Tysabri (natalizumab) Allowed Back to Market with Restrictions

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By Peggy Peck [1]

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Tysabri is a monoclonal antibody that was approved in November 2004 for relapsing forms of MS because it demonstrated efficacy in reducing the frequency of exacerbations. But in February 2005 it was withdrawn by its maker, Biogen Idec, and distributor, Elan, after three patients in clinical trials developed progressive multifocal leukoencephalopathy (PML), a rare viral infection of the brain. Two of the cases were fatal. At the same time, the FDA stopped clinical trials of the drug.

In February of 2006, after an independent safety review of patients who had participated in the previous trials found no additional cases of PML, the FDA permitted a resumption of Tysabri studies. To decrease the possibility of patients developing PML in the future, while also making Tysabri available to appropriate MS patients, FDA consulted in March 2006 with its Peripheral and Central Nervous Systems Drugs Advisory Committee.

The advisory committee recommended a risk-minimization program with mandatory patient registration and periodic follow-up to identify as early as possible any cases of PML that may occur, and to try to determine the reason the infection occurs. In response, Biogen Idec and Elan submitted to the FDA a risk management plan, called the TOUCH Prescribing Program, to help ensure safe use of the product.

Following a thorough review of the risk management plan and proposed changes to the drug's original marketing application, the FDA determined that Tysabri can be made available under the TOUCH Program with the following main features:

- The drug will only be prescribed, distributed, and infused by prescribers, infusion centers, and pharmacies registered with the program.
- Tysabri will only be administered to patients who are enrolled in the program.
- Prior to initiating the therapy, health care professionals are to obtain the patient's MRI scan to help differentiate potential future multiple sclerosis symptoms from PML.
- Patients taking Tysabri are to be evaluated at three and six months after the first infusion and every six months after that, and their status will be reported regularly to Biogen Idec and Elan.

In addition to its activity in MS, Tysabri is being studied for Crohn's disease. Last month in a study reported at Digestive Disease Week, researchers said that 51% of patients with moderate to severe Crohn's receiving Tysabri responded to the initial infusion versus 37% of patients in a placebo group (P=0.001). At eight weeks the difference was still significant, with 48% of Tysabri patients showing a response versus 32% of the placebo group.

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