Insights into the efficacy and safety of tildrakizumab in patients with moderate-to-severe plaque psoriasis across age quartiles: Pooled analyses from the Phase 3 reSURFACE 1 and reSURFACE 2 trials

Boni Elewski¹, George Han², Ranga Gogineni³, Brad Schenkel³, Scott Guenthner⁴

¹Department of Dermatology at the University of Alabama at Birmingham, AL, USA; ²Icahn School of Medicine at Mount Sinai, New York, NY, USA; ³Sun Pharmaceutical Industries, Inc., Princeton, NJ, USA; ⁴The Indiana Clinical Trials Center, Plainfield, IN, USA

DISCLOSURES

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Introduction, Objective, and Methods

INTRODUCTION

• Tildrakizumab is an anti-interleukin-23 p19 monoclonal antibody approved for the treatment of adults with moderate-to-severe plaque psoriasis\textsuperscript{1,2}.

• As both patients with psoriasis and the elderly population are at increased risk for comorbidities\textsuperscript{3,4}, it is important to assess the efficacy and safety of tildrakizumab across age groups and particularly in older patients with psoriasis.

OBJECTIVE

• To assess whether the efficacy and safety of tildrakizumab in patients with moderate-to-severe plaque psoriasis through 28 weeks differ across age groups.

METHODS

• Data were pooled from Part 1 (Weeks 0–12) and Part 2 (Weeks 12–28) of the 3-part Phase 3, randomized, double-blind, placebo-controlled trials, reSURFACE 1 (NCT01722331) and reSURFACE 2 (NCT01729754).
  -- Data from patients treated with the labeled dose of tildrakizumab 100 mg through Week 28 are reported.

• Patients with moderate-to-severe plaque psoriasis received tildrakizumab 100 mg at Week 0, Week 4, and every 12 weeks thereafter.

• Disease activity was assessed from median PASI scores reported as observed.

• Clinical improvement was assessed from proportions of patients achieving PASI 75/90/100 response and those achieving PGA score of 0 or 1 with ≥2-grade reduction from baseline.
  -- Missing response data were handled using nonresponse imputation.

• Safety was assessed from TEAEs in all patients as treated.

Results

Table 1. Baseline demographics and clinical characteristics by age quartile

<table>
<thead>
<tr>
<th>Age, years</th>
<th>Q1 18–35 years n = 146</th>
<th>Q2 36–44 years n = 142</th>
<th>Q3 45–54 years n = 156</th>
<th>Q4 55–82 years n = 150</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, years</strong></td>
<td>Mean ± SD</td>
<td>Median</td>
<td>Mean ± SD</td>
<td>Median</td>
</tr>
<tr>
<td>18–35 years</td>
<td>28.7 ± 4.9</td>
<td>29.0</td>
<td>40.2 ± 2.7</td>
<td>41.0</td>
</tr>
<tr>
<td><strong>Weight, kg</strong></td>
<td>Mean ± SD</td>
<td>Median</td>
<td>Mean ± SD</td>
<td>Median</td>
</tr>
<tr>
<td>18–35 years</td>
<td>88.9 ± 24.4</td>
<td>84.5</td>
<td>88.7 ± 24.0</td>
<td>86.0</td>
</tr>
<tr>
<td><strong>BSA, %</strong></td>
<td>Mean ± SD</td>
<td>Median</td>
<td>Mean ± SD</td>
<td>Median</td>
</tr>
<tr>
<td>18–35 years</td>
<td>32.4 ± 18.5</td>
<td>27.0</td>
<td>31.8 ± 18.8</td>
<td>25.5</td>
</tr>
<tr>
<td><strong>PASI score</strong></td>
<td>Mean ± SD</td>
<td>Median</td>
<td>Mean ± SD</td>
<td>Median</td>
</tr>
<tr>
<td>18–35 years</td>
<td>20.5 ± 8.1</td>
<td>18.1</td>
<td>19.8 ± 7.0</td>
<td>17.8</td>
</tr>
</tbody>
</table>

All patients received tildrakizumab 100 mg.

