

Webinar Presentation

20 March 2026 – Melbourne Australia: Neurizon® Therapeutics Limited (ASX: NUZ & NUZOA; OTCQB: NUZTF) ("Neurizon" or "the Company"), a clinical-stage biotechnology company dedicated to advancing innovative treatments for neurodegenerative diseases, is pleased to announce its participation in a community webinar hosted by the Healey & AMG Center for ALS.

Webinar details:

Title: "HEALEY ALS Platform Trial Regimen I Science with Neurizon",

Date: 19 March 2026 ET (20 March 2026 AEDT)

The session provides a high-level overview of the scientific rationale underpinning NUZ-001, which is currently being evaluated as Regimen I for the treatment of ALS in a Phase 2/3 clinical trial.

The webinar slides are attached to this announcement.

-ENDS-

This announcement has been authorised for release by the Board of Neurizon Therapeutics Limited.

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About Neurizon Therapeutics Limited

Neurizon Therapeutics Limited (ASX: NUZ) is a clinical-stage biotechnology company dedicated to advancing treatments for neurodegenerative diseases. Neurizon is developing its lead drug candidate, NUZ-001, for the treatment of ALS, which is the most common form of motor neurone disease. Neurizon's strategy is to accelerate access to effective ALS treatments for patients while exploring the potential of NUZ-001 for broader neurodegenerative applications. Through international collaborations and rigorous clinical programs, Neurizon is dedicated to creating new horizons for patients and families impacted by complex neural disorders. NUZ-001 is an investigational product and is not approved for commercial use in any jurisdiction.

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Healey & AMG Center

Sean M. Healey & AMG Center for ALS
at Massachusetts General Hospital



Massachusetts General Hospital

Founding Member, Mass General Brigham

NUZ-001 (Regimen I) HEALEY ALS Platform Trial

Speakers:

Dr. Chris Freitag- Chief Medical Advisor

Sharon Tamir- ALS Program Lead

Neurizon Therapeutics



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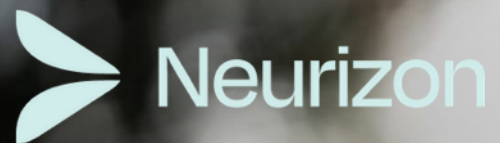
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Our Mission

Advancing groundbreaking science to reach a promising new horizon in treatments for people living with ALS and other neurodegenerative diseases.

NUZ-001 is an investigational therapy being developed for people living with ALS

In most people with ALS, a protein called TDP-43 becomes mislocalized and forms harmful aggregates inside motor neurons, contributing to cellular stress and degeneration.

NUZ-001 is designed to:

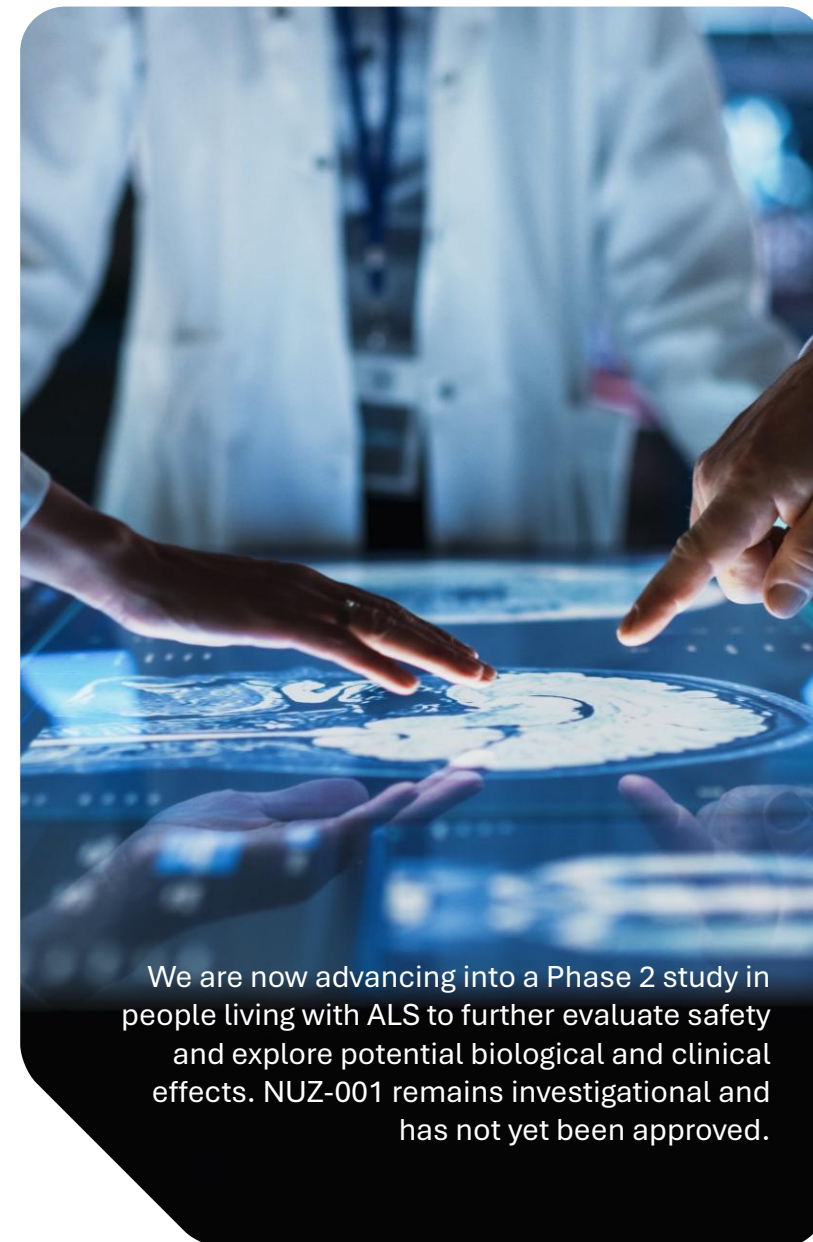
- Strengthen the cell's own internal natural clearance systems
- Switch on protective pathways that help clear away toxic protein buildup and support cell survival
- Address underlying disease biology and not just symptoms

