

## AXON's Tau Vaccine has Completed Phase II Enrolment in Alzheimer's

**LONDON, JULY 17, 2017.** AXON Neuroscience, as a leader in tau research took one further step, completing recruitment for its phase II clinical trial in Alzheimer's Disease. In total, 208 patients with mild AD were enrolled in the 24-month study, powered to evaluate the efficacy and safety of the AADvac1. With top line data available in mid-2019, the "ADAMANT" phase II study is now the most advanced tau program in the field of Alzheimer's research.

### Active Tau Vaccine AADVAC1 in Phase II Study

AADVac1 is designed to actively stimulate the patient's immune system to generate specific antibodies against the pathological tau protein. At the AD/PD 2017 conference, AXON presented that the amount of specific antibodies generated shows an encouraging correlation with slowing the progression of cognitive impairment and brain atrophy. Overall, from all the studies, the vaccine shows an outstanding safety profile. The results of the phase I study were recently published in The Lancet of Neurology journal.

Phase II, a 24-month, randomized, placebo-controlled, parallel group, double-blinded trial is running in 8 European countries at 44 clinical sites.

### Objectives of the ADAMANT Phase II Study

The primary objective of the trial is to evaluate the safety and tolerability of a long-term AADVac1 treatment of patients with a diagnosis of mild Alzheimer's disease as already positively proven in results of the Phase I. The secondary objectives are the results of AADVac1 treatment in stopping or slowing the progression of patients' functional and cognitive decline over the period of the trial by assessing multiple domains of cognition. To show the disease-modifying effect, the patients undergo Clinical Dementia Rating (CDR) Sum of Boxes, supported by a sensitive state-of-the-art custom cognitive battery and Activities of Daily Living scales.

Roman Sivak, CEO at AXON Neuroscience stated *"I would like to thank all study participants, patients, their caregivers and investigators for their efforts in completing the recruitment early. This will enable us to have top line data soon,"* adding *"and move us again a big step forward to our ultimate goal of preventive treatment with our active therapeutic approach."*

### Preventive use of AADVac1 in preclinical stages of Alzheimer's Disease

Currently, AADVac1 is being investigated in the treatment of mild Alzheimer's disease. As the antibodies elicited by vaccination are reactive with all Braak stages of tau pathology, a future extension of the indication to preclinical stages of AD is planned for further development. Completely understanding the structural and biological mechanism of action additionally supports the efficacy

potential for stages of the disease, when a clinical presentation is still absent. After proving the disease-modifying treatment in current clinical development, the active immune approach of AADvac1 may be well suited as a preventive vaccination against AD administered above a certain age.

## AXON NEUROSCIENCE

AXON Neuroscience is a clinical-stage biotech company founded in 1999 with the globally largest team of researchers focused exclusively on tau-immunotherapies and tau diagnostic platforms. AXON owns several compounds with disease-modifying as well as early diagnostic potential for Alzheimer's disease and other tauopathies. The two lead compounds are the active vaccine AADvac1 and the fully humanized monoclonal antibody AADvac2.

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