

THE SYMPATH PROJECT

The collaborative research project SYMPATH aims to forward the clinical development of PD01A and PD03A, two promising alpha-Synuclein (aSyn) targeting vaccines. AFFiRiS, the worldwide leader in the field of aSyn immunotherapy, is coordinating the project together with renowned medical and basic scientists in the fight against aSyn-driven neurodegenerative diseases. The consortium unifies 8 institutes from 3 European countries including Austria, Germany and France. Both PD01A and PD03A are applied within an innovative tandem phase I program to evaluate their safety and explore their activity in sporadic Parkinson's disease (PD) and multisystem atrophy (MSA), an orphan disease with no registered therapy. A part of the program is also devoted to the identification of biomarkers with diagnostic and prognostic value.

PD is one of the most common fatal neurodegenerative diseases in the elderly, affecting more than 1.2 M patients in Europe alone. Multisystem atrophy (MSA) is a rare neurodegenerative disease with Parkinson's-like symptoms leading to the death of the patients within 6-9 years on average. MSA is both a rapidly progressing and fatal disease. The cause of both PD and MSA are not fully understood and currently there are no treatment options available for either can alter the course of the disease. Both diseases are a type of synucleopathy, which are characterized by the aggregation of aSyn into Lewy Bodies in the brain. In the healthy population, aSyn is normally soluble, but in the case of disease it forms clumps within and among neighboring cells in the brain, eventually leading to cell death. Synucleopathies all share these aberrant structures, but in different regions leading to distinct pathologies.

SYMPATH proposes an innovative tandem phase I program to evaluate the safety and explore the activity of two therapeutic vaccine candidates in humans that would reduce the amount of aSyn in the cells, representing the first PD and MSA treatment option that could hinder disease progression. Both candidate vaccines, PD01A and PD03A, have already demonstrated their disease-modifying potential in numerous preclinical model systems. The primary objective of the clinical trials is to analyze the safety of the vaccine candidates in humans.

The envisaged program in SYMPATH capitalizes on the strength of partners involved to advance clinical development of aSyn-targeting AFFITOPE® vaccines in a rational and efficient manner to further strengthen their lead position, as a product of European science, in the race for a cure of aSyn-driven neurodegenerative diseases.

KEY FACTS

- ▶ **Title: "SYMPATH"**
Reach α -synuclein-dependent neurodegeneration: clinical development of therapeutic AFFITOPE vaccines for Parkinson's disease and multisystem atrophy
- ▶ **Grant Agreement No.:**
HEALTH-F4-2013-60299
- ▶ **Total Budget:**
7.69 million Euros
- ▶ **EU contribution:**
5.89 million Euros
- ▶ **Coordinator:**
AFFiRiS AG (Austria)
Mag. Vera Bürger
- ▶ **Start:**
October 1, 2013
- ▶ **Duration:**
48 Months
- ▶ **Contact:**
office@SYMPATH-project.eu
- ▶ **Website:**
www.sympath-project.eu

WWW.SYMPATH-PROJECT.EU



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THE CONSORTIUM

COORDINATOR

AFFiRiS AG (Austria) – Mag. Vera Bürger

Founded in 2003, AFFiRiS focuses on product development of tailor-made peptide-based vaccines for the treatment of AD, PD a.o. AFFiRiS is developing therapeutic vaccines based on its proprietary AFFITOME® technology and builds on its expertise in biochemistry, molecular biology, cell biology, genetics, immunology and veterinary medicine. To date, AFFiRiS has successfully translated 5 active vaccine candidates in 3 indications (AD, PD, Atherosclerosis) into phase I / II clinical testing.

PARTNERS

Biolution GmbH (Austria) – Dr. Iris Grünert

Biolution GmbH specializes in communication and project management services for the life sciences. The company's know-how focuses on the clear and efficient transport of complicated messages and combines proficiency in graphics, new media and science. Biolution has relevant expertise in the support of consortia of both FP6 and FP7 funded projects providing efficient solutions for project management and dissemination strategies.

University Hospital Bordeaux (France) – Prof. Wassilios Meissner

The University Hospital Bordeaux hosts since 2007 the French National Reference Centre for MSA (creation in the framework of the first French national plan for rare disorders 2005-2008). The French Reference Centre for MSA is unique in Europe bringing together expertise in multidisciplinary patient care and research with over 100 MSA patients seen every year.

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

F-CRIN is the National French Clinical Research Infrastructure Network founded in 2011 to facilitate academic and industry-sponsored clinical trials in France and within Europe. It is aimed at strengthening French competitiveness in critical sized clinical trials and management and analysis of academic studies. F-CRIN brings all French clinical research actors together around an infrastructure headquartered in Toulouse, offering to investigators and sponsors the necessary skills and services to conduct clinical trials.

Prosenex Ambulatoriumbetriebs GesmbH (Austria) – Dieter Volc, MD

PROSENEX AmbulatoriumbetriebsgesmbH was founded 1994 and was a clinical department for treatment of movement disorders. In 2011 it opened a clinical-scientific branch with implementation of a clinical study center at the site of Confraternitaet-Privatklinik Josefstadt, Vienna, a well-known and respected private hospital with emphasis on neurology, cardiology and surgery. The study center is conducting at present the phase I study AFF008, the first-in-man/first-of-kind vaccination against Parkinson's disease.

Medical University Innsbruck (Austria) – Prof. Dr. Werner Poewe

The Department of Neurology at the Innsbruck Medical University, Austria is an internationally recognized clinical research centre focusing on degenerative movement disorders. It runs a specialized movement disorders outpatient clinic with approximately 2000 patients annually corresponding to almost 4200 patient visits. The infrastructure available at Innsbruck Medical University including the Parkinson Centre and the Clinical Trial Center (KKS) enable the Department of Neurology to rapidly recruit a substantial number of eligible patients.

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

The Institute of Complex Systems (ICS-6: Structural Biochemistry) of the Forschungszentrum Jülich, focuses on the development and application of methods to precisely investigate three-dimensional structures and molecular mechanisms of biologically and medically relevant macromolecules involved in basic cellular processes. They investigate both the function and malfunction of proteins which play decisive roles in the development and progression of infectious as well as neurodegenerative diseases including Alzheimer's and Parkinson's disease.

University Hospital Toulouse (France) – Prof. Olivier Rascol

The University Hospital Toulouse hosts, in conjunction with the Bordeaux University Hospital, the French National Reference Centre for MSA since 2007. It was created with in the framework of the first French national plan for rare disorders 2005-2008. The French Reference Centre for MSA is unique in Europe bringing together expertise in multidisciplinary patient care and research. Around 100 MSA patients are seen every year.

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