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AXON'S PIONEERING TAU VACCINE AGAINST ALZHEIMER'S STARTED PHASE II

City: BRATISLAVA, JUNE 21, 2016. AXON Neuroscience announced the successful start of the ADAMANT phase II study, as the first patient has been vaccinated with the active tau vaccine. AXON's vaccine, AADvac1, is intended to be the first disease-modifying tau vaccine for Alzheimer's disease.

ADAMANT PHASE II CLINICAL STUDY

ADAMANT is a 24-month, randomized, placebo-controlled, parallel group, double-blinded, multi-centre, phase II study to assess the safety and efficacy of AADvac1 applied to patients with mild Alzheimer's disease. The primary objective is to confirm the positive phase I results by assessing safety and immunogenicity on a larger patient population with mild Alzheimer's disease. The secondary objective is to evaluate the efficacy of the AADvac1 vaccine in slowing down or halting cognitive decline in patients over a period of 24 months. The study is powered to explore and show the disease-modifying effect on the Clinical Dementia Rating (CDR) Sum of Boxes, supported by a custom cognitive battery (composite standard score) and Activities of Daily Living Scale.

ADAMANT will be conducted in several countries of Europe, where 185 patients are planned to be enrolled in the study.

AADVAC1 TAU VACCINE

AADvac1 is an active tau vaccine which is intended to be a disease-modifying treatment for Alzheimer's disease and other tauopathies. AADvac1 is designed to elicit antibodies against the pathological tau protein, which is the primary cause of neurofibrillary pathology in Alzheimer's disease. These antibodies are expected to prevent the tau protein from pathological interactions, to facilitate the removal of tau pathology, and thus slow down or halt the progress of Alzheimer's disease.

"We are grateful for all the efforts of the entire team, investigators, and partners, who helped us to move AADvac1 into the phase II study, which is a historical milestone for Alzheimer's research and clinical development", said Roman Sivak, Chief Executive Officer of AXON Neuroscience, and added: "This is an exciting era as we believe that the positive results from the phase I study could soon be confirmed by this phase II study."

TAU AS A DRIVING FORCE IN ALZHEIMER'S DISEASE

Tau protein pathology had already been identified as the main correlate of cognitive decline in AD in the early 1990s. This finding was further confirmed by several independent studies on animal models expressing diseased forms of the tau protein, where tau pathology induced neurodegeneration and caused cognitive impairment. The most recent imaging studies have

supported the fact that the progression of tau pathology correlates well with the cognitive decline and memory loss of Alzheimer's disease.

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's proprietary 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.

MEDIA CONTACT:

Michael Matis

+421 902 161 362

media@axon-neuroscience.eu