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Important Safety Information

February 2008

Dear Healthcare Professional,

Biogen Idec and Elan are writing to inform you of new safety information regarding TYSABRI® (natalizumab). The full Prescribing Information has been revised to add to the Warnings and Precautions section information related to clinically significant liver injury that has been reported in patients treated with TYSABRI in the post-marketing setting.

The following Warning has been added to the Prescribing Information:

5 Warnings and Precautions

***5.5* Hepatotoxicity**

Clinically significant liver injury has been reported in patients treated with TYSABRI in the postmarketing setting. Signs of liver injury, including markedly elevated serum hepatic enzymes and elevated total bilirubin, occurred as early as six days after the first dose; signs of liver injury have also been reported for the first time after multiple doses. In some patients, liver injury recurred upon rechallenge, providing evidence that TYSABRI caused the injury. The combination of transaminase elevations and elevated bilirubin without evidence of obstruction is generally recognized as an important predictor of severe liver injury that may lead to death or the need for a liver transplant in some patients.

TYSABRI should be discontinued in patients with jaundice or other evidence of significant liver injury (e.g., laboratory evidence).

Additionally, the Patient Counseling section has been updated to instruct physicians to inform their patients that TYSABRI may cause liver injury.

Patients should be instructed to read the Medication Guide for symptoms of liver damage.

17. PATIENT COUNSELING INFORMATION

17.5 Hepatotoxicity

Inform patients that TYSABRI may cause liver injury. Instruct the patient to contact their doctor if they develop symptoms of hepatoxicity [see *Warnings and Precautions (5.5)*].

At Biogen Idec and Elan, patient safety is our highest priority and we are committed to ensuring that healthcare professionals continue to receive the necessary information to prescribe TYSABRI appropriately.

As a reminder, healthcare professionals should report any serious adverse events possibly associated with the use of TYSABRI® to Biogen Idec at 1-800-456-2255. This information may also be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088), FAX (1-800-FDA-0178), via the MedWatch website at www.fda.gov/medwatch, or by mail to MedWatch, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787.

The revised full Prescribing Information and Medication Guide are enclosed. The labeling has been reformatted to comply with the new *Requirements on Content and Format of Labeling for Human Drug and Biologic Products* (commonly referred to as the Physicians Labeling Rule).

Should you have questions regarding the use of TYSABRI or have questions regarding the TOUCH™ Prescribing Program for TYSABRI, call 1-800-456-2255.

Sincerely,

Michael Panzara, MD, MPH
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Chief Medical Officer, Neurology
Biogen Idec Inc.

Gordon Francis, MD
Sr. Vice President,
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TYSABRI is a registered trademark and TOUCH is a trademark of Elan Pharmaceuticals, Inc.