Malta, 26 September 2008

Circular No. P10/2008

Dear Healthcare Professional,

Re: EMEA recommends update of product information of Tysabri and risk of progressive multifocal leukoencephalopathy (PML)

The European Medicines Agency (EMEA) 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 the symptoms of which are similar to those of an MS attack. The recommendation as issued by the EMEA's Committee for Medicinal Products for Human Use (CHMP), 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.

The Medicines Authority has participated in these discussions held at the EMEA and is in agreement with the full **press release** issued by the EMEA, attached here for your perusal.

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