January 18, 2012 — Topline results of a phase 3 trial of dimebon, also called latrepirdine, on top of ongoing treatment with donepezil has shown no benefit in patients with mild to moderate Alzheimer's disease (AD).

The companies developing dimebon in this indication, Medivation Inc and Pfizer Inc, issued a joint statement noting that results of the phase 3 CONCERT trial showed that the addition of dimebon had no statistically significant benefit on either of the 2 co-primary endpoints, change from baseline in the Alzheimer's Disease Assessment Scale – cognitive subscale (ADAS-cog) or the activities of daily living subscale (ADAS-ADL).

"Medivation and Pfizer will discontinue development of dimebon for all indications and will terminate the ongoing open label extension study in Alzheimer's disease," the joint company statement notes. The companies also plan to terminate their collaboration to codevelop and market dimebon.

The CONCERT trial was a 12-month global randomized, double-blind, placebo-controlled trial that enrolled 1,003 patients with mild to moderate AD. Patients receiving a stable dose of donepezil for at least 4 months were randomly assigned to 1 of 3 treatment groups: dimebon, 20 mg 3 times per day; dimebon, 5 mg 3 times per day; or placebo.

Although there was no apparent benefit, the drug was generally well tolerated in the study, the companies add. "A full analysis of the results from CONCERT will be conducted and submitted for presentation at an upcoming scientific congress," the statement concludes.

Although phase 2 results with this agent were extremely positive in the treatment of AD, previous negative results have been reported with dimebon in phase 3 in the CONNECTION trial, as well as in the treatment of Huntington's disease in the HORIZON trial.

Joint statement

Lancet. 2008;372:207-215. Full text