

HEALEY ALS Platform Trial Regimen I enrolment completed – Topline results for NUZ-001 accelerated to Q2 CY2027

- 250 participants enrolled in less than five months from first participant dosing, representing the fastest site activation and enrolment in the HEALEY ALS Platform Trial so far
- Anticipated topline efficacy and safety results for NUZ-001 now expected in late Q2 CY2027
- Completion of recruitment materially de-risks execution of Neurizon's lead late-stage clinical program
- Reflects strong recruitment and effective execution across the HEALEY ALS Platform Trial network
- Participants now progressing through the planned 36-week randomised treatment period

17 July 2026 – Melbourne Australia: Neurizon® Therapeutics Limited (ASX: NUZ; OTCQB: NUZTF) ("Neurizon" or "the Company"), a late-stage clinical biotechnology company dedicated to advancing innovative treatments for neurodegenerative diseases, is pleased to advise that enrolment has been completed in Regimen I of the Phase 2/3 HEALEY ALS Platform Trial evaluating the Company's lead investigational therapy NUZ-001 for the treatment of amyotrophic lateral sclerosis (ALS).

Neurizon advises that the final participant has completed their baseline visit and commenced treatment, completing enrolment into Regimen I. Reflecting the rapid pace of recruitment, the Company now expects to report topline efficacy and safety results in late Q2 CY2027, earlier than previously anticipated.

Completion of enrolment, together with the earlier anticipated timing of the topline results readout, further demonstrates the continued advancement of the late-stage clinical development program for NUZ-001 for the treatment of ALS. Regimen I completed enrolment in less than five months from first participant dosing, becoming the fastest regimen to activate sites and complete enrolment in the HEALEY ALS Platform Trial, even after the planned sample size expansion from 160 to 240 participants in response to strong recruitment momentum.

This achievement reflects the strength of recruitment across the HEALEY ALS Platform Trial network, one of the world's leading ALS clinical trial initiatives, the operational efficiencies introduced under the trial's next generation master protocol, and the commitment of investigators, research coordinators and clinical site teams across the United States.

Neurizon sincerely acknowledges every person living with ALS and their families who has chosen to participate in this research, recognising that their commitment is fundamental to advancing clinical research and the development of potential new treatment options for the ALS community.

Participants will now continue through the 36-week Randomised Controlled Trial phase before entering the 36-week Active Treatment Extension phase, with the Company's focus centred on continued execution ahead of the anticipated topline readout in late Q2 CY2027.

Interim Executive Chairman, Mr Sergio Duchini said: "Completion of enrolment represents a major milestone in the clinical development of NUZ-001. Importantly, the rapid completion of recruitment has enabled the anticipated timing of topline efficacy and safety results to be accelerated into late Q2 CY2027, bringing forward an important value inflection point for Neurizon and our shareholders.

On behalf of the Company, I would like to sincerely thank every person living with ALS and their families who chose to participate in this trial. Their willingness to contribute to research despite the immense challenges of this disease is inspiring and is fundamental to advancing the development of new treatment options for people living with ALS.

I would also like to acknowledge the outstanding work of the HEALEY ALS Platform Trial team, investigators, research coordinators and clinical site teams whose expertise, collaboration and commitment have made this achievement possible.

With recruitment now complete, our focus turns to delivering the study with the same operational discipline that has characterised the program to date. We look forward to advancing NUZ-001 through clinical development and towards the anticipated topline efficacy and safety results."

Director of the Sean M. Healey & AMG Center and Executive Director of the Mass General Brigham Neuroscience Institute, Merit Cudkowicz, MD, MSc said: “We are grateful to everyone who helped complete enrolment in Regimen I in such a short amount of time. We believe strongly in importance of speed, efficiency and high quality in clinical trials. Our patients tell us that the ALS clock is faster and we need to work collaboratively to develop treatments sooner. This is one of the guiding principles of the Healey ALS Platform Trial, Next Generation. The rapid speed of enrolment in this regimen is a testament to the hard work of participants and their families and study staff across all the participating NEALS sites, as well as to the optimised Platform Trial infrastructure.”

About the HEALEY ALS Platform Trial:

The HEALEY ALS Platform Trial (ClinicalTrials.gov identifier: NCT04297683) is a multicentre, double-blind, placebo controlled adaptive Phase 2/3 clinical trial conducted by the Sean M. Healey & AMG Center for ALS at Mass General Brigham in the United States (US), created in partnership with the Network of Excellence for ALS (NEALS). Entry into the HEALEY ALS Platform Trial is competitive, with drug candidates reviewed and selected by expert committees based on scientific merit and evidence of potential benefit in ALS. The goal of the HEALEY ALS Platform Trial is to accelerate the development of potential new ALS therapies.

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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 late-stage clinical 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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