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Phase III data: STELARA reduces active psoriatic arthritis

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Singapore: A study by Janssen Research and Development revealed that patients with active psoriatic arthritis, who were treated using Centocor's STELARA (ustekinumab), witnessed substantial improvements in signs and symptoms of the disease.

Data from the 615-patient phase III trial, which was presented at the European League Against Rheumatism (EULAR) Annual Congress, highlighted that patients who received STELARA 45 mg and 90 mg achieved the primary endpoint of the study, a significant reduction in arthritis signs and symptoms at week 24.

STELARA, a interleukin (IL)-12/23 inhibitor, also led to significant improvements in physical function, including dactylitis and enthesitis, which are the two common manifestations of psoriatic arthritis casusing pain and swelling.

STELARA is currently being investigated in a phase III program for the treatment of active psoriatic arthritis and is approved for the treatment of moderate-to-severe plaque psoriasis in 65 countries. The EULAR press committee selected the STELARA

psoriatic arthritis study findings to be presented during the official EULAR press conference on Friday, June 8, 2012.

Dr Iain B McInnes, professor, University of Glasgow, and a study investigator, said that, "Some 15 percent of patients living with psoriasis of the skin will develop psoriatic arthritis. This is a challenging disease that causes great distress for those afflicted, for which we currently have too few treatment options. We look forward to additional data from the phase III psoriatic arthritis clinical development program to allow us to more fully assess the efficacy and safety of STELARA in the treatment of this complex inflammatory disease."

The phase III 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 (PSUMMIT I) study, also assessed the efficacy of STELARA in the treatment of moderate to severe plaque psoriasis.

Treatment with STELARA was generally well-tolerated with similar proportions of patients experiencing at least one adverse event (AE) through week 16, the placebo-controlled period, among those receiving STELARA (42 percent) and placebo (42 percent). Serious AEs were reported in two percent of STELARA-treated patients and two percent of patients receiving placebo.

No malignancies, cases of tuberculosis, serious infections, opportunistic infections, major adverse cardiovascular events (MACE) or deaths occurred through the placebo-controlled portion, week 16 of the study; one stroke occurred in the STELARA 45 mg group after the placebo-controlled period.