

Neurizon Granted Orphan Medicinal Product Designation for NUZ-001 in Europe

17 December 2024 – Melbourne, Australia: Neurizon Therapeutics Limited (ASX: NUZ & NUZOA) (“Neurizon” or “the Company”), a clinical-stage biotech company advancing treatments for neurodegenerative diseases, is pleased to announce it has received the official decision from the European Medicines Agency (EMA) granting Orphan Medicinal Product Designation (OMPD) for its lead drug candidate, NUZ-001, for the treatment of Amyotrophic Lateral Sclerosis (ALS). This follows the EMA’s positive opinion on the Company’s OMPD application, as previously announced on 11 November 2024.

OMPD provides a robust framework of benefits, including reduced regulatory fees, free protocol assistance, and market exclusivity for 10 years in the EU upon product approval. During this exclusivity period, similar medicinal products will not be eligible for marketing authorisation in the same indication, offering a substantial commercial advantage for NUZ-001.

Dr. Michael Thurn, Managing Director and Chief Executive Officer of Neurizon Therapeutics, commented: “Securing Orphan Medicinal Product Designation from the European Commission is a significant achievement for Neurizon. Together with the positive preclinical results we’ve recently announced demonstrating its ability to reduce the aggregation of TAR DNA-binding protein 43, this milestone affirms the potential of NUZ-001 to address the substantial unmet medical needs of ALS patients. Not only does it bolster our position in Europe but also complements the Orphan Drug Designation previously granted by the U.S. Food and Drug Administration, providing global market exclusivity across key territories.

“With this milestone, we are well-positioned to continue our efforts to advance NUZ-001 through the Phase 2/3 HEALEY ALS Platform Trial, commencing patient enrolment in early H1 CY2025. Our goal remains steadfast: to bring innovative treatments to patients battling ALS and create value for our shareholders.”

Next Steps:

- Advance preparations for the Phase 2/3 HEALEY ALS Platform Trial to support clinical validation of NUZ-001.
- Continue strategic regulatory engagement with global agencies, including the EMA, TGA and the FDA.

-ENDS-

This announcement has been authorized for release by the Board of Neurizon Therapeutics Limited.
For further information, please contact:

Dr. Michael Thurn
Managing Director and Chief Executive Officer
Neurizon Therapeutics Limited
enquiries@neurizon.com
+61 (3) 9692 7222

Catherine Strong
Sodali & Co
catherine.strong@sodali.com
+61 (0)406 759 268

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 NUZ-001’s potential 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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