Secukinumab in Moderate to Severe Hidradenitis Suppurativa: Primary Endpoint Analysis From the SUNSHINE and SUNRISE Phase 3 Trials

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SYNOPSIS
- Hidradenitis suppurativa (HS) is a chronic autoinflammatory keratinization disease of the skin involving the hair follicle characterized by nodules, abscesses and draining tunnels
- HS is characterized by high patient burden and a recognized need for novel therapeutic options
- The IL-17 pathway has been implicated as a key orchestration of inflammation in HS
- The SUNSHINE and SUNRISE studies investigated the efficacy and safety of secukinumab, an anti-IL-17A agent, in the treatment of moderate to severe HS

OBJECTIVE
- To describe the primary endpoint analysis (Week 16) results from SUNSHINE (NCT03713619) and SUNRISE (NCT03713632), two double-blind, identical, Phase 3 randomised controlled trials of secukinumab in patients with moderate to severe HS

METHODS

Study Design
- SUNSHINE and SUNRISE were two randomised, double-blind, multicentre studies assessing short (16 weeks) and long-term (up to 1 year) efficacy, safety, and tolerability of two secukinumab dosing regimens
- A total of 1084 patients (mean age 36.2, 56.3% female) across 219 sites worldwide were randomised in SUNSHINE (n=541) and SUNRISE (n=543)

RESULTS
- In each study, adult patients with moderate to severe HS were randomly assigned in a 1:1 fashion to receive secukinumab 300 mg every 2 weeks (SECQ2W or 4 weeks (SECQ4W), or placebo (Figure 1)

Endpoints/assessments
- Primary endpoint (week 16): To demonstrate superiority of secukinumab versus placebo based on HiSCR (defined as at least a 50% decrease in AN count with no increase in the number of abscesses and/or in the number of draining fistulae relative to baseline).
- Secondary endpoints (Week 16): Percentage change in AN count from baseline, flares, and achievement of NRS30 in patients with a baseline skin pain NRS ≥3 (defined as at least a 30% reduction and at least a 2-point reduction in patient baseline’s global assessment of skin pain at worst)
- Exploratory objectives: To evaluate long-term safety, efficacy, and tolerability of secukinumab and its effect on patient-reported outcomes (PROs) and biomarkers

Patient demographics and baseline characteristics
- N=541 (SUNSHINE) and N=543 (SUNRISE) randomized to 509 (94.1%) and 506 (93.2%) patients completed Treatment Period 1 (Week 16), respectively
- Discontinuation rate of treatment up to Week 16 was very low and balanced despite COVID-19 pandemic (Table 1)

Table 1. SUNSHINE and SUNRISE: Patient Disposition

<table>
<thead>
<tr>
<th>Disposition</th>
<th>SUNSHINE</th>
<th>SUNRISE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed Treatment Period 1</td>
<td>509 (94.1%)</td>
<td>506 (93.2%)</td>
</tr>
<tr>
<td>Completed Treatment Period 2</td>
<td>509 (94.1%)</td>
<td>506 (93.2%)</td>
</tr>
<tr>
<td>Discontinued treatment</td>
<td>13 (2.2%)</td>
<td>11 (2.1%)</td>
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</tbody>
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The proportion of patients experiencing flares was lower with secukinumab compared to placebo at all time points from Week 2 to Week 16, with a rapid onset of action starting at Week 2 in both studies (Figure 4)

Efficacy: Primary endpoints
- The primary endpoint was met in both the SUNSHINE and SUNRISE studies
- Greater response rates for secukinumab compared to placebo were seen at all time-points from Week 2 to Week 16, with a rapid onset of action by Week 2 (Figure 2)

• Secukinumab reduced skin pain in patients with moderate to severe HS (Figure 5) – NR30 was defined as a ≥30% reduction and a ≥22-point reduction in baseline Patient’s Global Assessment of Skin Pain. Only patients with a baseline NR30 were included in the analysis of skin pain.
• Pooled CRP levels demonstrate numerical reductions from placebo group

A larger treatment effect was achieved with secukinumab compared with the placebo regimen as early as Week 4 and sustained up to Week 16

Efficacy: Secondary endpoints
• In both studies, secukinumab reduced the abscess and inflammatory nodule count in patients with moderate to severe HS (Figure 3) – A decrease in AN count with secukinumab appeared as early as Week 2, and further improved up to Week 16 in both studies

Safety
- Secukinumab was well tolerated, consistent with the known safety profile in other approved indications

REFERENCES
1. Frej J. JAAD Int 2020;10:100-72

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