

## Abstract of Souvenaid® clinical trial findings as presented at the Alzheimer's Association International Conference on Alzheimer's Disease 2008 (ICAD)

### **The efficacy of Souvenaid® in mild Alzheimer's Disease: a randomized, controlled, double-blind, parallel group, multi-centre, multi-country clinical trial.**

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### **Background**

Increasing evidence shows a role of nutrients in Alzheimer's Disease (AD). Extensive preclinical studies have demonstrated that a combination of nutrients increases synapse formation and reduces the production of beta-amyloid.

### **Objective**

To assess the effect of an intervention with a medical food on memory and cognitive performance in drug naïve mild AD patients.

### **Methods**

Drug naïve mild AD patients (MMSE 20-26) were randomly allocated to receive Souvenaid®, a 125ml (125kcal) once-a-day milk-based drink containing Fortasyn™ Connect [a specific combination of nutrients] or an iso-caloric control drink in a double-blind 12 weeks study. Primary outcome measures were a delayed verbal memory task (derived from Wechsler Memory Scale-revised) and the 13-item modified ADAS-cog at 12 weeks. In an optional double-blind 12

### **Methods**

week extension phase patients continued to receive the same study product. On both the intention-to-treat population and a pre-specified subgroup of very mild AD (MMSE>23) non-parametric statistics was used for the delayed verbal memory task and repeated-measures mixed model analysis was performed for the modified ADAS-cog. The trial was preregistered with the Dutch Trial Register (#ISRCTN72254645).

### **Results**

Of 212 enrolled study patients (mean MMSE 23.9, mean age 73.7, male 50%), 106 were assigned to Souvenaid® and 106 to control and no significant baseline differences were detected. There was no decline in modified ADAS-cog and verbal memory in the control group. In the Souvenaid® group a significant benefit was found in mild and very mild AD patients on the delayed verbal memory task. The unadjusted analyses showed no significant effect on the modified ADAS-cog. However, the baseline modified ADAS-cog score was a predictor for the intervention effect, i.e. patients with a higher baseline score showed a greater effect of Souvenaid®. Intervention with Souvenaid® was well tolerated (compliance was 94%) and safe. There was no significant difference in (S)AEs between the study groups throughout the study period.

### **Conclusion**

Souvenaid® is safe and well tolerated. This proof-of-concept study demonstrates that Souvenaid® given for 12 weeks improves memory in mild and very mild AD. These findings justify further studies with Souvenaid® in patients with AD.

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