MALTA MEDICINES AUTHORITY

Updated recommendations to minimise the risk of the rare brain infection PML with Tysabri

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Information on Tysabri®

- Tysabri (natalizumab) is a medicine used to treat adults with highly active multiple sclerosis (MS) specifically in the type of MS known as 'relapsing-remitting' MS.
- Tysabri was authorized in the European Union in June 2006 and is available in Malta via centralized procedure for hospital use

New advice from the European Medicines Agency that may help early detection of PML and improve patients' outcomes with Tysabri

The Pharmacovigilance Risk Assessment Committee (PRAC) at the EMA has completed its review of the risk of progressive multifocal leukoencephalopathy (PML) with the multiple sclerosis medicine Tysabri which was started in May 2015.

- PML is a rare and very serious brain infection caused by John Cunningham (JC) virus and has three important risk factors; the presence of anti-JCV antibodies, Tysabri treatment duration and prior treatment with immunosuppressants. Patients who have all three risk factors are considered to be at higher risk of PML
- Based on new evidence the PRAC concluded that patients with a high antibody index (index values above 1.5), who have not used immunosuppressants before Tysabri but have been treated with Tysabri for more than 2 years are also considered at higher risk of PML
- In patients who have a low antibody index (less than 0.9) and have not used immunosuppressant medicines before starting Tysabri and have been treated with Tysabri for longer than 2 years should have the antibody test repeated every 6 months. For patients who tested negative for anti-JCV antibodies, the antibody test should be repeated every 6 months
- The degree of brain damage and resulting disability can be limited by early detection and treatment of asymptomatic PML. Asymptomatic cases of PML can be detected on an MRI scan and for this reason the PRAC has concluded that for patients at higher risk of PML (above) frequent MRI scans (every 3 to 6 months) should be considered.

The PRAC recommendation will now be forwarded to the Committee for Medicinal Products for Human Use (CHMP) for the adoption of EMA final opinion.

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In Malta

For Healthcare Professionals

Further details including advice for patients and healthcare professionals will be published at the time of the CHMP opinion but in the mean time prescribers of Tysabri should be aware that;

- Patient groups at higher risk for PML are 1) Patients with all three risk factors (above) and 2) Patient with no prior immunosuppressant treatment, with high anti-JCV antibodies counts and Tysabri treatment for longer than 2 years.
- MRI scan can detect asymptomatic cases of PML and frequent MRI scans (every 3 to 6 months) should be considered for higher risk patient groups
- Antibody test should be repeated for specific patient groups as describe above.

Irrespective of the presence or absence of PML risk factors, heightened clinical vigilance for PML should be maintained in all patients treated with Tysabri and if PML is suspected at any time, treatment with Tysabri must be stopped until PML has been excluded.

Prescribers of Tysabri are encouraged to refer to the Summary of Product Characteristics (SmPC) and Physician Information and Management Guidelines for Multiple Sclerosis patients on Tysabri therapy provided by the marketing authorization holder and available online at www.medicinesauthority.gov.mt/rmm

For more information on the updated PRAC recommendations please see the press release issued by the European Medicines Agency

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Tysabri®. Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form or online at http://www.medicinesauthority.gov.mt/adrportal or to the marketing authorisation holder or their local representatives.

Prof. John J Borg PhD (Bristol)
Post-licensing Director

Healthcare professionals and patients are encouraged to regularly check the Medicine Authority website for product safety updates as these are issued on an ongoing basis.

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