



Multiple
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Medical Update Memo

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Biogen Idec and Elan Pharmaceuticals announce Health Canada priority review for Antegren®

SUMMARY

Biogen Idec and Elan Pharmaceuticals have announced that Health Canada has granted a priority review to Antegren® (natalizumab). Antegren is a monoclonal antibody designed to interfere with movement of potentially damaging immune cells from the bloodstream across the blood brain barrier into the brain and spinal cord. According to Dr. Paul O'Connor, director, MS Clinic at St. Michael's Hospital in Toronto, who was quoted in the company news release, "Health Canada has agreed to give priority review to a treatment based on one-year trial data. The 2001 Phase II results were very promising and demonstrated the ability of Antegren to reduce MRI activity and the number of MS disease relapses."

DETAILS

There are several criteria which must be met in order for a product to be accorded priority review status by Health Canada. The drug must:

- o provide a statistically significant and clinically relevant improvement in efficacy or decrease in risk over existing therapies on the Canadian market;
- o be intended for patients suffering from a serious, life-threatening or severely debilitating condition;
- o be indicated to treat, prevent or diagnose a serious symptom or manifestation of the condition.

Antegren is a monoclonal antibody that is given by monthly infusion into a vein. It is designed to interfere with the movement of potentially damaging immune cells from the bloodstream, across the blood-brain barrier, and into the brain and spinal cord. (The blood-brain barrier is a layer of tightly connected cells that normally prevents large molecules and cells from entering the brain.) Antegren blocks this movement by

attaching to alpha 4-integrin, a protein on the surface of immune T cells which enables them to pass through the blood-brain barrier. To date, approximately 2,800 people with MS have received natalizumab in clinical studies.

The AFFIRM study of Antegren alone is a two-year, placebo-controlled study involving approximately 900 participants in North America and Europe. It is designed to determine whether natalizumab is effective in slowing the rate of disability in MS and reducing the rate of MS attacks when used alone.

The SENTINEL study of Antegren combined with interferon beta-1a (Avonex®), or Avonex combined with placebo, is a two-year, multi-centre study involving approximately 1,200 participants. The SENTINEL study is designed to determine whether the treatment of MS with natalizumab in combination with Avonex is more effective than Avonex treatment alone in slowing the rate of disability and relapses.

Because Health Canada has granted a priority review halfway through the two-year clinical trials, the one-year data submitted from the trials primarily address whether the drug reduced relapse rates. The full, two-year trials are collecting data on both relapse rates and on any slowing of the progression of disability, as measured with the Expanded Disability Status Scale (EDSS).

A previous six-month, placebo-controlled trial of Antegren, involving 213 people with relapsing-remitting MS or secondary-progressive MS with relapses, suggested that the drug was well tolerated, reduced the accumulation of new "enhancing" brain lesions detected by MRI, and reduced the number of relapses. David H. Miller, MD (Institute of Neurology, Queen Square, London) and colleagues reported these findings in the January 2, 2003 issue of *The New England Journal of Medicine* (2003;348:15-23).

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