Safety Data:

- Phase 1 study completed, demonstrating safety and tolerability in a small group of participants
- Supported by extensive nonclinical animal safety data generated over more than 20 years in another indication

Today we will share:

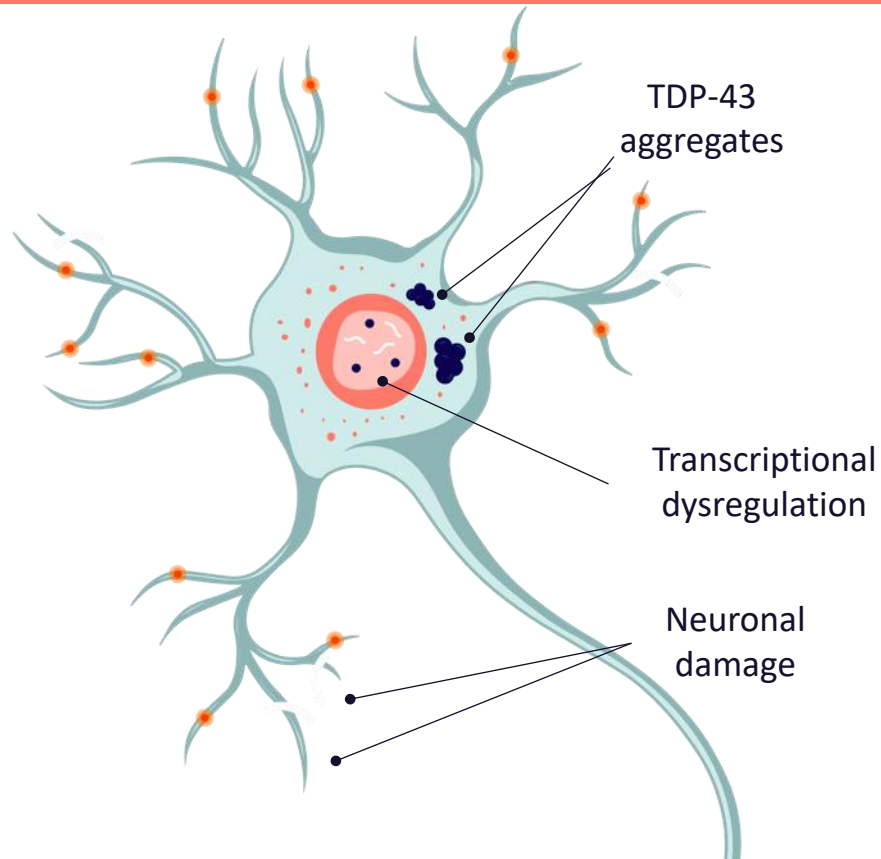
- Why TDP-43 biology is central to sporadic ALS
- What we have learned from preclinical research and Phase 1 studies
- How these findings inform our upcoming Phase 2 clinical trial



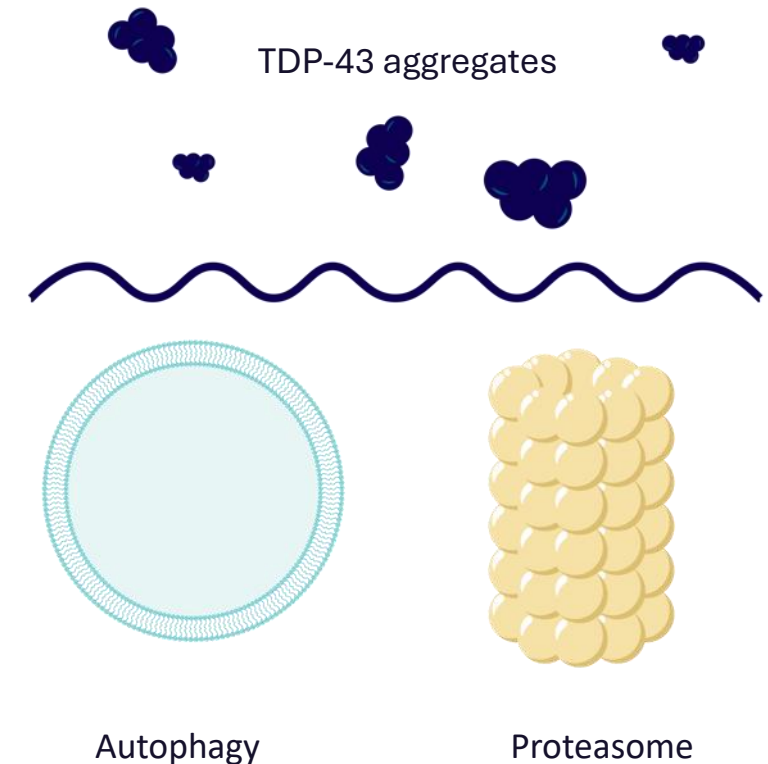
We are now advancing into a Phase 2 study in people living with ALS to further evaluate safety and explore potential biological and clinical effects. NUZ-001 remains investigational and has not yet been approved.

Protein Aggregation and Reduced Protein Clearance are Drivers of Neuronal Pathology in ALS

