European Medicines Agency
Press office

London, 13 August 2008
Doc. Ref. EMEA/CHMP/424554/2008

PRESS RELEASE
European Medicines Agency update on progressive multifocal leukoencephalopathy (PML) and Tysabri

At the end of July 2008, the European Medicines Agency (EMEA) received two reports of progressive multifocal leukoencephalopathy (PML) in patients with relapsing-remitting multiple sclerosis (MS) who have been treated with Tysabri.

PML is a rare brain infection with symptoms that are similar to those of an MS attack. The two cases occurred in patients who have been treated for MS with Tysabri only for more than 12 months. The two cases were reported as part of the continuous safety-monitoring of medicines following their authorisation and placing on the market.

The risk of PML with Tysabri is known and is kept under close monitoring by the EMEA. The product information advises healthcare professionals that the medicine must not be used in patients who have PML and that patients taking Tysabri should be regularly monitored for signs and symptoms suggestive of PML.

The two cases are currently being assessed by the EMEA's scientific Committee for Medicinal Products for Human Use (CHMP). Elan, the marketing authorisation holder for Tysabri, has also been asked to provide any additional information they may have. Following assessment of all available data, the CHMP will determine whether any changes to the currently approved product information or the existing risk minimisation measures, including the 'Physician Information and Management Guidelines for Multiple Sclerosis Patients on Tysabri' are necessary.

-- ENDS --

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. The 'Physician Information and Management Guidelines for Multiple Sclerosis Patients on Tysabri' are part of the agreed risk management plan for Tysabri. In accordance with this plan, the marketing authorisation holder for Tysabri committed to provide an information pack to all physicians who intend to prescribe Tysabri. The pack contains, among other elements, also information about the diagnosis and management of PML. For more information see: http://www.emea.europa.eu/humandocs/PDFs/EPAR/tysabri/H-603-Annex-en.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

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu