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Medical Update Memo

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Tysabri Update: FDA permits some clinical trial participants to resume treatment

On February 15, the U.S. Food and Drug Administration (FDA) removed the restrictions it had placed on clinical trials involving Tysabri® (natalizumab) after safety concerns led to the drug's withdrawal from the market in February 2005. The drug's sponsors, Biogen Idec and Elan Corporation, have announced intentions of resuming clinical trial dosing in multiple sclerosis in persons who were previously involved in phase 3 clinical trials with specific plans for closer monitoring of participants.

The lifting of the clinical hold on Tysabri does not make the drug available to persons outside the clinical trials. An FDA advisory panel will meet March 7-8, 2006 to consider whether the drug should be returned to market in the United States. A final decision about the drug's return to market is due from the FDA in late March.

According to a document released by the FDA, it is still concerned about the potential for PML (progressive multifocal leukoencephalopathy) associated with Tysabri use. However, "We received detailed information on the extensive re-examination that Biogen and Elan undertook on all patients who had received natalizumab in clinical studies under an IND. No additional cases of PML were identified. The better understanding of the actual occurrence of PML in these patients permitted better estimation of the potential risk of PML occurring in the future. In addition, Biogen has proposed a resumption of natalizumab administration under an IND study with very specific plans for close monitoring of patients."

The Multiple Sclerosis Society of Canada is monitoring closely the status of Tysabri, which had not been approved by Health Canada when its sales were suspended in the United States last year.

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

For more information, please see the following on the MS Society of Canada website:

Tysabri Update: Third case of progressive multifocal leukoencephalopathy (here's the link - <http://www.mssociety.ca/en/research/meddmmo-tysabri-update-apr05.htm>

Sales of Tysabri stopped in United States (here's the link -- <http://www.mssociety.ca/en/research/meddmmo-tysabri-stop-feb05.htm>

- With information from the National MS Society (USA)

ASK MS Information System Code: 1.4.1.60.5.c

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