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CLARITY Trial of Oral Cladribine in MS Meets Primary End Point

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Authors and Disclosures

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January 26, 2009 — Top-line phase 3 results with oral cladribine in relapse-remitting multiple sclerosis (MS) show that the trial met its primary end point, with a 58% reduction in annualized relapse rates with the low dose and a 55% reduction with the high dose at 2 years.

The announcement of results from the Cladribine Tablets Treating MS Orally (CLARITY) trial was released last week by Merck Serono (Geneva, Switzerland), maker of cladribine oral tablets.

"Based on successful completion of the CLARITY study, we plan to submit cladribine tablets for registration to the [European Medicines Agency] EMEA and to the [Food and Drug Administration] FDA for mid-2009," Elmar Schnee, president of the company, said in the announcement.

The CLARITY study was a randomized, double-blind, placebo-controlled trial. A total of 1326 patients with relapsing-remitting MS according to revised McDonald criteria were randomized in a 1:1:1 ratio to receive placebo or 1 of 2 dose regimens of cladribine.

Patients in the low-dose group received 2 treatment courses in the first year, with each course consisting of once-daily administration for 4 to 5 consecutive days. The high-dose group received 4 treatment courses in the first year. In the second year, both treatment groups were given 2 treatment courses.

The primary end point was the qualifying relapse rate at 96 weeks, the company release notes. Secondary analyses included magnetic-resonance-imaging (MRI) end points, the proportion of subjects who remained relapse-free, and disability progression at 96 weeks.

Of treated patients, 90% completed the study (92% in the lower-dose group and 89% in the higher-dose group), compared with 87% in the placebo group.

The release notes that at 96 weeks, there was a statistically significant reduction in the annualized relapse rate with both the higher- and lower-dose regimens compared with placebo.

CLARITY: Primary End Point

End point	Relative Reduction in Annualized Relapse Rate vs Placebo (%)	Annualized Relapse Rate for Total Dose	Annualized Relapse Rate for Placebo	*P*
Lower total dose	58	0.14	0.33	< .001
Higher total dose	55	0.15	0.33	< .001

Secondary end points were also met, the release notes, including reduction of lesion activity on MRI, the proportion of subjects who remained relapse-free, and disability progression.

The frequency of adverse events was low with cladribine and comparable to placebo, the statement adds. "Lymphopenia, an expected event based on the presumed mechanism of action of cladribine, occurred more frequently in the cladribine-tablet-treatment groups."

Except for lymphopenia, the most frequently reported adverse events in the 3 study groups were headaches and nasopharyngitis, the release adds.

The full data have been submitted for presentation at an upcoming medical meeting, the company notes.

The study was supported by Merck Serono, an affiliate of Merck.

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