TDP-43 protein aggregation is a major driver of neuronal damage in ALS



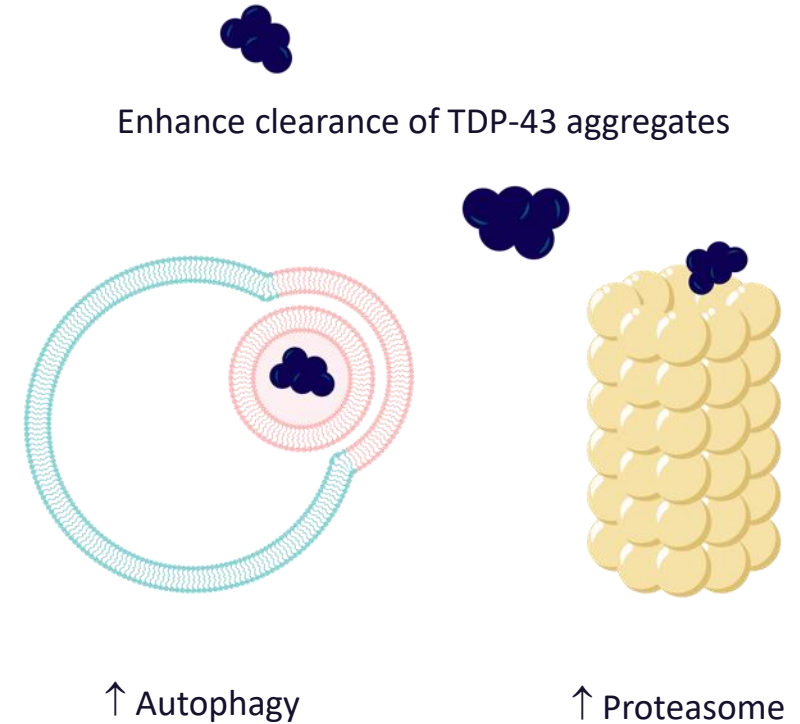
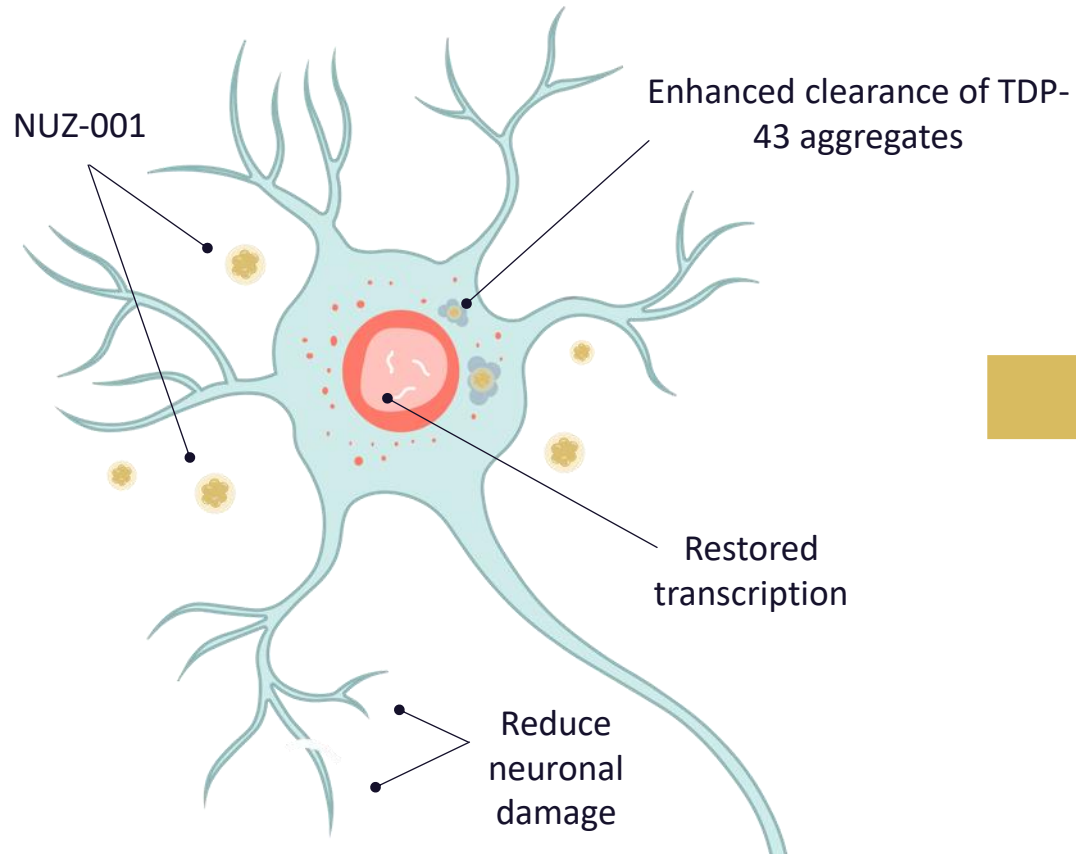
Protein aggregates block endogenous protein clearance pathways



NUZ-001 Enhances Endogenous Protein Clearance Pathways to Remove Toxic Protein Aggregates

