

AFFiRiS AG - ENCOURAGING RESULTS FROM PHASE I STUDIES OF TWO ALZHEIMER'S CANDIDATE VACCINES TRIGGER A EUR 10 MILLION MILESTONE PAYMENT

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Press release from: [AFFiRiS AG](#)

Vienna, 20. October 2009: AFFiRiS AG today announced that the primary endpoints have been met for the Phase I clinical studies of its two Alzheimer's vaccines AD01 and AD02, which demonstrated favourable safety and tolerability profiles. These results trigger a 10 million EUR milestone payment from licensee GlaxoSmithKline Biologicals.

All 48 patients treated in these studies were given four vaccinations which were well tolerated and no serious side effects associated with the vaccine candidates were observed.

The results demonstrate the potential value of the AFFITOME[®] technology, which forms the platform for both of these vaccines and could result in a generation of highly specific vaccines. While analysing the clinical outcome in detail the company, together with GSK Biologicals is progressing to the next development stage. AFFiRiS AG is also using AFFITOME[®] technology to develop vaccines for Parkinson's disease, atherosclerosis and four other indications.

AFFINITY TO SUCCESS

Commenting on the results, AFFiRiS' CEO, Dr. Walter Schmidt, said: "This initial demonstration of safety and tolerability is an outstanding milestone in our joint efforts with GSK Biologicals to develop a therapeutic Alzheimer's vaccination. However, the results also highlight the potential capability of our AFFITOME[®] technology, which forms the basis for the two vaccine candidates. This technology is also the platform for our six other vaccine programmes, including Parkinson's and atherosclerosis currently under development. The results not only represent an important milestone in the development of our Alzheimer's vaccination but also confirm our basic strategy. We will be investing all of this milestone payment in our research and development projects."

In October 2008 AFFiRiS concluded a licensing agreement with GSK Biologicals on jointly developing the Alzheimer's vaccines AD01 and AD02. Comprising total payments of up to EUR 430 million upon successful commercialisation, and the progress that has now been achieved is a key milestone in the collaboration. As part of this agreement, GSK Biologicals has gained access to the AFFITOME[®] technology of AFFiRiS, in the field of Alzheimer vaccination.

In other indications AFFiRiS retains the exclusive rights to this technology. In summary, the AFFITOME[®] technology delivers short synthetic peptides that mimic functionally highly specific original structures such as those of antigens. This can be used to generate vaccines - particularly important with Alzheimer's vaccines - that lead to the formation of antibodies which target only detrimental derivatives of human proteins and leaving their healthy precursor forms alone.

SUCCESS FOR BOTH VACCINE CANDIDATES

The clinical studies to test the two therapeutic Alzheimer's vaccines were conducted in Vienna, Austria, using two different peptide antigens. 24 patients with mild to moderate stage of the disease were recruited for each of the two studies. Each patient received four vaccinations at four-weekly intervals. Both groups were divided into two subgroups of 12 patients who received the vaccine with or without an adjuvant. Commenting on the results, Dr. Frank Mattner, CSO of AFFiRiS AG, said: "All 48 patients were able to complete the study without any problems, with the data now evaluated demonstrating acceptable tolerability of vaccine candidates AD01 and AD02. None of the 48 participants in the studies showed any indications of meningoencephalitis or other autoimmune reactions that have caused severe problems for other Alzheimer's vaccine candidates. We are now analysing the immunological data and results of the cognitive tests in detail."

AFFiRiS AG (as at October 2009):

Based on its proprietary patent position AFFiRiS AG develops tailor-made peptide-vaccines against Alzheimer's, Atherosclerosis, Parkinson's and another four diseases with unmet medical need and attractive markets. Alzheimer's disease is

currently the lead indication and recently two vaccine candidates have completed the phase I clinical testing. In October 2008, the company closed a licensing deal with GlaxoSmithKline Biologicals on its Alzheimer's vaccine program. The contract foresees payments of up to EUR 430 million. AFFiRiS currently has 60 highly-qualified employees and recently extended its facilities at the Campus Vienna Biocenter, Austria, up to 1,700 square meters (www.affiris.com).

Contact at AFFiRiS AG:

Agnes Meyer
Karl-Farkas-Gasse 22
1030 Vienna
Austria
T +43 / 1 / 798 15 75-390
E agnes.meyer@affiris.com
W www.affiris.com

Copy Editing & Distribution:

PR&D - Public Relations for Research & Education
Campus Vienna Biocenter 2
1030 Vienna
Austria
T +43 / 1 / 505 70 44
E contact@prd.at
W www.prd.at

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