Neurizon Therapeutics Limited
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FDA Clears NUZ-001 for Entry into HEALEY ALS Platform Trial

Highlights:

- **FDA has completed their review of the Neurizon NUZ-001 regimen to the HEALEY ALS Platform Trial Master Protocol**
- **This marks the official entry of NUZ-001 as Regimen I in the HEALEY ALS Platform Trial**
- **Next steps include obtaining single IRB approval, site initiations and clinical start-up activities ahead of commencement of patient enrollment expected early in 2026**
- **Milestone strengthens Neurizon's pathway toward advancing a potential new treatment for ALS**

11 December 2025 – 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 announce that the Sean M. Healey & AMG Center for ALS at Mass General Brigham has received clearance from the US Food and Drug Administration (FDA) to proceed with Neurizon's NUZ-001 regimen in the HEALEY ALS Platform Trial (ClinicalTrial.gov identifier: NCT04297683) following completion of the FDA's 30-day review. NUZ-001 is officially Regimen I.

The FDA's acceptance of the protocol amendment allows the commencement of clinical activities under the Sean M. Healey & AMG Center for ALS Investigational New Drug (IND). It represents another significant regulatory milestone for Neurizon, enabling the Company and the HEALEY ALS Platform Trial team to progress to the next operational phases, including Institutional Review Board (IRB) submissions and approvals, activation of clinical trial sites, and initiation of study start-up activities. The first patients are expected to be enrolled early in 2026.

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.

NUZ-001 is in development for treating amyotrophic lateral sclerosis (ALS). It aims to address key pathological mechanisms, including TDP-43 protein aggregation and impaired autophagy, which are central features across multiple neurodegenerative diseases. Preclinical and clinical data to date indicate favourable oral bioavailability, central nervous system penetration, an encouraging long-term safety profile, and early signs of potential clinical benefit.

Dr Michael Thurn, Managing Director & CEO, commented: "Receiving the FDA's clearance is a major milestone for Neurizon and a critical step in advancing NUZ-001 as a potential new treatment option for people living with ALS. The HEALEY ALS Platform Trial represents the gold standard for efficient and collaborative clinical development in this field, and we are proud to progress into the next phase of activation. We look forward to working closely with the HEALEY team as we move toward site initiations and study start-up, bringing us one step closer to addressing this significant unmet medical need."

Professor Merit Cudkowicz, Principal Investigator, HEALEY ALS Platform Trial & Director, Sean M. Healey & AMG Center for ALS, Mass General Brigham, commented: "We are pleased to welcome Neurizon's NUZ-001 regimen into the HEALEY ALS Platform Trial. The HEALEY ALS Platform Trial Therapy Evaluation Committee previously selected NUZ-001 for inclusion as a new regimen. The FDA's clearance to proceed with the NUZ-001 regimen is an important next step. We look forward to initiating clinical sites and beginning enrollment so we can evaluate the potential of NUZ-001 to benefit people with ALS."

Neurizon remains dedicated to developing novel, disease-modifying therapies for ALS and other serious neurodegenerative diseases, leveraging international collaborations and world-leading clinical platforms to accelerate clinical progress.

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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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