NUZ-001 enters neuron and binds molecular target

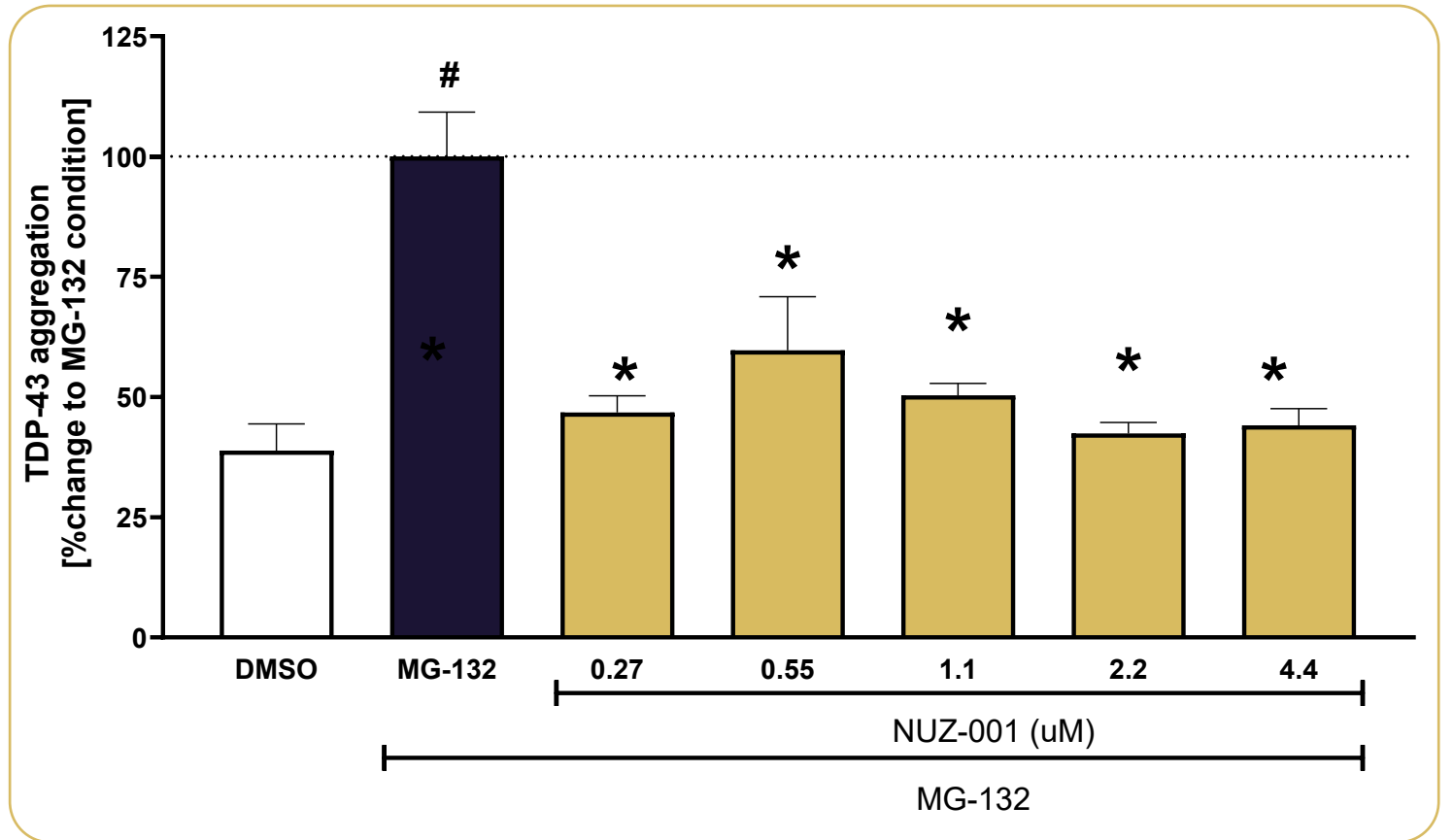
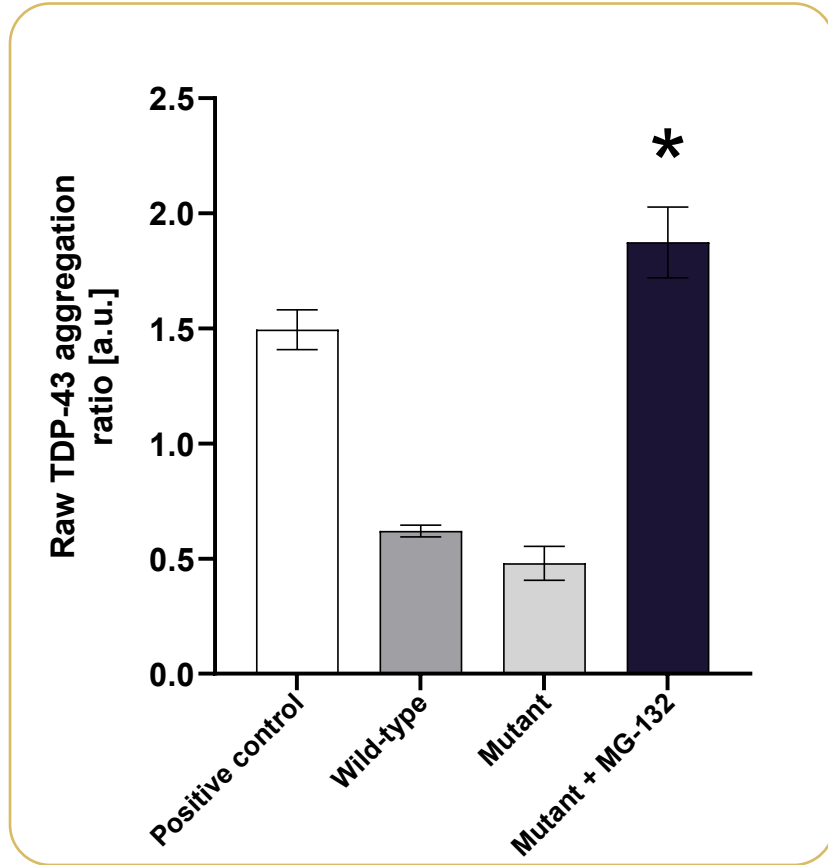
NUZ-001 enhances endogenous protein clearance pathways



NUZ-001 Prevents TDP-43 Aggregation in ALS Neuronal Model Under Stress

Proteasome inhibitor, MG-132, induces TDP-43 aggregation in an ALS mutant neuronal model

NUZ-001 prevented TDP-43 aggregation in ALS mutant neuronal model



Human iPSC-derived motor neurons were treated with NUZ-001 at multiple concentrations for 6 days. TDP-43 aggregation was evaluated 24 hr following the last treatment. * $p < 0.05$ vs MG-132 treatment. # $p < 0.05$ DMSO

A close-up portrait of a woman with curly hair, looking slightly to the side. Overlaid on her face and the background are several blue, semi-transparent brain scan images (MRI or CT slices) showing different cross-sections of a human head. The background is dark and textured with a grid pattern.

