

## **AXON Neuroscience to Present New Results from Phase II Clinical Study at 2021 Alzheimer's Association International Conference**

- *New Results from Phase II Clinical Study for AADvac1, vaccine against Alzheimer's disease to be presented at the Conference*
- *On Monday, July 26th, the founder of AXON Neuroscience, Prof. Michal Novak to be awarded AAIC Lifetime Achievement Award*

**26 July 2021, New York – [AXON NEUROSCIENCE SE](#)** ("Axon"), a clinical stage biotech company at the forefront of treating and preventing Alzheimer's disease, today announced it will present new results from its Phase II clinical study of its tau vaccine AADvac1 against Alzheimer's disease at the 2021 Alzheimer's Association International Conference, which is being held in Denver, Colorado and virtually, 26th - 30th July.

As part of the Conference, the founder of Axon, Prof. Michal Novak, D.V.M., Ph.D., D.Sc. will be awarded the Khalid Iqbal Lifetime Achievement Award. Prof. Novak played a crucial part in the discovery of tau protein as the main constituent of neurofibrillary pathology. In addition, he independently proposed tau protein as a potential drug target for Alzheimer's disease therapy. He has spent his whole career researching tau pathology, which is confirmed to be the main driver and direct correlate of the cognitive decline and memory loss in the disease.

### **New Results from Phase II and Mechanism of Action**

On Thursday, July 29th, Chief Scientific Officer of Axon Norbert Zilka will give an oral presentation at AAIC, titled "The mechanism of action and efficacy of AADvac1, an active immunotherapy against pathological tau protein, in a Phase II study".

In this presentation, Axon will give an in-depth look at the new results of its Phase II clinical trial and present data on its lead asset AADvac1's mechanism of action.

Axon's Chief Scientific Officer will show clinical data demonstrating that AADvac1 showed a strong therapeutic signal in a well-defined subgroup of patients (n=122) with confirmed Alzheimer's disease biomarker profile (A+T+). In this subgroup, AADvac1 in comparison to placebo significantly slowed the clinical decline by 32% as measured by CDR-SB ( $p$  value<0.05) and functional decline by 32% as measured by ADCS-MCI-ADL ( $p$  value<0.05). The efficacy signal was mirrored by a strong reduction of NfL blood levels by 67% ( $p$  value=0.005) as compared to placebo.

In addition, Dr. Zilka will present new findings regarding AADvac1's complete mechanism of action. Blood samples analysed from Phase II patients showed that AADvac1-induced antibodies have

triple therapeutic effect. The antibodies can stop pathological tau-tau interaction, inhibit neuronal tau uptake and facilitate removal of extracellular pathological tau from the brain via microglial uptake.

Michal Fresser, CEO of Axon Neuroscience, commented: *“We are enormously pleased and honoured to have the opportunity to present our Phase II results at the AAIC, which is all the more special because it coincides with the AAIC’s lifetime award to Prof. Michal Novak, founder of Axon. The new results from our Phase II trial give us an even stronger basis to enter the next phase of our clinical development.”*

Michal Novak, board member and founder of Axon Neuroscience, said: *“It is a great honour to receive this award. I would like to thank the committee, especially Maria Carrillo, Khalid Iqbal and Bengt Winblad for recognising the importance of our work. This award belongs to my team and my family, as well as my supporters. We have come a long way together since those early days and I am happy to say that our work on the vaccine has come to fruition.”*

Clinical Dementia Rating – Sum of Boxes (CDR-SB), Activities of Daily Living (ADL) are widely accepted clinical outcome measures to assess cognitive and functional decline in Alzheimer’s disease.

NfL (neurofilament light chain) is a sensitive and dynamic biomarker of neurodegeneration. NfL is associated and correlates with cognitive, biochemical and imaging hallmarks of Alzheimer’s disease.

### **About AADvac1**

Axon is developing AADvac1 as a vaccine with the potential to halt the progression of tau pathology in Alzheimer’s disease. AADvac1 is currently the most clinically-advanced tau immunotherapy in development.

### **About Alzheimer’s Disease**

Alzheimer’s disease is a fatal illness that causes progressive decline in memory and other aspects of cognition. Dementia due to Alzheimer’s is the most common form of dementia, accounting for 60 to 80 percent of all cases. There are currently over 50 million people living with dementia around the world, with numbers expected to increase to nearly 152 million by 2050. Almost 10 million new cases of dementia are diagnosed each year worldwide, implying one new case every 3 seconds, and a significant increase in the caregiving burden placed on society and families. In the US alone, there was an increase of 8 million new caregivers from 2015 to 2020. The annual societal and economic cost of dementia is estimated at \$1 trillion, an amount that is expected to double by 2030 unless an effective treatment exists.

## **About AAIC**

The Alzheimer's Association International Conference (AAIC) is the largest and most influential international meeting dedicated to advancing dementia science. Each year, AAIC convenes the world's leading basic science and clinical researchers, next-generation investigators, clinicians and the care research community to share research discoveries that will lead to methods of prevention and treatment and improvements in the diagnosis of Alzheimer's disease.

## **About Axon Neuroscience**

Axon Neuroscience was founded in 1999 by immunologist Professor Michal Novak. In 1988 Professor Novak discovered tau protein as the major component of neurofibrillary pathology in Alzheimer's disease while working in Laboratory of Molecular Biology, MRC in Cambridge, UK. Axon now has the single biggest team in the world dedicated exclusively to tau research, with over 60 scientists and 15 senior scientists. Over the last two decades, Axon has published a large body of evidence demonstrating that pathological tau is the main driver of Alzheimer's disease.

For more information please visit <https://www.axon-neuroscience.eu/>.

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