

FDA approves Tysabri's return to market

The U.S. Food and Drug Administration has **approved** the return to market of Tysabri® (natalizumab), produced by Biogen Idec and Elan Pharmaceuticals, to delay the accumulation of physical disability and reduce the frequency of relapses in those with relapsing multiple sclerosis (MS). 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 those with relapsing MS.

The approval hinges on a **mandatory registration** program for patients and 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 drug, which is taken by monthly IV infusion, will be dispensed at registered infusion centers across the country.

According to company sources, there will be a delay between the time of FDA approval and the time when Tysabri is available to patients. Several weeks are needed to develop training materials and to finalize the patient data collection system. The companies hope to commercially launch Tysabri, or make it available for use, in **July 2006**. Individual patients may experience additional delays, depending on the availability of a nearby registered infusion site and any health insurance coverage issues.

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 centers 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 must be obtained prior to starting treatment with Tysabri;
- Prior to each infusion, the patient and infusion nurse complete a checklist to screen for symptoms suggestive of PML; and
- Patients on Tysabri are to be evaluated by the prescribing physician 3 and 6 months after the first infusion and every 6 months thereafter, and their status will be reported to Biogen Idec.

For information about the FDA approval, go to the FDA's [web site](#).