Early and maintained response levels in psoriasis patients treated with tildrakizumab

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tildrakizumab is a humanized, monoclonal antibody that selectively inhibits the p12 subunit of interleukin-23 and is approved for the US, Europe and Australia to treat patients with moderate to severe plaque psoriasis.

The efficacy and safety of tildrakizumab has been demonstrated in two phase 3, double-blind, randomized, controlled trials: NCT01722331 and NCT01729754. This post hoc analysis examined the long-term efficacy of tildrakizumab 100 mg up to week 148 among patients achieving various Psoriasis Area and Severity Index (PASI) responses at week 28 in NCT01722331 and 2-2.

The phase 3 reSURFACE trial was a 4-year, Phase III, randomized withdrawal study that evaluated the efficacy of tildrakizumab 100 mg every 8 weeks in patients with plaque psoriasis.

METHODS

• Both reSURFACE 1 and reSURFACE 2 used a three-part design.*

• Part 1 (0–24 weeks): Patients were randomized (2:2:2) to placebo, subcutaneous placebo or tildrakizumab 100 mg every 8 weeks.

• Part 2 (25–52 weeks): Patients previously receiving placebo or tildrakizumab 100 mg at week 24 were randomized to placebo treatment at week 25 and tildrakizumab 100 mg at week 52 or tildrakizumab 100 mg every 8 weeks, respectively.

• Part 3 (53–104 weeks): Patients previously receiving placebo or tildrakizumab at week 52 were treated with placebo every 8 weeks or tildrakizumab 100 mg every 8 weeks.

• Patients who achieved PASI 75 at week 28 in Part 1 and were randomized to placebo in Part 2 were eligible to enroll in the long-term extension (LTE) study.

RESULTS

• Total of 583 patients were included in the analysis.

Table 1. Baseline demographics and clinical characteristics by % PASI improvement from baseline to week 28

<table>
<thead>
<tr>
<th>PASI 75-74</th>
<th>PASI 75-89</th>
<th>PASI 80-99</th>
<th>PASI 100</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>48.9 (14.6)</td>
<td>49.1 (12.5)</td>
<td>48.2 (13.0)</td>
<td>48.2 (12.7)</td>
</tr>
<tr>
<td>Male, %</td>
<td>56.3 (76.0)</td>
<td>56.7 (76.1)</td>
<td>56.2 (76.0)</td>
<td>56.1 (75.9)</td>
</tr>
<tr>
<td>Body surface area, %</td>
<td>34.8 (20.1)</td>
<td>31.1 (26.0)</td>
<td>32.7 (27.6)</td>
<td>32.6 (27.6)</td>
</tr>
<tr>
<td>Baseline PASI response</td>
<td>18.8 (13.1)</td>
<td>18.8 (13.1)</td>
<td>18.8 (13.1)</td>
<td>18.8 (13.1)</td>
</tr>
<tr>
<td>Baseline PASI score</td>
<td>20.5 (9.8)</td>
<td>19.6 (9.4)</td>
<td>19.9 (9.0)</td>
<td>18.9 (6.2)</td>
</tr>
<tr>
<td>Change, %</td>
<td>7.0 (3.5)</td>
<td>11.3 (5.9)</td>
<td>22.1 (18.8)</td>
<td>16.7 (6.9)</td>
</tr>
<tr>
<td>flare</td>
<td>4.1 (11.3)</td>
<td>7.8 (6.9)</td>
<td>8.9 (6.9)</td>
<td>6.9 (6.9)</td>
</tr>
<tr>
<td>CVG</td>
<td>9.0 (26.9)</td>
<td>21.2 (4.6)</td>
<td>35.1 (31.1)</td>
<td>22.2 (24.9)</td>
</tr>
<tr>
<td>Peak integrals, %</td>
<td>4.1 (11.4)</td>
<td>10.0 (7.2)</td>
<td>2.1 (3.8)</td>
<td>11.3 (11.3)</td>
</tr>
</tbody>
</table>

Table 1. Baseline demographics and clinical characteristics by % PASI improvement from baseline to week 28.

PASI: Psoriasis Area and Severity Index

PASI 75: At least 75% clearing of index

PASI 90: At least 90% clearing of index

* Patients with long-standing psoriasis (mean 16.1 years); but 83.2% had not previously been treated with biological therapy.

** Mean PASI improvements at week 4 were 27.1%, 36.4%, 44.7%, and 52.2% for weeks PASI 50–74, 75–89, 80–89, and 100, respectively.

DISCUSSION

• Patients who achieved PASI 75 at week 28 had rapid PASI improvements as early as week 4.

• Among patients achieving PASI 75 at week 28, PASI improvements were sustained throughout 104 weeks.

REFERENCES


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DISCLOSURES

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