



European Medicines Agency
Press office

London, 25 September 2008
Doc. Ref. EMEA/CHMP/496612/2008

PRESS RELEASE

European Medicines Agency recommends update of product information of Tysabri and risk of progressive multifocal leukoencephalopathy (PML)

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended that the product information for Tysabri (natalizumab) be updated to further increase awareness about the risk of progressive multifocal leukoencephalopathy (PML) in patients with relapsing-remitting multiple sclerosis (MS) who have been treated with the medicine.

PML is a rare brain infection whose symptoms are similar to those of an MS attack. The CHMP's recommendation follows the reporting in July of two new cases of PML in patients who had been treated for MS with Tysabri alone for more than 12 months.

Following a review of the available data, the Committee concluded that the benefits of Tysabri continue to outweigh its risks in the treatment of relapsing-remitting MS, but that the existing warning on the risk of PML should be strengthened to heighten patients' and prescribers' awareness about this rare but serious side effect.

In addition, the Committee requested an update to the 'Physician Information and Management Guidelines for Multiple Sclerosis Patients on Tysabri'. These guidelines are part of the agreed risk management plan for Tysabri, which set out a series of risk minimisation measures. Following the update, doctors will be able to obtain more detailed guidance on how to differentiate PML from a relapse of MS, and how to manage suspected cases of PML.

The CHMP's recommendation will now be sent to the European Commission for the adoption of a decision.

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Notes:

1. Tysabri is used to treat relapsing-remitting MS in patients with high disease activity despite treatment with a beta-interferon or whose disease is severe and progressing rapidly.
2. More information about Tysabri is available on the EMEA website:
<http://www.emea.europa.eu/humandocs/Humans/EPAR/tysabri/tysabri.htm>
3. A press release with an update on PML and Tysabri was issued in August 2008:
<http://www.emea.europa.eu/humandocs/PDFs/EPAR/tysabri/42455408en.pdf>
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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