Bimekizumab versus secukinumab in plaque psoriasis: Cumulative clinical and health-related quality of life benefit through 2 years of the BE RADIANT phase 3b trial and open-label extension

PRESENTED FOR SHAREHOLDERS, INVESTORS AND OTHER CAPITAL MARKET PARTICIPANTS ONLY

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Objective
To compare the cumulative clinical and health-related quality of life (HRQoL) benefit through 96 weeks for patients who received continuous bimekizumab (BKZ) vs patients who switched from secukinumab (SEC) to BKZ upon entering the BE RADIANT open-label extension (OLE) at Week 48.

Introduction
Clinical trials in psoriasis typically focus on treatment outcomes at specific timepoints.1 Evaluating the cumulative benefit of treatment over time using area under the curve (AUC) analyses captures the speed, level, and durability of patient responses.1 By using this approach and considering HRQoL, a more holistic assessment of the impact of psoriasis treatment can be obtained.1

Materials and Methods
In the BE RADIANT phase 3b trial (NCT03356884), patients received BKZ or SEC, as shown in Figure 1. At Week 48, patients could enroll in the BE RADIANT OLE and received BKZ 320 mg every 4 weeks (Q4W) or Q8W based on treatment, dose, and Week 48 Psoriasis Area and Severity Index (PASI) response (Figure 1).2 We report total AUC and cumulative clinical and HRQoL benefit through 48 weeks (AUC0–48) and 96 weeks (AUC0–96) for ≥PASI 90/100% improvement from baseline in PASI 90/100 and Dermatology Life Quality Index 0 or 1 (DLQI 0/1).2 Cumulative clinical and HRQoL benefit was defined as the estimated number of days on which patients achieved PASI 90, PASI 100, and DLQI 0/1. It was calculated as the proportion of the total possible AUC achieved for each outcome multiplied by the number of days in 48 or 96 weeks. Data are reported using modified non-responder imputation (mNRI) and NRI. For mNRI, patients who discontinued due to lack of efficacy were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data.

Results
Baseline demographics have been reported previously and were similar in patients randomised to BKZ (N=373) or SEC (N=370).2 Through 48 weeks, total AUC and the estimated number of days on which patients achieved PASI 90, PASI 100, and DLQI 0/1 was higher in patients randomised to BKZ vs SEC (Figure 2). At Week 48, PASI 100 was achieved for an estimated 50 more days in patients randomised to BKZ vs SEC. In patients who switched from SEC to BKZ at Week 48, there were increases in PASI 90, PASI 100, and DLQI 0/1 response rates from Week 48–96 as compared to Week 0–48. However, after the switch, total AUC and the estimated number of days on which patients achieved these outcomes remained higher in patients who received continuous BKZ (Figure 2). Results were consistent between mNRI (Figure 2) and NRI (Table 1).

Conclusions
High levels of cumulative clinical and HRQoL benefit were observed for patients who received continuous BKZ or who switched from SEC to BKZ upon entering the OLE. Despite an increase in cumulative clinical and HRQoL benefit in patients who switched from SEC to BKZ at Week 48, the benefit through 96 weeks remained higher in patients randomised to BKZ. These results demonstrate the rapid, high level, and durability of treatment responses that can be obtained with BKZ.

*Editors are thanked for their kind support and patience with the multiple imputation was used for all other missing data.

**AUC 0–48 = area under the curve 0–48 weeks; AUC 0–96 = area under the curve 0–96 weeks; PASI = Psoriasis Area and Severity Index; DLQI = Dermatology Life Quality Index; HRQoL = health-related quality of life; mNRI = modified non-responder imputation; NRI = non-responder imputation; OLE = open-label extension; PASI 90/100 = PASI 90 or PASI 100; SEC = secukinumab; BKZ = bimekizumab; 4QW = every 4 weeks; Q8W = every 8 weeks.

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A) PASI 90

B) PASI 100

C) DLQI 0/1

Data are presented as the total AUC and estimated number of days on which patients achieved PASI 90, PASI 100, and DLQI 0/1 on BE RADIANT and on the BE RADIANT OLE. Data are reported for patients who received continuous BKZ from Week 0–116 for patients who switched from SEC to BKZ at Week 48.

AUC: area under the curve; BKZ: bimekizumab; DLQI: Dermatology Life Quality Index; HRQoL: health-related quality of life; mNRI: modified non-responder imputation; NRI: non-responder imputation; OLE: open-label extension; PASI 90/100: Psoriasis Area and Severity Index 90% or 100%; SEC: secukinumab; BKZ: bimekizumab; 4QW = every 4 weeks; Q8W = every 8 weeks.

2 AUC 0–48 = area under the curve 0–48 weeks; AUC 0–96 = area under the curve 0–96 weeks; PASI = Psoriasis Area and Severity Index; DLQI = Dermatology Life Quality Index; HRQoL = health-related quality of life; mNRI = modified non-responder imputation; NRI = non-responder imputation; OLE = open-label extension; PASI 90/100 = PASI 90 or PASI 100; SEC = secukinumab; BKZ = bimekizumab; 4QW = every 4 weeks; Q8W = every 8 weeks.

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References

Figure 1: BE RADIANT study design

Figure 2: Total AUC and cumulative benefit through 48 weeks and 96 weeks for clinical and HRQoL outcomes (mNRI)

Table 1: Cumulative clinical and HRQoL benefit through Weeks 0–48 and 0–96 (NRI)

<table>
<thead>
<tr>
<th>Week</th>
<th>BKZ</th>
<th>SEC</th>
<th>BKZ</th>
<th>SEC</th>
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<tbody>
<tr>
<td>0–48</td>
<td>259 (77.0)</td>
<td>218 (64.8)</td>
<td>195 (58.2)</td>
<td>144 (42.9)</td>
</tr>
<tr>
<td>0–96</td>
<td>468 (63.7)</td>
<td>451 (61.8)</td>
<td>349 (51.9)</td>
<td>346 (48.0)</td>
</tr>
</tbody>
</table>

Table 2: Estimated number of days on which patients achieved PASI 90, PASI 100, and DLQI 0/1 (mNRI)

<table>
<thead>
<tr>
<th>Week</th>
<th>PASI 90</th>
<th>PASI 100</th>
<th>DLQI 0/1</th>
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<tbody>
<tr>
<td>0–48</td>
<td>451 days</td>
<td>242 days</td>
<td>232 days</td>
</tr>
<tr>
<td>0–96</td>
<td>565 days</td>
<td>352 days</td>
<td>342 days</td>
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</tbody>
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Table 3: Estimated number of days on which patients achieved PASI 90, PASI 100, and DLQI 0/1 (NRI)

<table>
<thead>
<tr>
<th>Week</th>
<th>PASI 90</th>
<th>PASI 100</th>
<th>DLQI 0/1</th>
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