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Press Office

**Press release**

# European Medicines Agency recommends additional measures to better manage risk of progressive multifocal leukoencephalopathy (PML) with Tysabri

## Risk of PML increases after two years, but benefits of Tysabri continue to outweigh risks for patients with highly active relapsing-remitting multiple sclerosis

The European Medicines Agency has finalised a review of Tysabri (natalizumab) and the risk of progressive multifocal leukoencephalopathy (PML), a rare brain infection caused by the JC virus. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the risk of developing PML increases after two years of use of Tysabri although this risk remains low. However, the benefits of the medicine continue to outweigh its risks for patients with highly active relapsing-remitting multiple sclerosis, for whom there are few treatment options available.

Because it is important that PML is detected early, the Committee recommended that a number of measures be put in place to ensure that patients and doctors are fully aware of the risks of PML. These include:

- an update of the product information to add information about the increase in the risk of PML after two years of treatment and additional advice on how to manage patients who show signs of PML;
- forms to be signed by patients at the beginning of treatment with Tysabri, and again after two years of treatment, after in-depth discussions about the risk of PML with their doctor.

Measures to minimise the risk of PML were part of the initial marketing authorisation for Tysabri, issued in June 2006. Since then, they have been continuously updated and strengthened to increase awareness of the risk of PML.

The new measures are designed to complement the existing recommendations that patients, and their carers, partners and families should be made aware of the symptoms of PML and that patients should be closely monitored throughout treatment.

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## Notes

1. Tysabri, from Elan Pharma International Ltd, is used to treat relapsing-remitting multiple sclerosis in patients with high disease activity despite treatment with a beta-interferon or whose disease is severe and progressing rapidly.
2. More information about the review of Tysabri is available in a question-and-answer document.
3. More information about Tysabri is available in the European Public Assessment Report: http://www.ema.europa.eu/humandocs/Humans/EPAR/tysabri/tysabri.htm
4. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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