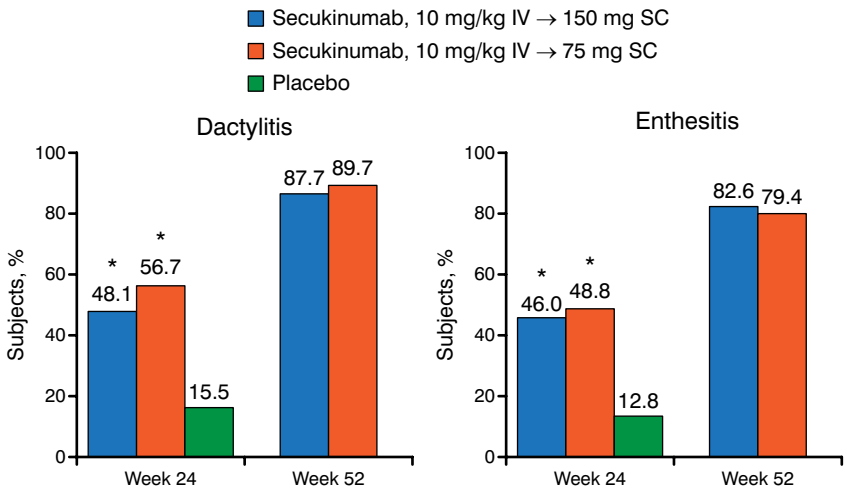
Figure 2. Resolution of Dactylitis and Enthesitis at Weeks 24 and 52



IV, intravenous; SC, subcutaneous.

*P<.0001 vs placebo.

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including PASI 75 and PASI 90, DAS28-CRP, resolution of dactylitis and enthesitis, HAQ-DI scores, SF-36 scores, and ACR50/70. For example, ACR50 responses at week 24 were 34.7% and 30.7% for patients treated with 150 mg and 75 mg of secukinumab and were sustained at 50.0% and 38.4%, respectively, at week 52. The ACR70 responses at week 24 were 18.8% and 16.8%, respectively, and 28.2% and 25.6%, respectively, at week 52 (Figure 2).

Serious infections occurred at the rate of 2.9, 2.6, and 1.4 events per 100 patient-years in the 150-mg, 75-mg, and placebo groups, respectively. Dr Mease highlighted a few cases of mild to moderate candida infections and neutropenia, adverse events known to be specifically related to IL-17 inhibition. Dr Mease stated that based on the overall safety data, secukinumab is overall well tolerated with no unexpected safety findings and low immunogenicity.

FUTURE 1: Secukinumab Inhibits Radiographic Disease Progression in PsA

Written by Mary Beth Nierengarten

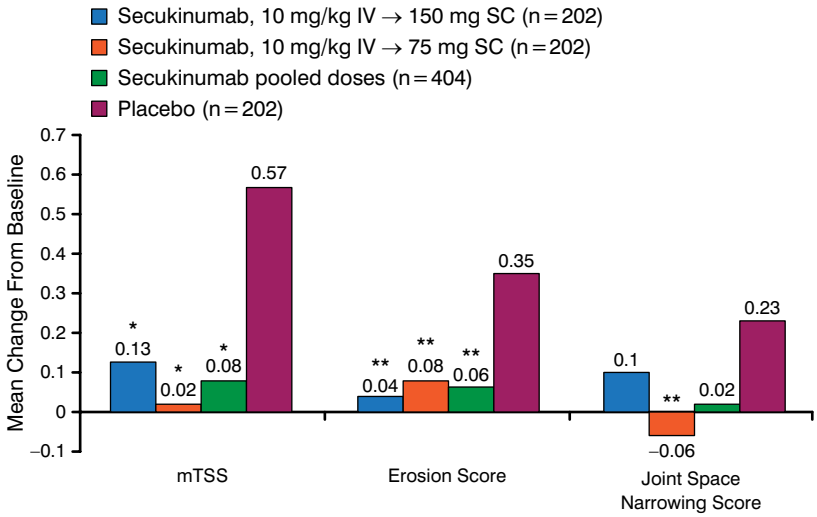
In patients with psoriatic arthritis (PsA) treated with secukinumab, radiographic progression of joint structural damage at 24 weeks was significantly inhibited compared with placebo, an effect sustained through 52 weeks of treatment. Desiree van der Heijde, MD, Leiden University Medical Center, The Netherlands, presented the relevant radiographic data for the Efficacy at 24 Weeks and Long-Term Safety, Tolerability, and Efficacy up to 2 Years of Secukinumab (AIN457) in Patients With Active Psoriatic Arthritis (PsA) trial [FUTURE 1; NCT01392326]. Prof van der Heijde focused on one of the secondary outcomes of the study, radiographic analysis at week 24 (primary analysis) and radiographic analysis at week 52 (secondary analysis).

