



Multiple  
Sclerosis  
Society of  
Canada

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# Medical Update Memo

October 4, 2006

## Health Canada approves Tysabri for treatment of relapsing MS

### Summary

Health Canada has approved Tysabri® (natalizumab) as a therapy for people with relapsing-remitting multiple sclerosis. The general prescribing indication for Tysabri is for people with MS who have had an inadequate response to other disease modifying therapies or are unable to tolerate them. The approval is based on positive results from two clinical trials which showed Tysabri significantly reduced the risk of sustained progression of disability, the rate of MS relapses and reductions in MS brain lesions as shown on MRI scans in people with relapsing-remitting MS. The Health Canada decision follows the reintroduction of Tysabri in the United States in early June 2006 following an extensive safety review of the product and the approval of Tysabri in the European Union in late June. It was voluntarily withdrawn from the U.S. market in February 2005 following the development of serious adverse side effects in three people who received Tysabri.

### Details

On October 4th following a priority review, Health Canada approved Tysabri® (natalizumab) as a therapy for people with relapsing-remitting multiple sclerosis. The general prescribing indication for Tysabri is for use as a monotherapy (single therapy not to be combined with other agents) for people with MS who have had an inadequate response to other disease modifying therapies or are unable to tolerate them. Tysabri is administered once every four weeks by intravenous (IV) infusion. Tysabri is produced by Biogen Idec and Elan Pharmaceuticals.

The approval is based on positive results from two clinical trials. The largest study, the AFFIRM clinical trial, involved 942 people with relapsing-

remitting MS and evaluated the effect of Tysabri on the rate of clinical relapses and the progression of disability. The study found Tysabri reduced the rate of clinical relapse by 68 percent compared to placebo and the risk of disability progression was reduced by 42 percent as a primary end point compared to placebo. It also had a statistically significant reduction in the number and size of active brain lesions identified on magnetic resonance imaging (MRI) scans.

Tysabri is a laboratory-produced monoclonal antibody. It is also described as a selective adhesion molecule inhibitor or SAM. Tysabri is designed to hamper the movement of potentially damaging immune cells from the bloodstream, across the blood-brain-barrier into the brain and spinal cord. Specifically, the drug inhibits this movement across the blood-brain-barrier by attaching to alpha 4-integrin, a protein on the surface of immune T cells that normally enables them to adhere to and pass through the barrier.

The Health Canada decision follows the reintroduction of Tysabri in the United States in early June 2006 following an extensive safety review of the product and the approval of Tysabri in the European Union in late June. It was voluntarily withdrawn from the U.S. market in February 2005 following the development of serious adverse side effects in two people who received Tysabri and in another person with Crohn's disease (inflammatory bowel disease). That person received Tysabri alone although the individual's prior medication history included multiple courses of immunosuppressant agents. All three developed PML, (progressive multifocal leukoencephalopathy caused by a common virus called the JC virus). One person with MS and the person with Crohn's disease died.

To address the safety issue, Biogen Idec is recommending that people who are prescribed Tysabri should enrol in the Tysabri Care Program, which will support both physicians and people with MS in the safe and effective use of the product. According to the company, the program will optimize improved compliance, standardize infusion treatment at clinics, provide education and on-going surveillance to support safety and assist in reimbursement issues and patient support.

In the United States, FDA approval of Tysabri to re-enter the U.S. market included a mandatory registration program for both people who take the drug and their prescribing physicians to minimize the risk that patients will develop PML. In addition, Biogen Idec and Elan Pharmaceuticals must

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conduct a post-marketing study to follow 5,000 people with MS prescribed Tysabri for five years to evaluate the long-term safety of the drug in the clinical practice setting.

"The Multiple Sclerosis Society of Canada is pleased there is another approved treatment option for Canadians with relapsing-remitting MS. It is also important that safety issues are being addressed through a program that will monitor compliance and provide surveillance of people who choose to take the product," said Dr. William J. McIlroy, national medical advisor.

**Key aspects of the approval:**

- At this time, the cost of Tysabri has not been released. In the United States, the annual wholesale cost is \$28,400 US. According to Biogen Idec, physicians can begin to write prescriptions for Tysabri on November 15, 2006. Because it will take some time for reimbursement applications to be approved, infusions are likely to begin in January 2007.
- According to Biogen Idec, Tysabri will likely be covered by the majority of private/ employer health care programs shortly after it is made available.
- For reimbursement by provincial or federal drug programs, typically following Health Canada approval, the pharmaceutical company applies to the Common Drug Review (a federal/provincial/territorial agency) that determines whether a drug is cost effective and should be covered by public drug programs. Provincial drug programs use this information in making their decisions.

The Multiple Sclerosis Society of Canada will provide more details when they are available.

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