

HEALEY ALS Platform Trial surpasses 50% dosing milestone ahead of schedule

- 129 of 240 participants dosed in Regimen I of the HEALEY ALS Platform Trial evaluating NUZ-001
- Achievement follows recent expansion of Regimen I from 160 to 240 participants, supporting a larger and more informative clinical dataset
- Recruitment and dosing momentum continues to exceed expectations, with 167 participants assigned to Regimen I as at 9 June 2026
- Rapid dosing highlights the operational strength and efficiency of the HEALEY ALS Platform Trial network and continued strong engagement from investigators, clinical sites and the ALS community
- Neurizon remains well positioned for last participant dosing in Q2 CY2027 and release of topline results in early Q3 CY2027

12 June 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 more than 50% of participants have now been dosed in Regimen I of the HEALEY ALS Platform Trial evaluating NUZ-001 for the treatment of Amyotrophic Lateral Sclerosis (ALS), the most common form of Motor Neurone Disease (MND).

As at 9 June 2026, 167 participants have been assigned to Regimen I and 129 participants have been dosed. A total of 78 clinical trial sites are now activated across the United States, with recruitment momentum tracking ahead of expectations.

The milestone follows the expansion of Regimen I from 160 to 240 participants, reflecting the stronger than anticipated recruitment rates and the absence of a concurrent regimen during the recruitment period. The expanded study is intended to support a larger and more informative dataset while maintaining the original statistical assumptions underpinning the primary efficacy analysis (refer ASX announcement: 27 May 2026).

The achievement of the 50% dosing milestone shortly after the expansion of Regimen I underscores the operational strength and efficiency of the HEALEY ALS Platform Trial network. With more than half of participants now dosed, the milestone reflects continued strong engagement from investigators, clinical sites and the ALS community, while demonstrating the platform's ability to efficiently progress patients through recruitment, screening, randomisation and treatment.

Based on the ongoing operational momentum, Neurizon remains exceptionally well placed for last participant dosing in Q2 CY2027 and release of topline results in early Q3 CY2027, subject to ongoing recruitment rates and operational factors.

Interim Executive Chairman, Mr Sergio Duchini said: "Surpassing the 50% dosing milestone in Regimen I represents another important achievement for the NUZ-001 program and provides further evidence of the strong execution capabilities of the HEALEY ALS Platform Trial network.

Importantly, this milestone has been achieved shortly after the expansion of the study from 160 to 240 participants, highlighting the continued enthusiasm from investigators, clinical sites and the ALS community, as well as the efficiency of the platform in progressing patients through recruitment, screening, randomisation and treatment.

The pace of enrolment and dosing continues to exceed our original expectations and reinforces our confidence in the operational timelines for the study. With more than half of participants now dosed, we believe Neurizon remains well positioned to deliver a robust dataset that has the potential to support future regulatory, partnering and commercial opportunities for NUZ-001.

We look forward to maintaining this momentum as we continue advancing towards full enrolment, last patient dosing and the release of topline results."

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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