

Nutricia Press Release for 30 October CTAD

FINAL

Nutricia will invest in a new medical nutrition study, targeting patients at the earliest stage of Alzheimer's disease

Nutricia Advanced Medical Nutrition, the specialised healthcare unit of Danone, will invest in a new study of the effects of a medical nutrition concept in brain function, targeting people at the earliest measurable stage of Alzheimer's disease. The new study will extend a decade-long programme of research and clinical studies of the concept, which was originally developed at MIT.

The announcement was made at CTAD, the annual conference for clinical trial researchers working in the field of Alzheimer's disease. New data from a recent clinical trial sponsored by Nutricia was presented at the conference.

The new study is still in the design stage, but may start as early as 2013. It will be the next in a series of clinical trials to test the medical nutrition concept. The concept was designed to meet the nutritional needs of patients with early Alzheimer's disease, by supporting the normal metabolic pathways involved in formation of new synapses in the brain. Results from two completed trials, published in 2010 and 2012, have demonstrated a positive effect in patients with early Alzheimer's disease, or AD.

"I am delighted to confirm that Nutricia will continue its investigations into the role that specialised nutrition can play in supporting brain function, by targeting people at the earliest stages of AD with memory problems," said Dr Rolf Smeets, Nutricia's Chief Medical Officer. "Early research suggested that our approach could effectively address the nutritional needs of patients with early AD, and we now have strong clinical trial data to support this hypothesis. A further study will help to establish the clinical relevance of our medical nutrition approach in this important disease area, at an even earlier stage."

Cognitive decline in early AD is thought to be associated with synapse loss, and the reduction of synaptic contacts in the brain, even before the emergence of other clinical symptoms. Plasma levels of the specific nutrients needed to form new synapses are lower in patients with AD, compared with age-matched controls.

Medical Nutrition, developed to address this need, offers a new approach in the management of patients in the early stages of AD, a disease where millions of people need support.

Nutricia and Alzheimer's disease: A Clinical Trial History

Souvenir I (2010)

Souvenir I was a study designed to investigate the safety and efficacy of a nutritional concept in drug-naïve patients with mild AD. A total of 225 patients (mean MMSE score of 23.9) participated in a double-blind controlled trial. Patients were randomised to a 125ml drink containing the patented nutrient combination Fortasyn Connect®, or an iso-caloric control drink, taken once-daily for 12 weeks.

At 12 weeks, significant improvement in the delayed verbal recall task of the Wechsler Memory Scale (revised) was noted in the active group compared with control. The results were published in the peer-reviewed journal *Alzheimer's & Dementia* in 2010.

S-Connect (2011)

The primary objective of the S-Connect study was to investigate the 24-week effect of a daily drink containing Fortasyn Connect® on cognitive performance in 527 patients with mild-to-moderate AD on stable doses of AD medication. Initial results from this trial, which showed no positive effect in patients in this stage of the disease, were presented in a poster at the 4th Conference of Clinical Trials Into Alzheimer's Disease (CTAD) in San Diego, in November 2011.

Souvenir II (2012)

The Souvenir II study was a 24-week, randomised, controlled, double-blind, multi-country trial conducted across 27 study centres in six European countries. A total of 259 drug naive patients participated.

Results from the study, published in the *Journal of Alzheimer's Disease* (JAD, July 2012) demonstrated improved memory performance at 24 weeks in patients with mild AD, taking a once-a-day drink containing Fortasyn Connect®. EEG measures of synaptic activity also showed changes over 24 weeks. The test product was well-tolerated and adherence to intervention was high.

LipiDiDiet (ongoing)

LipiDiDiet was initiated to investigate a nutritional concept in individuals with prodromal AD, a condition between healthy aging and dementia. The primary objective of the ongoing, independent, EU-funded study (300 patients) is to assess whether cognitive performance is maintained over 24 months of use of a daily drink containing Fortasyn Connect®. The study will also assess whether the concept can delay progression to AD (secondary endpoint). Results from the trial may be expected in 2015.

About Nutricia Advanced Medical Nutrition

Nutricia is a specialised healthcare unit of Danone, one of the fastest-growing food companies in the world. Nutricia expands and completes Danone's mission to bring health through food to as many people as possible, by focusing on support for vulnerable people whose health is at risk, either because they have particular nutritional requirements that must be addressed, or they suffer from undernutrition or the risk of undernutrition. Nutricia works with healthcare professionals to provide specialised nutritional support as an integral part of disease management - in paediatrics, in adult patients, and in the care of the elderly.

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