



AFFiRiS Announces Results of a Phase I Clinical Study Using AFFITOPES® PD01A and PD03A, Confirming Safety and Tolerability for Both Compounds as well as Immunogenicity for PD01A in Early MSA patients

- **AFFITOPES® PD01A and PD03A Safe and Well Tolerated: Primary Endpoint of Phase I Study Met**
- **Immune Response against AFFITOPE® PD01A and Alpha-Synuclein Seen in Patients with Early Multiple System Atrophy (MSA), an Orphan Disease**
- **Prof. Wassilios Meissner, Principal Investigator of the Study and Leading MSA Expert, Presented Results at Today's "Disease Modifying Treatments in the Pipeline" Session of the 6th Multiple System Atrophy Congress in New York**

VIENNA, Austria, March 01, 2018 — **AFFiRiS AG**, a pharmaceutical company developing specific active immunotherapies (SAITs) for treatment of neurodegenerative diseases, announces results of their pilot phase 1 **randomized, placebo-controlled, parallel group, patient-blinded, bi-center study, assessing the safety and exploring the immunogenicity and therapeutic activity of AFFITOPES® PD01A and PD03A, new SAITs against alpha-Synuclein (aSyn), in patients with early Multiple System Atrophy.**

The study was part of SYMPATH, a collaboration of eight academic and industry partners within the 7th framework of the EU, funded by an € 6 Mio grant.

AFFITOPES® PD01A and PD03A are synthetically produced alpha-Synuclein (aSyn)-mimicking peptide active immunotherapies. In study AFFiRiS009, 30 patients were randomized to either AFFITOPE® PD01A (75µg), AFFITOPE® PD03A (75µg) or to the placebo group treated with Alhydrogel (aluminium hydroxide) alone. Patients received 5 injections, 4 for priming every 4 weeks and the 5th as boost immunization 9 months after the first immunization in an outpatient setting. Key objectives were to show safety and tolerability as well as immunogenicity of AFFITOPES® PD01A and PD03A.

Summary of key results: The data presented today by Prof. Wassilios Meissner at the 6th MSA congress in New York are from the pilot phase 1 study in patients with early MSA treated with 5 applications of either AFFITOPE® PD01A or PD03A over a period of 36 weeks. The primary endpoint of the trial was safety and tolerability of repeated s.c. administration of AFFITOPES® PD01A or PD03A. A total of 30 patients were enrolled with 6 patients of the active treatment groups discontinuing early. At screening, the average time of MSA after first diagnosis was between 0.6-0.8 years. Patients were allowed to continue their standard of care MSA medication.

Safety and Tolerability: Both AFFITOPES® PD01A and PD03A were locally and systemically well tolerated. Two patients died during study participation and one patient shortly afterward. This is in

line with the safety results of other MSA trials reporting a mortality rate of up to 10%. No evidence of significantly more progression of motor impairment was seen in the active treatment groups compared to the placebo group. No other safety signals (including data from imaging and safety lab) were reported. Overall, the extensive monitoring of patient's safety during study AFF009 did not evidence any safety concern associated with AFFITOPE® PD01A and PD03A administration. The majority of adverse events (AE), appr. 30%, were local reactions (LRs), the great majority of LR's being only mild.

Immunogenic Profile: AFFITOPE® PD01A showed a clear immune response against the peptide itself and cross-reactivity against aSyn targeted epitope over time, and showed antibody reactivation upon booster immunization. Regarding the immunogenicity of AFFITOPE® PD03A, no significant differences were seen compared to placebo.

Conclusions: AFFITOPES® PD01A and PD03A were well tolerated in early MSA patients. PD01A induced a clear immune response versus the peptide itself and aSyn epitope.

"The safety profile of both compounds are in line with our expectations and similar to what we have seen in other MSA studies with a follow-up period of 52 weeks" stated Prof. Wassilios Meissner, PI of the study, Chairman of the French Reference Center for MSA at the Bordeaux University Hospital, and leading MSA expert. "The immunogenicity profile of AFFITOPE® PD01A looks encouraging and seems to indicate that patients with early MSA elicit an antibody response specific to alpha-Synuclein, a protein that is believed to be contributing to the pathogenesis of the disorder." Oliver Siegel, CEO of AFFiRiS AG explained: "Further clinical development of PD01A will focus on its pharmacodynamic and pharmacokinetic properties in synucleinopathies. The board will take a decision on the next clinical trial once we have further consulted with our key opinion leaders and after having evaluated the results of all our studies."

About AFFITOPES® PD01A and PD03A:

AFFITOPES® PD01A and PD03A target the protein aSyn, which plays a key role in the onset and progression of Multiple System Atrophy (MSA), as well as Parkinson's Disease (PD). Both AFFITOPE® PD01A and PD03A are specific active immunotherapies and have been studied in phase I studies. So far, 98 PD and MSA patients have participated in studies investigating either AFFITOPE® PD01A or PD03A. During these phase I studies patients were observed for up to 48 months (AFFITOPE® PD01A) or 12 months (AFFITOPE® PD03A), respectively, with regard to long-term safety, immunological and clinical parameters.

About SYMPATH:

AFFiRiS has launched the collaborative research project SYMPATH with funding from FP7 to forward the clinical development of the aSyn targeting vaccines AFFITOPE® PD01A and PD03A together with experts from three European countries including Austria, Germany and France. SYMPATH implemented a tandem phase I program to evaluate the safety and explore the activity of these two active immunotherapy candidates in humans. A part of the program is devoted to the identification of biomarkers with diagnostic and prognostic values. The causes of both, MSA and PD, are not fully understood and currently there are no treatment options available to alter the courses of the diseases.

About AFFiRiS AG:

On the basis of its proprietary patented AFFITOME® technology, AFFiRiS develops preventative and therapeutic peptide vaccines against chronic diseases. Its clinical pipeline consists of four vaccine candidates against PD, MSA and Atherosclerosis. Further vaccine candidates against Alzheimer as well as Huntington's Disease are in preclinical development. AFFiRiS has been able to attract funding of approx. € 165 Mio to date, half of which comes from license income and government grants.

AFFiRiS is part of a consortium receiving funding from the European Union's 7th Framework Programme under SYMPATH Grant Agreement No. 602999 (<http://www.sympath-project.eu/>) and MULTISYN Grant Agreement No. 602646 (<http://www.multisyn.eu/>). AFFiRiS currently employs 60 highly qualified staff at the Campus Vienna Biocenter in Vienna, Austria.

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