

Medical Update Memo

December 10, 2004

FDA approves natalizumab (Tysabri® – formerly known as Antegren) for relapsing forms of MS

On November 23, 2004, the US Food and Drug Administration (FDA) approved natalizumab (Tysabri®, formerly known as Antegren) as a treatment for relapsing forms of MS, creating another treatment option in the United States. (Tysabri is pronounced tie-SAB-bree.)

Tysabri is currently under priority review by Health Canada with a decision anticipated in 2005. The MS Society of Canada is closely monitoring the therapy's review status.

Details

The FDA approval was based on results from the first year of two ongoing clinical trials of the drug alone compared to placebo (inactive treatment) or added to beta interferon-1a (Avonex®).

Tysabri reduced the rate of clinical relapses (MS attacks) by up to 66% and reduced the development of new or newly enlarging MRI-detected brain lesions. A greater proportion of those on therapy remained relapse-free compared to the placebo groups.

Tysabri appears to be safe and well tolerated; the most common side effects included headache, fatigue, urinary tract infection, depression, lower respiratory tract infection, joint pain and abdominal discomfort. There is no information available about long-term safety or its relative benefits or safety in comparison with other currently available treatments for MS.

The drug is given by monthly intravenous (into the vein) infusions in a doctor's office.

In the United States, the wholesale price of Tysabri has been announced to be \$1,808 per vial or dose, which would be \$23,504 (US) per year if taken every four weeks. The Canadian price will not be established until it is approved by Health Canada.

(With information courtesy, National MS Society [USA])

Biogen Idec Canada has made available an information line in English and French for further inquiries about Tysabri (natalizumab): 1-877-674-6365

ASK MS Information System Code: 1.4.1.12.2.p

National Research Department
National Communications & Government Relations Department

Disponible en français.

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