Key insights from Phase 1 ALS MEND and Open Label Extension (OLE) Study

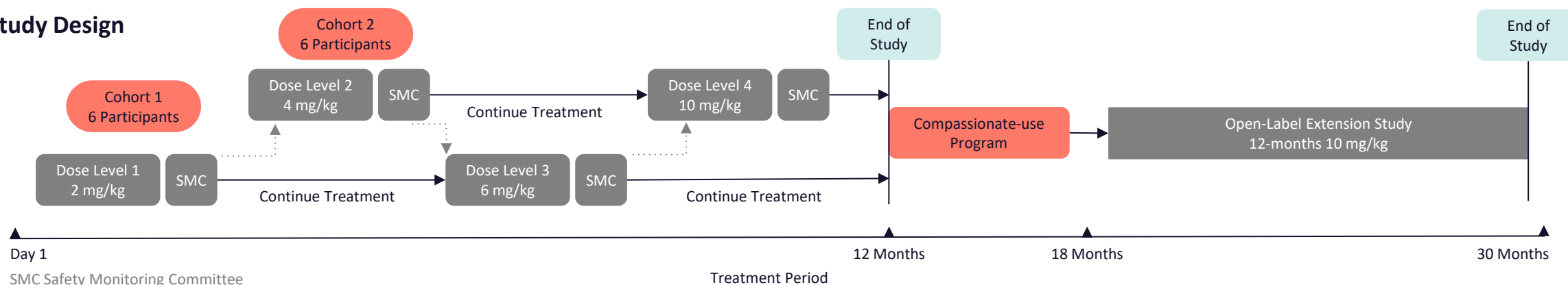


Neurizon

Phase 1 ALS MEND and Open Label Extension (OLE) Study Design

The Phase 1 MEND Study was an open-label, multicentre study involving 12 participants with ALS that commenced in October 2022, followed by a compassionate-use program and later a 12-month open-label extension study.

Study Design



Study Completed



- Phase 1 MEND Study top-line results released in Q1 CY2024
- 12 participants continued treatment with NUZ-001 under a compassionate-use program
- 10 participants rolled-over into a 12-month Open-Label Extension (OLE) Study.
- Top-line results demonstrated long-term safety and preliminary efficacy signals of ALS treatment with NUZ-001
- NUZ-001 has been safely used for more than 3 years, with three participants still receiving treatment under the TGA's Special Access Scheme
- Recommended Phase 2 dose selected as 10 mg/kg

Phase 1 Open Label Extension

Safety and Tolerability Summary

Study drug was well tolerated during long-term administration in the OLE, with no dose-limiting toxicities and no treatment-related deaths.

	Total (n)	Related to Treatment (n)
Adverse Events	25	3
Serious Adverse Events	5	0

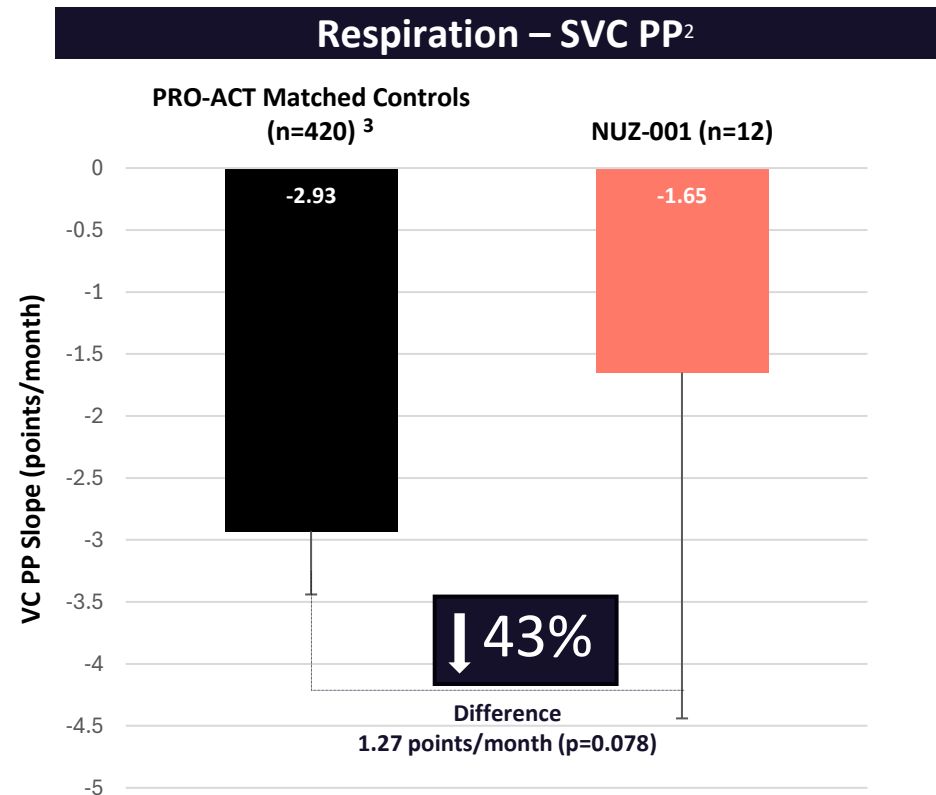
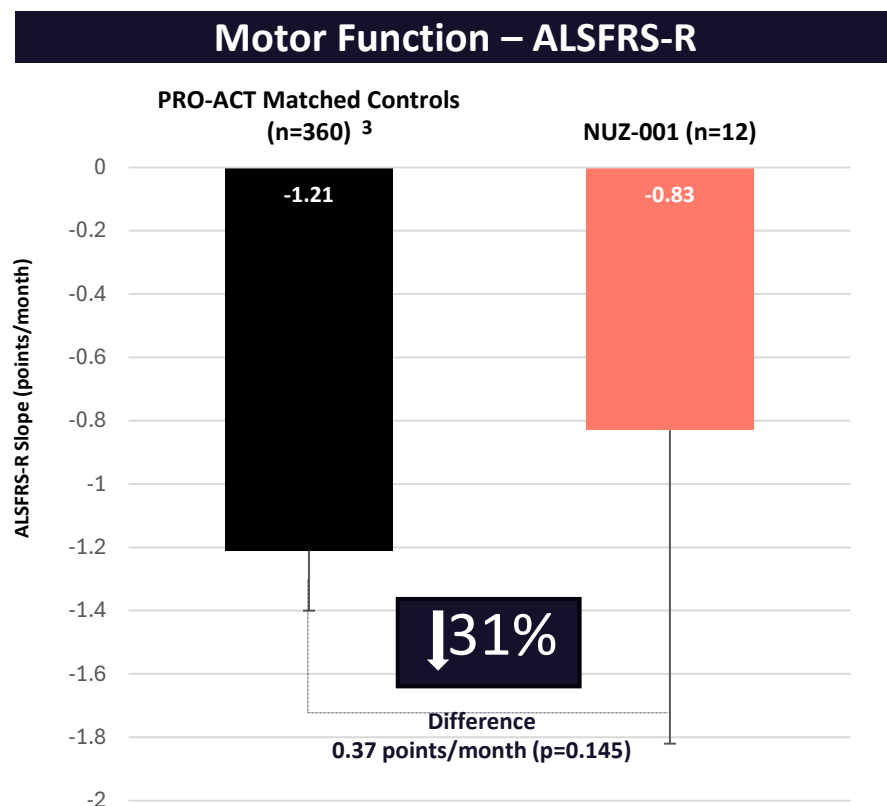
- No participants withdrew from study
- No serious adverse events related to study drug
- Three (30%) participants reported AEs possibly related to study treatment, mild to moderate
 - Raised liver enzyme, Increased hair growth, Dry mouth at night
- Four (40%) participants experienced serious adverse events, all unrelated to study drug
 - Polymyalgia Rheumatica, Pneumonia, Respiratory Failure, Soft Tissue Injury, Suicide Attempt – Overdose

