

PRESS RELEASE

Parkinson's Vaccine – Top Experts Unite in European Consortium

EU support boosts development of therapeutic vaccines against Parkinson's and Multiple System Atrophy. AFFiRiS leads consortium.

Vienna, 28 April 2014 – An international consortium of top European research teams has received significant EU funding for the development of therapeutic vaccines against Parkinson's Disease (PD) and Multiple System Atrophy (MSA). Led by the Austrian biotech company AFFiRiS AG, the consortium will use a novel tandem strategy to advance the development of two therapeutic vaccine candidates in parallel. They are both unique in the potential for disease modification, something which is sorely missing in PD as well as in MSA. Both candidates target a protein called alpha-synuclein, which plays a key role in the onset and progression of PD and MSA. Additionally, the group attempts to identify biomarkers with diagnostic and prognostic value. Altogether, the consortium exerts medical and scientific key opinion leaders from Germany, France and Austria. The project SYMPATH has been awarded € 6 Mio. from the 7th Framework Program of the EU and will run for 48 months.

A consortium of top European scientists has been awarded € 6 Mio. for advancing the clinical development of two therapeutic vaccines for the treatment of both Parkinson's Disease (PD) and Multiple System Atrophy (MSA). The vaccine candidates (PD01A and PD03A) form part of the development pipeline of the Austrian biotech company AFFIRIS AG that leads the consortium and the clinical development in the field. Based on the company's renowned AFFITOME[®]-technology, both vaccines target the protein alpha-synuclein (alpha-syn) which plays a key role in the onset and progression of PD and MSA, the latter being an orphan disease with no registered therapy. Both candidates have already demonstrated their disease-modifying potential in various preclinical model systems.

International & Innovative

Acknowledged as the world-leader in the field of alpha-syn-Immunotherapy, AFFiRiS rallied medical experts and basic scientist from eight high-profile European organizations for the successful FP7 project named SYMPATH. These institutions include the Forschungszentrum Jülich in Germany, the INSERM F-CRIN Toulouse and the departments of Neurology at the University Hospitals of Bordeaux and Toulouse from France, as well as the Medical University of Innsbruck's Department of Neurology and PROSENEX from Austria.

The SYMPATH project especially focuses on an outstanding, innovative approach to the clinical testing of the two candidate vaccines. Using a novel tandem strategy, the consortium will concomitantly evaluate the safety and explore the activity of both vaccine candidates in clinical phase I studies for both indications, PD and MSA. In fact, the tandem strategy allows for direct comparison of the two vaccines already at an early stage in clinical development.

New Standard

Commenting on this innovative approach, Prof. Achim Schneeberger, responsible for clinical development at AFFiRiS and coordinator of SYMPATH, explained: "This clinical testing strategy developed by the SYMPATH consortium sets a new standard for therapeutic vaccines and disease-modifying agents in neurodegenerative diseases such as PD and MSA." Dr. Markus Mandler of AFFiRiS AG adds: "The tandem strategy is in full accordance with AFFiRiS' clinical maturation program. Based on the excellent safety profile of all vaccine candidates, this program allows for a very quick testing of new vaccine candidates in man. We are very excited that top key opinion leaders are working with us on this project."

In addition to its innovative tandem strategy, the SYMPATH consortium aims to identify biomarkers with diagnostic and prognostic value for both, PD and MSA. Furthermore, it will test the viability of using MSA as a clinical reference indication for synucleinopathies, a group of diseases characterized by the aggregation of alpha-synuclein into so called Lewy Bodies. Using MSA as a clinical reference for synucleinopathies could also greatly benefit therapies in general as MSA treatment gives the fastest positive readout for disease modification upon vaccination. "Based on recent research in neurodegenerative diseases, we have chosen to target not only PD, but also MSA with PD01A and PD03A. If successful, this would address an additional and intense unmet clinical need as MSA is an orphan disease with no registered therapy. Our approach might at the same time provide new scientific insights into the common origin of PD and MSA", Prof. Wassilios Meissner of University Hospital Bordeaux and clinical expert in MSA concludes.

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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 (alpha-Syn)-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 Ambulatorium Betriebs-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 (Status: April 2014)

Based on the company's own patent positions, AFFiRiS develops tailor-made peptide vaccines for Alzheimer's disease, Atherosclerosis, Parkinson's disease, diabetes and several other conditions with urgent requirement for new treatments and attractive market volumes. Alzheimer's is the current lead indication. AFFiRiS currently employs 100 highly-qualified staff at the Campus Vienna Biocenter in Vienna, Austria (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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