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## **AFFiRiS Announces Top Line Results of First-in-Human Clinical Study Using AFFITOPE® PD03A, Confirming Immunogenicity and Safety Profile in Parkinson's Disease Patients**

- **AFFITOPE® PD03A Safe and Well Tolerated: Primary Endpoint of Phase I Study Met**
- **Dose Dependent Immune Response Against AFFITOPE® PD03A and Alpha-Synuclein Seen in Patients With Early Parkinson's Disease**
- **Prof. Werner Poewe, PI of the Study and Leading PD Expert, Presented Results at Today's Plenary Session of the 21<sup>st</sup> International Congress of Parkinson's Disease and Movement Disorders in Vancouver, Canada**

VIENNA, Austria, June 07, 2017 — **AFFiRiS AG**, a pharmaceutical company developing novel active immunotherapies for treatment of neurodegenerative diseases, announces top line results of their pilot phase 1 **randomized, placebo-controlled, parallel group, patient-blinded, bi-center study, assessing tolerability and safety of repeated subcutaneous (s.c.) administration of two doses of AFFITOPE® PD03A formulated with adjuvant to patients with early Parkinson's disease (PD).**

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

AFFITOPE® PD03A is a synthetically produced alpha-Synuclein (aSyn)-mimicking peptide vaccine. In study AFFiRiS011, 36 patients were randomized to either AFFITOPE® PD03A high dose (75µg), low dose (15 µg) or to the placebo group treated with Alhydrogel (aluminium oxihydroxide) 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 AFFITOPE® PD03A.

**Summary of key top level results:** The data presented today by Prof. Werner Poewe on behalf of the SYMPATH partners at the 21<sup>st</sup> International Congress of Parkinson's Disease and Movement Disorders in Vancouver are from the pilot phase 1 study in patients with early PD treated with 5 applications of AFFITOPE® PD03A over a period of 36 weeks. The primary endpoint of the trial was safety and tolerability of repeated s.c. administration of AFFITOPE® PD03A. A total of 39 patients were screened, 36 treated with 1 patient of the control group discontinuing early. At screening, the average time of PD after first diagnosis was between 1.6-2.3 years; Patients were allowed to continue their standard of care PD medication.

**Safety and Tolerability:** Both doses were locally and systemically well tolerated. No study drug related serious adverse events (SAE) or suspected unexpected serious adverse reactions (SUSAR) occurred. The majority of adverse events (AE), appr. 59%, were local reactions (LRs), the great majority of LRs being only mild and without dose dependency.

**Immunogenic Profile:** AFFITOPE® PD03A showed a clear dose dependent immune response against the peptide itself and crossreactivity against aSyn targeted epitope over time, and showed antibody reactivation upon booster immunization.

**Conclusions:** 15 and 75µg of AFFITOPE® PD03A were well tolerated in early PD patients. The compound induced a clear dose dependent immune response versus AFFITOPE® PD03A and aSyn epitope.

"The immunogenicity profile looks encouraging and supports the hypothesis that patients elicit an antibody response specific to alpha synuclein, a protein that is believed to be contributing to the pathogenesis of Parkinson's" stated Prof. Werner Poewe, PI of the study, Chairman of the Department of Neurology at the Medical University Innsbruck, Austria, and leading PD expert. "Based on additional data covering alpha synuclein lowering in plasma and cerebrospinal fluid (CSF), expected in Q3 2017 we should see clearer about PD01A vs PD03A for future development in Parkinson's patients."

#### **About AFFITOPE® PD03A:**

AFFITOPE® PD03A targets the protein aSyn, which plays a key role in the onset and progression of PD as well as Multiple System Atrophy (MSA), an orphan disease. AFFITOPE® PD03A is one of two vaccine candidates currently being 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. Final results of studies with both compounds are expected for Q4 2017.

#### **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 value. The cause of both PD and MSA are not fully understood and currently there are no treatment options available for either to alter the course of the disease.

#### **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. € 156 Mio to date, half of which comes from license income and government grants. AFFiRiS has received grants of \$ 3 Mio for its phase I studies with AFFITOPE® PD01A from The Michael J. Fox Foundation (MJFF). Furthermore, AFFiRiS is part of collaborative projects 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.

[www.affiris.com](http://www.affiris.com)

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