Neurizon Therapeutics Limited
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HEALEY ALS Platform Trial Regimen I expands to 240 participants

Highlights:

- **Neurizon announces an expansion to the size of Regimen I intended to support a larger and more informative dataset, with accelerated time to topline readout and no change in funding requirements**
- **Increase in sample size driven by enrolment rate exceeding original expectations and the absence of a concurrent regimen during the expected recruitment period**
- **Regimen I expands from 160 to 240 participants to maintain statistical power for the primary endpoint aligned with the original trial assumptions**
- **The increased sample size allows more robust analysis of subgroups and biomarkers and ensures a fully powered study at topline results**
- **Based on current enrolment momentum, Neurizon anticipates that last participant dosing will now occur in Q2 CY2027 with topline results to be released early Q3 CY2027, exceeding previous trial timeframe projection**
- **Expanded participant cohort cost is materially offset by a contribution of philanthropic funds from the Sean M. Healey & AMG Center for ALS at Mass General Brigham**
- **As a result of diligent cost management and rapid recruitment, this change is expected to have no impact on Neurizon's costs through to topline results and only a very modest increase in the total cost of completing the full trial**
- **Larger, consistent dataset expected to strengthen partnering and commercial positioning for NUZ-001**
- **113 participants assigned and 74 dosed as of 22 May 2026, with 64 US clinical trial sites activated and 193 participants screened under the master protocol to date**
- **Neurizon to host a shareholder webinar on 28 May to discuss the trial recruitment expansion in further detail**

27 May 2026 – Melbourne Australia: Neurizon® Therapeutics Limited (ASX: NUZ & NUZOA; OTCQB: NUZTF) ("Neurizon" or "the Company"), a clinical-stage biotech company dedicated to advancing innovative treatments for neurodegenerative diseases, is pleased to advise that Regimen I of the HEALEY ALS Platform Trial will increase its total patient cohort from 160 to 240 participants. The expansion is driven by the enrolment rate exceeding original expectations and the absence of a concurrent regimen during the expected recruitment period. Expanded design maintains statistical power for the primary endpoint aligned with the original assumptions underpinning the study and allows more robust analysis of subgroups and biomarkers.

Importantly, the current recruitment momentum is expected to accelerate the overall trial timeline relative to previous expectations, despite the increased recruitment target. Based on current trends, the Company now anticipates last participant dosing in Q2 CY2027, with topline results expected in early Q3 CY2027.

Following an extensive review of the scientific, statistical, financial and regulatory considerations, as well as ongoing engagement with the Sean M. Healey & AMG Center, Regimen I will now comprise 180 NUZ-001 participants and 60 Regimen I placebo controls.

As of 22 May 2026, 113 participants have been assigned to Regimen I and 74 participants have been dosed. There are 64 clinical trial sites activated across the United States and 193 participants have been screened to date under the master protocol. While current recruitment momentum continues to track ahead of prior expectations, future recruitment rates may vary over time.

Based on the expanded 240-patient design, accelerated enrolment timelines and a meaningful financial contribution of philanthropic funds from the Sean M. Healey & AMG Center for ALS at Mass General Brigham, Neurizon expects the total funding requirements through to study completion to remain unchanged.

Neurizon remains focused on efficiently delivering a scientifically meaningful outcome from the HEALEY ALS Platform Trial. The expansion of the trial has no impact on Neurizon's expected costs through to topline results, with only a modest overall increase in the total cost of completing the full trial. This increase is expected to be further offset through eligibility under the Australian Federal Government's R&D Tax Incentive Program, together with the

financial contribution of philanthropic funds from the Sean M. Healey & AMG Center for ALS at Mass General Brigham. This demonstrates Neurizon's continued focus on cost and capital efficiency and ensures the Company remains fully funded through completion of the trial.

Neurizon believes expanding the regimen is a fiscally disciplined and strategically attractive decision to generate a larger, more statistically robust, and internally consistent ALS dataset, which eliminates reliance on placebo groups from other regimens and maintains the original statistical assumptions underpinning the study at topline results.

Interim Executive Chairman, Mr Sergio Duchini said: "The expansion of Regimen I to 240 participants reflects our considerable confidence in NUZ-001 and is underpinned by strong momentum being delivered across the HEALEY ALS Platform Trial study. Importantly, this decision maintains the statistical power for the analysis of the primary endpoint and the potential for topline results ahead of our previously stated schedule."

"The strength of recruitment and engagement across the HEALEY ALS Platform Trial network has positioned Neurizon to proactively optimise the study design at an important point in the trial. We believe the expanded dataset will strengthen the statistical robustness, interpretability and strategic value of the program as we advance toward topline results."

"Importantly, the larger and more internally consistent dataset is expected to enhance future regulatory, partnering and commercial opportunities for NUZ-001, while also strengthening our ability to generate valuable biomarker and translational insights relevant to the broader neurodegenerative disease landscape."

"ALS remains an area of urgent unmet medical need, and we believe this decision further strengthens Neurizon's positioning as we continue advancing NUZ-001 through late-stage clinical development."

Merit Cudkowicz, MD, MSc, Director of the Healey & AMG Center and Executive Director of the Mass General Brigham Neuroscience Institute, said: "This partnership with Neurizon reflects a shared commitment to advancing meaningful science while keeping people living with ALS at the center of everything we do. We thank our patient advisory committee members and the entire ALS community for active participation in this important clinical trial. By working collaboratively, we can accelerate progress, strengthen the research ecosystem, and ultimately deliver solutions that better serve the ALS community."

Sabrina Paganoni, MD, PhD, Co-Principal Investigator of the HEALEY ALS Platform Trial and Co-Director of the Neurological Clinical Research Institute (NCRI) said: "I want to sincerely thank the Network of Excellence for ALS (NEALS) investigators and site teams for achieving our most rapid enrollment to date — an extraordinary milestone that reflects their dedication and collaboration. I also want to recognize the coordination center at the Healey & AMG Center and key vendors for outstanding implementation and execution of the study, which made this success possible, as well as participants and their families for their dedication and support."

Webinar details:

Neurizon will host an informational webinar on Thursday, 28 May 2026 at 4:00pm AEST (2:00pm AWST) to discuss this announcement and provide additional context around the expanded enrolment in the HEALEY ALS Platform Trial. Registration details are provided below. Participants are encouraged to submit questions in advance during the registration process or via company email to enquiries@neurizon.com.

Registration Link: https://bit.ly/NUZ-001
Date: 28 May 2026
Time: 4:00pm AEST

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 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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