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RESEARCH/CLINICAL UPDATE

Keyword:	Tysabri (natalizumab)
Section:	TREATMENTS, APPROVED

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MS TRIAL ALERT:

Study Enrolling to Evaluate Effects of Tysabri on Fatigue and Cognition

Summary: Researchers nationwide are enrolling people who have relapsing forms of MS in a study to evaluate the effects of Tysabri® (natalizumab, Biogen Idec and Elan Pharmaceuticals) on fatigue and cognition. Forty-eight sites will recruit a total of 200 patients for this study, which is funded by Biogen Idec.

For the purposes of this study, “relapsing forms of MS” would include individuals who experience repeated, acute attacks or relapses of symptoms, followed by periods of full or partial recovery.

Rationale: Tysabri is a laboratory-produced monoclonal antibody that has been approved for marketing by the U.S. FDA for relapsing forms of MS, based on data from two clinical trials. Tysabri is designed to hamper the movement of potentially damaging immune cells from the bloodstream, across the “blood-brain barrier,” and into the brain and spinal cord. The drug inhibits this movement by attaching to alpha 4-integrin, a protein on the surface of immune T-cells that normally enables them to adhere to and pass through the blood-brain barrier.

In a recently published study involving data available from 2,113 people enrolled in clinical trials of natalizumab, the drug was shown to significantly improve quality of life as measured by several clinical scales (*Ann Neurol.* 2007 Oct;62[4]:335-46). In addition, the sponsor has unpublished data from those trials, along with anecdotal reports, suggesting that Tysabri may have positive impacts against fatigue. This new study is investigating the extent to which Tysabri may affect fatigue and cognitive problems in people with MS.

Eligibility and Details: To enroll in this study, people must be between 18 and 55 years of age, have a diagnosis of a relapsing form of MS, and have had an inadequate response to, or be unable to tolerate, alternate therapies.

Patients must be enrolled in the TOUCH™ prescribing program in the U.S., which is designed to track opportunistic infections and to understand their risk factors. This program was set up due to of PML (progressive multifocal leukoencephalopathy), a brain disease that occurred in three people (two of whom died) who had been in earlier clinical trials of Tysabri. As of September 2007, 10,500 have been enrolled in this program with no new PML cases having been confirmed.

All participants will receive Tysabri intravenously every four weeks for 12 months. The primary objective of this study is to determine the effects of Tysabri treatment on fatigue as measured by changes in the Visual Analog Scale for Fatigue, and secondary objectives are to measure changes in the Modified Fatigue Impact Scale and Fatigue Severity Scale. These are questionnaires in which patients report the effects of fatigue in terms of physical, cognitive, and psychosocial functioning. Patients also will undergo neuropsychological assessments to explore the effects of Tysabri on cognition.

Contact: For enrollment information, please contact MS Active Source at (800) 456-2255, and ask for Medical Information. Although not all sites are enrolling yet, participating sites will be in the following cities:

Birmingham, AL	Freehold, NJ
Huntsville, AL	Voorhees, NJ
Phoenix, AZ	Plainview, NY
Fresno, CA	Stony Brook, NY
Los Angeles, CA	Las Vegas, NV
Melbourne, FL	Canton, OH
Atlanta, GA	Columbus, OH
Des Moines, IA	Bethlehem, PA
Idaho Falls, ID	Collegeville, PA
Evanston, IL	Philadelphia, PA
Indianapolis, IN	Anderson, SC
Lexington, KY	Nashville, TN
Louisville, KY	Dallas, TX
Brighton, MA	Round Rock, TX
Brookline, MA	San Antonio, TX
Lexington, MA	Park City, UT
Ann Arbor, MI	Richmond, VA
Detroit, MI	Vienna, VA

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.

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-- Research & Clinical Programs Department

Tysabri is a registered trademark of Biogen Idec and Elan
TOUCH is a trademark of Biogen Idec and Elan

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