RESULTS OF A LONG-TERM SAFETY STUDY OF RIVASTIGMINE CAPSULES AND PATCH IN PATIENTS WITH MILD TO MODERATE DEMENTIA ASSOCIATED WITH PARKINSON'S DISEASE

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Introduction: Dementia is common among patients with Parkinson's disease. Rivastigmine capsules have demonstrated improvements in symptoms of dementia associated with Parkinson's disease (PDD) in a 24-week double-blind placebo-controlled trial, and also in patients receiving treatment for up to 48-weeks. Rivastigmine is the only cholinesterase inhibitor approved for treating PDD.

Aims: To present results from a long-term study evaluating rivastigmine 12 mg/day capsules and 9.5 mg/24 h patch in mild-to-moderate PDD.

Methods: A 76-week, prospective, randomized, multicentre, open-label study of rivastigmine capsules and patch was conducted in 50-85 year old patients, with MMSE scores of 10-26, and a Modified Hoehn and Yahr Stage < 5 in “on” state. Primary outcomes were incidence of, and discontinuation rates due to, pre-defined adverse events (AEs): tremor, muscle rigidity, bradykinesia and fall. Other safety assessments included: Unified Parkinson's Disease Rating Scale Part III; serious AEs; Pulmonary function tests (FEV1 and PEF); Schellong test; Epworth Sleepiness Scale. Main efficacy assessments included: Mattis Dementia Rating Scale (MDRS); Neuropsychiatric Inventory (NPI-10); Alzheimer's Disease Cooperative Study-Activities of Daily Living (ADCS-ADL).

Results: 583 patients were randomized. At screening, mean age was 72.4 (SD 6.31) years, 32% were women and mean MMSE score was 20.9 (SD 3.36). Safety and efficacy data will be available by late 2010 and presented during AD/PD-2011.

Conclusions: This is the largest study in PDD with a cholinesterase inhibitor to date. These findings will add to longer-term safety data on treatment of PDD with rivastigmine.