Neurizon Therapeutics Limited
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Neurizon® Submits Clinical Hold Complete Response to FDA for NUZ-001

Highlights:

- **Neurizon submits formal response to FDA to resolve the NUZ-001 clinical hold**
- **Submission includes new bridging PK data to demonstrate comprehensive exposure data in rats and dogs**
- **FDA review now underway, with feedback expected within 30 calendar days**
- **Company targeting participation in the HEALEY ALS Platform Trial in Q4 CY2025**

25 July 2025 – Melbourne, Australia: Neurizon Therapeutics Limited (ASX: NUZ & NUZOA) ("Neurizon" or "the Company"), a clinical-stage biotech company dedicated to advancing innovative treatments for neurodegenerative diseases is pleased to announce it has submitted a formal response to the United States (U.S.) Food and Drug Administration (FDA) addressing the clinical hold on its Investigational New Drug (IND) application for NUZ-001, the Company's lead investigational therapy for amyotrophic lateral sclerosis (ALS).

The Clinical Hold Complete Response (CHCR) includes new bridging pharmacokinetic (PK) data from 28-day studies in rats and dogs. These studies were designed to address the FDA's request for more comprehensive animal exposure data to support the safety margins of NUZ-001 and its primary sulfone metabolite. The response was submitted following constructive FDA engagement and within the Company's previously guided timeline. This submission marks a significant step toward lifting the clinical hold and initiating enrolment in the HEALEY ALS Platform Trial, anticipated in Q4 2025.

The new PK results demonstrate:

- Greater than 10-fold safety margins based on projected human plasma exposure levels for both NUZ-001 and its active sulfone metabolite.
- Enhanced confidence in dose selection and systemic tolerability to support progression to Phase 2/3 clinical evaluation.

FDA review of the CHCR is now underway. Neurizon expects formal feedback within 30 calendar days, in line with the FDA's standard statutory review period for hold responses. The company remains focused on advancing NUZ-001 into the HEALEY ALS Platform Trial in Q4 CY2025, subject to regulatory clearance.

Managing Director and Chief Executive Officer, Dr Michael Thurn commented: "With continued momentum and scientific clarity, we are advancing NUZ-001 toward a potentially first-in-class therapy for ALS, aligned with our commitment to create meaningful treatment options for patients. This submission underscores our disciplined execution and ability to deliver critical development milestones ahead of schedule. By proactively completing the required PK studies, we have significantly de-risked the regulatory path moving forward. We anticipate resolution of the clinical hold in August 2025, positioning Neurizon to initiate participation in the HEALEY ALS Platform Trial before year-end."

The Company will continue to update the market as key milestones are achieved in the lead-up to anticipated trial participation in Q4 CY2025.

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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.

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