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## Experimental Drug Reduces Pseudobulbar Affect in Patients With MS, ALS: Presented at ANA

By Charlene Laino

BALTIMORE, Md -- October 18, 2009 -- Treatment of pseudobulbar affect, the involuntary and seemingly inappropriate outbursts of laughter or crying associated with some neurological disorders, maybe possible with an experimental treatment combining dextromethorphan and quinidine, doctors reported here at the American Neurological Association 134th Annual Meeting.

"Both doses of dextromethorphan/quinidine met the primary efficacy outcome by significantly reducing pseudobulbar affect episode rates compared with placebo," said Benjamin Rix Brooks, MD, Carolinas Medical Center, Charlotte, North Carolina, in his October 13 poster presentation.

Pseudobulbar affect is commonly associated with a number of neurologic disorders such as multiple sclerosis (MS) and amyotrophic lateral sclerosis (ALS), Dr. Brooks said in his report describing the use of dextromethorphan/quinidine (also known as AVP-923), which is being developed by study sponsor, Avanir Pharmaceuticals, Aliso Viejo, California.

The researchers enrolled 326 patients diagnosed with ALS or MS in the past 30 months. The patients averaged about 35 episodes of outbursts per week. Patients were randomly assigned to receive placebo or 1 of 2 doses of dextromethorphan/quinidine -- dextromethorphan/quinidine 30/10 mg or dextromethorphan/quinidine 20/10 mg.

Dr. Brooks reported that after 3 months of treatment, about 30% of patients in the placebo group had achieved remission from pseudobulbar affect, that is, they had been free of episodes for the last 14 days. In contrast, about 70% of patients taking the higher dose of dextromethorphan/quinidine, and 67% of those on the lower dose, achieved remission under the same criteria.

"The impact of pseudobulbar affect on social function is severe and may result in social withdrawal," Dr. Brooks said. "We observed that dextromethorphan/quinidine 30/10 mg significantly improved quality of life as related to mental health. Improvements in social functioning and mental health subscale scores suggest that the social and psychological disability associated with pseudobulbar affect may be reduced with dextromethorphan/quinidine 30/10 mg."

In the standard SF-36 Health Survey, patients improved their summary score 4.51 points on dextromethorphan/quinidine 30/10 mg ( $P = .0193$ ), and 1.77 points on dextromethorphan/quinidine 20/10 mg ( $P = \text{NS}$ ) compared with 0.28 points on placebo. Patients especially did well on the social functioning subscale and on the mental health scale subscale.

Dr. Brooks said the treatment was generally well tolerated. "While commonly reported, the incidence of falls, headache, somnolence, and fatigue for dextromethorphan/quinidine-treated patients was not different from the placebo group," he said.

Seven patients died in study: 3 in each of the active treatment groups and 1 in the placebo group. He said all the deaths were among patients with ALS and were associated with disease progression.

*[Presentation title: Double-Blind, Placebo-Controlled Study of AVP-923 for Pseudobulbar Affect. Abstract WIP-24]*