**ABSTRACT NUMBER: 961**

**Secukinumab Provides Sustained Improvements in the Signs and Symptoms of Active Psoriatic Arthritis through 3 Years: Efficacy and Safety Results from a Phase 3 Trial**

**Philip J Mease**, 1 Arthur Kavanaugh 2, Andreas Reimold 3, Hasan Tahir 4, Juergen Rech 5, Stephen Hall 6, Piet Geusens 7,8, Pellet Pascale 9, Evie Maria Delicha 10, Luminita Pricop 11 and Shephard Mpofu 12, 1 Swedish Medical Center and University of Washington, Seattle, WA, 2 UC San Diego School of Medicine, La Jolla, CA, 3 Dallas VA Medical Center and University of Texas Southwestern Medical Center, Dallas, TX, 4 Barts Health NHS Trust, London, United Kingdom, 5 Department of Internal Medicine 3 – Rheumatology and Immunology, Universitätsshospital Erlangen, Friedrich-Alexander-University Erlangen-Nürnberg (FAU), Erlangen, Germany, 6 Monash University, Melbourne, Australia, 7 University of Hasselt, Hasselt, Belgium, 8 Maastricht University Hospital, Maastricht, Netherlands, 9 Novartis Pharma AG, Basel, Switzerland, 10 Novartis Pharma AG, Basel, Switzerland, 11 Novartis Pharmaceuticals Corporation, East Hanover, NJ

Meeting: 2016 ACR/ARHP Annual Meeting

Date of first publication: September 28, 2016

Keywords: monoclonal antibodies, Psoriatic arthritis, randomized trials and safety

**SESSION INFORMATION**

**Date:** Sunday, November 13, 2016  
**Session Type:** ACR Concurrent Abstract Session  
**Session Time:** 2:30PM-4:00PM

**Background/Purpose:** Secukinumab, an anti-interleukin-17A monoclonal antibody, provided rapid and significant improvements in the key clinical domains of psoriatic arthritis (PsA) in the FUTURE 1 study (NCT01392326) with improvements sustained through 2 years. Here, we present efficacy and safety results through 3 years in the extension of the FUTURE 1 study.

**Methods:** A total of 606 adults with active PsA were randomized to receive secukinumab or placebo (PBO). Secukinumab patients (pts) received a 10 mg/kg i.v. loading dose at baseline (BL), Weeks (Wks) 2 and 4, and then either 150 mg s.c. (IV→150 mg) or 75 mg s.c. (IV→75 mg) every 4 wks. PBO was given on the same dosing schedule. At Wk 16 or Wk 24, based on Wk 16 clinical response, PBO-treated pts were re-randomized to receive secukinumab 150 or 75 mg s.c. At Wk 104, pts could enter the extension phase of the study. Efficacy results at Wk 156 are presented for pts that were originally randomized to secukinumab (n = 308). Clinical assessments at Wk 156 included: ACR20/50/70, PASI 75, DAS28-ESR, SF-36 PCS, HAQ-DI, dactylitis, and enthesitis. Multiple imputation was applied to missing binary variables. Summary statistics are based on relative frequencies for binary variables and mean (±SD) for continuous variables. Analyses stratified by anti-TNFα status (anti-TNFα-naive and anti-TNFα inadequate response [IR]) were pre-specified and reported as observed. Safety analysis is based on exposure adjusted incidence rate (EAIR). All pts (n = 587) who received ≥1 dose of study treatment through 156 wks were included in the
Results: Overall, 457 of the original 606 pts entered the extension study (including 308 originally randomized to secukinumab) of which 435 pts completed 156 wks (151 pts in IV – 150 mg group; 142 in IV – 75 mg group; 142 in PBO → secukinumab groups). At Wk 156, ACR 20/50/70 response rates were 76.8/54.9/32.9% with IV – 150 mg and 65.2/39.0/26.0% with IV – 75 mg, respectively. Sustained clinical improvements through Wk 156 were observed across other clinically important domains of PsA. Improvements were sustained in both anti–TNFα-naïve and anti–TNFα-IR pts (Table). Over the entire study period (mean [± SD] exposure to secukinumab of 1025.1 ± 372.7 days) the type, incidence and severity of adverse events (AEs) were consistent with those reported previously. 1 EAIRs for serious infections/infestations, candida infections, Crohn's disease, malignant/unspecified tumors, and major adverse cardiac events with secukinumab were 1.7, 1.2, 0.1, 0.9, and 0.7 per 100 pt-years, respectively.

