European Medicines Agency
Press office

London, 20 March 2008
Doc. Ref. EMEA/CHMP/139489/2008

EMEA PRESS RELEASE
EMEA concludes new advice to doctors and patients for Tysabri (natalizumab) needed

The European Medicines Agency (EMEA) has concluded that warnings about liver injury should be added to the product information for Tysabri (natalizumab).

Tysabri is used to treat relapsing-remitting multiple sclerosis (MS) in patients with high disease activity despite treatment with a beta-interferon or whose disease is severe and evolving rapidly.

Following a review of reports of liver injury in patients treated with Tysabri, the EMEA's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to update the product information for Tysabri to warn patients and prescribers that liver injury may occur.

Doctors should monitor the liver function of patients receiving Tysabri. Patients who observe any signs of liver injury, such as yellowing of the skin or the whites of the eyes, or unusual darkening of the urine should see their doctor.

The CHMP has requested that Elan, the marketing authorisation holder for Tysabri, submits a variation to the marketing authorisation to implement these changes.

As with all medicinal products, the EMEA will continue to monitor Tysabri closely to ensure that the benefits of the medicine continue to outweigh its risks.

-- ENDS --

Notes:

1. More information about the EMEA recommendation is available in a question-and-answer document.
2. More information about Tysabri, including the currently approved information to prescribers and patients can be found in the European Public Assessment Report: http://www.emea.europa.eu/humandocs/Humans/EPAR/tysabri/tysabri.htm
3. 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