

PRESS RELEASE

Parkinson's Vaccine: EU-Team Launches Clinical Trial

Vaccine candidate based on proprietary technology by AFFiRiS AG

Vienna, 9 December 2014 – A novel Parkinson's vaccine will now be tested in a clinical Phase I trial in Austria by an EU-funded consortium. The vaccine was developed by the Austrian biotech company AFFiRiS AG and targets a protein called alpha-Synuclein. The protein plays a key role in the onset and progression of Parkinson's as well as multiple system atrophy (MSA), an orphan disease. This vaccine has the potential to modify disease progression, rather than only symptomatic improvements available with current treatment strategies.

The start of the Parkinson's trial follows in the wake of positive results from a similar Parkinson's vaccine trial recently conducted by AFFiRiS with support from the Michael J. Fox Foundation.

Today the EU-consortium SYMPATH starts recruitment for a Phase I study of a Parkinson's vaccine candidate called AFFITOPE® PD03A. This vaccine is one out of a designated pool of promising vaccine candidates based on AFFiRiS' proprietary AFFITOME® technology. These candidates aim at disease modification of Parkinson's instead of only ameliorating the severe motor symptoms of the disease, such as tremor. All vaccines in this pool target alpha-Synuclein, a protein that is key to the onset and the progression of both, Parkinson's and multiple system atrophy (MSA). Recently, encouraging clinical results of a Parkinson's trial of one other of the pool's vaccines, namely PD01A, were presented by the Michael J. Fox Foundation and AFFiRiS. These confirmed the safety and tolerability of the vaccine, as well as its ability to induce an immune response and even achieve functional stabilization.

Commenting on the latest clinical trial, Prof. Achim Schneeberger, Chief Medical Officer at AFFiRiS and coordinator of SYMPATH, explains: "The results we achieved with the Parkinson's vaccine PD01A were very encouraging. Now, PD03A will be tested in a comparable setting and we are eagerly awaiting the results. "The current trial of PD03A is a multi-centric patient blinded, randomized, placebo-controlled, parallel group Phase I trial. It

will be conducted in Vienna and Innsbruck, Austria. Prof. Werner Poewe, chairman of the Department of Neurology at the Medical University of Innsbruck and principal investigator of the study, explains the objectives of the trial: "The primary endpoint of the trial aims to demonstrate the safety and tolerability of the vaccine. It will also assess the vaccine's immunological and clinical activity in vaccinated patients as its secondary endpoint."

Dr. Dieter Volc of PROSENEX Ambulatorium BetriebsgmbH, leading the trial in Vienna, adds: "PD03A is one of the first medications worldwide aiming for clinical efficacy by modulating the metabolic pathway of alpha-Synuclein. It has the potential to treat the cause of Parkinson's – not just the symptoms." Current scientific understanding is that Parkinson's – as well as MSA – is caused by deposits of pathological forms of alpha-Synuclein in the nervous system. The reduction of pathological alpha-Synuclein levels is believed to have a beneficial impact on the progress of the diseases. PD03A aims to accomplish this by inducing the production of antibodies that target and promote clearance of alpha-Synuclein in order to neutralize its toxic impact.

The start of the clinical trial comes only a year after the SYMPATH-Consortium was launched. This rapid progress is owed to the high expertise in Parkinson's and related diseases of all members of the consortium including the Forschungszentrum Jülich in Germany, the INSERM F-CRIN Toulouse, the Departments of Neurology at the University Hospitals of Bordeaux and Toulouse, France, as well as the Medical University of Innsbruck's Department of Neurology and PROSENEX, Vienna, Austria.

Additionally, the successful track record of the AFFiRiS AFFITOME® platform that forms the basis of PD01A and PD03A significantly accelerated the vaccine development. Dr. Markus Mandler, head of the Neurodegeneration Department at AFFiRiS explains: "Both vaccines are based on AFFiRiS' AFFITOME® technology. This technology delivers not only a single vaccine for the treatment of a certain disease but a whole pool of product candidates with excellent safety profiles and strong specificity to their targets."

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ClinicalTrials.gov Identifier: NCT02267434

About SYMPATH (<http://www.sympath-project.eu/>)

SYMPATH ("Reach α -synuclein-dependent neurodegeneration: clinical development of therapeutic AFFITOPE vaccines for Parkinson's disease and multiple system atrophy") is a collaborative project of the Seventh Framework Programme of the European Union, holding Grant Agreement No. HEALTH-F4-2013-60299. SYMPATH aims to advance the clinical development of therapeutic vaccines targeting alpha-Synuclein-driven neurodegenerative diseases including Parkinson's disease (PD) and multiple system atrophy (MSA) where no causal therapy currently exists. The project will run for 48 months. It has received 5.99 million Euros in funding from the European Union. AFFiRiS AG located in Vienna, Austria serves as the coordinator for the

projects ambitious research program and is supported by Biolution in project management tasks. Project partners include 5 universities and 3 SMEs:

AFFiRiS AG (Austria) – Prof. Dr. Achim Schneeberger

Biolution GmbH (Austria) – Dr. Iris Grünert

University Hospital Bordeaux (France) – Prof. Wassilios Meissner, MD

INSERM F-CRIN Toulouse (France) – Claire Levy Marchal, MD, MSc

Prosenex Ambulatoriumsbetriebs-GmbH (Austria) – Dieter VOLC, MD

Medical University Innsbruck, Department of Neurology (Austria) – Prof. Werner Poewe, MD & Prof. Klaus Seppi, MD

Forschungszentrum Jülich GmbH (Germany) – Prof. Dr. Dieter Willbold

University Hospital Toulouse (France) – Prof. Olivier Rascol, MD

About AFFiRiS AG (By: December 2014)

Based on its proprietary IP positions AFFiRiS develops tailor-made drugs mainly as Peptide-based vaccines. Target diseases include Alzheimer, Parkinson, Diabetes and other indications with attractive markets and unmet medical need. Alzheimer is the lead indication. Current investors are: MIG-Fonds and Athos Service GmbH, both Munich, Germany. AFFiRiS is located at the campus of the Vienna Biocenter, Vienna Austria and employs 80 highly qualified employees. www.affiris.com

About Parkinson's disease

Parkinson's disease is the second most common neurodegenerative disorder among the elderly with approximately 1.2 Mio European patients alone. Currently there is no cure for the disease and existing therapeutic measures are only able to treat its symptoms. Its classical motor symptoms result from the death of dopamine-generating cells in the substantia nigra, a specific region of the midbrain. The disease typically starts with non-motor symptoms, progresses slowly but steadily to a debilitating state.

About Multiple System Atrophy

Multiple system atrophy is a rare, orphan status neurodegenerative disorder. It progresses rapidly leading to death of the affected individual within, on average, 6-9 years. There is currently no cure for the disease. MSA is associated with the degeneration of nerve cells in specific areas of the brain. This causes problems with movement, balance, and autonomic functions of the body. Unlike Parkinson's disease, where symptomatic treatments are well established, there are no drugs approved for the treatment of MSA.

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