European Medicines Agency
*Pre-Authorisation Evaluation of Medicines for Human Use*

London, 20 November 2008
Doc.Ref. EMEA/CHMP/580914/2008

**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE**
**SUMMARY OF POSITIVE OPINION***
**for**
**ROACTEMRA**

International Nonproprietary Name (INN): ***tocilizumab***

On 20 November 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product RoActemra, 20 mg/ml concentrate for solution for infusion intended for treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients. The applicant for this medicinal product is Roche Registration Limited.

The active substance of RoActemra is tocilizumab, an immunosuppressant, interleukin inhibitor (ATC code: L04AC07). RoActemra is a recombinant humanised anti-human interleukin-6 receptor (IL-6R) monoclonal antibody of the immunoglobulin IgG1 subclass. It blocks the activity of interleukin-6 (IL-6), which is a multi-functional cytokine, produced by a variety of cell types and involved in T-cell activation, induction of acute phase proteins and stimulation of haematopoiesis.

The benefits with RoActemra are the alleviation of the signs and symptoms of RA. The most common side effects are upper respiratory tract infections, nasopharyngitis, headache and hypertension. Main recognised risks with tocilizumab therapy are infections, gastrointestinal disorders, infusion reactions, skin disorders, neutropenia, elevation in hepatic enzymes and lipid parameters. A pharmacovigilance plan for RoActemra, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "RoActemra, in combination with methotrexate (MTX) is indicated for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. In these patients, RoActemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate."

Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of RA. Patients treated with RoActemra should be given the Patient Alert Card.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for RoActemra and therefore recommends the granting of the marketing authorisation.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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