Neurizon Therapeutics Limited
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Neurizon Initiates Dosing of NUZ-001 in HEALEY ALS Platform Trial

Highlights:

- **First participant enrolled and dosed with NUZ-001 in Regimen I of the HEALEY ALS Platform Trial evaluating NUZ-001 for the treatment of ALS**
- **Approximately 160 participants with ALS will be enrolled in a 36-week randomised, double-blind, placebo-controlled adaptive Phase 2/3 clinical trial in leading ALS clinical centres across the United States**
- **Follows a successful Phase 1 clinical program in a small study population (n=12) in people living with ALS, which showed encouraging preliminary signals of efficacy and NUZ-001 was safe and well-tolerated**
- **Study is expected to complete enrolment in H2 CY2026**

26 February 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 that the first participant has been dosed in Regimen I of the HEALEY ALS Platform Trial evaluating Neurizon's lead candidate, NUZ-001, for the treatment of amyotrophic lateral sclerosis (ALS).

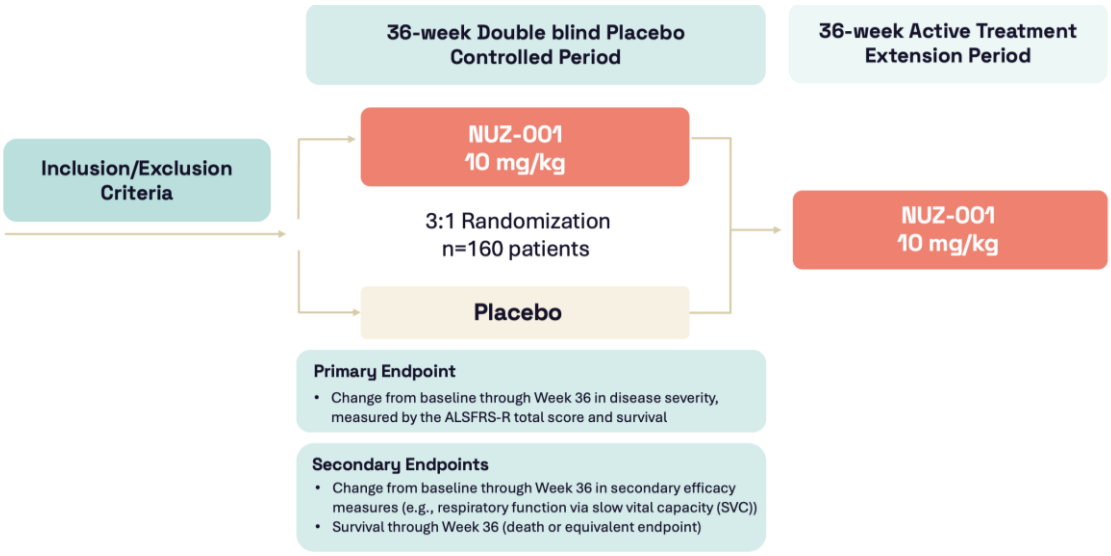
HEALEY ALS Platform Trial

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 Hospital 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. The trial evaluates multiple investigational drugs (Regimens) concurrently under a single framework or master protocol, leveraging shared infrastructure across over 70 participating clinical sites. By streamlining start-up and enrollment processes, it accelerates study execution and delivers results more efficiently.

Regimen I

Regimen I (NUZ-001) includes a randomised, placebo-controlled treatment (RCT) phase followed by an active treatment extension (ATE) phase, both with a 36-week treatment period. Approximately 160 participants with ALS will be randomised to receive either daily NUZ-001 at the recommended Phase 2 dose of 10 mg/kg or placebo at a 3:1 ratio. The primary objective is to evaluate the efficacy of NUZ-001 compared with placebo on ALS disease progression, with secondary objectives including additional measures of disease progression and safety.

Figure 1: Regimen I Study Design



Participation in the HEALEY ALS Platform Trial provides Neurizon with access to an established clinical development framework supported by the world's most highly regarded ALS investigators and leading clinical centres across the US. This infrastructure improves trial efficiency, supports consistent data generation and facilitates ongoing engagement with regulatory authorities, including the U.S. Food and Drug Administration (FDA), as the trial progresses.

Professor Merit Cudkowicz, Principal Investigator, HEALEY ALS Platform Trial & Director, Sean M. Healey & AMG Center for ALS, Mass General Brigham, commented: "We look forward to working with Neurizon on this new regimen in the HEALEY ALS Platform Trial and implementing our updated master protocol. Beginning enrolment is a significant step for the regimen, and would not be possible without the dedication of people living with ALS and their families, collaborators, and our top trials sites."

Managing Director and Chief Executive Officer, Dr Michael Thurn commented: "The dosing of the first participant in Regimen I of the HEALEY ALS Platform Trial marks a defining milestone for Neurizon and for NUZ-001. This study represents our registrational trial in ALS - a rigorous, adaptive Phase 2/3 program designed to generate the clinical evidence required to support potential regulatory submissions."

"Entry into the HEALEY ALS Platform Trial reflects our scientific data package and the favourable safety and tolerability profile observed in our Phase 1 and Open Label Extension studies. The master protocol structure enables efficient study execution across leading ALS centres in the United States, while maintaining the scientific rigour required at this stage of development."

"We are deeply grateful to the participants and their families who commit their time and energy to clinical research, often while navigating the significant challenges associated with living with ALS. For people living with ALS, urgency matters. Through this pivotal study, we are advancing NUZ-001 with scientific discipline, operational focus, and deep respect for the ALS community as we work toward delivering meaningful progress in this devastating disease."

-ENDS-

This announcement has been authorized 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.

About the HEALEY ALS Platform Trial

The HEALEY ALS Platform Trial is a multicenter, double-blind, placebo-controlled, adaptive trial for ALS created in partnership with the Network of Excellence for ALS (NEALS). The goal of the HEALEY ALS Platform trial is to accelerate the development of potential new ALS therapies. The trial tests and evaluates multiple investigational drugs simultaneously, shares infrastructure across trial sites, and improves start up and enrollment efficiencies, allowing for fast results.

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