- No unexpected safety findings observed in the OLE compared with Phase 1 MEND.
- 3 participants still receiving treatment under the TGA's Special Access Scheme.

Phase 1 Open Label Extension

Preliminary Efficacy ALSFRS-R and SVC

Treatment with NUZ-001 across combined Phase 1 and OLE studies showed slower progression of ALS in all participants by 31% for ALSFRS-R and 43% for SVC percent predicted (PP) when compared to matched controls from the PRO-ACT historical database¹.



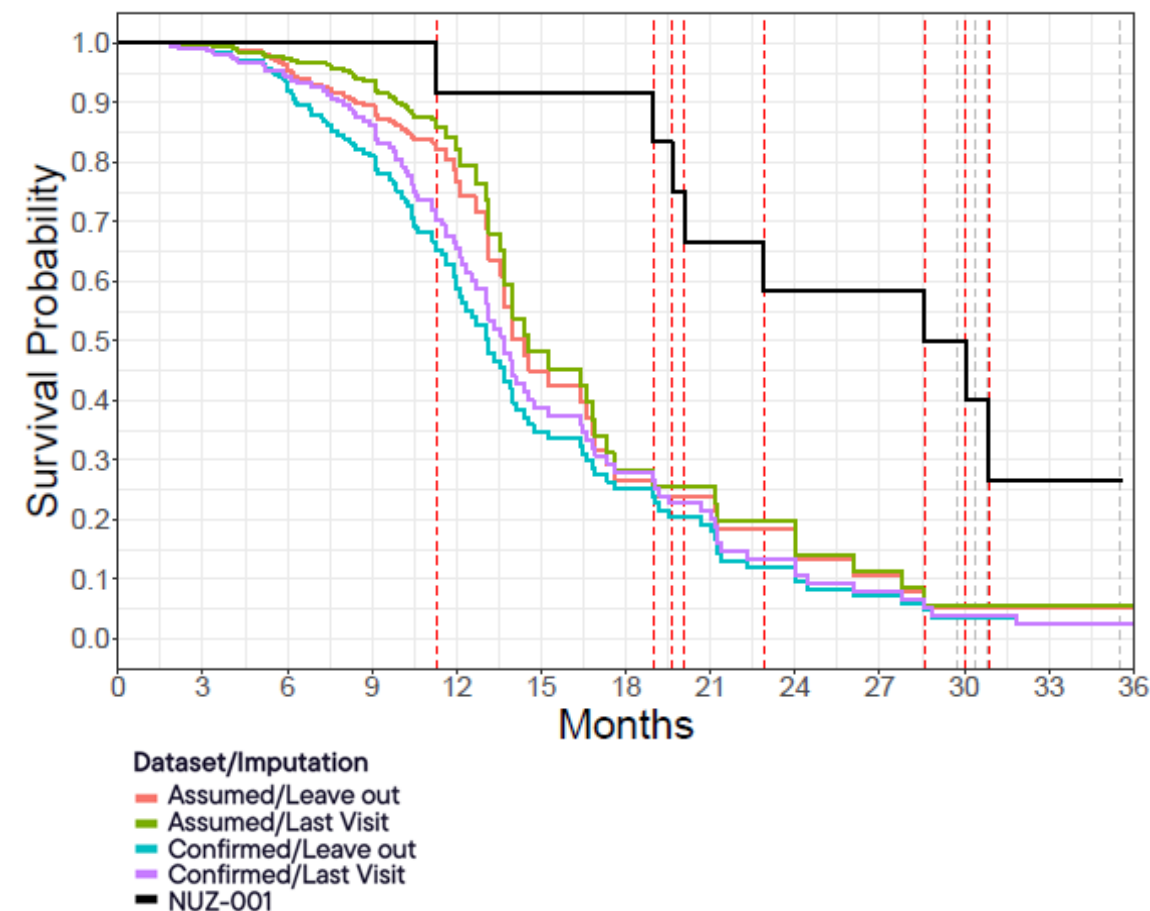
Phase 1 Open Label Extension

Survival Probability Analysis

Treatment with NUZ-001 resulted in significantly longer survival of participants with ALS, ($X^2=10.95$, $p=0.00094$), when compared to matched controls¹ from the PRO-ACT database²

Analysis suggests that treatment with NUZ-001 reduces the risk of death by 70.2%:

Hazard ratio of 0.298 (95% CI: (0.135, 0.659), $p = 0.0028$)



Phase 1 Open Label Extension

Conclusion

These results support the potential of NUZ-001 as a disease-modifying therapy for ALS and provide strong justification for advancing the program into further clinical development with the HEALEY ALS Platform Trial

Highlights (Based on a small study population of 12 participants)



Primary Objectives

- Long-term treatment with NUZ-001 at the recommended Phase 2 dose was well-tolerated



Slowed Functional Decline

- Sustained slowing in disease progression by 31% compared to PRO-ACT matched control ALS participants



Respiratory Stabilisation

- 43% reduction in VC PP compared to PRO-ACT matched controls



Survival*

- Longer survival compared to PRO-ACT matched controls
- Estimated life extension of ~16 months