Conclusion: Secukinumab provided sustained improvements in signs and symptoms and multiple clinical domains of active PsA in pts who completed 3 years of therapy. Secukinumab was well tolerated with a safety profile consistent with that previously reported. References: 1. Mease PJ, et al. Arthritis Rheumatol. 2015; 67 (suppl 10).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Secukinumab</th>
<th>Secukinumab</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IV – 150 mg</td>
<td>IV – 75 mg</td>
</tr>
<tr>
<td></td>
<td>(n = 161)</td>
<td>(n = 147)</td>
</tr>
<tr>
<td>ACR 20/50/70a (%) responders</td>
<td>76.8/54.9/32.9</td>
<td>65.2/39.0/26.0</td>
</tr>
<tr>
<td>PASI 75a,b (%) responders</td>
<td>75.6</td>
<td>58.6</td>
</tr>
<tr>
<td>DAS28-CRPc, mean change (SD)</td>
<td>–1.94 (1.3)</td>
<td>–1.85 (1.5)</td>
</tr>
<tr>
<td>SF-36 PCSc, mean change (SD)</td>
<td>6.0 (8.5)</td>
<td>5.5 (7.3)</td>
</tr>
<tr>
<td>HAQ-DIc, mean change (SD)</td>
<td>–0.43 (0.6)</td>
<td>–0.42 (0.6)</td>
</tr>
<tr>
<td>Resolution of dactylitisa,d (%)</td>
<td>88.1</td>
<td>86.8</td>
</tr>
<tr>
<td>Resolution of enthesitis a,d (%)</td>
<td>76.7</td>
<td>74.8</td>
</tr>
</tbody>
</table>

Table. Summary of Efficacy Results at Week 156
## Analysis by anti-TNFα status

<table>
<thead>
<tr>
<th></th>
<th>Anti-TNFα-naïve</th>
<th>Anti-TNFα-IR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Secukinumab</td>
<td>Secukinumab</td>
</tr>
<tr>
<td></td>
<td>IV → 150 mg</td>
<td>IV → 75 mg</td>
</tr>
<tr>
<td>(n = 120)</td>
<td>(n = 110)</td>
<td>(n = 41)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(n = 37)</td>
</tr>
<tr>
<td>ACR20/50/70 (% responders)</td>
<td>81.0/62.9/38.8</td>
<td>67.3/43.0/28.0</td>
</tr>
<tr>
<td>PASI 75 (% responders)</td>
<td>76.2</td>
<td>60.0</td>
</tr>
</tbody>
</table>

\(^a\)Multiple imputation (missing binary variables); \(^b\)Analysis performed in psoriasis subset pts, i.e. pts with psoriasis ≥3% body surface area at time of randomization (n = 89 in secukinumab IV → 150 mg and n = 82 in secukinumab IV → 75 mg); \(^c\)Observed data; \(^d\)Data from the pts with these symptoms at BL (dactylitis, n = 83 in secukinumab IV → 150 mg and n = 77 in secukinumab IV → 75 mg and enthesitis, n = 99 in secukinumab IV → 150 mg and n = 91 in secukinumab IV → 75 mg). ACR, American College of Rheumatology response criteria; BL, baseline; DAS28-CRP, Disease Activity Score 28 using C-reactive protein; HAQ-DI, Health Assessment Questionnaire Disability Index; IV, intravenous; n, number of pts in the extension study; PASI, Psoriasis Area-and-Severity Index; SF-36 PCS, short form-36 physical component summary.