Significant improvements in psoriatic arthritis with ustekinumab

June 12 2013

New PSUMMIT 2* data first presented at EULAR 2013, the Annual Congress of the European League Against Rheumatism, further demonstrate the efficacy of ustekinumab in Psoriatic Arthritis (PsA).

Anti-TNF naïve and anti-TNF-experienced patients randomised to one of two ustekinumab doses (45mg or 90mg) demonstrated significant and sustained improvements in the signs and symptoms of PsA, with favourable safety profiles.

PsA is a chronic inflammatory arthritis associated with psoriasis which significantly impacts health-related quality of life and function in patients, and increases risk of co-morbid cardiovascular and gastrointestinal diseases.2 Prevalence of psoriasis varies from 0.3% to 3% of the population, with PsA occurring in 25% of cases.3

Lead author of the study Dr Christopher Ritchlin, University of Rochester Medical Centre, Rochester, US, commented "While the development of anti-TNF treatments has drastically improved the treatment of PsA, there are still substantial numbers of patients who fail to respond to therapy. That ustekinumab demonstrates improvements not just in anti-TNF-naïve patients, but in those who have been treated with one or more drugs, shows that it has the potential to fulfil a significant unmet patient need."

312 adults with active PsA were randomised to ustekinumab 45mg or 90mg (week 0, week 4 and every 12 weeks subsequent to Week 40) or

placebo (week 0, week 4 and week 16) followed by crossover to ustekinumab 45mg (week 24, week 28 and week 40). The primary endpoint was ACR20† at week 24; secondary endpoints were HAQ-DI, ACR50, ACR70 and >75% improvement in the Psoriasis Area and Severity Index (PAS175).‡

Anti-TNF-experienced patients in PSUMMIT 2 had more active disease at baseline than anti-TNF naïve. At week 24, more patients treated with ustekinumab than placebo had achieved ACR20 (combined 43.8%; 45mg 43.7%; 90mg 43.8%; placebo 20.2% – all p>0.001). Efficacy was sustained at week 52, with patients on 45mg, 90mg and placebo -ustekinumab reaching ACR20 (46.8%, 48.4% and 55.8% respectively).

Efficacy demonstrated was more robust in anti-TNF-naïve (ACR 20 59-73%) than anti-TNF-experienced (37-41%) patients, and patients who had previously received one (50-55%) vs. two (13-39%) or three or more (13-30%) agents.

Ustekinumab was well tolerated with no deaths or TB and similar rates of adverse events (45mg 78.6%; 90mg 77.9%), serious adverse events (45mg 5.8%, 90mg 5.8%) and adverse events leading to discontinuation (45mg 5.8%, 90mg 3.8%) reported through to week 60.

More information: * PSUMMIT II, Phase 3 Multicenter, Randomized, Double-blind, Placebo-controlled trial of Ustekinumab, a Fully Human anti-IL-12/23p40 Monoclonal Antibody, Administered Subcutaneously, in Subjects with Active Psoriatic Arthritis Including Those Previously Treated with Biologic Anti-TNF-alpha Agent(s)

† 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 in three of the five criteria. ACR50 and ACR70 refer to 50% or 70% improvement respectively

‡HAQ-DI, Health Assessment Questionnaire for Rheumatoid Arthritis. PASI, Psoriasis Area Severity Index; index used to express the severity of psoriasis. It combines the severity (erythema, induration and desquamation) and percentage of affected area

1. Ritchlin C et al., Maintainence of efficacy and safety of ustekinumab in patients with active psoriatic arthritis despite prior conventional nonbiologic and anti-TNF biologic therapy: 1 yr results of the PSUMMIT 2 trial [abstract]. EULAR Annual European Congress of Rheumatology; 12-15 June 2013; Madrid, Spain. Abstract nr. OP0001

2. Gladman DD. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. Ann Rheum Dis. 2005; 64:ii14-ii17

3. Zachariae H. Prevalence of joint disease in patients with psoriasis: implications for therapy. Am J Clin Dermatol. 2003;4:441=7

Provided by European League Against Rheumatism