No Needle Needed: Post Pain Controller Gains FDA Approval

BY ELIZABETH MECHCATIE Senior Writer

Tysabri is Back, With Black Box Warning

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Safety information that has been added to the revised label of natalizumab is highlighted in a "Dear healthcare professional" letter and timed to coincide with the reintroduction of the monoclonal antibody in the United States as monotherapy for people with relapsing forms of multiple sclerosis.

The letter, released in July by Biogen Idec and Elan, the companies that market natalizumab as Tysabri, includes a copy of the black box warning about the risk of progressive multifocal leukoencephalopathy (PML) associated with treatment. It also refers to the two cases of PML diagnosed in 1,849 patients with MS who were treated for a median of 120 weeks, and a third case in a patient with Crohn’s disease who had received 8 doses, among 1,043 patients with Crohn’s who received the treatment.

The warning also includes the recommendation that health care professionals monitor patients on natalizumab for any new sign or symptoms “that may be suggestive of PML,” and that treatment should be immediately stopped at the first sign or symptom suggestive of PML.

Because of this risk, which cannot be precisely estimated, the Food and Drug Administration approved the reintroduction of natalizumab under a restricted distribution program, called the TOUCH Prescribing Program, which requires prescribing physicians, infusion centers, and pharmacies associated with infusion centers to register with the program to prescribe, distribute, or infuse the product.

Natalizumab was approved in November 2004, and withdrawn by the manufacturer in February 2005 after two cases of PML were reported. Earlier this year, the FDA’s Peripheral and Central Nervous System Drugs Advisory Committee recommended that natalizumab should become available again, with a stringent risk management program, and that it be limited to patients with relapsing features of the disease, only as monotherapy.

The dear doctor letter is available on the FDA’s Medwatch site at www.fda.gov/medwatch/safety/2006/safety06.htm#Tysabri. The letter advises health professionals to report serious adverse events possibly associated with natalizumab to Biogen Idec at 1-800-436-2251, or to the FDA’s MedWatch adverse event reporting program by phone (1-800-FDA-1088), online at www.fda.gov/medwatch, or by mail to MedWatch, HFE-2, 5600 Fishers Lane, Rockville, Md. 20852-9787.