Secukinumab 300 mg showed fast and high efficacy in Chinese moderate to severe plaque psoriasis patients

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INTRODUCTION

- Secukinumab is a fully human monoclonal antibody that selectively neutralizes interleukin-17A, a pro-inflammatory cytokine involved in the development of psoriasis. It has shown long-lasting efficacy and safety in the various domains of the disease, including scalp, palm, soles, and joints.1,2
- In the pivotal Phase 2 studies, secukinumab was associated with a rapid and high efficacy in Chinese moderate to severe plaque psoriasis patients with IGA mod 2011 score of 4 or less with no new or unexpected safety signals identified.1

METHODS

Study design

- The current study (NCT0306600, CAM55752136i) was an ongoing 52 week, multicenter, randomized, double-blind, placebo-controlled, parallel-group, Phase 3 trial. Randomization was stratified by geographical region and presence of psoriatic arthritis (PsA).
- Prior to receiving the Week 12 data, all PASI 75 non-responder placebo patients were randomized to secukinumab 300 mg, while PASI 75 responder placebo patients continued on placebo. The secukinumab 75 mg dose was defined as a 70% or more reduction in the baseline PASI score.

RESULTS

Patient disposition

- A total of 543 patients were randomized globally including 441 Chinese patients. The data for Chinese patients who were randomized to either secukinumab 300 mg (n = 221), secukinumab 150 mg (n = 110), or placebo (n = 112) were analyzed here. The key secondary endpoint was PASI 90 response at Week 12.

Efficacy

- Secukinumab 300 mg and 150 mg groups showed higher efficacy in terms of PASI 75/100 and PASI 20/50/75 at Week 12 (Table 1) compared with placebo, at each visit up to Week 12 (Figure 2).
- The co-primary objectives of the study were met: secukinumab 300 mg and 150 mg were superior to placebo with respect to PASI 75 response at Week 12 (17.7% and 10.3%, respectively). The reduction in mean PASI score was 72.7 ± 15.5 and 70.1 ± 16.2 in the secukinumab 300 mg and secukinumab 150 mg groups, and none of the patients in the placebo group.
- Hyperuricemia 29 (13.1) 14 (12.7) 14 (12.7)
- Pruritus 17 (7.7) 4 (3.6) 7 (6.4)
- Mean absolute PASI scores up to Week 16, and their percentage change from Baseline, are presented in Table 1. 

Demographic and baseline characteristics

- In general, demographic and baseline characteristics were well balanced across groups (Table 1). The mean age of patients was 39.3 years and the majority were male (70.4%) with a mean BMI of 27.3 kg/m2. The mean body surface area (BSA) affected was 45.3% and mean PASI score was 26.7 ± 10.4. The majority of patients (69.6%) had a PASI >20 at Week 16.

Safety

- Incidence of treatment-emergent adverse events (AEs) was higher with secukinumab treatment relative to placebo and was comparable in the secukinumab 150 mg and secukinumab 300 mg up to Week 12 (Table 2).
- At Week 12, PASI 100 was achieved by 32.7% of patients in the secukinumab 300 mg group, and 20.1% patients in the secukinumab 150 mg group, and none of the patients in the placebo group.

REFERENCES


DISCLOSURES

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Table 1. Patient disposition and demographic baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Placebo (n = 110)</th>
<th>Secukinumab 150 mg (n = 110)</th>
<th>Secukinumab 300 mg (n = 221)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (Mean ± SD)</td>
<td>48.7 ± 10.4</td>
<td>48.2 ± 10.4</td>
<td>47.8 ± 10.4</td>
</tr>
<tr>
<td>Race – Asian, n (%)</td>
<td>177 (80.1)</td>
<td>84 (76.4)</td>
<td>89 (80.9)</td>
</tr>
<tr>
<td>Gender – Male, n (%)</td>
<td>107 (97.3)</td>
<td>104 (94.5)</td>
<td>156 (70.3)</td>
</tr>
<tr>
<td>Body weight, kg (Mean ± SD)</td>
<td>84.2 ± 13.8</td>
<td>84.1 ± 13.8</td>
<td>84.3 ± 13.8</td>
</tr>
<tr>
<td>BMI, kg/m² (Mean ± SD)</td>
<td>26.4 ± 3.0</td>
<td>26.0 ± 3.1</td>
<td>26.2 ± 3.0</td>
</tr>
<tr>
<td>PASI &gt;20, n (%)</td>
<td>157 (71.0)</td>
<td>81 (73.6)</td>
<td>115 (52.1)</td>
</tr>
<tr>
<td>Baseline PASI (Mean ± SD)</td>
<td>26.7 ± 10.4</td>
<td>25.2 ± 10.4</td>
<td>25.0 ± 9.3</td>
</tr>
<tr>
<td>% of patients with IGA mod 2011 0/1 score</td>
<td>54 (24.7)</td>
<td>54 (24.7)</td>
<td>54 (24.7)</td>
</tr>
<tr>
<td>Mean PASI score at Baseline (Mean ± SD)</td>
<td>26.7 ± 10.4</td>
<td>25.2 ± 10.4</td>
<td>25.0 ± 9.3</td>
</tr>
</tbody>
</table>
| Mean absolute PASI scores up to Week 16, and their percentage change from Baseline, are presented in Table 4.

Figure 2. Study design

Figure 3. Efficacy up to Week 16

Figure 4. Absolute PASI scores (A), and their percentage change from Baseline (B) up to Week 16

Figure 5. Patient disposition

Table 2. Treatment-emergent AEs up to Week 12

<table>
<thead>
<tr>
<th>AE Category</th>
<th>Placebo (n = 110)</th>
<th>Secukinumab 150 mg (n = 110)</th>
<th>Secukinumab 300 mg (n = 221)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All AEs</td>
<td>40 (36.4)</td>
<td>34 (30.9)</td>
<td>54 (24.4)</td>
</tr>
<tr>
<td>All non-fatal SAEs</td>
<td>22 (20.0)</td>
<td>18 (16.4)</td>
<td>31 (14.0)</td>
</tr>
<tr>
<td>Treatment emergent AEs</td>
<td>26 (23.6)</td>
<td>22 (19.1)</td>
<td>40 (18.1)</td>
</tr>
<tr>
<td>Most frequent AEsa</td>
<td>15 (13.6)</td>
<td>12 (10.9)</td>
<td>23 (10.4)</td>
</tr>
<tr>
<td>All AEs</td>
<td>40 (36.4)</td>
<td>34 (30.9)</td>
<td>54 (24.4)</td>
</tr>
</tbody>
</table>