



175 Bloor Street East
Suite 700, North Tower
Toronto, Ontario M4W 3R8
Telephone: (416) 922-6065
Fax: (416) 922-7538
www.mssociety.ca

Medical Update Memo

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Tysabri Update: Third case of progressive multifocal leukoencephalopathy

Biogen Idec and Elan Corporation announced March 31 that a third case of progressive multifocal leukoencephalopathy (PML) has been identified in a clinical trial of Tysabri® (natalizumab). The individual, who died in 2003, had participated in a study of Tysabri for Crohn's disease (inflammatory bowel disease) and had received eight doses of Tysabri over an 18-month period.

In February, the companies suspended Tysabri for sale in the United States following the diagnosis of two cases of PML in people with MS treated with Tysabri in combination with Avonex® (interferon beta-1a) in a clinical trial. They have asked doctors to stop prescribing the medication and have stopped its use in clinical trials. PML is a rare but very serious central nervous system disease called progressive multifocal leukoencephalopathy (PML). Both people had received Tysabri in combination with Avonex for more than two years in a clinical trial setting.

This is the first case of PML diagnosed in a person taking Tysabri alone. According to the companies, the person's prior medication history included multiple courses of immunosuppressant agents. In 2003, the death was reported as being the result of malignant astrocytoma (a type of tumour). Upon further investigation, it has been determined the person actually had PML.

The companies report that they are continuing to review the data on 3,000 people who were involved in Tysabri treatment studies for multiple sclerosis, Crohn's disease, and rheumatoid arthritis. The companies, which are both involved in the development and

marketing of the medication, are working with clinical investigators to evaluate people who have been treated with Tysabri and with medical experts and government regulatory agencies to investigate the adverse events. Biogen Idec Canada said it has informed Health Canada of the new developments.

Tysabri was approved by the US Food and Drug Administration (FDA) on November 23, 2004. It is currently under review by Health Canada.

Biogen Idec Canada has available an information line in English and French for further inquiries about Tysabri (natalizumab): 1-866-477-3462.

ASK MS Information System Code: 1.4.1.60.5.d

National Research Department
National Communications & Government Relations Department

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