European League Against Rheumatism
London, 25–28 May

Certolizumab delivers for patients in real world situations

Certolizumab pegol (Cimzia) delivered rapid and consistent improvements in a broad range of rheumatoid arthritis patients after 12 weeks of treatment, regardless of whether or not they had received prior tumour necrosis factor-alpha inhibitors or whether or not they were receiving concomitant disease-modifying antirheumatic drugs. This was the conclusion of the latest analysis of the phase IIIb REALISTIC (RA Evaluation in Subjects Receiving TNF Inhibitor Certolizumab Pegol) trial presented at the EULAR meeting (abstract FRI0214).

'These results ... demonstrate the clinical usefulness of certolizumab pegol in a broad population of patients with rheumatoid arthritis and reflect the patient variability we see day-to-day in clinical practice,' said Dr Roy Fleischmann, one of the investigators, from the Department of Internal Medicine at the University of Texas Southwestern Medical School.

In previous studies of certolizumab pegol patient populations have been largely homogenous, with the treatment used either as monotherapy or as add-on therapy to methotrexate in rheumatoid arthritis patients who have had no prior exposure to tumour necrosis factor-alpha inhibitors.

In the REALISTIC trial, 1063 patients were randomized 4:1 to certolizumab pegol (n=851) or control (n=212). Patients, who were recruited from north America and western Europe, had active rheumatoid arthritis at screening and baseline defined by more than five tender joints, more than four swollen joints and C-reactive protein levels >10 mg/litre and/or erythrocyte sedimentation rates >28 mm/hour.

The main results of the REALISTIC study, presented at the American College of Rheumatology meeting in November 2010, showed that ACR20 response rates at week 12 were 51.1% in the certolizumab pegol group *vs* 25.9% in the placebo group (P<0.001).

In the current abstract investigators undertook a subgroup analysis of the REALISTIC data to investigate whether there were differences in efficacy for certolizumab pegol according to whether it was used in patients with and without prior tumour necrosis factor-alpha inhibitor use, and whether it was being used with or without concomitant disease-modifying antirheumatic drugs.

For patients who had used prior tumour necrosis factor-alpha inhibitors the ACR20 response rate was 47.2% for those randomized to certolizumab pegol *vs* 27.5% for those randomized to the control group (P<0.01). For patients with no prior tumour necrosis factor-alpha inhibitor use the ACR20 was 53.5% for those randomized to certolizumab pegol *vs* 25% for those randomized to the control group (P<0.0001).

'Based on these ACR20 responses we found no significant difference for patients with prior anti-tumour necrosis factor-alpha and no prior anti-tumour necrosis factor-alpha,' said Professor Paul Emery, from Leeds Teaching Hospital, Leeds, president of EULAR and a REALISTIC study investigator.

Furthermore, in a post-hoc analysis investigators found no significant difference in ACR20 results regardless of whether patients received monotherapy, one concomitant disease-modifying antirheumatic drug or two concomitant disease-modifying antirheumatic drugs.

A second abstract study (EULAR 11-6261) showed that week 12 ACR20 responses were similar in certolizumab pegol patients regardless of whether they had discontinued prior tumour necrosis factor-alpha inhibitors because of a lack of efficacy or intolerance (49.7% *vs* 52.6%) and also that ACR20 rates were similar regardless of the number of prior tumour necrosis factor-alpha inhibitors patients had received – with 46.7% of patients who had one prior treatment achieving ACR20 *vs* 48.3% who had two prior treatments.

'The study is good news for patients with rheumatoid arthritis because regardless of their prior treatment history they stand a similar chance of responding to certolizumab pegol,' said Professor Emery.

UCB plans to launch the first industry-sponsored anti-tumour necrosis factor-alpha head to head study. This will randomize patients to receive either certolizumab pegol plus methotrexate or adalimumab plus methotrexate for 12 weeks, after which patients who respond will continue on their treatment, while non-responders will switch.

Janet Fricker

Weinblatt ME, Fleischmann R, van Vollenhoven R et al (2011) Certolizumab pegol as monotherapy or with concomitant DMARDs in patients with active rheumatoid arthritis (RA) with or without prior TNF inhibitor use: analyses of the REALISTIC 12-week Phase IIIb randomised controlled study. Poster FRI0214 presented at the EULAR Congress, London: 25–28 May

Musculoskeletal disease needs 'radical reform' of management

UK arthritis experts have condemned the government for failing to meet the needs of millions of people with musculoskeletal diseases in England, causing pain and unnecessary suffering for the largest group of people living with long-term conditions.

Arthritis Care, supported by Professor Paul Emery, President of EULAR, is calling on the Department of Health in England to radically reform the management of musculoskeletal diseases to stop the worrying variations in services, the waste of NHS money and, most importantly, poor patient outcomes.

Arthritis Care has published a report, *Get a grip: making the case for a national strategy for musculoskeletal disorders*, which can be downloaded from www.arthritiscare.org.uk The development and printing of the report was sponsored by Roche Products Ltd and Chugai Pharma UK Ltd.