Efficacy and Safety of Bimekizumab in Patients with Moderate to Severe Plaque Psoriasis: Results from BE VIVID, a 52-Week Phase 3, Randomized, Double-Blinded, Ustekinumab- and Placebo-Controlled Study

Presented at Fall Clinical Dermatology Conference 2020 | October 29–November 1 | Las Vegas, NV

Objectives
To compare the efficacy and safety of bimekizumab with ustekinumab and placebo in patients with moderate to severe plaque psoriasis treated for one year.

Background
Bimekizumab is a monoclonal IgG antibody that selectively inhibits IL-17F in addition to IL-17A. Both of these interleukins are implicated in the immunopathogenesis of psoriasis. 1–3 Bimekizumab led to substantial clinical improvements in patients with moderate to severe plaque psoriasis (Psoriasis Area and Severity Index [PASI] 75) in the phase 2 ABLE study with no unexpected safety findings. 4–7

Methods
Adult patients with moderate to severe PsO were enrolled in the phase 3 BE VIVID study (NCT03307055), a randomized double-blind study in which patients were treated with bimekizumab, ustekinumab, or placebo (Figure 1). The co-primary endpoints were PASI 75 at Week 16, with significantly higher PASI 90 and IGA 0/1 responder rates in bimekizumab; superiority in ustekinumab was also demonstrated

Results
BE VIVID met both of its co-primary endpoints at Week 16, with superior PASI 75 response rates observed with bimekizumab compared with ustekinumab. Clinical responses with bimekizumab, compared with ustekinumab, were generally well tolerated and the safety profile was consistent with previous studies. 8–11

Synopsis
Objective
To compare the efficacy and safety of bimekizumab with ustekinumab and placebo in patients with moderate to severe plaque psoriasis.

Methods
Patients were randomized 4:1:2 to receive bimekizumab every four weeks, placebo or ustekinumab.

Results
Week 16 PASI 90 responses were highest for bimekizumab (77.9%), followed by ustekinumab (64.1%) and placebo (8.4%). responders were generally well tolerated and the safety profile was consistent with previous studies.

Conclusion
Bimekizumab was superior to ustekinumab and placebo in PASI 90 and IGA 0/1 at Week 16, and was generally well tolerated with a safety profile consistent with previous phase 2 studies.

Author Contributions:
A) Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data:
B) Drafting of the article:
C) Critical revision of the article for important intellectual content:
D) Final approval of the publication:
E) Administrative/technical/material support:
F) Study supervision:

Table 1: Baseline characteristics

<table>
<thead>
<tr>
<th>Treatment</th>
<th>N</th>
<th>Age (years), median (IQR)</th>
<th>Sex, male, n (%)</th>
<th>Body mass index (kg/m²), mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bimekizumab</td>
<td>321</td>
<td>83.3 (72.0–92.0)</td>
<td>170 (53.0)</td>
<td>26.6 (4.0)</td>
</tr>
<tr>
<td>Ustekinumab</td>
<td>163</td>
<td>83.3 (72.0–92.0)</td>
<td>91 (55.7)</td>
<td>26.6 (4.0)</td>
</tr>
<tr>
<td>Placebo</td>
<td>83</td>
<td>83.3 (72.0–92.0)</td>
<td>35 (42.5)</td>
<td>26.6 (4.0)</td>
</tr>
</tbody>
</table>

Table 2: Safety

<table>
<thead>
<tr>
<th>Event</th>
<th>Bimekizumab</th>
<th>Ustekinumab</th>
<th>Placebo</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse events</td>
<td>31.2%</td>
<td>29.8%</td>
<td>24.7%</td>
<td>0.26</td>
</tr>
<tr>
<td>Serious adverse events</td>
<td>0.3%</td>
<td>0.6%</td>
<td>0.0%</td>
<td>0.50</td>
</tr>
<tr>
<td>Discontinuations due to adverse events</td>
<td>0.3%</td>
<td>0.6%</td>
<td>0.0%</td>
<td>0.50</td>
</tr>
</tbody>
</table>

Conclusions
Superior PASI 90 and IGA 0/1 responses were observed with bimekizumab compared with ustekinumab at Week 16. After one dose, faster onset of response was observed with bimekizumab compared with ustekinumab. Clinical responses with bimekizumab were generally well tolerated and the safety profile was consistent with previous studies. 8–11

References:

Figures:
Figure 1: Study design
Figure 2: Proportion of patients achieving PASI 75 (%)

Tables:
Table 1: Baseline characteristics
Table 2: Safety

Appendix:
Appendix A: Author Affiliations:
Appendix B: Acknowledgements:
Appendix C: References:

Author Affiliations:
AA: Janssen Pharmaceuticals, LEO Pharma, Boehringer Ingelheim, Eli Lilly, and Valeant Pharmaceuticals for serving as an advisory board member, principal investigator, and speaker.

Acknowledgements:
AM: Consultant and/or investigator for AbbVie, Aclaris, Almirall, Amgen, Biogen, Celgene, Dermavant, Eli Lilly, Forward Pharma, Fresenius Medical Care, Galapagos, GlaxoSmithKline, Janssen-Cilag, Kyowa Kirin, LEO Pharma, Medac, Merck Sharp & Dohme, Miltenyi Biotec, Novartis, Ocean Pharma, Pfizer, Regeneron, Samsung Bioepis, Sanofi, Sun Pharma, Takeda, UCB Pharma, Valeant, and Xenoport.

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