

# Breakthrough in Alzheimer's Disease

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## AFFiRis halted clinical progression in Alzheimer patients upon treatment with AD04 in a phase II clinical study

AFFiRis announced today the results of a phase II study in Alzheimer patients. AFFiRis' proprietary compound AD04 is the first drug ever to demonstrate clinical and biomarker effects consistent with disease modification in Alzheimer patients.



Upon treatment with AD04, effects consistent with disease modification were achieved for at least 18 months in 47 % of treated patients. This beneficial effect was dose dependent and more effective in early disease patients. Furthermore, prevention of hippocampal decline was correlated with the beneficial impact on clinical progression and was statistically significant. Therefore, these results for the very first time meet all of the criteria for disease modification as defined by US and European Regulatory Agencies FDA (Food and Drug administration) and EMA (European Medicines Agency).

AFFiRis AG of Vienna, Austria, today released for the first time results of a clinical phase II study in Alzheimer patients of its proprietary compound AD04, a therapeutic drug against Alzheimer's disease. The results show an impressive therapeutic effect of AD04 and make it the first ever compound demonstrating clinical and biomarker evidence consistent with disease modification of Alzheimer's disease. A statistically significant correlation was demonstrated between the cognitive/functional outcome and the volume of the hippocampus, the region of the brain locating the cognitive/memory functions, both of which demonstrated positive impact on disease progression over 18 months. Similar stabilization was also seen across behavioral and quality of life outcomes.

There was also a stabilization of the cognitive/functional endpoint found in those patients of this study who were treated with AD02, so far the company's lead compound in AD. Dependent on dosage and formulation of AD02 in three different study arms, 24 – 31 % of the patients showed cognitive/functional stabilization or improvement. However, statistically significant correlation with biomarker Hippocampus volume could not be demonstrated within the observation period of 18 months. Altogether 332 patients were treated in an international multi-centric clinical trial into five different study arms, and over 85 % completed the study.

### SIGNIFICANT IMPACT

Commenting on these results Dr. Walter Schmidt, CEO and Co-founder of AFFiRis AG, states: "Our results demonstrate that AD04 is the first drug ever to show disease modifying properties in Alzheimer's patients. This success is owed to our strategy of clinical maturation, which in the case of Alzheimer has so far moved forward four different product candidates namely AD01 – AD04 into clinical development."

Dr. Frank Mattner, CSO and Co-founder, adds: "Both compounds applied in this trial, AD02

and AD04, showed excellent safety profiles. Top compound AD02 performed very well in stabilization of cognitive functions in a dose dependent manner. 24 – 31 % of treated patients showed stabilization of clinical progression. However, AD04 turned out to be superior to AD02 as 47 % of the patients stabilized regarding their cognitive/ functional status. On top of this, this effect was statistically significantly correlated with the rescue of the hippocampus, the region of the human brain, where cognitive and memory functions are located ( $p=0.0016$ ). This correlation of significant clinical and biomarker effects meets EMA's and FDA's definition of disease modification in the context of a compound with a consistent mode of action. Therefore, we decided to have a strong focus on AD04 for further clinical development. Our strategy of clinical maturation allows for an efficient progress during clinical development. By doing so, it reduces financial risks associated with any clinical trial." In fact, the clinical maturation strategy has been established by AFFiRiS and is based on parallel clinical testing of several drug candidates against a certain disease to ensure that the best therapy for humans will be developed.

Prof. Achim Schneeberger, Chief Medical Officer at AFFiRiS, extends: "From the beginning we were running our Alzheimer's therapy program with several drug candidates. AD04 now shows the most convincing therapeutic benefits including an effect on NPI and quality of life, which are relevant to patients and their caregivers. Because the current results are so extremely positive and consistent across clinical outcomes and brain volumes we expect to verify them in further clinical investigations."

## PROFITABLE PROGRAMS

In addition to its Alzheimer's therapy program AFFiRiS' pipeline contains product candidates against Parkinson, Atherosclerosis, Diabetes and several other conditions. Dr. Mattner comments: "AFFiRiS focuses on the development of drugs against conditions with urgent requirement for new treatments and attractive market volumes. Our Alzheimer's and our Parkinson developments are successful examples for this. Indeed AFFiRiS was the first company world-wide that started clinical testing of Parkinson drug with the potential for disease modification. Eagerly awaited results of this clinical trial will be released within the next two months."

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