RESEARCH HIGHLIGHTS

In the news

CLADRIBINE HOPE FOR MULTIPLE SCLEROSIS

Clinical trial results announced at the 61st annual meeting of the American Academy of Neurology suggest that the immunosuppressant drug cladribine (Leustatin, <u>Ortho Biotech</u>; marketed for the treatment of leukaemia) could be a new therapy for patients with multiple sclerosis.

The Phase III CLARITY (CLAdRIbine Tablets in treating multiple sclerosis orallY) clinical trial conducted by <u>Merck Serono</u> involved 1,326 patients with relapsing-remitting multiple sclerosis over 2 years who were given two or four treatment courses per year. Cladribine reduced the chance of a relapse by 55% compared with placebo, and those patients who received cladribine were 30% less likely to suffer worsening in their disability.

Cladribine, which is the first oral treatment for multiple sclerosis, therefore gives comparable results to existing treatments "without the need for constant injections that are associated with unpleasant side effects," said study leader Gavin Giovannoni of Barts and The London School of Medicine and Dentistry (*Telegraph.co.uk*, 30 Apr 2009).

Lee Dunster, head of research at the <u>Multiple Sclerosis Society</u>, commented: "we now need to see cladribine move smoothly through the regulatory process" (<u>BBC News</u>, 29 Apr 2009). Merck Serono, the shares of which rose 2% in early trade on the news (<u>Reuters</u>, 30 Apr 2009), plans "to submit cladribine tablets for registration to the [European Medicines Agency] EMEA and to the [Food and Drug Administration] FDA for mid-2009," said Elmar Schnee, president of Merck Serono (<u>Medscape</u> <u>Medical News</u>, 30 Apr 2009).

But some sources have suggested that cladribine could face regulatory hurdles regarding immunosuppressive side effects, including increased risk of malignancy. It will not be suitable for pregnant women or those of child-bearing age owing to the risk of serious infection (*Financial Times*, 27 Apr 2009).

Kirsty Minton