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GATE opens for generic equivalent to glatiramer acetate in MS

Published on October 15, 2015 at 5:15 PM

By Lucy Piper, Senior medwireNews Reporter

Findings from the GATE study have shown equivalent efficacy and tolerability for a generic version of glatiramer acetate to that of the original brand version in the treatment of relapsing–remitting multiple sclerosis (MS).

"The patents for the first approved treatments for [relapse-remitting] MS are expiring, creating the opportunity to develop generic alternatives, with the goal of cost savings for payers and patients", note the study researchers, led by Jeffrey Cohen (Cleveland Clinic, Ohio, USA).

For their phase III equivalence study involving 794 patients aged 18 to 55 years with relapsing–remitting MS, the researchers adopted gadolinium-enhancing lesion activity as the primary efficacy endpoint. The patients had at least one and no more than 15 gadolinium-enhancing brain magnetic resonance imaging lesions at the start of treatment, ruling out highly active disease.

During months 7 through 9 of follow-up, the 710 patients randomly assigned to daily subcutaneous injections of either generic or brand glatiramer (20 mg) had significantly fewer gadolinium-enhancing lesions than the 84 receiving placebo, at an average of 0.42 and 0.38 versus 0.82, and a combined ratio for active treatments to placebo of 0.488. This confirmed study sensitivity, the researchers note in *JAMA Neurology*.

Moreover, the generic drug, taken by 353 patients, reduced gadolinium-enhancing lesions to the same extent as the brand drug, with an estimated generic to brand drug ratio of 1.095, which was within the predefined equivalence margin of 0.727 to 1.375.

While formal equivalence margins were not defined for other clinical endpoints, such as annualised relapse rates, the researchers report that the 95% confidence intervals for the generic and brand drugs substantially overlapped.

The proportion of patients reporting adverse events, including injection site reactions, were similar across the three treatment groups, with no significant difference in the type of events reported or the severity.

"These results may allow for a generic alternative to the originator brand glatiramer acetate, [a relapsing–remitting] MS treatment with established long-term efficacy and safety", conclude the researchers.

But in a related editorial, Dennis Bourdette and Daniel Hartung, from Oregon Health & Science University in Portland, USA, question whether the advent of generic versions of glatiramer acetate will massively lower the cost of disease-modifying therapies in MS.

They believe the study by Cohen et al "provides reassurance" that the generic glatiramer acetate can be as efficacious as the brand version, but point out that as the first of its kind to be marketed, the price will only be modestly discounted.

"As other bioequivalent glatiramer acetate products receive regulatory approval and become available, we would expect that generic glatiramer acetate prices will drop much more", they add.

But in the meantime, the editorialists note that any moderate financial benefit of the once a day generic glatiramer will be further mitigated by more recent brand versions that are administered just three times a week.