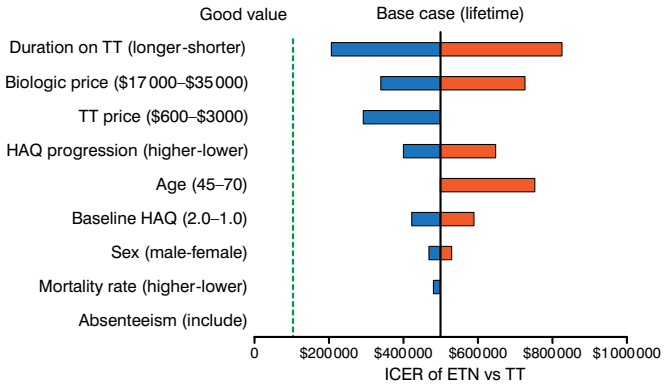
Figure 2. Sensitivity Analysis Showing No Cost-effectiveness With Etanercept



ETN, etanercept; HAQ, Health Assessment Questionnaire; ICER, incremental cost-effectiveness ratio; TT, triple therapy.

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The consequence, concluded Dr Bansback, is that money from taxes, copays, deductibles, and premiums could have been saved or spent elsewhere to produce additional health on more interventions that are cost-effective.

Efficacy of Secukinumab Sustained Over Time for Treatment of Active PsA

Written by Mary Beth Nierengarten

For patients with active psoriatic arthritis (PsA), treatment with secukinumab confers rapid clinical improvements in signs, symptoms, physical function, quality of life, and inhibition of radiographic disease progression.

Philip Mease, MD, Swedish Medical Center and University of Washington, Seattle, Washington, USA, presented the results of 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) study [FUTURE 1; NCT01392326].

FUTURE 1 is a multicenter, 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).

The primary end point of the study was the American College of Rheumatology 20% improvement response criteria (ACR20), indicating ≥ 20% improvement in signs and symptoms of PsA, at week 24.

Secondary end points included 75% and 90% improvement in Psoriasis Area and Severity Index score (PASI 75 and PASI 90), change from baseline in 28-joint Disease Activity Score (DAS28) using C-reactive protein (CRP), physical function assessed by SF-36 Health Survey physical component summary scores and by the Health Assessment Questionnaire Disability Index (HAQ-DI), ACR 50%/70% improvement response criteria (ACR50/70) response, proportion of patients with dactylitis and enthesitis, and overall safety and tolerability.

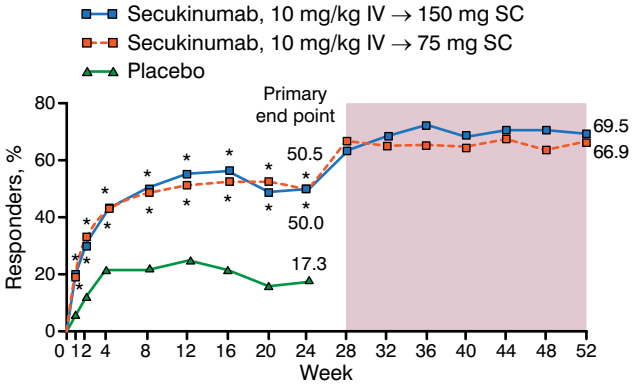
Of 606 patients, more than half were women, and the average age was 49 years. The mean weight was about 84 kg, and about 80% of patients were white.

The study found that significantly more patients achieved ACR20 response at week 24 than placebo (50.5% and 50.0% for secukinumab 75- and 150-mg treatment arms vs 17.3% for placebo; $P < .0001$). In addition, patients treated with secukinumab had improved clinical benefit as measured by the secondary end points.

Dr Mease focused some of his presentation on an exploratory analysis of FUTURE 1 that looked at the extended outcomes beyond week 24 to week 52. The study found that most of the patients treated with secukinumab at 75 mg and 150 mg who achieved ACR20 responses at week 24 also maintained the response at week 52 with continuation of treatment (66.9% and 69.5%, respectively; Figure 1).

The clinical benefits of secukinumab also extended to week 52 when looking at secondary end points,

Figure 1. Sustained Response to Secukinumab at Week 52



Missing values were imputed as nonresponse (nonresponder imputation) up to week 24. Observed data from week 28 to 52.

IV, intravenous; SC, subcutaneous.

*$P < .0001$ vs placebo (P values at week 24 adjusted for multiplicity of testing).

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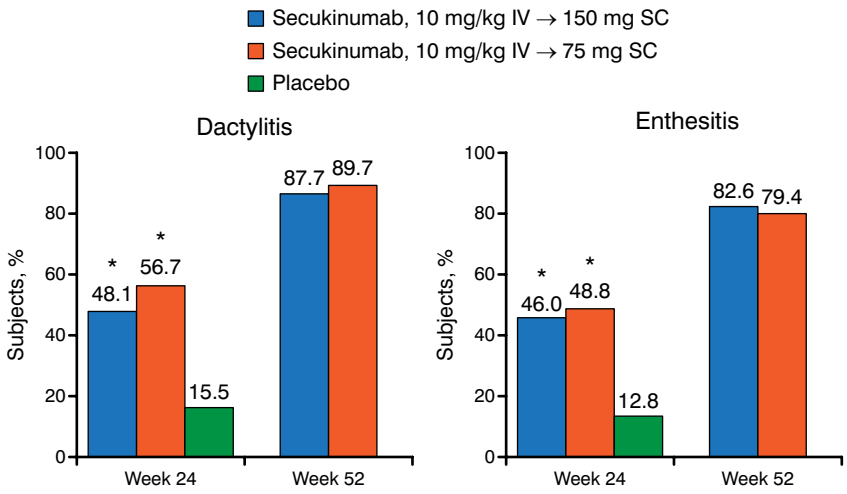
Figure 2. Resolution of Dactylitis and Enthesitis at Weeks 24 and 52



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