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Neurizon Receives Ethics Approval for Phase 1 NUZ-001 Oral Liquid Formulation Study

Highlights:

- **Bellberry Human Research Ethics Committee (HREC) approves Neurizon's Phase 1 formulation study supporting development of the NUZ-001 oral liquid formulation and continued advancement of NUZ-001 for amyotrophic lateral sclerosis (ALS)**
- **Oral liquid formulation developed to improve treatment accessibility, administration flexibility and continuity of treatment as ALS progresses and swallowing difficulties increase**
- **Study designed to generate additional pharmacokinetic, safety and tolerability data to support clinical, regulatory and commercial development activities for NUZ-001**
- **Study forms part of Neurizon's broader NUZ-001 development program, alongside ongoing participation in the Phase 2/3 HEALEY ALS Platform Trial in the United States**

13 May 2026 – Melbourne Australia: Neurizon® Therapeutics Limited (ASX: NUZ & NUZOA; OTCQB: NUZTF) ("Neurizon" or "the Company"), is pleased to announce that the Bellberry Human Research Ethics Committee (HREC) has approved the Company's Phase 1 formulation study supporting development of the NUZ-001 oral liquid formulation, representing a further milestone in the development of NUZ-001 for ALS.

Neurizon previously announced development of an oral liquid formulation of NUZ-001 as part of its broader development strategy for ALS (refer to announcement 26 June 2025). ALS is associated with progressive impairment in speech and swallowing function (dysphagia), increasing the importance of flexible treatment administration options as the disease progresses.

The oral liquid formulation is intended to improve treatment accessibility, administration flexibility and continuity of treatment for people living with ALS, particularly as swallowing difficulties progress, supporting longer-term treatment administration across different stages of the disease.

The study will enrol 32 healthy volunteers in Australia in a randomised, four-arm Phase 1 clinical trial evaluating NUZ-001 oral liquid and tablet formulations under fed and fasted conditions. The study is designed to generate pharmacokinetic, safety and tolerability data, alongside exploratory biomarker and palatability data, to support formulation development and the broader clinical and regulatory development program for NUZ-001.

Interim Executive Chairman, Sergio Duchini commented: "Receipt of HREC approval marks another important milestone in the advancement of the NUZ-001 development program and reflects Neurizon's commitment to developing patient-centred therapeutic solutions in ALS."

"The oral liquid formulation was developed in direct response to the practical challenges faced by people living with ALS, particularly as swallowing difficulties become more prominent during disease progression. In addition to supporting flexibility and continuity of treatment, the formulation is intended to improve the overall practicality of administration for patients, caregivers and clinical teams."

"The advancement of the oral liquid formulation reflects Neurizon's broader strategy to support long-term treatment accessibility and expand the potential utility of NUZ-001 across different stages of disease progression."

Study initiation is targeted for Q3 CY2026, subject to completion of remaining operational and site initiation activities, with study completion anticipated in Q4 CY2026.

-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.

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