was also suggested that further evaluation of the potentially-increased GI toxicity of aspirin-NSAID therapy was needed.

54 Week Results from IMPACT 2: Infliximab Inhibits Progression of Radiographic Damage in Patients with Active Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic inflammatory arthropathy condition characterized by an association of arthritis and psoriasis that can lead to progressive joint damage, disability, and reduced life expectancy *(Rheumatol* 2003;42:1460–8). A substantial proportion of patients have persistent inflammation. The extent of radiographic progression in patients with established PsA is comparable with that of RA patients when matched for age, sex, and disease duration (*Rheumatol* 2001;28:1041–4).

Historically, the decision to use a particular treatment modality for PsA has been mainly derived from the extrapolation of data from patients with RA. Results from the recent Infliximab Multinational Psoriatic Arthritis Controlled Trial (IMPACT), indicated that therapy with infliximab (IFX) 5 mg/kg significantly improved the signs and symptoms of arthritis, as well as reduced skin psoriasis, in patients with active PsA resistant to prior DMARD therapy (*Arthritis Rheum* 2005;52:1227–36).

Using data from the 54 week IMPACT 2 trial data, the authors assessed the effect of IFX 5mg/kg compared with a placebo on structural damage in 200 PsA patients. Radiographic data was obtained from hand and feet measurements at weeks 0, 24, and 54. Erosions and joint space narrowing were evaluated by the van der Heijde-Sharp method modified for PsA.

Radiographic data indicated that IFX was an effective inhibitor of radiographically documented progression of joint structural damage. At week 24, IFX-treated patients had significantly less radiographic damage than placebo patients (mean change in total van der Heijde-Sharp score = -0.70 ± 2.53 vs 0.82 ± 2.62, p<0.001). Twelve placebo-treated patients vs 3 patients in the IFX group had changes in the total van der Heijde-Sharp scores exceeding the the smallest detectable change at week 24 (p = 0.017). In patients continued on IFX through week 46, mean change was –0.94 vs 0.53 in patients who crossed over from placebo to IFX (p=0.001). These results indicate that IFX provides effective inhibition of radiographic progression in PsA patients as early as 24 weeks and continues to provide protection after 1 year of treatment.

The ATLAS Trial: Long-Term Adalimumab Treatment Reduces Signs and Symptoms in Ankylosing Spondylitis Patients

The Adalimumab Trial Evaluating Long-Term Efficacy and Safety in Ankylosing Spondylitis (AS) or ATLAS trial was a double-blind, phase III, placebo-controlled study to evaluate the ability of adalimumab to reduce signs and symptoms of AS over a one-year period. Patients with active AS refractory to at least one NSAID were given 40 mg adalimumab bi-weekly or placebo for 24 weeks.

Adalimumab efficacy was evaluated by ASsessment in AS (ASAS) 20 Criteria (inflammation, total back pain, function, and patient's global assessment of disease activity). The primary endpoint (ASAS20) was at Week 12, at which point patients had the option to switch to early escape therapy (EET) of open-label 40 mg adalimumab. One-year efficacy of ADA was assessed using the following analyses: 1) a non-responder imputation to Week 52 for

patients using EET (any EET patients and dropouts were considered non-responders), 2) observed data for all patients from baseline, and 3) observed data for only EET patients during the entire 1-year period.

Signs and symptoms of AS were reduced in patients treated with adalimumab in the first 12 weeks and improvements were sustained for 52 weeks. There were 66 placebo patients at week 12, 7 at week 16, and 2 at week 20 that switched to EET. By week 52, 88.6% of the patients remained in the study.

The Clinical Efficacy and Safety of Subcutaneous Oral Application of Methotrexate in Patients with Active Rheumatoid Arthritis — Results of a Randomized, Controlled, Double-Blind, Multi-Center Study

Although oral MTX for the treatment of RA has been shown to be effective, adverse events may lead to discontinuation of treatment. This study reports the 24-week comparison of the safety and efficacy of subcutaneous (sc) vs orally administered MTX in patients with active RA. Patients with insufficient oral responses were switched to sc application or dose augmentation after 4 months.

Patients were randomly assigned to 15 mg oral MTX (two 7.5 mg tablets + a dummy pre-filled syringe) or sc MTX (15 mg via a pre filled syringe at 10mg/ml + dummy tablets) given weekly until week 24. At week 16 ACR20 nonresponders were switched from oral MTX to 15 mg sc and from 15 mg MTX sc to 20 mg sc for the remaining 8 weeks in a blinded fashion, respectively. The primary outcome parameters were the ACR20 after 24 weeks. Secondary outcome parameters were ACR50/70/90 and DAS28/EULAR response criteria after 24 weeks, and time to onset of ACR20.

Only 15% of the patients were classified as ACR20 nonresponders at week 16 and switched medication. After 24 weeks the sc route of MTX application yielded a significantly higher efficacy in various relevant parameters including improvement in ACR20/50/70 response rates and EULAR response rates compared to the oral administration. Remission (defined as DAS28 <2.6) was achieved by 34% of the sc MTX patients compared with 24% of the oral MTX treated patients ($p<0.05$).

In this first of kind study, the authors concluded that MTX given sc is significantly more effective than the oral form.

Intensive Treatment with MTX of Early Rheumatoid Arthritis Patients is Beneficial When Compared to Conventional Treatment With MTX: A Two Year Study

Intensive treatment with MTX can increase the number of patients responding to treatment. In a two-year study conventional and intensive MTX treatment strategies were compared in the treatment of patients with early RA using a computer assisted program. In the conventional strategy, patients came to the outpatient clinic once every 3 months and were given an adjusted MTX dose based on daily practice.

In the intensive strategy, patients came to the clinic monthly and were given an adjusted dose of MTX tailored to the individual, aimed for remission, and based on predefined criteria (>20% improvement from the previous visit for the number of swollen joints, number of tender joints, ESR and VAS general well-being). In both groups, starting dose of MTX was 7.5 mg/wk and could be increased up to 30 mg/wk, if needed.

The computer program, used to determine the clinical response, was also evaluated in this study.

Continued on page 20