Neurizon Therapeutics Limited
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Neurizon Provides a Regulatory and Development Update

02 January 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 provide an update on the regulatory and clinical development status of its investigational new treatment for Amyotrophic Lateral Sclerosis (ALS), NUZ-001.

NUZ-001 is being developed as a novel therapeutic approach for ALS and has the potential to address key disease mechanisms, including the inhibition of TDP-43 aggregation, which is understood to underlie motor neuron degeneration and disease progression in patients with ALS.

Regulatory Update

The Company advises that it has received regulatory correspondence from the US Food and Drug Administration (FDA) stating that its request for Fast Track Designation has been denied at this time. The FDA confirmed that ALS represents a serious condition with an unmet medical need and provided constructive feedback outlining the additional data that could support a future Fast Track Designation request as NUZ-001 advances through clinical development.

Based on NUZ-001's current stage of development, the FDA indicated that additional clinical information would be required to demonstrate its differentiation from other FDA approved therapies. Neurizon views this feedback as providing a clear regulatory pathway and will assess the additional data requirements as it continues to progress NUZ-001 and evaluates the timing of a subsequent new Fast Track Designation request.

The FDA's Fast Track program is designed to facilitate the development and expedite the review of drugs intended to treat serious or life-threatening conditions and address unmet medical needs. Clinical programs with Fast Track Designation benefit from early and more frequent communication with the FDA throughout the regulatory review process.

Development Update

The Company also reports that NUZ-001 has advanced to the next operational phases of the HEALEY ALS Platform Trial, with activities underway, including Institutional Review Board (IRB) submissions, clinical site activation, and associated study start-up activities. The Company expects the first patients to be enrolled very early this year, representing an important near-term clinical milestone.

This progress follows Neurizon's recent announcement that it has secured sufficient funding to complete the pivotal registration-adaptive Phase 2/3 clinical trial, providing clear visibility through to key clinical outcomes.

About HEALEY ALS Platform Trial

The HEALEY ALS Platform Trial (ClinicalTrials.gov identifier: NCT04297683) is a large-scale, multicentre, double-blind, placebo-controlled, adaptive Phase 2/3 clinical trial for ALS, conducted in partnership with the Network of Excellence for ALS (NEALS). The trial comprises two sequential 36-week phases: a Randomised Clinical Trial (RCT) phase followed by an Active Treatment Extension (ATE) phase. Designed to accelerate the development of promising ALS therapies, the HEALEY ALS Platform Trial evaluates multiple investigational treatments simultaneously, leverages shared infrastructure across sites, and enhances enrolment and operational efficiencies, enabling the faster generation of robust clinical data for candidates such as Neurizon's lead asset, NUZ-001.

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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.

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