LONG-TERM EFFECTS OF GALANTAMINE ON COGNITIVE FUNCTION IN ALZHEIMER’S DISEASE: A LARGE-SCALE INTERNATIONAL RETROSPECTIVE STUDY

B. Schaeuble¹, S. Kavanagh², B. van Baelen³

¹Janssen, Pharmaceutical Companies of Johnson & Johnson, Neuss, Germany, ²Janssen, Pharmaceutical Companies of Johnson & Johnson, Beerse, ³SGS Life Science Services, Mechelen, Belgium

Introduction: Limited information is available on long-term cognitive effects of Galantamine in Alzheimer Disease (AD) measured by Mini-Mental State Examination (MMSE) scores.

Aim: To evaluate long-term effects of Galantamine with MMSE for up to 7 years.

Method: Combined data were assessed from 258 patients who were recruited into 3 randomized clinical trials involving galantamine: 2 placebo-controlled trials in mild-to-moderate AD (of 3 and 6 months’ duration, followed by open-label extensions), together with the galantamine-treatment arm of a 12-month comparative study with donepezil in moderate AD. Up to 5 years of follow-up data were obtained for completers and for individuals who withdrew. Information about disease progression was collated (up to 5 MMSE scores, separated minimum 3 months interval, for each patient). Changes in MMSE scores over time were based on observed data. In the absence of long-term placebo data, the rate of cognitive decline without treatment was projected using a previously described epidemiological model. In addition, a new, exploratory statistical model was developed to explore the effects of galantamine treatment, or withdrawal of treatment, on MMSE progression.

Results: Showed that patients with mild-to-moderate AD on long-term galantamine treatment maintained cognitive function, as assessed by MMSE, compared with the predicted decline in the absence of treatment. Furthermore, patients who stopped treatment experienced subsequent cognitive decline at a rate similar to that predicted for untreated patients.

Conclusion: This analysis maybe particularly relevant in the context of current treatment and research in AD, in which treatment with new drugs may be adjunctive in nature.