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US study shows that tofacitinib is an efficacious treatment for active RA

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Results of a Phase III study presented today at the EULAR 2011 Annual Congress show that at 6 months, 58.3 percent of patients who had previously not responded to treatment with DMARDs, achieved ACR20 response (a 20 percent improvement in symptoms) when treated with the novel oral Janus kinase inhibitor tofacitinib at 10mg BID compared to 31.2 percent in the placebo group. Significant improvements were also observed in the 5 mg BID dose.

Most adverse events were mild and no new safety signals were reported, according to study authors.

Results of the 12 month multinational study, conducted with 792 patients also show that 36.6% and 16.2% of patients achieved ACR50 and ACR70 responses respectively in the 10mg BID group, a significant improvement in symptoms compared to placebo, where 31.2%, 12.7% and 3.2% of patients achieved ACR 20, 50 and 70 respectively. Significant improvements in the Disease Activity Score physician index (DAS28) were also observed in the treatment groups compared to placebo, along with improvements in the Health Assessment Questionnaire (HAQ) compared to placebo.

"We know that JAK plays a fundamental role in the signalling pathways that regulate RA and interrupting the uncontrolled inflammatory cascades seen in this study provides a novel way of modifying the progression of the disease said Professor Joel Kremer of the Albany Medical College in Albany USA. "Tofacitinib appears to reduce the

signs and symptoms of RA very rapidly, and we hope that after carefully considering the benefit/risk equation that this compound will provide an additional valuable treatment option for patients who have experienced an inadequate response to prior treatments."

According to researchers, significant ACR 20, ACR50 and ACR70 responses were seen after 2 weeks of therapy (results not published). Patients received concurrent non-biologic background therapy with DMARDs (including methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, penicillamine and gold, both as single agents and as combination therapies). 81.4% of the 792 patients studied were female, with ages ranging between 50.8-53.3 years. Whilst the majority of adverse events reported were mild (infections and infestations), four deaths were reported in the 5 mg and 10mg BID arms. Four opportunistic infections were also reported.

Results of a separate study shows promising results in several patient subgroups

Results of a further, multinational Phase III tofacitinib study (SAT0243) of 610 patients analysing selected subgroups in the USA have shown that clinically significant efficacy and safety was demonstrated in a number of subgroups investigated, including age, weight, prior DMARD status and the presence of RF / anti-CCP antibodies. Of note, patients who were younger (those aged up to 65 years), slimmer (those weighing less than 50kg), those testing positive to anti-CCP and negative to Rheumatoid Factor showed an improved response to 5mg or 10mg tofacitinib compared to placebo.

Provided by European League Against Rheumatism