European Medicines Agency
Press office

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PRESS RELEASE
EU-wide recall of Raptiva (efalizumab) to be initiated

The European Medicines Agency has agreed to an EU-wide recall of all of the remaining batches of Raptiva, from Merck Serono. This means that within the next few days all batches of Raptiva will be recalled from wholesalers, pharmacies and hospitals. Following this, the medicine will no longer be available anywhere in the European Union.

In February 2009, the Agency's Committee for Medicinal Products for Human Use (CHMP) had recommended the suspension of Raptiva's marketing authorisation, because its benefits in the treatment of psoriasis were modest, while there was a risk of serious side effects in patients receiving the medicine, including the occurrence of progressive multifocal leukoencephalopathy (PML).

Patients were advised not to stop their treatment abruptly but to switch to alternative treatment gradually.

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. However, the Marketing Authorisation Holder informed the CHMP in April 2009 that it did not intend to conduct further clinical trials. In May 2009, Merck Serono formally requested the Marketing Authorisation in the EU to be withdrawn. The European Commission decision is expected to be issued soon.

All patients who were treated with Raptiva before the suspension should now have been switched to alternative treatments. The Agency has been working closely with the company to organise the complete recall of all remaining batches of Raptiva in the EU, in accordance with the process agreed in each individual Member State.

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Notes:

1. More information about the suspension of Raptiva is available in a press release and a question-and-answer document.
2. Raptiva was authorised for the treatment of adults with moderate to severe chronic plaque psoriasis (a disease causing red, scaly patches on the skin) who have failed to respond to or cannot take other systemic treatments for psoriasis, including ciclosporin, methotrexate and PUVA (psoralen ultraviolet-A).
3. The suspension of a marketing authorisation is a temporary measure, during which time a medicinal product is not available. The lifting of the suspension is conditional on the marketing authorisation holder being able to demonstrate a positive benefit-risk balance for certain groups of patients.
4. The withdrawal of a marketing authorisation is a permanent measure, removing a medicine from the EU market.
5. More information about Raptiva is available in the European public assessment report here: http://www.emea.europa.eu/humandocs/Humans/EPAR/raptiva/raptiva.htm
6. This press release, together with other information on the work of the Agency, can be found on the Agency website: www.emea.europa.eu

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