

Abbott reveals 10-year study data for HUMIRA

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Singapore: Abbott revealed the results from two long-term, open-label studies, which evaluated the results of HUMIRA

(adalimumab) treatment for up to 10 years in patients with long-standing, moderate-to-severe rheumatoid arthritis (RA). The studies, named DE019 and DE020, are among the longest, open-label trials in RA.

Results were presented at the European League Against Rheumatism (EULAR) 2012 Congress in Berlin, Germany. The results include information on clinical response, radiographic inhibition and physical function data in patients with long-standing RA. Abbott's global clinical trial database for HUMIRA is extensive and includes more than 14,000 RA patients representing more than 23,000 patient years of exposure to the medication.

In both studies, named DE019 and DE020, patients were assessed for improvements in signs and symptoms of the disease, such as joint pain, swelling and stiffness, as well as physical function and achievement of clinical remission. Following up to 10 years of HUMIRA therapy, patients in the studies continued to maintain improvements in disease activity.

In both the studies, DAS28 (CRP) <2.6, a measure of clinical remission, was observed in more than half of patients who continued on HUMIRA for up to 10 years (59.6 percent and 57.2 percent, respectively). A DAS28 score of <2.6 as a measure of clinical remission is supported by both EULAR and the American College of Rheumatology (ACR).

DE019 also assessed the ability of HUMIRA to inhibit radiographic progression. Patients who completed 10 years of treatment and also had X-rays available at baseline and year 10 demonstrated an average change of 2.8 in modified total Sharp score (mTSS), a measure of radiographic inhibition. In this study, patients who were initially treated with HUMIRA plus methotrexate (MTX) for the first year had less radiographic progression (measured as mean change in mTSS) at year 10 compared with patients who initially received placebo plus MTX. This result was driven by the change in mTSS during the one year randomized controlled trial.

Clinical outcomes were assessed by Disease Activity Score 28 (DAS28), which is a composite index that includes variables such as the number of tender and swollen joints and either erythrocyte sedimentation rate or C-reactive protein (CRP), both of which are measures of inflammation.

Dr John Medich, divisional vice president, clinical development, immunology, Abbott, said that, "Many patients with RA are not diagnosed early in the disease process and then may not be treated as quickly as they should, which can result in long-term, and sometimes irreversible, effects of the disease. These long-term results on clinical response and radiographic inhibition provide additional data about the use of HUMIRA in long-standing RA and further demonstrate Abbott's continued commitment to improving the standards of care for patients with the disease."