Patients taking certolizumab pegol are twice as likely to achieve ACR20 compared to placebo

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A new Phase III study presented today at EULAR 2012, the Annual Congress of the European League Against Rheumatism, shows that patients treated with certolizumab pegol (CZP) were twice as likely to meet the primary endpoint of ACR20* response at week 12 than those on placebo: 58% on CZP200mg Q2W; and 51.9% on CZP 400 mg Q4W compared to 24.3% on placebo.

This randomised, placebo controlled, 24 week period of an ongoing Phase III study of 409 patients indicated that more patients treated with both doses of CZP achieved ACR50* and ACR70* response compared to placebo (CZP 200mg Q2W: 36.2%, CZP 400mg Q4W: 32.6%, PBO: 11% for ACR50, CZP 200mg Q2W: 24.6%, CZP 400mg Q4W: 12.6%, PBO: 2.9% for ACR70). HAQ-DI** scores were also higher in the combined CZP groups at week 24. In addition patients treated with both doses of CZP also showed greater improvements in PASI 75*** than placebo (62.2% and 60.5% respectively vs 15.1%).

"We know that certolizumab is effective in rheumatoid arthritis but this is the first study to review its efficacy and safety in psoriatic arthritis," commented Dr. Mease, University of Washington, USA and lead author of the study. "Not only were the signs and symptoms of arthritis improved, but so too were patients' physical function and skin manifestations, which is a great breakthrough for us and our patients."

The study followed 409 patients with active psoriatic arthritis who had failed one or more disease modifying anti-rheumatic drugs (DMARDs) including a maximum of one anti-TNF. Patients were randomised 1:1:1 to placebo, or started on a loading dose of 400mg CZP every two weeks for the first four weeks then continued either on 200mg CZP Q2W or 400mg CZP Q4W. Patients receiving placebo who failed to achieve a ≥10% improvement in tender joint count (TJC) and swollen joint count (SJC) at both weeks 14 and 16 were rescued and randomized to one of the CZP arms following loading dose.

CZP use in psoriatic arthritis was associated with a similar safety profile to what has been observed in rheumatoid arthritis. Adverse events occurred at the rates of 68% for the placebo group versus 62% for the combined CZP group, and serious adverse events at 4% for the placebo group versus 7% for the combined CZP group. Two deaths occurred during this 24 wk double-blind phase of the study, one sudden death of unknown cause (CZP 400mg Q4W) and one myocardial infarction (CZP 200mg Q2W).

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*ACR (American College of Rheumatology) criteria measures improvement in tender or swollen joint counts and improvement in three of the following five parameters: acute phase reactant (such as sedimentation rate), patient assessment, physician assessment, pain scale and disability/functional questionnaire. ACR20 refers to a 20% improvement in tender/swollen joint counts, as well as three of the five other criteria. ACR50 refers to a 50% improvement and ACR70 refers to a 70% improvement.

**HAQ DI (Health Assessment Questionnaire – Disease Index) is a patient questionnaire that measures function and health-related quality of life through measuring a patient's ability to perform everyday tasks

***PASI (Psoriasis Area and Severity Index) is an index used to express the severity of psoriasis. It combines the severity (erythema, induration and desquamation) and percentage of affected area. PASI 75 is equal to a 75% reduction in the PASI score and is the current benchmark of primary endpoints for most clinical trials of psoriasis.

Provided by European League Against Rheumatism