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## AXON's Alzheimer tau vaccine phase 1 study results published in Lancet Neurology

**City: BRATISLAVA, December 9, 2016.** AXON Neuroscience announced that the results of the first-in-man study of an active tau vaccine have been published in Lancet Neurology, a leading journal in the clinical neurology field. The results demonstrated an excellent safety and immunogenicity profile of AXON's vaccine, AADvac1, which is intended to be the first disease-modifying tau treatment for Alzheimer's disease.

### ENCOURAGING RESULTS OF THE AADVAC 1 VACCINE

This first-in-man, first-in-class study was designed to assess safety and tolerability of the AADvac1 active vaccine in the treatment of patients with mild-to-moderate Alzheimer's disease. The study was conducted in Austria with Professor Reinhold Schmidt from the Medical University Graz as the coordinating investigator.

The vaccine displayed a very favourable safety profile. Targeting tau pathology via immunotherapy did not induce abnormal accumulation of fluid and inflammation in the brain commonly observed with anti-amyloid antibodies. The safety of AADvac1 is the first positive milestone in the treatment of Alzheimer's disease, since many late phase trials have failed due to severe side effects in patients.

While immune senescence is a common hurdle in vaccine development for the elderly, treatment with AADvac1 was able to induce a robust immune response in 29 of 30 vaccinated patients. The article in Lancet Neurology further provides insight on measurements of the immune competence of patients, and discusses its role in the immune response against novel antigens in aging patients, providing valuable clues for the development of vaccines for the elderly.

The cognition of the patients remained stable on average for the whole duration of the Phase I study. Though the study was not designed to meaningfully address cognition, this is an encouraging sign, and the ongoing Phase II study of AADvac1 "ADAMANT" is expected to provide more insight into the cognitive efficacy of the vaccine in 2019.

Bengt Winblad, co-author and Chairman of the Clinical Advisory Board of AXON said: *"This is the first active vaccine to harness the body's ability to produce antibodies against pathological tau. Even though this study is only a phase 1 trial, its success so far gives the authors confidence that it may be the answer they are looking for to halt the progress of this devastating disease."*

## AADVAC1 TAU VACCINE AGAINST ALZHEIMER'S DISEASE

Alzheimer's disease is one of the most important health challenges facing aging populations worldwide. The development of the next generation of Alzheimer's disease drugs is becoming essential to face up to this challenge. A key hallmark of the disease are neurofibrillary tangles, consisting of disease-modified protein tau. The quantity and distribution of disease-modified protein tau correlates with cognitive impairment and brain atrophy. AXON's vaccine AADvac1 stimulates patients' immune systems to generate specific antibodies against disease-modified protein tau, with the aim to stop the process of neurodegeneration.

## AXON NEUROSCIENCE

AXON Neuroscience is a clinical-stage biotech company and a global leader in tau-immunotherapy. Researchers from AXON Neuroscience have worked extensively on the tau hypothesis for more than 25 years. AXON owns several proprietary 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 humanised monoclonal antibody AADvac2.

## ARTICLE REFERENCE

Novak P et al., "Safety and immunogenicity of the tau vaccine AADvac1 in patients with Alzheimer's disease: a randomised, double-blind, placebo-controlled, phase 1 trial" *Lancet Neurology*. 2016; [http://www.thelancet.com/journals/laneur/article/PIIS1474-4422\(16\)30331-3/fulltext](http://www.thelancet.com/journals/laneur/article/PIIS1474-4422(16)30331-3/fulltext)

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