Patients with PsA treated with ustekinumab are twice as likely to achieve acr20 vs. 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 with active psoriatic arthritis (PsA) treated with Ustekinumab (UST) 90mg were more than twice as likely to achieve the study's primary endpoint, ACR20* at 24 weeks, than those treated with placebo (49.5% vs 22.8%). 42.4% of patients treated with UST 45mg were also more likely to achieve ACR20 at 24 weeks compared to placebo.

Significant improvements were also seen with UST 45mg and 90mg in ACR50* (24.9% and 27.9% respectively vs 8.7%), in ACR70* (12.2% and 14.2% respectively vs 2.4%) and in DAS28-CRP** responses at week 24 vs placebo (65.9% and 67.6% for UST 45mg and 90mg respectively vs 34.5%). Changes from baseline in HAQ-DI*** at week 24 were also significantly greater in patients treated with UST versus placebo and for a greater proportion of patients these changes were clinically meaningful (≥0.3).

In addition, patients in the UST groups who were affected with enthesitis (n=425) or dactylitis (n=286) at baseline, showed greater improvements at week 24 than those in the placebo groups.

"There are a number of patients with psoriatic arthritis who do not respond to currently available treatment options, including biologic medicines targeting TNF. As physicians, we struggle to manage such people as well as we would like," commented Professor Iain McInnes, lead study author from University of Glasgow, Scotland. "The

development of this new medicine is a welcome step forward. These results highlight not only Ustekinumab's efficacy but also its promising safety profile. We look forward now to seeing how it compares in trials with standard treatments."

Safety profiles were similar between the two groups. The proportion of patients suffering from one or more adverse events was 41.8% in the UST group compared to 42% in the placebo group. Infections were the most common adverse event; serious adverse events (>1) were reported in 1.7% UST and 2% placebo of patients.

This double-bind placebo controlled trial followed 615 patients with active PsA (≥5 swollen joint counts and ≥5 tender joint counts; c-reactive protein ≥0.3mg/dL) despite treatment with disease modifying anti-rheumatic drugs (DMARDs) and/or non-steroidal anti inflammatory drugs (NSAIDs). Patients were randomised to UST 45mg, 90mg or placebo at weeks zero, four and 12 weeks thereafter. At week 16, patients with