

ROCHE - CHUGAI, RoActemra monotherapy Superior to Humira: ADACTA Study

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Abstracts

In a Ph IV ADACTA monotherapy study, RoActemra has shown superior improvement compared to Humira in signs and symptoms of rheumatoid arthritis. The study enrolled 326 severe rheumatoid arthritis patients who are intolerant to Methotrexate. ADACTA Study met its primary endpoint of a superior reduction in the mean change from baseline in the DAS28 score at 24 weeks and the key secondary endpoints of DAS28 remission and low disease activity, ACR20, 50 and 70. Adverse effects were similar between the groups, however we await to see the differences in the two drugs on the serious safety issues front. One in every three RA patient on biologic agent is intolerant to RA, hence an approval in this market would give access to 33% of the biologic RA market (~ \$10B). The data should support Roche's sNDA for 1st line approval in the US (submitted in December -2011), while in EU where Actemra is already approved in first line, Roche will file for a label change based on this data.

Contents

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