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RESEARCH/CLINICAL UPDATE

Keyword:	Copaxone (glatiramer acetate)
Section:	TREATMENTS, APPROVED

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Study Suggests Copaxone Treatment Reduces Risk of Developing MS

Copaxone® (glatiramer acetate, Teva Pharmaceutical Industries) significantly reduced the risk of developing MS and delayed the development of MS in individuals with CIS (clinically isolated syndrome, a first event suggestive of MS) enrolled in the PreCISe study, according to a company press release dated December 3, 2007. Based on these results, the company is stopping the study early and is giving all participants, including those who were taking inactive placebo, an opportunity to receive Copaxone for two years. The company also reports that it plans to file requests with regulatory authorities in the U.S., Europe and Canada to expand the labeling of Copaxone to include patients with CIS.

Details: In the PreCISe study, 481 people with CIS with lesions typical of MS on brain MRIs were randomly assigned to receive either Copaxone (given by daily under-the-skin injections) or inactive placebo for up to 36 months. The primary outcome measure was the time it took individuals to experience a second attack that would confirm the diagnosis of definite MS. An interim analysis of data was performed as initially planned at the outset of the trial. According to the press release, the results showed that, in the Copaxone group, the risk of developing clinically definite MS was reduced by 44% versus placebo, and the time to development of definite MS was delayed by 386 days more than in the placebo group. The proportion of patients who developed MS was 43% in the placebo group versus 25% in the Copaxone group.

These data, which have not yet been published in a peer-reviewed journal, add to growing evidence for using disease-modifying drugs early to treat people with CIS who have lesions typical of MS as detected by brain MRI. Based on similar studies, Avonex® (interferon beta-1a, Biogen Idec) and Betaseron® (interferon beta-1b, Bayer Healthcare Pharmaceuticals) have already received approval to expand their labels to treat this indication.

-- Research and Clinical Programs Department