biogen idec

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on TYSABRI® (natalizumab)

February 13, 2009

Subject: **Reports of Progressive Multifocal Leukoencephalopathy (PML) with TYSABRI® (natalizumab)**

Biogen Idec Canada Inc, in consultation with Health Canada, has informed Canadian healthcare professionals of an important update to safety information concerning TYSABRI (natalizumab).

TYSABRI is authorized for the treatment of patients with a form of multiple sclerosis (MS) called relapsing-remitting (periods of symptoms alternating with periods without symptoms).

- There have been reports of a rare brain infection called progressive multifocal leukoencephalopathy (PML) in patients who have been given TYSABRI. PML can cause disability or death. PML usually happens in people with weakened immune systems.
- Since TYSABRI became available on the market worldwide, five (5) cases of PML have been reported. One case resulted in death.
- Signs and symptoms of PML include progressive weakness on one side of the body, clumsiness of limbs, disturbance of vision, changes in thinking, memory and orientation, confusion, and personality changes. Some of the symptoms are similar to MS, so if you develop any of these symptoms or any other unusual symptoms, or if your MS gets worse, contact your doctor immediately.

The prescribing information for TYSABRI has been updated to include more information on PML signs and symptoms. The prescribing information is available by contacting the Tysabri Care Program™ at 1-888-827-2827.

TYSABRI is generally recommended in MS patients who have not responded to, or can not tolerate other treatments for MS, and should not be used in combination with other medicines that affect the immune system.

As of the end of December 2008, approximately 37,600 patients were receiving TYSABRI worldwide.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Any serious or unexpected adverse reactions in patients receiving TYSABRI should be reported to the Tysabri Care Program™ or Health Canada at the following addresses:

Tysabri Care Program™
Phone: 1-888-827-2827

Biogen Idec Canada Inc.
3 Robert Speck Parkway, Suite 300
Mississauga, ON L4Z 2G5

Any suspected adverse reaction can also be reported to:
Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
Ottawa, Ontario, K1A 0K9
Tel: 613-957-0337 or Fax: 613-957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866-234-2345
Fax: 866-678-6789
CanadaVigilance@hc-sc.gc.ca

The AR Reporting Form and the AR Guidelines can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form_e.html
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html

For other inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate
E-mail: mhpd_dpsc@hc-sc.gc.ca
Tel: (613) 954-6522
Fax: (613) 952-7738

Sincerely,

original signed by

Dr. Len Walt M.D., M.B.A.
Medical Director