FUTURE 1 was a multicenter, randomized, placebo-controlled phase 3 study in which 606 patients with PsA received an intravenous loading dose of secukinumab at 10 mg/kg every 2 weeks for the first 4 weeks, followed by subcutaneous doses of 75 mg (n = 202) or 150 mg (n = 202) monthly, compared with placebo (n = 202).

Radiographic assessment was based on the modified total Sharp score (mTSS), with total scores ranging from 0 to 528, consisting of erosion scores (maximum score of 360) and joint space narrowing (JSN) scores (maximum score of 168); the higher scores indicate more articular damage. Baseline characteristics of the 3 treatment groups (secukinumab 150 mg, secukinumab 75 mg, and placebo), focusing on the radiographic variables, showed that the mean mTSS was about 20 in all groups, albeit a little higher in the placebo group; roughly half of this score was due to erosions and half to JSN. About 70% of patients were anti-tumor necrosis factor (TNF) naïve, and about 60% were using concurrent methotrexate (MTX).

Using the mTSS, radiographic assessment was done on each hand/wrist and foot at baseline and at weeks

Figure 1. Secukinumab Significantly Inhibits Radiographic Disease Progression at Week 24



IV, intravenous; mTSS, modified total Sharp score; SC, subcutaneous.

*$P < .05$ vs placebo (P values at week 24 adjusted for multiplicity of testing).

**$P < .05$ vs placebo.

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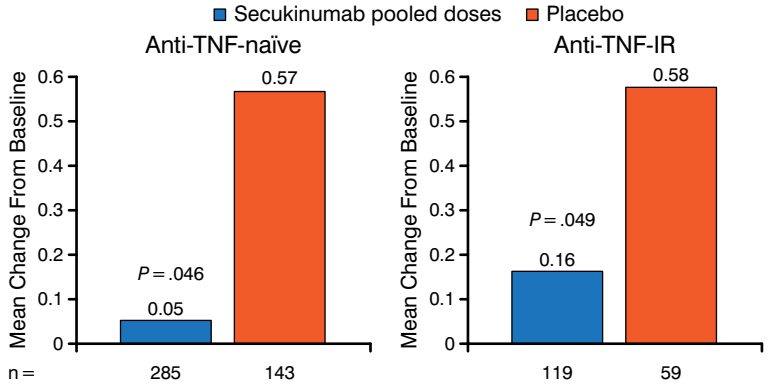
Figure 2. Significant Radiographic Progression Inhibition With Secukinumab Regardless of Tumor Necrosis Factor Status



Full analysis set using nonparametric analysis of covariance with linear extrapolation for missing values at week 24; anti-TNF-IR: subjects with inadequate response or intolerance to previous therapy with an anti-TNF.

IR, inadequate responder; TNF, tumor necrosis factor.