Biomarker Trends

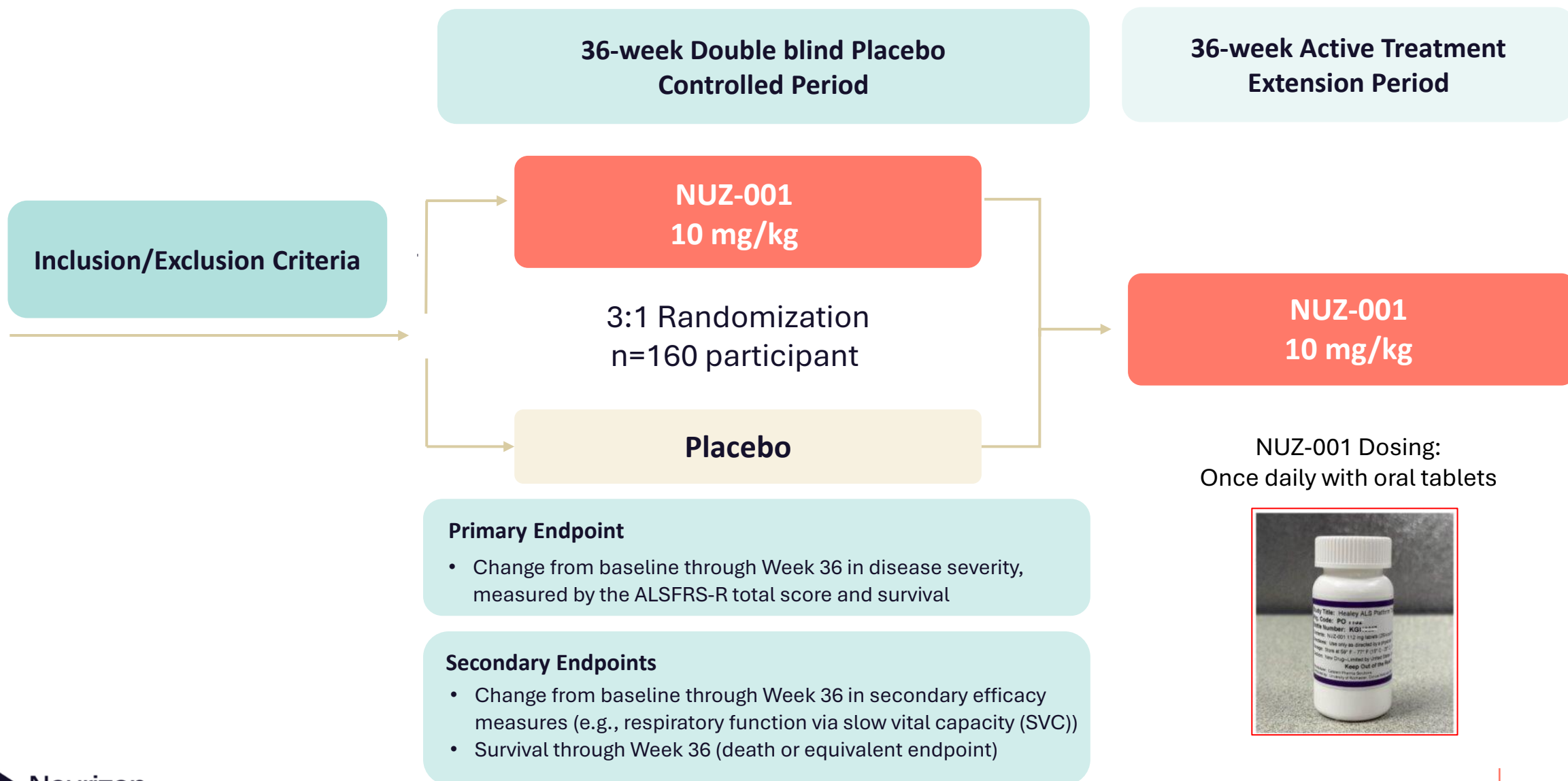
- Encouraging biomarkers trends in NfL and urinary p75^{ECD}



Patient Satisfaction

- No study discontinuations; 3 of the 4 remaining participants continue to access NUZ-001 under the TGA's Special Access Scheme**

HEALEY ALS Platform Trial Regimen 'I' for NUZ-001



Key Inclusion Criteria

- Sporadic or familial ALS diagnosed as clinically possible, probable, lab-supported probable, or definite ALS defined by revised El Escorial criteria.
- Age 18 years or older.
- Time since onset of weakness due to ALS $\leq$ 24 months.
- Participants must either not take riluzole or be on a stable dose of riluzole for $\geq$ 30 days prior to the Master Protocol Screening Visit.
- Participants must either not take edaravone or have completed at least one cycle (typically 14 days) of edaravone prior to the Master Protocol Screening Visit.
- Participants must have the ability to swallow pills and liquids.

Key Exclusion Criteria

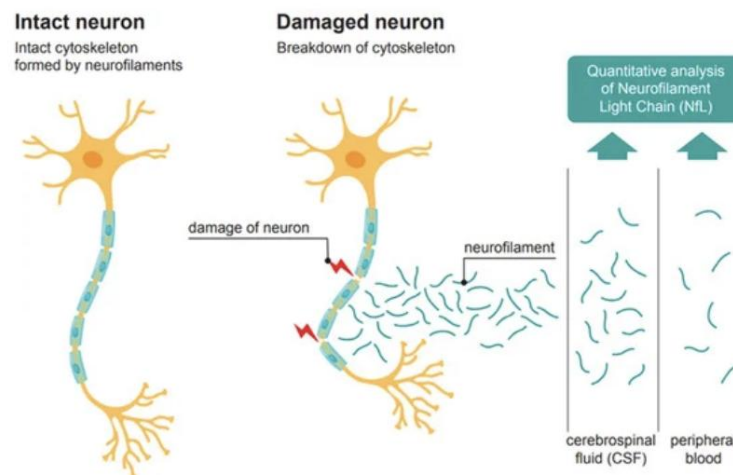
- Clinically significant unstable medical condition (other than ALS) that would pose a risk to the participant. Use of investigational treatments for ALS Exposure at any time to any gene therapies under investigation for the treatment of ALS (off-label use or investigational).
- Anything that would place the participant at increased risk or preclude the participant's full compliance with or completion of the study, in the SI's opinion.

