Neurizon Therapeutics Limited
ABN 35 094 006 023
www.neurizon.com

FDA Type C Meeting affirms ongoing HEALEY ALS Platform Trial as potentially registrational

- **US Food and Drug Administration (FDA) provides written feedback on NUZ-001's clinical development plan and regulatory pathway in amyotrophic lateral sclerosis (ALS)**
- **FDA notes positive results from the Phase 2/3 HEALEY ALS Platform Trial may support a traditional approval pathway, subject to meeting the requirement for substantial evidence of effectiveness**
- **FDA also noted HEALEY ALS Platform Trial may serve as the single registrational study for a New Drug Application (NDA)**
- **Feedback is consistent with Neurizon's regulatory strategy and informs preparation of an NDA**
- **HEALEY Regimen I is fully enrolled and remains on track, with topline results expected in late Q2 CY2027**

6 October 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 it has received written responses from the US Food and Drug Administration (FDA) to its Type C meeting request for NUZ-001, its investigational treatment for amyotrophic lateral sclerosis (ALS).

The feedback provides guidance on the Company's clinical development plan, potential regulatory pathways and use of biomarkers, and will inform preparation of a New Drug Application (NDA).

Potential pathway to traditional approval

The FDA noted that the HEALEY ALS Platform Trial, in which NUZ-001 is being evaluated as Regimen I, is a placebo-controlled study designed to assess clinically meaningful endpoints after 36 weeks of treatment, and that positive results could potentially support a traditional approval pathway.

The FDA also noted that the HEALEY ALS Platform Trial may serve as the single registrational study for a NDA, subject to meeting the requirement for substantial evidence of effectiveness, including supporting evidence alongside the study results.

Biomarkers and supporting evidence

The FDA agreed with Neurizon's approach to measuring plasma neurofilament light chain (NfL), a marker of nerve damage, and outlined the types of evidence that would be needed for NfL to support accelerated approval. The FDA noted that a strong scientific rationale would be required if HEALEY's primary endpoint were not met. Neurizon's regulatory strategy remains focused on preparing an NDA seeking traditional approval, with biomarker data from HEALEY, including NfL, intended to form part of the supporting evidence.

Fast Track Designation

Following the FDA's January 2026 decision not to grant Fast Track Designation (FTD), the FDA advised that the Company may resubmit an FTD request considering the data available, with eligibility determined on review. Neurizon continues to evaluate the possibility of a resubmission.

Phase 2/3 HEALEY ALS Platform Trial Status

Regimen I remains on track, with study fully enrolled and topline results expected in late Q2 CY2027.

Complementing Regimen I, the NIH-funded NUZ-001 expanded access program is expected to commence in Q1 CY2027. The program will provide NUZ-001 to approximately 200 people living with ALS in the US for up to 96 weeks, broadening access to NUZ-001 while generating longer-term safety and biomarker data.

Chief Executive Officer, Dr Chris Bremer said: "This feedback gives us valuable guidance as we prepare the evidence package for the NDA for NUZ-001. It identifies the possibility of Regimen I serving as the single registrational study, subject to the results and supporting evidence meeting the applicable requirements.

"With Regimen I fully enrolled and topline results expected in late Q2 CY2027, our focus is on completing the trial and building the clinical and supporting evidence needed for the NDA submission."

For personal use only

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.

-ENDS-

This announcement has been authorised for release by the Board of Neurizon Therapeutics Limited.

For further information, please contact:

Marketing and Corporate Affairs
Lidija Damjanovic
Email: lidija@neurizon.com
Phone: +61 (0) 425 700 504

Investor Relations - Australia
Henry Jordan
Email: henry.jordan@sdir.com.au
Phone: +61 (0) 431 271 538

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.

Neurizon Investor Hub

We encourage you to utilise our Investor Hub for any enquiries regarding this announcement or other aspects concerning Neurizon.
This platform offers an opportunity to submit questions, share comments, and view video summaries of key announcements.

To access Neurizon Investor Hub please scan the QR code or visit
https://investorhub.neurizon.com

Neurizon® is a registered trademark of Neurizon Therapeutics Limited

For personal use only