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

London, 25 June 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
SIMPONI

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

On 25 June 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Simponi 50 mg solution for injection in a pre-filled pen and Simponi 50 mg solution for injection in a pre-filled syringe intended for the treatment of rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS) in adult patients. The applicant for this medicinal product is Centocor B.V.

The active substance of Simponi is golimumab, a tumor necrosis factor alpha (TNF-α) inhibitor (ATC Code L04AB06). Golimumab is a human immunoglobulin G1κ (IgG1κ) monoclonal antibody that binds with high affinity and specificity to both soluble and transmembrane forms of TNF-α, thereby neutralizing the biological activity of TNF-α. Abnormally high levels of TNF-α have been implicated in the pathophysiology of several immune-mediated diseases, including RA, PsA, and AS.

The benefits with Simponi are its improvement of signs and symptoms of patients with moderate to severe, active RA and those with active and progressive PsA who had inadequate response to previous DMARD therapy. Simponi also improves symptoms in patients with severe, active AS. The most common side effects are bacterial or viral infections, as well as general disorders and administration site conditions (e.g. pain, pyrexia). Main identified or potential risks include (serious) infections including tuberculosis and opportunistic infections, malignancy, congestive heart failure, hypertension, demyelinating disorders, hepatotoxicity, serious systemic hypersensitivity and autoimmune processes.

A pharmacovigilance plan for Simponi, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indications are:

"Rheumatoid arthritis (RA): Simponi, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease modifying anti rheumatic drug (DMARD) therapy including MTX has been inadequate. Simponi has also been shown to improve physical function in this patient population.

Psoriatic arthritis (PsA): Simponi, alone or in combination with MTX, is indicated for the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous disease modifying anti rheumatic drug (DMARD) therapy has been inadequate. Simponi has also been shown to improve physical function in this patient population.

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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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Ankylosing spondylitis (AS): Simponi is indicated for the treatment of severe, active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy."

It is proposed that Simponi treatment is initiated and supervised by qualified physicians experienced in the diagnosis and treatment of rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis. Patients treated with Simponi 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 Simponi and therefore recommends the granting of the marketing authorisation.