## News & Events

### FDA NEWS RELEASE

**FOR IMMEDIATE RELEASE**
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This press release was revised June 6, 2006, to clarify information in the first paragraph.

### FDA Approves Resumed Marketing of Tysabri Under a Special Distribution Program

The Food and Drug Administration (FDA) today approved an application for resumed marketing of Tysabri (natalizumab) subject to a special restricted distribution program. Tysabri is a monoclonal antibody used to treat patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of exacerbations (flare-ups). Tysabri is indicated for use as monotherapy, because we don't know enough about how its use with other immune modifying drugs could impact risk. It is also meant for patients who have not responded adequately to, or cannot tolerate, other treatments for MS.

Tysabri was initially approved by the FDA in November 2004, but was withdrawn by the manufacturer, Biogen-Idec, in February 2005, after three patients in the drug's clinical trials developed progressive multifocal leukoencephalopathy (PML), a serious and rare viral infection of the brain. Two of the cases were fatal. Based on this information, FDA put clinical trials of the drug on hold in February 2005. FDA allowed a clinical trial of Tysabri to resume in February 2006, following a re-examination of the patients who had participated in the previous clinical trials, confirming that there were no additional cases of PML.

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, submitted to FDA a Risk Management Plan, called the TOUCH Prescribing Program, to help ensure safe use of the product.

Following a thorough review of Biogen-Idec's Risk Management Plan and proposed changes to its original marketing application, 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 Magnetic Resonance Imaging (MRI) scan to help differentiate potential future multiple sclerosis symptoms from PML.
- Patients on Tysabri are to be evaluated at 3 and 6 months after the first infusion and every 6 months after that, and their status will be reported regularly to Biogen Idec.

More information, including a detailed product history, is available at www.fda.gov/cder/drug/infopage/natalizumab/default.htm.

Biogen Idec is the manufacturer and Elan the distributor for Tysabri. Additional information on the TOUCH Prescribing Program is available from the companies by calling 1-800-456-2255.

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