European Medicines Agency

London, 17 December 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION[*]
for
ORENCIA

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

On 17 December 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion[**] to recommend the variation to the terms of the marketing authorisation for the medicinal product Orencia. The Marketing Authorisation Holder for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

The CHMP adopted a new indication as follows[***]:

Rheumatoid arthritis
ORENCIA in combination with methotrexate is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have had an insufficient response or intolerance to other disease-modifying anti-rheumatic drugs (DMARDs) including at least one tumour necrosis factor (TNF) inhibitor. A reduction in the progression of joint damage and improvement of physical function have been demonstrated during combination treatment with abatacept and methotrexate.

Polyarticular juvenile idiopathic arthritis
ORENCIA in combination with methotrexate is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (JIA) in paediatric patients 6 years of age and older who have had an insufficient response to other DMARDs including at least one TNF inhibitor. ORENCIA has not been studied in children under 6 years old.

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

[*] Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

[**] Marketing Authorisation Holders 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.

[***] The text in bold represents the new or the amended indication.

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