



Multiple
Sclerosis
Society of
Canada

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en plaques



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Medical Update Memo

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FDA approves Tysabri's return to market in U.S. for relapsing MS

SUMMARY

The Food and Drug Administration (FDA) has approved the return to market in the United States of Tysabri® (natalizumab) as a therapy for people with relapsing multiple sclerosis. The approval is based on positive results from two clinical trials showing that Tysabri significantly reduced the risk of sustained progression of disability and the rate of clinical relapse in people with relapsing MS. It follows an extensive FDA review of the product after the withdrawal of Tysabri from the market in 2005 because of safety concerns. In Canada, Tysabri is currently under priority review by Health Canada.

DETAILS

The FDA approval of Tysabri to re-enter the US market requires a mandatory registration program for both people who take the drug and their prescribing physicians to minimize the risks that patients will develop PML (progressive multifocal leukoencephalopathy), caused by a common virus called the JC virus. Three people who had been in clinical trials involving Tysabri developed PML, two of whom died. The identification of PML in people who had taken Tysabri resulted in the drug being withdrawn from the US market in 2005. The drug, which is taken by monthly intravenous (into the vein) infusion, will be dispensed at registered infusion centres across the United States.

Tysabri is generally recommended for people who have had inadequate response to, or are unable to tolerate, other approved MS therapies (such as Copaxone®, Betaseron®, Avonex®, Rebif®, and Novantrone®). It is approved as a monotherapy (single therapy), not to be combined with other immune system-modifying agents, and is not recommended for individuals who have compromised (weakened) immune systems.

Biogen Idec and Elan Pharmaceuticals, the companies that produce Tysabri, hope to commercially launch it or make it available for use in the United States in July 2006. As part of the FDA approval, the companies have agreed to conduct a post-marketing study that will follow some 5,000 people with MS prescribed Tysabri for five years to evaluate the long-term safety of the drug in the clinical practice setting.

Key aspects of the approval include:

- Tysabri is approved to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations (flare-ups or relapses) in patients diagnosed with relapsing MS;
- Tysabri will only be available under a restricted distribution program called TOUCH, and prescribing physicians and patients must enroll in this mandatory registry program;
- Tysabri can be given only at registered infusion centres where the medical personnel have been trained in its proper use and in the risks of PML;
- Tysabri should be given as a monotherapy, meaning it should not be combined with other medications that alter immune function;
- Tysabri is generally recommended for patients who have had inadequate response to, or are unable to tolerate, other approved MS therapies;
- Tysabri is not recommended for patients who have compromised (weakened) immune systems or who are taking other drugs that suppress or modulate the immune system, with the exception of periodic steroids to treat relapses;
- Prescribing information carries a "Black Box Warning" to highlight the increased risk of PML and the importance of monitoring patients for any new signs or symptoms that may be suggestive of PML;
- An MRI scan should be obtained prior to starting treatment with Tysabri;

Disclaimer

The Multiple Sclerosis Society of Canada is an independent, voluntary health agency and does not approve, endorse or recommend any specific product or therapy, but provides information to assist individuals in making their own decisions.

- Prior to each infusion, the patient and infusion nurse complete a checklist to identify any new neurological signs or symptoms that require evaluation by a physician; and
- Patients on Tysabri are to be evaluated by the prescribing physician three and six months after the first infusion and every six months thereafter.

The Multiple Sclerosis Society of Canada is looking forward to having Tysabri available as a treatment choice for Canadians with MS if it passes Health Canada's strict safety and efficacy guidelines. Currently, Tysabri is undergoing priority review by Health Canada. The MS Society will closely monitor the Health Canada process.

[With information from the National MS Society (USA)]

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