Long-Term Benefits of Rivastigmine in Dementia Associated With Parkinson’s Disease: An Active Treatment Extension Study

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Abstract: In patients with dementia associated with Parkinson's disease (PD), the efficacy and safety of rivastigmine, an inhibitor of acetylcholinesterase and butyrylcholinesterase, were previously demonstrated in a 24-week double-blind placebo-controlled trial. Our objective was to determine whether benefits were sustained over the long term. Following the double-blind trial, all patients were permitted to enter an active treatment extension study, during which they received rivastigmine 3-12 mg/day. Standard safety assessments were performed. Efficacy assessments included the Alzheimer's Disease Assessment Scale cognitive subscale (ADAS-cog) and other measures of cognition, daily function, neuropsychiatric symptoms, and executive function. Of 433 patients who completed the double-blind trial, 334 entered and 273 completed the active treatment extension. At 48 weeks, the mean ADAS-cog score for the whole group improved by 2 points above baseline. Placebo patients switching to rivastigmine for the active treatment extension experienced a mean cognitive improvement similar to that of the original rivastigmine group during the double-blind trial. The adverse event profile was comparable to that seen in the double-blind trial. Long-term rivastigmine treatment appeared well tolerated and may provide sustained benefits in dementia associated with PD patients who remain on treatment for up to 48 weeks. Copyright 2005 Movement Disorder Society.

Appendix: The following were principal investigators in this study: Austria: Werner Poewe; Belgium: Peter Paul DeDeyn, Rene Dom, Anne Jeanjean, Eric Salmon; Canada: Sylvain Chouinard. Giovanni Marotta, Tilak de Mendis, Michel Panisset, Emmanuelle Pourcher, Alain Robillard, Teodore Rosenberg; France: Jean-Philippe Azulay, Jacques Boulliat, Alain Destee, Franck Durif, Lucette Lacomblez, Rosemarie Marié, Pierre Pollak, Francois Tison, Jacques Touchon; Germany: Dolores Backhaus, Ralf Bodenschatz, Guenther Deuschl, Georg Ebersbach, Juergen Faiss, Thomas Gasser, Fabian Klostermann, Wolfgang Mattern; Wolfgang Oertel, Bemhard Ralhay, Helma Sommer, Konstanze Tinscher; Italy: Giovanni Abbruzzese, Alberlo Albanese, Paolo Barone, Ubaldo Bonuccelli, Margherita Canesi, Luigi Grimaldi, Giuseppe Meco, Giampiero Nordera, Marco Onofrj. Paolo Stanzione, Carlo Alberlo Tassinari; The Netherlands: Teus van Laar, Erik Wolters; Norway: Dag Aarsland; Portugal: Mario Rosa; Spain: Guillermo Amer, Emesl Balaguer, Malilde Calopa, Jaume Kulisevsky, Juan Lopez, Dolores Maleo, Jordi Peija, Eduardo Tolosa; Turkey: Bulent Elibol. Murat Emre (Lead investigator), Sibel Ozekmekcil; United Kingdom: Anthony Bayer, David Burn, Jane Byrne, D. Gunawardena, Andrew J. Lees, Marie-Helene Marion, Chris McWilliam, Malcolm Steiger, Stephen Vethanayagam.