Neurizon Therapeutics Limited
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NUZ-001 Registration Batch Manufacturing Commences to Support NDA and Global Commercialisation

Highlights:

- **Manufacture of the initial registration batch of NUZ-001 tablets has successfully commenced, marking a key milestone towards commercialisation and FDA NDA regulatory submission**
- **Manufacturing carried out by Catalent, a leading global contract manufacturer, utilising full-scale commercial processes and equipment, compliant with FDA and ICH guidelines**
- **Batches manufactured at a 1:10 scale of intended commercial production supporting stability studies, NDA Module 3 (CMC), shelf-life determination, and validation of commercial-scale manufacturing**
- **Highlights the benefit of the licensing deal with Elanco Animal Health, reducing supply chain risks, enabling scalability, and bringing NUZ-001 closer to potential regulatory approval and launch**
- **Neurizon is on track to initiate Phase 2/3 clinical trial participation in the HEALEY ALS Platform Trial in Q4 CY2025**

12 August 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, today announced the commencement of manufacturing of the first registration batch of NUZ-001 tablets. This milestone marks a significant step forward in Neurizon's regulatory and operational readiness, enabling the supply of NUZ-001 for supplemental pivotal clinical trials, future regulatory submissions, and potential commercial sale. It highlights the Company's growing momentum toward global market access and long-term value creation.

The registration batch will support formal stability studies, validation activities, and the Chemistry, Manufacturing and Controls (CMC) requirements for Neurizon's planned New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA). This is the first of three planned registration batches, all to be manufactured over the coming months in partnership with Catalent Inc., a leading global contract development and manufacturing organization (CDMO) with deep expertise in supporting commercial production of orphan drug products like NUZ-001.

Managing Director and Chief Executive Officer, Dr Michael Thurn commented: "Commencing GMP manufacturing of NUZ-001's first registration batch is a critical milestone on our path to commercial readiness and regulatory submission. It reflects the advanced stage of our development program and our confidence in NUZ-001 as a potentially effective treatment for people living with ALS and related neurodegenerative diseases. This progress is further underpinned by our exclusive global licensing agreement with Elanco Animal Health, which significantly de-risks the supply chain of NUZ-001 and enhances our commercial scalability. Together, these achievements demonstrate a clear and executable path toward market readiness, reinforcing Neurizon's commitment to delivering innovative therapies to patients and their families worldwide."

Manufactured under Good Manufacturing Practice (GMP), the registration batches are being produced at a minimum 1:10 scale of the intended commercial production volume of 1.4 million tablets. All manufacturing is being conducted using processes and equipment representative of full-scale commercial manufacturing, in alignment with FDA and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) 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 will be 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.

Head of Manufacturing, Dr Herbert Brinkman commented: "It gives me great pleasure to share this update on a major milestone: initiation of the registration batch manufacturing and stability studies for NDA submission. With this step, we have commenced a key regulatory requirement for the NDA and made significant progress toward ensuring commercial readiness for NUZ-001."

NUZ-001 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.

This manufacturing milestone supports Neurizon's readiness to advance NUZ-001 into the next phase of clinical development. The Company is preparing to initiate a Phase 2/3 study as part of the HEALEY ALS Platform Trial in Q4 CY2025, pending FDA clearance to lift the existing clinical hold.

Neurizon continues to strengthen its regulatory and clinical strategy, with a focus on accelerated approval pathways and biomarker-informed approaches to support future global 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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