EFFICACY AND SAFETY OUTCOMES OF GALANTAMINE IN PATIENTS WITH ALZHEIMER’S DISEASE TRANSITIONING FROM DONEZEPIL

B. Schaeuble1, U. Richarz2, M. Gaudig3, J. Han4, K. Engedal5

1Janssen, Pharmaceutical Companies of Johnson & Johnson, Neuss, Germany, 2Janssen, Pharmaceutical Companies of Johnson & Johnson, Baar, Switzerland, 3Janssen, Pharmaceutical Companies of Johnson & Johnson, High Wycombe, UK, 4Janssen, Pharmaceutical Companies of Johnson & Johnson, Titusville, NJ, USA, 5Norwegian Centre for Dementia Research, Ulleval University Hospital, Oslo, Norway

Introduction: Galantamine, has allosteric modulating activity at nicotinic receptors and inhibits acetylcholinesterase. This dual mechanism of action may make galantamine an attractive option for patients with Alzheimer’s disease who have not benefited from current therapy

Objectives: To explore clinical outcomes in subjects with AD transitioning from Donepezil due to insufficient tolerability and/or efficacy

Methods: Post hoc analyses of an open-label, 12-weeks flexible dose study including patients with mild to moderate AD transitioning from Donepezil onto Galantamine. After screening and a 7 day washout period, subjects were randomly allocated to either Galantamine fast (8mg/week increments) or slow titration (8mg/4week increments) to maximal total daily dose between 16mg - 24mg. Data presented are based on pooled analyses. Efficacy and safety outcomes included ADAS-cog/11; CIBIC-plus, safety parameters.

Results: Eighty-six out of 89 patients (ITT population) completed the study. Comparing screening to endpoint at week 13, ADAS-cog/11 score improved by -1.6 (p=0.009), and MMSE by 0.9 (p=0.002). Results were similar for subjects with ≥ 6 months donepezil exposure. Overall, 68% of subjects either maintained or improved on ADAS-cog/11, and 35% improved by at least 4 points. CIBIC-Plus analyses showed no change / improvement in 66% of the subjects. Galantamine was generally well tolerated with nausea (5.6%) and bradycardia (4.5%) most commonly reported. 5 patients reported SAEs unrelated to study drug.