Neurizon Therapeutics Limited
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Neurizon Completes GMP Tablet Registration Batches

Highlights:

- **Manufacture of three registration batches of NUZ-001 tablets was successfully completed ahead of schedule, marking a key milestone towards regulatory submissions with the FDA and commercialisation**
- **Manufacturing undertaken by Catalent, a leading global contract manufacturer, utilising full-scale commercial processes and equipment, compliant with FDA and ICH guidelines**
- **Registration batches manufactured at a 1:10 scale of the intended commercial production**
- **Batch production will support ICH long-term stability studies, NDA Module 3 (Quality), shelf-life, and provide validation of commercial-scale manufacturing ahead of potential commercial sales opportunities**
- **Manufacturing completion underscores benefit of the licensing deal with Elanco Animal Health, reducing supply chain risks, enabling scalability, and bringing NUZ-001 closer to regulatory approval and launch**
- **Neurizon® remains on track to commence enrolment in the HEALEY ALS Platform Trial in Q1 CY2026**

04 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 manufacturing of 3 Good Manufacturing Practice (GMP) registration batches of NUZ-001 tablets has been completed. The completion of these registration batches enables Neurizon to pursue a Rolling Review of the New Drug Application (NDA) and could allow the U.S. Food and Drug Administration FDA to review Chemistry, Manufacturing and Controls (CMC) details prior to the full NDA submission under the Fast Track Designation or Breakthrough Therapy Designation.

This marks a significant step forward in Neurizon's regulatory and operational readiness, enabling the supply of NUZ-001 for supplemental pivotal clinical trials, pending regulatory submissions, and future commercial sale opportunities. The development highlights the Company's continued momentum toward global market access and long-term value creation, in line with its stated strategy.

The registration batches will also support formal pivotal stability studies (a minimum of 12 months of stability data required for submission), validation activities, and the CMC requirements for Neurizon's planned NDA submission to the FDA. The batches were manufactured in partnership with Catalent Inc., a leading global contract development and manufacturing organisation with extensive expertise in supporting commercial production of orphan drug products similar to NUZ-001.

Manufactured under GMP, the registration batches are being produced at a minimum 1:10 scale of the intended commercial production. All manufacturing is being conducted using processes and equipment representative of full-scale commercial manufacturing, in alignment with FDA and International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use regulatory expectations. The batches are being manufactured at Catalent's certified GMP facility, which operates under U.S. and international regulatory standards.

Upon completion, the batches have been placed on both long-term and accelerated stability programs to establish product shelf-life and generate data to support Module 3 (Quality) of the NDA dossier.

NUZ-001, the Company's lead asset, is being developed for the treatment of Amyotrophic Lateral Sclerosis (ALS) and is designed to target key pathological mechanisms such as TDP-43 protein aggregation and impaired autophagy, common features across multiple neurodegenerative diseases. NUZ-001 has demonstrated favourable oral bioavailability, central nervous system (CNS) penetration, and a strong safety profile in preclinical and Phase 1 studies, supporting its continued development.

Manufacturing supports Neurizon's readiness to advance NUZ-001 in the next phase of clinical development, which includes the HEALEY ALS Platform Trial, which is on track to commence enrolment in Q1 CY2026.

Dr Michael Thurn, Managing Director and Chief Executive Officer, commented: "Completion of the NUZ-001 registration batch manufacturing marks a significant milestone in our journey towards FDA and other regulatory submissions, while also showcasing Neurizon's operational and regulatory readiness. This milestone also significantly reduces the risks associated with bringing our lead asset to market and supports commercial-scale production in the future.

Working with Catalent, one of the world's most respected contract manufacturers, ensures that NUZ-001 has been produced to the highest global standards for quality and compliance, aligning with full-scale commercial production. This strengthens Neurizon's capacity to deliver on its clinical and commercial strategy.

With manufacturing completed and regulatory preparations well advanced, we remain confidently on track to commence patient enrolment in the HEALEY ALS Platform Trial early next year - a crucial step towards delivering NUZ-001 to patients with ALS and other severe neurodegenerative diseases."

Neurizon continues to strengthen its regulatory and clinical strategy, with a focus on accelerated approval pathways and biomarker-informed approaches to support future global regulatory submissions and deliver value to patients, healthcare systems, and shareholders.

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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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