

## Press Release

### AFFiRiS AG:

## Alzheimer's Vaccination Shows Promising Results

#### AFFiRiS AG

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**Vienna (Austria), 11th March 2011: AFFiRiS` Alzheimer's vaccine candidate AD02 showed indicative evidence for potential efficacy in a phase I clinical trial. This was demonstrated by the analysis of the data from secondary clinical study endpoints.**

AFFiRiS AG previously announced that their Alzheimer vaccine candidate AD02 met the primary endpoints of phase I clinical testing by demonstrating safety and tolerability. 24 subjects were vaccinated, 12 received the vaccine with adjuvant and 12 without.

The recently completed analysis from this study of secondary clinical endpoints of AD02 based treatment – regarding cognitive performance of the subjects, body weight development and vaccine induced immune responses – suggests evidence for potential disease modifying activity of this vaccine candidate.

CEO and co-founder of AFFiRiS, Dr. Walter Schmidt, comments: "We really observed some positive results from this phase I trial. Most important was the stabilisation of the cognitive capabilities of 9 out of 12 subjects treated with the adjuvanted AD02 formulation over the complete observation period of 18 months. During the clinical trial all adverse events were mild to moderate in nature, like pain at the injection site and itching."

### **Cognitive Performance Better Than Expected**

These Phase I results indicated a surprisingly robust and persistent stabilisation of the cognitive functions. The subjects' cognitive decline did not occur as expected from the natural course of disease. Furthermore, a boost vaccination was applied and the positive trend was prolonged.

The obtained disease stabilisations were related to the subjects' MMSE<sup>1</sup> values at study entry. It became evident that patients with a MMSE score of 20 and above were found to have stable scores

at the end of the study, while this could not be observed for the study participants with an entry score below 20.

These results were further supported by findings from the development of the body weight of the subjects. This is a potential biomarker<sup>2,3</sup> that has hardly been considered in clinical studies in the past. Typically, Alzheimer patients lose weight during the course of their disease. Their sense of taste might be disturbed or they might just simply forget to eat. In contrast, patients treated with adjuvanted AD02 experienced a stabilisation of their body weight.

Finally, the analysis of the immunological data regarding antibody titers induced upon vaccination further supported the possible correlation between AD02 based vaccination and the observed stabilisation of cognitive functions.

Dr. Walter Schmidt adds: "It is important to keep in mind that the promising Phase I data with AD02 have been observed in a relatively small cohort of 24 subjects only. This is a normal number of subjects to be treated in phase I studies to demonstrate safety and tolerability; however, this number is typically too small to draw significant conclusions based on broad statistical significance. We are aware of this situation and we are cautious to make sure not to overestimate or overinterpret our positive findings. Our actively ongoing phase II study is designed to further investigate and reproduce the experienced observed positive trends with a cohort of several hundred Alzheimer subjects to meet the respective clinical and statistical significance."

### **Phase II Study Started**

Since the end of last year, vaccine candidate AD02 is in clinical phase II testing designed to evaluate the efficacy in Alzheimer patients. The study design already takes into account the indicative results of the phase I study. The study is currently in the recruitment phase with 30 study centers in Austria, Germany, France, Croatia and Slovakia (Czech Republic in preparation) being involved. A total of 420 patients will be included (<http://klinische-studien-vienna.info/>). Preliminary results regarding this study are expected to be available by the end of 2012.

Co-founder and CSO of AFFiRiS, Dr. Frank Mattner, comments on the successful development of the Alzheimer vaccine programme: "We are very delighted about the positive results of AD02 in its first clinical testing. This vaccine candidate was delivered by our AFFITOME®-platform technology. However, due to the relative small number of patients, we are aware of the fact that we should handle these data with care. Nevertheless, do we see them as first indicators implying that product candidates based on our AFFITOME®-platform technology are capable of yielding proof of concept in humans. Based on the existing clinical data, we gathered valuable knowledge for our vaccine

candidates in other indications including Parkinson's disease and atherosclerosis which were also derived from our AFFITOME®-platform technology. This knowledge will now be included into the design of the respective clinical phase I trials which are scheduled to start later this year."

The collaboration is based on a license and option agreement announced in October 2008. The deal has a total potential value of up to EUR 430 million plus royalties. EUR 36 million have already been paid within the framework of this collaboration. Recently, the company announced that Alzheimer vaccination development partner GlaxoSmithKline Biologicals exercised its option on alternative vaccine candidates including AD03. This triggered a payment of EUR 2.5 million and opens the therapy options via targeting modified beta-amyloid variants.

Pictures of the press conference are available from Friday, 11th March 2011, 12:00 am CET at:  
[http://www.affiris.com/html/de/presse\\_medien/pressekonferenz\\_110311.html](http://www.affiris.com/html/de/presse_medien/pressekonferenz_110311.html)

<sup>1</sup> The Mini-Mental State Examination (MMSE) Test is a standard test to determine the disease severity of Alzheimer patients by applying a measurement scale from 0-30. The smaller the determined value, the more progressed is the state of the disease.

<sup>2</sup> Low body weight in Alzheimer's disease is associated with mesial temporal cortex atrophy. M. Grundman et al., *Neurology*, 1996; 46: 1585 – 1591

<sup>3</sup> Weight loss in people with Alzheimer's disease: a prospective population based analysis. D. Cronin-Stubbs, *British Medical Journal* 1997; 314: 178

About AFFiRiS AG (date March 2011):

On the basis of the company's own patent positions AFFiRiS develops tailor-made peptide vaccines for Alzheimer's disease, Atherosclerosis, Parkinson's disease, Hypertension and several other conditions with unmet medical need and attractive market sizes. Alzheimer's is the current lead indication. For the Alzheimer's vaccine programme, a license and option agreement with GlaxoSmithKline was closed in October 2008, triggering an upfront payment of EUR 22.5 million. The contract envisages (milestone-dependent) payments of up to EUR 430 million. A first milestone payment of EUR 10 million was made in October 2009 followed by EUR 3.5 million as announced recently. AFFiRiS currently employs 80 highly-qualified staff at the Campus Vienna Biocenter in Vienna, Austria ([www.affiris.com](http://www.affiris.com)).

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