

Alzheimer's Vaccine Candidate AD02 into Clinical Phase II Testing

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AFFiRiS AG: Interim Analysis of Clinical Phase I Data Triggered Decision to Move Alzheimer's Vaccine Candidate AD02 into Clinical Phase II Testing

Vienna, November 18, 2009: AFFiRiS AG will focus its Alzheimer's vaccine program on one product candidate at an unexpectedly early stage of development: the vaccine candidate AD02 is planned to enter into Phase II clinical trial early in 2010. This decision by the company immediately follows the completion of two Phase I trials with the candidates AD01 and AD02. The company based its fast decision on the first interim analysis of the secondary endpoints at the six month time point. Furthermore, based on this analysis, the AD02 patients from the completed Phase I study will now be offered an AD02 booster vaccination.

AFFiRiS AG announced today, that Alzheimer's vaccine candidate AFFITOPE AD02 will undergo immediate tests for potential efficacy in a Phase II trial. This means that the company can focus its diversified development program for Alzheimer's vaccines earlier than initially planned. The reason for the decision is based on the interim analysis of the preceding Phase I testing.

Dr. Walter Schmidt, CEO and co-founder of the company, explains the company's surprisingly rapid decision: "Both vaccines AD01 and AD02 met the primary phase I endpoints demonstrating safety and tolerability and therefore both qualified for phase II testing. However, as a small biotech with a strong focus on optimized resourcing, we are always keen to prioritize. Based on the first interim analysis of secondary endpoints, which is confidential at this stage, we decided to focus in the first instance on AD02. The Phase II trial will start as early as possible, hopefully early next year."

Dr. Frank Mattner, CSO and co-founder, adds: "It is part of our strategy in the early phase of vaccine development to focus on more than one candidate, if possible. In this way, we diversify our risk. Based on this, we can then back in the first instance the potentially most promising candidate and put the others on hold. This is exactly what we did with our Alzheimer's vaccination program and the outcome in the Phase I trials at this stage enabled us to make this decision earlier than we expected and to offer a booster vaccination to the AD02-treated patients. Finally, we can also redirect our resources which will now be available for our other vaccination programs." AFFiRiS AG can also invest all of the EUR 10 million, paid by licensing partner GSK Biologicals as a milestone payment for the positive completion of the Phase I studies, in the other R&D programs.

The vaccine development program of AFFiRiS is based on of the company's AFFITOME® technology, which also delivered the vaccines tested so far. Also based on this technology are six other vaccination programs being developed by AFFiRiS AG, which target, among other indications, Parkinson's disease and atherosclerosis.

About AFFiRiS AG (status November 2009):

Based on proprietary patent positions, AFFiRiS has developed tailored peptide vaccines against Alzheimer's Disease, Parkinson's and four other diseases characterized by urgent medical requirement and attractive market volumes. Alzheimer's is the current lead indication and clinical Phase I trials have just been completed on two product candidates. AFFiRiS succeeded in attracting GlaxoSmithKline Biologicals as its licensing partner in October 2008. The contract contains provisions for (milestone-dependent) payments of up to EUR 430 million. Based on the successful completion of two clinical Phase I trials, a payment of EUR 10 million was made in October. AFFiRiS currently employs 60 highly-qualified staff at its premises on the St. Marx Campus in Vienna, Austria (www.affiris.com).

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Contact AFFiRiS AG:

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

Copy Editing & Distribution:

PR&D - Public Relations für Forschung & Bildung
Campus Vienna Biocenter 2
1030 Vienna
T +43 / 1 / 505 70 44
E contact@prd.at
W www.prd.at

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