FDA APPROVES TYSABRI’S RETURN TO MARKET FOR RELAPSING MS
-- Company Hopes to Make Drug Available in July

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 (clinical exacerbations) in those 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 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.

Tysabri is generally recommended for patients 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, not to be combined with other immune system-modifying agents, and is not recommended for individuals who have compromised (weakened) immune systems.

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.
As part of its approval, the companies have agreed to conduct a post-marketing study that will follow some 5,000 patients prescribed Tysabri for five years to evaluate the long-term safety of the drug in the clinical practice setting.

“It’s important that people with relapsing MS now have a new treatment option,” said Dr. John R. Richert, National MS Society Vice President of Research and Clinical Programs. “We believe that the mandatory patient registry and post-marketing observational study will help clarify the potential risks and benefits of this new therapy for people with MS,” he added.

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 should be obtained prior to starting treatment with Tysabri;
- 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 3 and 6 months after the first infusion and every 6 months thereafter.

Additional details about how and when Tysabri will become available for infusion will be forthcoming.

✓ For information about the FDA approval, go to the FDA’s Web site at:  
http://www.fda.gov/cder/drug/infopage/natalizumab/default.htm
✓ For Questions & Answers and other updated information from the National MS Society, visit our Web site at http://www.nationalmssociety.org/tysabri.asp.
✓ For further information about the availability of Tysabri, individuals may call Biogen Idec’s MS Active Source information line at: 1-800-456-2255, or go to the Biogen Idec Tysabri information site at http://www.biogenidec.com.

-- Research and Clinical Programs

*The National MS Society is proud to be a source of information about MS. Our comments are based on professional advice, published experience and expert opinion, but do not represent individual therapeutic recommendation or prescription. For specific information and advice, consult your personal physician.*