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Medical Food Linked to Memory Improvement in Mild Alzheimer's

Caroline Cassels

July 23, 2012 (Vancouver, British Columbia) — Administration of a medical food designed to improve synaptic dysfunction is associated with continuous memory improvement in patients with mild Alzheimer's disease (AD), new research shows.

Presented here at the Alzheimer's Association International Conference (AAIC) 2012, results from an open-label extension (OLE) trial of a medical nutrition product (*Souvenaid*, Nutricia/Danone) showed that memory performance continued to improve in drug-naïve patients with mild AD for up to 48 weeks.

These latest OLE results immediately follow those of the double-blind, randomized controlled Souvenir II study, published in the July issue of the *Journal of Alzheimer's Disease*, which showed significant improvement in memory performance compared with placebo over 24 weeks.

As presented by Philip Scheltens, MD, PhD, professor of cognitive neurology and director of the Alzheimer Center at the VU University Medical Center in Amsterdam, the Netherlands, the results from the 24-week OLE study "were exactly what we hoped for."

Dr. Philip Scheltens

At 48 weeks, memory of participants in the group randomly assigned to receive active treatment and who continued to receive Souvenaid in the OLE part of the study improved even further.

"There was no ceiling effect," he said.

Furthermore, study participants who were in the placebo group in the randomized controlled period of the trial and who were switched to the active treatment in the OLE study also experienced significant memory improvement.

"The bottom line is that we have now conducted 2 large studies with this medical food that aims to restore the function of synapses in mild to very mild Alzheimer's disease and have proven that it improves memory," Dr. Scheltens told *Medscape Medical News*.

He added that the findings also show that Souvenaid is "very safe and well tolerated" and confirm the results of the Souvenir I trial, the very first proof of concept study, which was published in the journal *Alzheimer's & Dementia* and reported by *Medscape Medical News* at that time.

New Management Approach?

Developed by researchers at the Massachusetts Institute of Technology, in Boston, Souvenaid is a medical nutrition test product designed to support synapse formation.

"It is medical nutrition, and we think it may offer a new approach — a dietary management approach, if you like — for people with very early AD," Dr. Scheltens told reporters attending a press briefing.

Synapse loss, he said, is an early event in the AD process. By providing the nutritional precursors and cofactors for synapse formation, researchers hope to support the formation and function of synapses.

The once-a-day drink contains a patented nutrient combination with the following ingredients:

- Eicospentaenoic acid, 300 mg
- Docosahexaenoic acid, 1200 mg
- Phospholipids 106 mg
- Choline, 400 mg
- Uridine monophosphate, 625 mg
- Vitamin E (alpha-tocopherol equivalents), 40 mg
- Selenium, 60 µg
- Vitamin B12, 3 µg
- Vitamin B6, 1 µg
- Folic acid, 400 µg

The Souvenir I trial demonstrated a small but statistically significant effect on the primary outcome measure of memory at 3 months in favor of Souvenaid. Although the findings were "modest," they provided a sufficient signal for researchers to pursue the product's safety and efficacy in a larger trial.

The Souvenir II study was a 6-month trial that also had memory as its primary endpoint and that looked at safety over a longer period in 259 participants with mild AD (Mini–Mental State Examination score, 25.0) who were randomly assigned to receive either 125 ml of Souvenir once daily or a control drink.

Favorable Risk/Benefit Profile

The current findings also showed there was a statistically significant beneficial effect on memory in favor of Souvenaid at 6 months. Of the 238 patients who completed this trial, 198 participants entered the OLE study. Of these participants, 181 completed it.

The results revealed that at 48 weeks, the product was well tolerated with no serious adverse events. In addition, the compliance rate was more than 90%

The OLE results also revealed that memory performance as measured by the neuropsychological test battery (NTB) continued to improve significantly in study participants who received Souvenaid for the full 48 weeks (P = .025).

In addition, in the group that received placebo for the first 24 weeks, there was a significant improvement in NTB memory scores during the OLE following conversion to the active treatment (P = .009).

Approximately 30% of the patients who went into the open-label follow-up actually began therapy on cholinesterase inhibitors. The researchers found no difference in the effect of Souvenaid with our without these drugs.

Dr. Scheltens noted that on the basis of the primary endpoint of memory, the effect size of Souvenaid was on the order of cholinesterase inhibitors, which are 1 of 2 classes of drugs used to treat AD symptoms.

However, he added, because there were virtually no side effects associated with Souvenaid, the medical food had a more favorable risk/benefit ratio vs cholinesterase inhibitors.

Souvenaid will launch in Europe sometime this fall. It requires a diagnosis of mild AD and a prescription from a physician. It is as yet uncertain whether its cost will be reimbursed by insurers. Exactly when it will be launched in the United States is not clear.

The investigators are currently conducting a study of Souvenaid funded by European Commission of prodromal AD. Known as the LIPIDDi Diet study, it will include 300 participants with 3-year follow-up.

On the Right Track

Commenting on the findings for *Medscape Medical News*, Majid Fotuhi, MD, PhD, a practicing neurologist and chairman and medical director of the Neurology Institute for Brain Health and Fitness in Lutherville, Maryland, said the treatment approach makes sense.

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Dr. Majid Fotuhi

"We need to aim for treatments that are financially acceptable and which carry minimal risk. I really believe we should put most of the research focus on prevention.

"I think, in general, interventions that are inexpensive, safe, and tolerable are more likely to be broadly used. This was a multicenter study that showed positive results, and I think the researchers are on the right track," said Dr. Fotuhi.

Dr. Scheltens and Dr. Fotuhi have disclosed no relevant financial relationships.

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