Neurizon Therapeutics Limited
ABN 35 094 006 023
www.neurizon.com

First patient in the HEALEY ALS Platform Trial enters Active Treatment Extension

Highlights:

- **First participant in Neurizon's Regimen I of the Phase 2/3 HEALEY ALS Platform Trial completes the 36-week Randomised Controlled Trial (RCT) phase and transitions into the Active Treatment Extension (ATE)**
- **Development marks an important clinical milestone for the ongoing development of NUZ-001, with eligible participants able to receive active treatment under the HEALEY ALS Platform Trial protocol**
- **ATE will generate additional long-term safety, tolerability, functional and biomarker data, contributing to the broader clinical evidence package supporting NUZ-001's development**
- **Regimen I is fully enrolled with 250 participants across 78 US clinical sites, with topline results from the RCT anticipated in late Q2 CY2027**
- **Follows recent US FDA feedback that Regimen I may serve as a single registrational study supporting a New Drug Application (NDA) for NUZ-001, subject to the results and confirmatory evidence meeting applicable regulatory requirements**

13 November 2026 – Melbourne Australia: Neurizon® Therapeutics Limited (ASX: NUZ; OTCQB: NUZTF) ("Neurizon" or "the Company"), a late clinical-stage biotechnology company dedicated to advancing innovative treatments for neurodegenerative diseases, is pleased to advise that the first participant in Regimen I of the Phase 2/3 HEALEY ALS Platform Trial has completed the 36-week placebo-controlled (RCT) phase and transitioned into the Active Treatment Extension (ATE).

The milestone marks the next stage in the progression of Regimen I, following the completion of enrolment of 250 participants in July 2026. As eligible participants reach Week 36, they may voluntarily continue into the extension, where all participants receive investigational NUZ-001 under the trial protocol.

Building longer-term clinical evidence

The ATE is designed to generate additional longer-term safety, tolerability, functional and biomarker data, beyond the clinical evidence collected during the RCT phase. All participants entering the extension will receive NUZ-001, irrespective of their original treatment allocation.

Participants will continue to undergo regular clinical and safety assessments, including measures of functional decline using the ALS Functional Rating Scale-Revised (ALSFRS-R), respiratory function and quality of life. Blood and urine biomarker assessments, including neurofilament light chain (NfL), will also continue throughout the extension period. Treatment assignments remain blinded through the extension period.

Importantly, these additional observations are expected to complement the RCT dataset and contribute to the broader clinical evidence package supporting the continued development of NUZ-001. The extension is not a separate controlled assessment of efficacy. The contribution of ATE data to any future regulatory submission remains subject to applicable requirements.

The transition follows rapid enrolment completion in Regimen I, with all 250 participants enrolled across 78 activated clinical sites throughout the US in around five months, the fastest in ALS Trial history.

The milestone also follows Neurizon's recent receipt of written feedback from the US Food and Drug Administration (FDA), which noted that positive results from the HEALEY ALS Platform Trial may support a traditional approval pathway and that Regimen I may serve as a single registrational study for NUZ-001, subject to the results and confirmatory evidence meeting the applicable regulatory requirements.

Chief Executive Officer, Dr Chris Bremer, said: "The first participant entering the Active Treatment Extension is an important milestone for Regimen I and reflects the continued progress of our clinical development program.

For people living with ALS, a progressive disease with limited treatment options, advancing research into potential new therapies is critically important. We are grateful to the participants who continue to contribute to this research, and to their families and clinical teams for their commitment.

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The extension provides an opportunity to build our understanding of NUZ-001 through longer-term treatment exposure and clinical observations, complementing the randomised evaluation at the heart of the trial.

With all 250 participants enrolled, our focus remains on rigorous trial execution and the anticipated topline readout in late Q2 CY2027, while continuing to build the clinical evidence needed to inform the next stages of NUZ-001 development."

Merit Cudkowicz, MD, MSc, Executive Director of the Mass General Brigham Neuroscience Institute and Director of the Healey & AMG Center for ALS, said: "We believe strongly that it is critical to design clinical trials to get clear results in the shortest time period. Through the HEALEY ALS Platform Trial, we worked closely with our Network for Excellence in ALS (NEALS) partners and our patient advisory committee to innovate to accelerate study start up, enrolment and maintain high retention and quality to get answers as fast as possible. After enrolling 250 participants in 5 months, we are excited to now have taken this next step in Regimen I of the HEALEY ALS Platform Trial. We sincerely thank the study teams, research partners, and participants and their families for their dedication to this trial and helping to advance ALS research."

Next steps

Neurizon will continue to work with the Healey & AMG Center for ALS at Mass General Brigham as Regimen I participants progress through their respective treatment periods and eligible participants transition into the ATE.

The Company remains focused on completing the RCT phase, progressing towards database lock and delivering topline results in late Q2 CY2027. These results will inform subsequent regulatory engagement with the FDA and other relevant regulatory authorities regarding the potential approval pathway for NUZ-001.

HEALEY ALS Platform Trial Regimen I overview

Regimen I is part of the HEALEY ALS Platform Trial evaluating NUZ-001 in 250 people living with amyotrophic lateral sclerosis (ALS) across 78 US trial sites. Participants are randomised 3:1 to NUZ-001 or placebo for 36 weeks, followed by an optional 36-week ATE. The study's primary evaluation combines functional decline, measured using ALSFRS-R, and survival. Topline results from the RCT phase are anticipated in late Q2 CY2027.

-ENDS-

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

For further information, please contact:

Marketing & Corporate Affairs
Lidija Damjanovic
Email: lidija@neurizon.com
Phone: +61 (0) 425 700 504

Investor Relations
Henry Jordan
Email:henry.jordan@sdir.com.au
Phone: +61 (0) 431 271 538

About Neurizon Therapeutics Limited

Neurizon Therapeutics Limited (ASX: NUZ) is a late 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 program, 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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