Biomarkers: Understanding Disease Activity and Treatment Response



Neurofilament Light Chain (NfL):

A protein found in CSF & blood that increases when motor neurons are under stress or damaged cerebrospinal fluid (CSF) required at baseline and Week 24 visits)



p75 neurotrophin receptor:

Helps track nerve cell stress and disease progression with urine sample



Protein Assays (TDP-43) & Proteomics:

Cutting-edge technologies used to explore the body's biological response to disease and treatment



Mitochondrial health markers:

Indicators of cellular stress, energy function, and nerve cell well-being



RNA & DNA expression:

Measures gene expression changes to understand disease activity and treatment effects

Innovative Digital Biomarker

Speech intelligibility in ALS is both a functional outcome (how well a person communicates) and a biological signal of disease progression, making it highly relevant for patient care, prognosis, and clinical research.

Earlier Detection of Changes

Speech analysis can sometimes detect small changes related to ALS up to six months earlier than traditional rating scales.

Reflects Multiple Important Functions

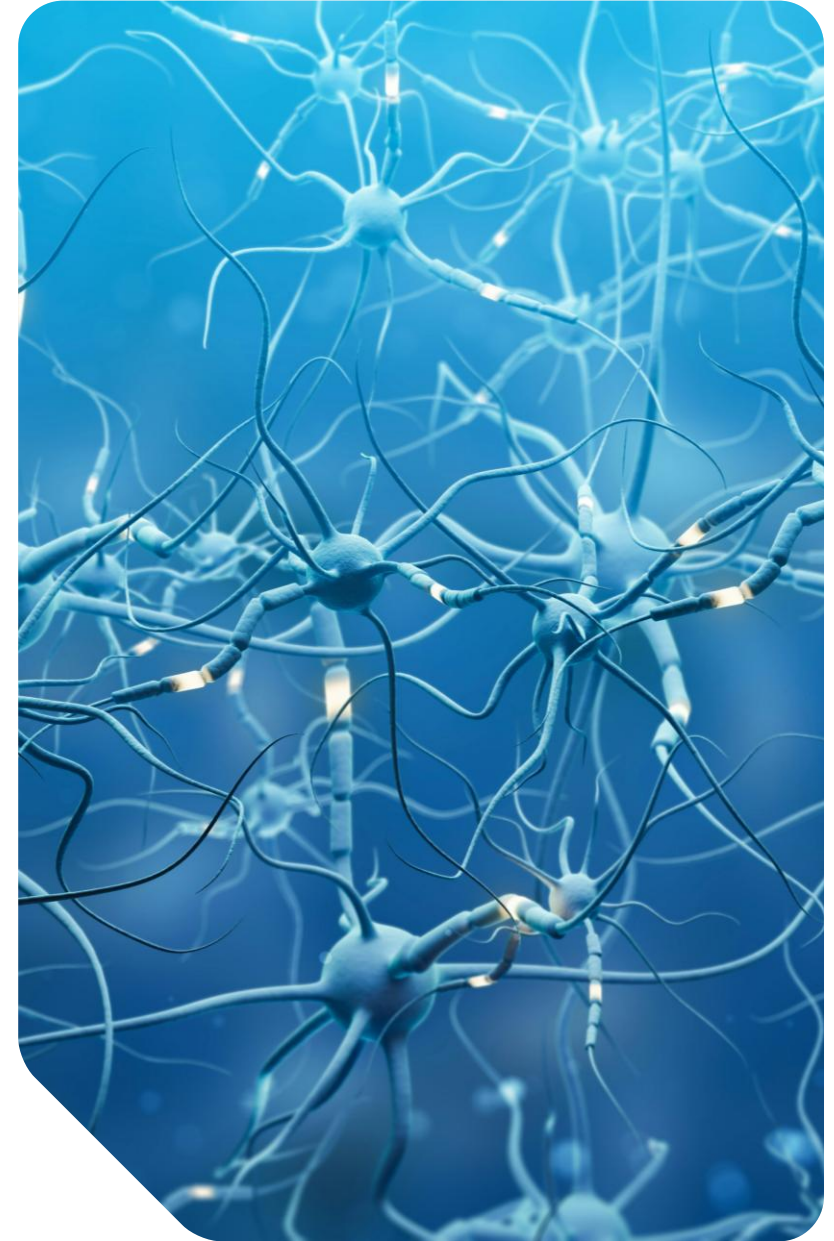
Speaking involves many body systems, including muscles, breathing, and thinking.

Focus on What Matters to Patients

Communication is a key part of quality of life. Speech-based assessments directly measure how well someone can communicate.

What we measure

- Speech intelligibility and naturalness outcomes
- Speech timing and sequencing
- Voice quality, breath support and contributes to speech intelligibility and naturalness



Our Strategic Progress for People Living with ALS

- Our focus remains on advancing our ALS clinical program by commencing enrolment in the HEALEY ALS Platform Trial for NUZ-001
- Accelerated approval may be possible on Phase 2 data
- NUZ-001 has been granted Orphan Drug Designation by the U.S. FDA
- Studies are on-going for a liquid formulation of NUZ-001, for ease of use

Expanded Access Protocol (EAP) Compassionate Use -
we are exploring options to offer EAP in the future



For more information, please check out:

Learn More About the Clinical Trial

HEALEY ALS Platform Trial- Master Protocol (including inclusion/exclusion criteria)

<https://clinicaltrials.gov/study/NCT04297683>

Regimen I NUZ-001 Details:

<https://clinicaltrials.gov/study/NCT07410806>

Learn More About Neurizon Therapeutics



<https://www.neurizon.com>

Thank You!

To the individuals and families living with ALS, the caregivers who stand beside them, and the clinicians dedicated to their care, thank you for your strength, your trust, and your commitment to advancing research for the entire ALS community.



Thank You
from the Neurizon Team

