RESULTS OF A ONE-YEAR RANDOMIZED, PLACEBO-CONTROLLED TRIAL OF DIMEBON FOR THE TREATMENT OF MILD TO MODERATE ALZHEIMER'S DISEASE

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Background: Dimebon is a novel oral small molecule shown to be well-tolerated and to improve cognition, function, behavior, and global impression of change in a randomized, controlled 6-month study. One-year results from the continuation of that previously reported study will be presented.

Objective(s): Study **o**bjectives were to evaluate the safety and efficacy of Dimebon after 12 months of treatment.

Methods: 183 patients in Russia with mild to moderate AD (MMSE of 10-24 inclusive) were randomized to Dimebon, 20 mg orally three times a day, or placebo for 6 months and then offered blinded continuation for an additional 6 months. ADAS-cog (primary endpoint), CIBIC-plus, MMSE, NPI, and ADL at baseline and at weeks 12, 26, 39 and 52 were assessed. Other anti-dementia drugs were not allowed. The primary analysis was performed following completion of 26 weeks of treatment. A secondary analysis following 52 weeks of treatment will be presented.

Results: The mean screening MMSE was 18 (SD 3.3). 85% of patients completed the first 6-months of the trial (Dimebon 87.6%; placebo 81.9%). Intention-to-treat analyses with LOCF are reported. Dimebon resulted in statistically-significant improvements in ADAS-cog, CIBIC-plus, MMSE, NPI, and ADL scores relative to placebo at week 26. The mean drug-placebo differences were: ADAS-cog (4.0 units, $p < 0.0001$); CIBIC-plus (0.6 units, $p<0.0001$); MMSE (2.2 units, $p< 0.0001$); NPI (3.6 units, $p = 0.006$), and ADL (3.4 units, $p= 0.002$). Treatment with Dimebon also resulted in significant improvements in all 5 endpoints when the mean baseline scores were compared with the week 26 scores. Eighty-six percent of patients completing week 26 continued treatment for an additional six months in their originally-randomized treatment groups. The 52-week safety and efficacy data from this trial will be available for presentation at this meeting.

Conclusions: Dimebon-treated patients were significantly improved after 6 months compared to placebo patients on all five efficacy endpoints, and also as compared to their mean baseline at the beginning of the trial. One year randomized controlled data will be presented to demonstrate the durability of the treatment effect and one-year safety profile of Dimebon.