

## AXON meets the first milestone in an nfvPPA Phase 1 study with AADvac1

**Bratislava, December 12, 2017.** AXON has announced the initiation of open recruitment in the currently running Phase 1 study in patients suffering from the non-fluent variant of Primary Progressive Aphasia (nfvPPA). The data obtained from the initial 18-week period which assess a high dose of the active vaccine administered for the first time show no safety concerns and allow continuation of the recruitment. The independent DSMB has confirmed the results and did not identify any issue that would interfere with continuation of the study.

In August 2017, AXON launched in cooperation with the German FTLD consortium a Phase I study assessing its active tau vaccine in patients with nfvPPA. For the first time, this study assesses a high dose of AADvac1 in humans. After the initial incremental recruitment of 6 patients randomly allocated to a regular dose or a high dose in a 1:1 ratio, these were treated and observed during a period of 18 weeks. An independent DSMB evaluated the safety data and concluded that during this period no safety concerns emerged and the enrollment can continue in both arms up to achieving the planned 30 patients.

Prof. Markus Otto, the co-ordinating investigator of the study confirms the exceptionally high demand for a disease-modifying treatment for patients with nfvPPA: *"I am extremely pleased that we can continue with the recruitment of additional patients for our study in non-fluent primary progressive aphasia. Based on the strong preclinical data we have solid hope that this vaccine has potential to treat this rare disease."*

AXON has already showed in the preclinical research and in the completed Phase 1 study in patients with Alzheimer's disease (AD) that the antibodies produced by the active vaccine have a treatment potential and target the common denominator for all tauopathies. Therefore, the successful completion of this study could lead directly to a pivotal phase 2 study also in larger indications such as CBD or PSP. All tauopathies are rare diseases and could qualify for an orphan designation in both the US and Europe.

### Non-fluent variant of primary progressive aphasia (nfvPPA)

The non-fluent variant of primary progressive aphasia (also known as 'non-fluent/agrammatic subtype of PPA') is a neurodegenerative disorder from the group of frontotemporal lobar degenerations, where a tau pathology is the driver of the disease. During the initial phase of the disease, nfvPPA manifests itself with a prominent, isolated language deficit. There is a progressive impairment of language during conversation or speech. Other cognitive functions and motor problems may also be affected as the disease progresses.

### AADvac1 active tau vaccine

AADvac1 is an active vaccine designed to stop the progression of AD and other tauopathies by eliciting an immune response which blocks pathological tau aggregation and spreading and eliminates the formation of neurofibrillary pathology. That will result in preventing the cognitive and functional decline in the patients.

### AXON NEUROSCIENCE

AXON Neuroscience is a clinical-stage biotech company and a global leader in the development of tau-immunotherapies. Researchers from AXON Neuroscience have worked extensively on the tau hypothesis for more than 25 years. AXON's focus is to deliver a disease-modifying drug and a diagnostic tool for Alzheimer's disease and other tauopathies and provide a complex solution for people suffering from these devastating diseases.

### MEDIA CONTACT

MEDIA CONTACT:

Andrea Becker

AXON Neuroscience

+421 903 576 315

[media@axon-neuroscience.eu](mailto:media@axon-neuroscience.eu)