Complete regional clearance of scalp, nail, or palmoplantar psoriasis over 2 years in patients with scalp IGA ≥3.
- **Figure 2B:** Complete regional clearance of scalp, nail, or palmoplantar psoriasis over 2 years in patients with mNAPSI ≥10.

**Table 1**

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**Figure 1**

- **Figure 1A:** Study design (included patients).
- **Figure 1B:** Study design (included patients).

**Figure 2**

- **Figure 2A:** Tools used to assess disease severity.
- **Figure 2B:** Tools used to assess disease severity.

**Figure 3**

- **Figure 3A:** Complete regional clearance of scalp, nail, or palmoplantar psoriasis over 2 years in patients with scalp IGA ≥3.
- **Figure 3B:** Complete regional clearance of scalp, nail, or palmoplantar psoriasis over 2 years in patients with scalp IGA ≥3.
- **Figure 3C:** Complete regional clearance of scalp, nail, or palmoplantar psoriasis over 2 years in patients with mNAPSI ≥10.