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Boost Vaccination Data Encourage Continued Development of AFFiRiS Therapeutic Parkinson´s Disease Vaccine against Alpha-Synuclein

- **PD01A was Safe and Well Tolerated: Primary Endpoint of Phase I "Boost" Study Met**
- **Immune Response was Seen in 86% of Patients, Resulting in an Increase of Responder Rate after Boost Immunization**
- **PD01A-induced Antibodies Preferentially Bind to Fibrilic Alpha-Synuclein (aSyn)**
- **Data will be Presented at the Poster Tour of Leading Abstracts at the 4th World Parkinson Congress in Portland, Oregon, USA on September 21**

VIENNA, Austria, September 07, 2016 — AFFiRiS AG announced today results of AFF008A, a Phase I clinical trial to assess boost immunizations with AFFITOPE® PD01A, an active vaccine against Parkinson's disease (PD). The study was funded by a $1.04 million grant from The Michael J. Fox Foundation for Parkinson's Research.

The "boost" study AFF008A was designed to assess one boost immunization with AFFITOPE® PD01A per patient with regard to safety/tolerability and immunological and clinical activity in those patients who had already received the vaccine (four "priming" vaccinations at four-week intervals) within the first-in-man clinical study AFF008. Six PD patients on best medical care, including standard symptomatic medication, served as a comparison group. In the "boost" study, two different doses of AFFITOPE® PD01A (15 µg and 75 µg) were again safe and well tolerated, meeting the primary endpoint of the trial.

Patients belonging to the low-dose group of AFF008 were randomized in two equally distributed groups receiving either 15 µg or 75 µg AFFITOPE® PD01A. The same was done with patients of the AFF008 high-dose group, in order to allow for evaluation of four different vaccination schedules.

Across all patients, no antibody concentration limiting toxicity was observed. Adverse events were similar across all five groups except injection site reactions, which only occurred in the active treatment groups, and psychiatric disorders, reported at a lower rate in the active groups. All of the 28 patients completed the study and received all planned vaccinations. Only one serious adverse event was reported, which was classified as being not related to AFFITOPE® PD01A administration.

An immune response against AFFITOPE® PD01A was seen in 19 of 22 (86%) of vaccinated patients and 12 of 19 (63%) of these responders generated aSyn-specific serum antibodies. The immune response sustained throughout the entire observation period of 24 weeks. Patients on low dose and then high dose had a clear immunological boost. This data supports that further dose and scheduling may significantly influence antibody titer/concentration and further studies need to be performed. Additionally, vaccine-induced antibodies were detectable in cerebrospinal fluid. This

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induction of antibodies against aSyn supports the concept of the principle of AFFiRiS' proprietary therapeutic vaccine.

Parallel laboratory experiments using recombinant aSyn protein to assess selectivity showed that AFFITOPE® PD01A-induced antibodies preferentially bind to aSyn fibrils, which are believed to be the toxic form of the protein, as compared to the monomeric form.

Due to the limitations of the Phase I trial design (the study was not double-blind, and assignment to the comparison group was not randomized), it is not known whether effects seen in the active groups are indicative of treatment effects or due to confounding factors. Efficacy variables were evaluated in an explorative manner with regard to the small sample size. Preliminary observations showed that in eight of the 19 (42%) immunological responders, no increase of the concomitant dopaminergic PD medication was needed throughout the observational period (on average three years per subject). Among the same group, five of eight (63%) patients had stable UPDRS III scores at the end of the "boost" study.

Continuous efforts are undertaken to follow this patient cohort and to further characterize their immunological and clinical response to treatment with AFFITOPE® PD01A. The next study, AFF008AA, is focusing primarily on the long-term safety and, in addition, on the assessment of the immunological and clinical effects of a second boost vaccination ("reboost"). That study is also funded by The Michael J. Fox Foundation, as was the AFF008 trial. Recruitment of patients for AFF008AA has been completed; results are expected in Q2 2017.

About AFFITOPE® PD01A:

AFFITOPE® PD01A targets the protein alpha-Synuclein, which plays a key role in the onset and progression of Parkinson's as well as multiple system atrophy (MSA), an orphan disease. During the first-in-man study AFF008, AFFITOPE® PD01A was safe and well tolerated, meeting the primary endpoint of the trial. PD01A is one of two vaccine candidates currently being studied in three ongoing Phase I studies AFF008AA, AFF009 and AFF011 in which currently 92 Parkinson's and Multiple System Atrophy (MSA) patients are receiving either PD01A or PD03A. During these Phase I studies patients are being observed for up to 48 months with regard to long-term safety, immunological and clinical parameters. Results are expected for Q4 2017.

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 Parkinson's, MSA and Atherosclerosis prevention. Further vaccine candidates against diabetes, allergies as well as Huntington's disease are in preclinical development. AFFiRiS has been able to attract funding of approx. € 130m to date, half of which comes from license income and government grants. Furthermore, AFFiRiS is part of collaborative projects receiving funding from the European Union's Seventh Framework Programme under SYMPATH Grant Agreement No. 60299 (http://www.sympath-project.eu/) and MULTISYN Grant Agreement

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No. 602646 (http://www.multisyn.eu/). AFFiRiS currently employs 60 highly qualified staff at the Campus Vienna Biocenter in Vienna, Austria.
www.affiris.com

About The Michael J. Fox Foundation for Parkinson's Research:

As the world's largest nonprofit funder of Parkinson's research, The Michael J. Fox Foundation is dedicated to accelerating a cure for Parkinson's disease and improved therapies for those living with the condition today. The Foundation pursues its goals through an aggressively funded, highly targeted research program coupled with active global engagement of scientists, Parkinson's patients, business leaders, clinical trial participants, donors and volunteers. In addition to funding more than $600 million in research to date, the Foundation has fundamentally altered the trajectory of progress toward a cure. Operating at the hub of worldwide Parkinson's research, the Foundation forges groundbreaking collaborations with industry leaders, academic scientists and government research funders; increases the flow of participants into Parkinson's disease clinical trials with its online tool, Fox Trial Finder; promotes Parkinson's awareness through high-profile advocacy, events and outreach; and coordinates the grassroots involvement of thousands of Team Fox members around the world. Learn more at www.michaeljfox.org.

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