Axon Neuroscience's immunotherapy selected for a landmark combination-therapy Alzheimer's clinical trial in US, supported by a USD 151 million grant

Axon Neuroscience's active tau immunotherapy AADvac1 has been selected as the first tau-targeted therapy to enter a groundbreaking U.S. Alzheimer's disease phase 2 clinical trial (supported by a USD 151 million grant) and, simultaneously, a new platform trial for progressive supranuclear palsy (PSP) (supported by a USD 75 million grant).

San Francisco, USA – 04 February 2026 – Axon Neuroscience, a global leader in immunotherapy for human neurodegenerative diseases with an internationally recognized scientific team, announces the achievement of two historic milestones with the potential to significantly influence the future treatment of Alzheimer's disease and progressive supranuclear palsy (PSP):

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1. AADvac1 Selected as the First Tau Therapy in the Phase 2 Alzheimer's Tau Platform (ATP) Combination-Therapy Trial

An independent panel of leading U.S. scientific and clinical experts **selected AADvac1 as the first therapy targeting pathological tau protein** to be evaluated in a clinical trial supported by a USD 151 million grant from the U.S. National Institutes of Health (NIH). The study is led by **Professor Adam Boxer of the University of California, San Francisco** and **Professor Keith Johnson of Harvard Medical School, Boston**.

The Alzheimer's Tau Platform (ATP) is the first clinical study to systematically combine therapies targeting the two main disease-driving proteins: amyloid and tau. This innovative platform design helps bring promising therapies to patients sooner, reduces the number of participants assigned to placebo, and allows new treatment options to be added quickly as evidence grows. AADvac1 will be evaluated as the first tau-directed regimen, with additional promising medicines to be added in the future.

The Phase 2 trial aims to assess the **safety and efficacy of AADvac1 both as a monotherapy and in combination with an approved anti-amyloid monoclonal antibody** for Alzheimer's disease. Approximately up to 450 participants aged 50–80 with late preclinical or early prodromal Alzheimer's disease will be enrolled.

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2. AADvac1 Also Selected for the New Platform Trial for Progressive Supranuclear Palsy (PSP)

Progressive supranuclear palsy (PSP) is a rare and rapidly progressing neurodegenerative disease that typically leads to death within approximately seven years of symptom onset. There are currently no approved therapies capable of slowing disease progression.

The new PSP Trial Platform (PTP), led by the University of California, San Francisco, will be conducted at 50 clinical centers across the U.S. and Canada. The study is similarly like the ATP designed as a long-term platform protocol evaluating multiple investigational therapies.

The platform is funded by a five-year NIA/NIH grant of up to USD 75.4 million—one of the largest grants UCSF has ever received for rare neurodegenerative diseases. The initial phase of the platform will test three therapeutics; the first two selected regimens are AADvac1 and AZP2006/Ezeprogind

from a French biotechnology company AlzProtect. A third regimen has been selected and will be announced in early 2026. Approximately 440 patients with PSP-Richardson syndrome are expected to be enrolled in all therapeutic arms.

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3. Why is AADvac1 a strong Candidate: A Strong Clinical and Scientific Basis

AADvac1 is an active immunotherapy that stimulates the body to generate antibodies against pathological forms of tau protein. In the completed 24-month Phase 2 ADAMANT clinical trial in Alzheimer's patients, AADvac1 demonstrated:

- a favorable safety profile,
- a strong immune response (most patients generated high levels of anti-tau antibodies),
- pronounced effects on blood and CSF biomarkers of neurodegeneration and neuroinflammation,
- supportive clinical effects indicating potential to slow the disease progression, particularly in patients with confirmed tau pathology.

Results from AADvac1's multi-year development program have been published in leading scientific journals, including *Nature Aging*, *Lancet Neurology*, and others. A key recent post-hoc analysis published in *Alzheimer's Research & Therapy* further strengthened the evidence that AADvac1 can modulate critical biological processes in Alzheimer's disease.

Independent scientific and clinical expert groups in the U.S. have therefore **selected AADvac1 as one of the first candidates** for both platform trials:

- **in ATP as the first tau-targeted regimen** and the first active immunotherapy tested in combination with anti-amyloid antibody therapy,
- **in the PSP Platform as one of the first two therapies** evaluating the potential to slow brain-volume loss and clinical progression in PSP.

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4. Global Recognition of Scientific Expertise

Axon Neuroscience was founded in 1999 by a Slovak immunologist Professor Michal Novak, who was part of the MRC Laboratory of Molecular Biology team in Cambridge that identified tau protein as the main component of neurofibrillary pathology in Alzheimer's disease. For his lifelong contribution to research, he has received prestigious awards including the Alzheimer's Association Lifetime Achievement Award (2021) and the WHO Prize for Research in Healthcare of the Elderly (2016).

Axon Neuroscience, the company he founded:

- is among the **pioneers of tau immunotherapy** in Alzheimer's disease and related tauopathies,
- has conducted **four clinical trials across eight European countries**,
- was among the first to identify and validate the **diagnostic potential of the blood biomarker pTau217**, now one of the principal biomarkers for blood-based Alzheimer's diagnostics,
- was highlighted by independent research led by Karolinska Institutet (2024), which concluded that AADvac1 is among the possible future Alzheimer's therapies and particularly suitable for combination treatment with amyloid-targeting medicines,

- has in its pipeline a **promising humanized antibody AADvac2**, whose mechanism of action has been indirectly validated by the AADvac1 clinical data and which may offer a more effective treatment for later disease stages or patients with weaker immune responses.

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5. Prestigious Collaborations, European Grants, and Partnerships

Axon Neuroscience has received two major **Horizon 2020 – Marie Skłodowska-Curie Actions** grants, among the prestigious European scientific funding schemes supporting excellent research and the mobility of top scientists. The company also maintains a long-term project partnership with the **University of Cambridge**, supported by the grants from UK Research and Innovation funding system. Axon further collaborates with leading global pharmaceutical and biotechnology companies on the development of therapeutics for neurodegenerative diseases.

Executive and Scientific Leadership Quotes

Norbert Žilka, DrSc., Chief Scientific Officer:
"The selection of AADvac1 for two independent NIA/NIH-funded platform trials led by prestigious U.S. academic centers is a strong confirmation of the high standard of our clinical research. The active tau immunotherapy we have been developing for more than a decade is now rightfully at the forefront of future combination therapies for Alzheimer's disease and tauopathies."

Branislav Kováčech, PhD., Chief Operating Officer:
"The ATP and PTP platform trials fundamentally change how drugs are developed. Instead of isolated, lengthy, and expensive studies, a dynamic infrastructure is emerging in which the most devastating brain diseases are studied more efficiently—with fewer patients on placebo and faster pathways for promising therapies. This is a major advantage for both patients and investors."

Michal Fresser, Chief Executive Officer:
"The fact that NIH, UCSF, Harvard, and leading U.S. centers have chosen AADvac1 as the first tau therapy in the Alzheimer's Tau Platform and as one of the first therapies in the PSP Platform is not only a scientific milestone but also a strategic validation of our approach. It is clear evidence that technology developed by our innovators has the potential to become part of future treatment standards for Alzheimer's disease and PSP."

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