Spesolimab for hidradenitis suppurativa: A proof-of-concept study

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AIM

For the first time, we present results from patients with HS who were treated continuously with spesolimab over a 24-week period, including data from Week 12 of a phase Ia PoCC study, and further interim analyses from Week 12 of an ongoing OLE study.

RESULTS

Baseline demographics and clinical characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Baseline PoCC study N=52</th>
<th>Baseline OLE study N=45</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean (SD)</td>
<td>35.7 (11.3)</td>
<td>34.1 (11.0)</td>
</tr>
<tr>
<td>Gender, male</td>
<td>24</td>
<td>27</td>
</tr>
<tr>
<td>BMI, kg/m², mean (SD)</td>
<td>30.7 (6.8)</td>
<td>30.4 (7.0)</td>
</tr>
</tbody>
</table>

Efficacy: Interim analysis OLE at Week 12

- Percentage change from baseline in dT count:
  - Placebo (n=13): -27.9% (95% CI: -32.8 to -22.9)
  - Spesolimab-to-spesolimab (n=30): -40.1% (95% CI: -45.0 to -35.2)
  - Placebo-to-spesolimab (n=15): -19.6% (95% CI: -24.6 to -14.6)

- Percentage change from baseline in IHS4 score:
  - Placebo (n=13): -12.8% (95% CI: -17.8 to -7.8)
  - Spesolimab-to-spesolimab (n=30): -27.1% (95% CI: -32.0 to -22.2)
  - Placebo-to-spesolimab (n=15): -16.5% (95% CI: -21.5 to -11.5)

Efficacy: Over 24 weeks of spesolimab treatment

- Percentage change from baseline in dT count:
  - Spesolimab (n=30): -36.1% (95% CI: -41.0 to -31.2)

- Percentage change from baseline in IHS4 score:
  - Spesolimab (n=30): -25.7% (95% CI: -30.6 to -20.8)

CONCLUSIONS

- In the PoCC study, total counts for all HS lesions decreased over 12 weeks of treatment with spesolimab.
- A greater proportion of patients in the spesolimab arm experienced a decrease in dT count at Week 12 than in the placebo arm.
- The observed decreases in lesion counts and the percentage change in dTs were sustained over 24 weeks of continuous spesolimab treatment.
- Similarly, patients treated with spesolimab had a decrease in IHS4 score that was sustained up to Week 24 of continuous spesolimab treatment.
- Patients previously randomized to placebo also had a decrease in HS lesion count and IHS4 score at Week 12 of the OLE.
- Spesolimab was generally well tolerated, in line with previous trials in other indications.

Safety profile

- No serious adverse events (AEs) were reported.
- The most commonly reported AEs were injection site erythema (15/30) and injection site pain (9/30).
- The proportion of patients experiencing injection site reactions was similar across treatment arms.

DISCLOSURES & ACKNOWLEDGMENTS

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REFERENCES