

[S41.008] Dimebon Improves Memory, Orientation, Language, and Praxis in Patients with Mild to Moderate Alzheimer's Disease: Results of a One-Year Placebo-Controlled Study

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OBJECTIVE: A one-year double-blind placebo-controlled trial of Dimebon was conducted in patients with mild to moderate Alzheimer's disease (AD). Dimebon-treated patients were improved on all five outcomes at Week 52 (observed case analysis [OC]): Alzheimer's Disease Assessment Scale-cognitive (ADAS-cog), CIBIC-plus, MMSE, ADL, and NPI. We report an analysis of the subdomains of the ADAS-cog to explore whether the cognitive benefits were specific to particular aspects of cognition. **BACKGROUND:** Patients with AD have deficits in cognition and memory, a decrease in their ability to perform activities of daily living and behavioral problems. The effect of Dimebon, a new investigational drug for AD, on these aspects of the disease has been reported in a study of 183 patients with mild to moderate AD (MMSE 10-24). Dimebon demonstrated a 6.9 point benefit over placebo at week 52 on memory and cognition as assessed by the 11-item ADAS-cog ($p < 0.0001$; OC). The ITT-LOCF analysis results were similar. **DESIGN/METHODS:** ADAS-cog was assessed at baseline and at weeks 12, 26, 39 and 52. Exploratory subdomain analyses of the drug-placebo difference for each item on the ADAS-cog at week 52 was conducted using OC with no statistical correction for multiplicity. **RESULTS:** Patients treated with Dimebon improved compared to placebo on each of the ADAS-cog subdomains at Week 52 (OC); 9 of the 11 demonstrated statistical significance ($p < 0.05$). Benefit was observed in memory: word recall (-0.5, $p = 0.04$), word recognition (-1.62, $p = 0.03$), remembering instructions (-0.24, $p = 0.10$). Orientation was improved (-0.88, $p = 0.01$), as were constructional and ideational praxis (-0.47, $p = 0.005$; -0.47, $p = 0.006$). Improvements were also seen in language: following commands (-0.65, $p < 0.0001$), naming objects (-0.78, $p < 0.0001$), word finding (-0.39, $p = 0.005$), comprehension (-0.24, $p = 0.15$), and overall language (-0.62, $p = 0.0002$). **CONCLUSIONS/RELEVANCE:** Dimebon improves memory, orientation, praxis, and language as compared to placebo through one year of treatment in patients with mild to moderate AD. These subtest results suggest that Dimebon provides a broad rather than domain-specific cognitive benefit. Supported by: Medivation, Inc.

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