Low occurrence of predefined safety events across six randomized clinical trials of spesolimab in dermatologic conditions

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Aim: To describe rates of predefined safety events, using available data from six randomized trials of spesolimab across GPP and other dermatologic conditions in this pooled analysis

Methods

- Predefined events included: Infections; malignant tumors; peripheral neuropathy; and potential hypersensitivity events

Table 1. Summary of included trials

<table>
<thead>
<tr>
<th>Study</th>
<th>GPP (LD) (N=53)</th>
<th>GPP (IV) (N=39)</th>
<th>PPP (LD) (N=152)</th>
<th>PPP (IV) (N=59)</th>
<th>AD (LD) (N=51)</th>
<th>AD (IV) (N=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Randomization</td>
<td>Double-blind 1:1</td>
<td>Double-blind 1:1</td>
<td>Placebo-controlled 0:1</td>
<td>Placebo-controlled 2:1</td>
<td>Placebo-controlled 0:1</td>
<td>Placebo-controlled 2:1</td>
</tr>
<tr>
<td>Duration (wks)</td>
<td>16</td>
<td>16</td>
<td>52</td>
<td>52</td>
<td>26</td>
<td>26</td>
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<tr>
<td>Placebo recipients (%)</td>
<td>70</td>
<td>70</td>
<td>70</td>
<td>70</td>
<td>70</td>
<td>70</td>
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<tr>
<td>Mean age (yrs)</td>
<td>46</td>
<td>46</td>
<td>46</td>
<td>46</td>
<td>46</td>
<td>46</td>
</tr>
<tr>
<td>Gender (M:F)</td>
<td>1:1</td>
<td>1:1</td>
<td>1:1</td>
<td>1:1</td>
<td>1:1</td>
<td>1:1</td>
</tr>
<tr>
<td>Total exposure (pt-yrs)</td>
<td>342.3</td>
<td>342.3</td>
<td>180.9</td>
<td>180.9</td>
<td>86.4</td>
<td>86.4</td>
</tr>
</tbody>
</table>

Figure 2. Duration of exposure to spesolimab across dermatologic indications

Figure 3. Infections* and malignancies

Figure 4. Peripheral neuropathy and potential hypersensitivity events

Based on data from randomized placebo-controlled periods plus OLE trials, a substantial number of patients have had long-term exposure to spesolimab

References

4. St John’s Institute of Dermatology, Faculty of Life Sciences and Medicine, King’s College London, London, UK; 5Boehringer Ingelheim (China) Investment Co. Ltd, Shanghai, China; 6Koninklijke Philips N.V., Amsterdam, The Netherlands; 7Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany; 8Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany

Conclusions

- Spesolimab has been studied across multiple dermatologic indications, with many patients having been treated 30 months to 8 years or longer
- With respect to infections, no pattern regarding pathogen or affected organ was identified
- Reported malignancies and peripheral neuropathy events were balanced between spesolimab and placebo
- Potential hypersensitivity events were numerically higher with spesolimab compared with placebo for study 2 (Effisayl® 2), and were mainly non-serious, non-severe, and not dose-dependent
- Underlying dermatologic conditions under investigation may account for some of the events of interest (particularly infections and potential hypersensitivity events)
- There were no consistent differences between spesolimab and placebo in the placebo-controlled trial periods
- Across all trials, spesolimab demonstrated a consistent and favorable safety profile

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