- Of 594 patients treated with tildrakizumab 100 mg (Table 1), the numbers completing Week 28 by age quartile were as follows:
  - 18 to 35 years: 135/146
  - 36 to 44 years: 136/142
  - 45 to 54 years: 145/156
  - 55 to 82 years: 141/150

- Baseline weight, BSA affected, and PASI scores were similar across age quartiles

Figure 1. Median PASI score from Week 0 to Week 28 by age quartile

All patients received tildrakizumab 100 mg. Data reported as observed.

- PASI scores decreased substantially across all age quartiles from baseline (Week 0) to Week 28:
  - 18 to 35 years: 18.1 to 1.1
  - 36 to 44 years: 17.8 to 1.5
  - 45 to 54 years: 17.7 to 1.8
  - 55 to 82 years: 17.5 to 1.8

BSA, body surface area; PASI, Psoriasis Area and Severity Index; SD, standard deviation; Q, quartile.
Results

Figure 2. Percentage of patients achieving PASI response thresholds at Week 12 and Week 28 by age quartile

- The percentages of patients achieving PASI 75, PASI 90, and PASI 100 responses increased over time and peaked at Week 28 in all age quartiles (Figure 2)
  - In all age quartiles, >50% of patients achieved PASI 75 response by Week 12, with continued improvement through Week 28
  - The percentage of patients achieving PASI 100 response by Week 28 was highest in the subgroup of patients aged 18 to 35 years (43/146 patients: 29.5%)

Figure 3. Percentage of patients achieving PGA of 0 or 1 with ≥2-grade decrease from baseline at Week 12 and Week 28 by age quartile

- Similar proportions of patients across age quartiles achieved PGA 0/1 with ≥2-grade decrease from baseline by Week 28 (Figure 3)
Results and Conclusions

Table 2. Summary of TEAEs and most common TEAEs (≥5% in any age quartile) through Week 28 by age quartile

<table>
<thead>
<tr>
<th></th>
<th>Q1 18–35 years</th>
<th>Q2 36–44 years</th>
<th>Q3 45–54 years</th>
<th>Q4 55–82 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with ≥1 TEAE</td>
<td>99 (64.7)</td>
<td>93 (63.3)</td>
<td>105 (66.0)</td>
<td>98 (62.4)</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>Nasopharyngitis</td>
<td>30 (19.6)</td>
<td>30 (20.4)</td>
<td>24 (15.1)</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Diarrhea</td>
<td>8 (5.2)</td>
<td>2 (1.4)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Arthralgia</td>
<td>3 (2.0)</td>
<td>2 (1.4)</td>
<td>12 (7.5)</td>
</tr>
<tr>
<td>Nervous system disorder</td>
<td>Headache</td>
<td>10 (6.5)</td>
<td>7 (4.8)</td>
<td>8 (5.0)</td>
</tr>
<tr>
<td>Patients with ≥1 severe TEAE</td>
<td></td>
<td>2 (1.3)</td>
<td>2 (1.4)</td>
<td>8 (5.0)</td>
</tr>
</tbody>
</table>

All patients received tildrakizumab 100 mg. Data shown as n (%).

- The frequency of TEAEs through Week 28 was similar among patients in all age quartiles (Table 2)
  - The most frequent TEAEs (>5% in any age quartile) were nasopharyngitis, diarrhea, arthralgia, and headache

- Severe TEAEs were reported in ≤5% of patients, with slightly higher frequency in patients ≥45 years of age

- The proportion of patients with any TEAE considered related to treatment trended down with age

- One death unrelated to tildrakizumab treatment occurred in the subgroup of patients aged 55 to 82 years through Week 28

CONCLUSIONS

- The efficacy and safety of tildrakizumab were comparable in patients with moderate-to-severe plaque psoriasis across age quartiles

- Tildrakizumab is a safe and effective option for the treatment of psoriasis in patients over 55 years of age