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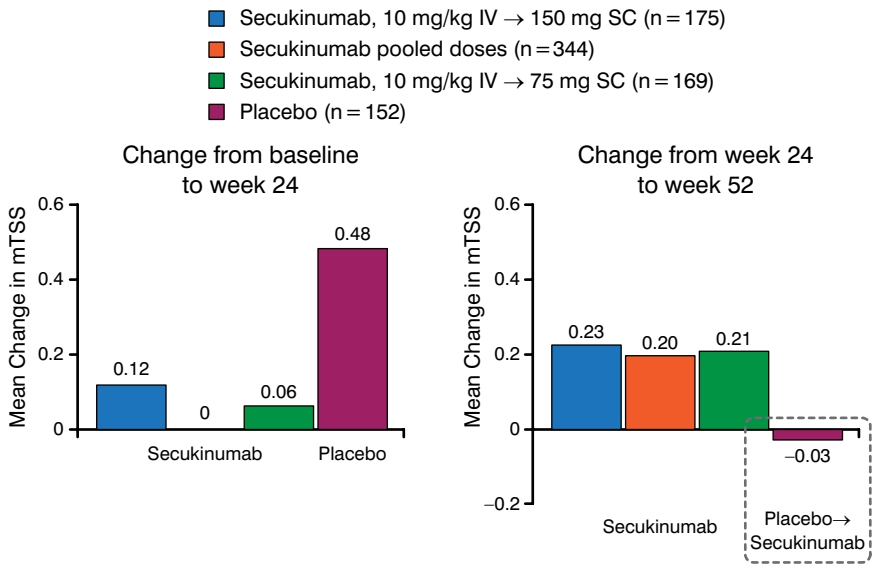
16/24 and 52. Among radiographic completers, 75% of patients completed radiographs up to 52 weeks and >94% completed radiographs up to 24 weeks.

The results of the study found that secukinumab significantly inhibited radiographic disease progression at week 24 compared with placebo, both when looking at the combined mTSS of the 150 and 75 mg secukinumab groups as well as each dose group separately (all $P < .05$; Figure 1).

When looking at a prespecified analysis of radiographic progression based on anti-TNF status, the study found significant radiographic progression inhibition in patients treated with secukinumab regardless of TNF status (Figure 2).

The study also found that patients treated with secukinumab had sustained inhibition of radiographic disease progression from baseline through week 52,

Figure 3. Inhibition of Radiographic Disease Progression Sustained Through Week 52 With Secukinumab[a]



IV, intravenous; mTSS, modified total Sharp score; SC, subcutaneous.

Radiographic disease progression was inhibited in placebo-treated subjects upon switching to secukinumab.

[a]X-ray completers (those subjects who had X-ray measures at baseline, week 16/24, and week 52).

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and that radiographic disease progression was inhibited between 24 and 52 weeks in patients initially treated with placebo who switched to secukinumab (Figure 3).

The inhibition of structural damage seen with secukinumab was seen in patients regardless of prior treatment with TNF inhibitor, or concurrent MTX use.

Negative Results End Development Program of Treating JIA With GLM

Written by Mary Beth Nierengarten

Children with juvenile idiopathic arthritis (JIA) treated with subcutaneous golimumab (GLM) showed a rapid response during the initial 16 weeks of treatment, which resulted in inactive disease in 34% of the patients. Despite this response, at week 48, there was no difference in flare rate between patients who continued on GLM and those randomized to placebo.

Hermine I. Brunner, MD, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, USA, presented the 48-week results of the Study of the Safety and Efficacy of CNTO 148 (Golimumab) in Children With Juvenile Idiopathic Arthritis (JIA) and Multiple Joint Involvement Who Have Poor Response to Methotrexate [GO KIDS; NCT01230827].

The multicenter, double-blind, randomized-withdrawal phase 3 trial involved 2 parts. In the first part, 173 children with JIA received GLM 30 mg/m^2 every 4 weeks with methotrexate (MTX) until week 16. In part 2, children who achieved clinical response at week 16 were randomized to placebo or continued GLM from week 16 to week 48, with GLM given to patients in the placebo group on flare.

Patients included in this analysis were children aged 2 to 17 years with JIA, active arthritis involving ≥5 joints despite >3 months of MTX at 10 to 30 mg/m^2, disease duration of ≥6 months, and prior exposure to one anti–tumor necrosis factor drug or background therapy with a stable dose of prednisone.

Patients were excluded if they had current or prior uveitis, latent or active tuberculosis or other chronic infection, a history of severe progressive or uncontrolled liver or renal insufficiency (or significant other organ involvement), or a history of or current malignancy.

The primary end point of the study was the proportion of treatment responders at week 16 who did not display flare-up to week 48. Among the secondary end points was the proportion of patients with inactive disease status in part 2.

For part 1, the study found that 151 of 173 (87.3%) children achieved a 30% improvement from baseline in 3 of 6 criteria. Overall, 34.3% of children displayed inactive disease status at the end of part 1 of the study.