European Medicines Agency

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PUBLIC STATEMENT ON

Raptiva
(efalizumab)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 20 September 2004 the European Commission granted a marketing authorisation valid throughout the European Union for the medicinal product Raptiva (efalizumab), indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who have failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including cyclosporin, methotrexate and PUVA.

On 19 February 2009, the Committee for Medicinal Products for Human Use (CHMP) issued an Opinion recommending the suspension of the marketing authorisation for Raptiva in all Member States in which the product was marketed, as its benefits in the treatment of psoriasis were modest, while there was a risk of serious side effects, including the occurrence of progressive multifocal leukoencephalopathy (PML). As a condition for lifting the suspension, the CHMP recommended that new evidence should be provided to identify a subgroup of patients for which the benefits of Raptiva would outweigh the risks.

On 12 May 2009, the Marketing Authorisation Holder for Raptiva (Serono Europe Limited) notified the European Commission of its decision to voluntarily withdraw the marketing authorisation for the product, as it did not intend to conduct the clinical trials necessary to fulfil the requirements for lifting the suspension.

On 9 June 2009 the European Commission issued a decision to withdraw the marketing authorisation for Raptiva. Pursuant to this decision the European Public Assessment Report for Raptiva will be updated to reflect that the marketing authorisation is no longer valid.

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