

AFFiRiS AG: ALZHEIMER'S VACCINE AD02 ALREADY IN CLINICAL PHASE II

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Press release from: [AFFiRiS AG](#)

Vienna (Austria), 23. April 2010: AFFiRiS AG's clinical Alzheimer's vaccine candidate AD02 has already progressed to phase II clinical testing. It may therefore be possible to confirm the efficacy of the vaccine as early as during 2012. Indeed the start of this efficacy study comes only five months after the completion of the corresponding phase I study. The company is active in several disease areas and is currently developing a total of twelve prospective products in all stages of the development pipeline up to clinical phase II.

The prospective Alzheimer's vaccine AD02 by AFFiRiS AG will with immediate effect be used in a multicentre phase II clinical study in Austria and five other European countries. Clinical centres in Germany, France, the Czech Republic, Slovakia and Croatia are taking part in the study. A total of 420 patients will be recruited. Interested parties can find further information about the study on the homepage www.affiris.com. There is also a link to study registration via a trustee. You can also phone +43 512 56 73 73-0 (reference "Alzheimerstudie") please ask Ms Weiss.

During the past year the safety and tolerability of the vaccine has been confirmed; now the focus is on its efficacy. With regard to this, CEO and co-founder of the company Dr. Walter Schmidt said: "Last year AD02, along with our second prospective Alzheimer's vaccine AD01, was primarily tested in terms of its safety and tolerability. Those primary endpoints have been met by vaccine formulations. The decision to nominate AD02 for phase II testing study is based on currently still confidential results of the interim analysis of the secondary endpoints of the preceding phase I studies".

ATTRACTIVE PRODUCT PIPELINE - CLEAR PRIORITIES

The other reason for deciding to accelerate the progress of AD02 is the company's principle to set clear priorities in respect of its broad product pipeline. The pipeline also comprises vaccines for treating atherosclerosis, hypertension and three other indications, which are currently still confidential. In addition, AFFiRiS AG announced only a few weeks ago that a prospective vaccine for the treatment of Parkinson's disease will start phase I clinical studies at the beginning of 2011.

With regard to the extent of the development pipeline CSO Dr. Frank Mattner stated: "Even before the start of the company's first phase II study we were able to build up a very broad product pipeline. This success is based on two components: our AFFITOME® technology and our solid financial basis. The AFFITOME® technology is increasingly proving itself to be more than an ideal platform technology for our product developments. It provides innovative solutions for the therapeutic treatment of chronic diseases with unmet medical need and opens up attractive markets for us. Our investors, the MIG Fonds, had already recognised this potential four years ago. In this way they assured us of early and substantial financing, which has contributed decisively to the rapid and successful progress of our development projects".

STRATEGY WITH SUCCESS

The first successes of this business strategy came in October 2008 when GlaxoSmithKline (GSK) Biologicals acquired the licence to the rights to the Alzheimer's vaccines in a milestone deal with a value of up to EUR 430 million. Two payments totalling EUR 32.5 million have already been triggered. AFFiRiS AG continues to hold all rights on the AFFITOME® technology for other indications. In summary, the AFFITOME® technology delivers short peptides which functionally mimic highly-specific original native structures that are the key targets for treatment of chronic diseases. Based on these peptides, vaccines can be generated which induce antibodies targeting pathological variants of human proteins, but leaving parental "healthy" structures untouched.

About AFFiRiS AG (date April 2010):

On the basis of the company's own patents, AFFiRiS develops tailor-made peptide vaccines against Alzheimer's disease, atherosclerosis, Parkinson's disease hypertension and four other conditions with an urgent medical requirement and attractive market volumes. Alzheimer's is currently the most advanced project, with two potential products having just completed the

phase I clinical studies. In October 2008 GlaxoSmithKline Biologicals became the licence partner for the Alzheimer's vaccine. The contract envisages (milestone-dependent) payments of up to EUR 430 million. A payment of EUR 10 million was triggered in October 2009 by the positive completion of two clinical phase I studies. At present AFFiRiS has 70 highly qualified employees working at the St. Marx campus in Vienna, Austria (www.affiris.com).

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