

## Medical Update Memo

November 10, 2004

### **Biogen Idec and Elan Pharmaceuticals release initial one-year results from Antegren clinical trial**

#### **Summary**

Biogen Idec and Elan Pharmaceuticals recently announced initial one-year data from the Phase III clinical trial of Antegren® (natalizumab). According to the news release, clinical trial participants treated with Antegren had a statistically significant 66 percent reduction in relapse rate compared to participants in the placebo group. Antegren is under active review for approval as a possible treatment for MS in Canada, the United States, Europe and Australia. Health Canada has granted priority review to Antegren, and a decision is expected to be announced sometime in 2005. The Food and Drug Administration (FDA) in the United States is scheduled to act on the Antegren submission later in November. 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.

#### **Details**

Biogen Idec and Elan Pharmaceuticals recently announced initial one-year data from the Phase III clinical trial of Antegren® (natalizumab), which is known as the AFFIRM clinical trial. According to the news release, clinical trial participants treated with Antegren had a statistically significant 66 percent reduction in relapse rate compared to participants in the placebo group. Reduction of relapse rate was the primary end point for the one-year analysis.

AFFIRM is a two-year clinical trial to evaluate the effect of Antegren on the progression of disability and the rate of relapses. It is a randomized, multi-centre, placebo-controlled, double-blind study of 942 people with relapsing-remitting MS. In addition, all secondary endpoints (including MRI scans of brain lesions) supported the positive primary outcome, according to the companies. The two-year data should be available in the

first half of 2005 and should include more information on relapse rates as well as the progression of disability as measured by the Expanded Disability Status Scale. The one-year data from the AFFIRM study was presented to study investigators at a recent meeting.

Antegren is a monoclonal antibody which is designed to interfere with the movement of potentially damaging immune cells from the bloodstream across the "blood-brain-barrier" into the brain and spinal cord. Study participants received either Antegren by infusion into the vein (intravenous infusion) or a placebo infusion once a month. The active treatment appeared to be well tolerated. Adverse side effects that were more common in Antegren than in placebo participants included headache, fatigue and joint pain. The overall incidence of infection was similar between people on Antegren and those on placebo.

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A second study called SENTINEL involving Antegren is also underway. This study is testing whether Antegren in combination with interferon beta-1a (Avonex<sup>®</sup>) is more effective than Avonex treatment alone in slowing the rate of disability and relapses. Information on this study was not included in the news release.

The data released at the one-year mark supports data from other smaller and shorter clinical trials of Antegren. If the data are reviewed positively, Antegren would become another treatment choice for relapsing MS, joining the three beta interferons (Avonex, Betaseron<sup>®</sup> and Rebif<sup>®</sup>), glatiramer acetate (Copaxone<sup>®</sup>) and mitoxantrone (Novantrone<sup>®</sup>).

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