January 27, 2006

**ADDITIONAL ROUTING**

_____ Research Advocate Staff Liaison  
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**MS TRIAL ALERT: NIH-SPONSORED COMBINATION THERAPY STUDY RECRUITING PATIENTS WITH MS**

**Summary:** Investigators are seeking participants for the first large-scale clinical trial testing the combined use of FDA-approved interferon beta-1a (Avonex®) and glatiramer acetate (Copaxone®) to treat relapsing-remitting multiple sclerosis. Approximately eighty medical centers in North America are recruiting patients who have relapsing-remitting MS for the study, called the CombiRx trial. Fred D. Lublin, MD (Corinne Goldsmith Dickinson Multiple Sclerosis Center at Mount Sinai School of Medicine, New York, NY) is lead investigator of this study, which is supported by the NIH's National Institute of Neurological Disorders and Stroke. The combination therapy will be compared to the use of either agent alone for a period of 36 months. All patients will receive at least one active medication and there will not be a placebo-only treatment arm.

An important ancillary study to this trial, the NIH-sponsored biomarker project, will examine genetic and other biological markers at baseline and at least one additional point during the study. The hope is that these biological markers will provide a means for identifying, in the future, those patients with more aggressive disease as well as patients who respond or fail to respond to therapy. Such markers would have considerable value in the management of patients.

**Rationale:** Treatment with disease-modifying agents can reduce future disease activity and improve quality of life for many individuals with relapsing forms of MS. However, researchers continue to explore whether using these agents in combination can enhance their effectiveness. This study is evaluating the effectiveness and safety of combination treatment with Avonex and Copaxone, each of which is approved by the U.S. Food and Drug Administration for the treatment of relapsing MS. A previous, smaller pilot trial of the combination therapy suggested it was safe and warranted further study.

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The National Multiple Sclerosis Society is proud to be a source of information about multiple sclerosis. Our comments are based on professional advice, published experience and expert opinion, but do not represent therapeutic recommendation or prescription. For specific information, and advice, consult your personal physician.
**Eligibility and Details:** People eligible for participation include men and women 18-60 years of age with relapsing-remitting MS (a course of MS in which clearly defined flare-ups are followed by complete or partial recovery periods), who have experienced at least two relapses in the previous three years and have never received either agent.

Participants will be randomly assigned to receive either 1) a combination of interferon beta-1a (30 micrograms given as a once-a-week intramuscular injection) and glatiramer acetate (20 milligrams injected subcutaneously once a day); 2) interferon beta-1a and an inactive placebo delivered subcutaneously; or 3) glatiramer acetate and a placebo delivered intramuscularly. Treatment is being administered for 36 months.

The primary objective of the study is to determine whether this combination treatment is effective in reducing relapse rates, when compared to treatment with either drug alone. Secondary objectives are to determine the safety and tolerability of this combination.

**Contact:** A list of states and provinces in which there are study sites follows. For specific contact information, please visit “Trials Recruiting Patients” section of the National MS Society Web site, at: http://www.nationalmssociety.org/Research-trialsrecruiting.asp. Please note that only sites that are currently recruiting patients will be listed in this area; check back for future updates if the site in your state is not listed yet.

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