Neurizon Therapeutics Limited
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FDA Review Timeline Extended for NUZ-001 IND Clinical Hold

15th 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, has been informed by the U.S. Food and Drug Administration (FDA) that the decision on its Clinical Hold Complete Response (CHCR) to the Investigational New Drug (IND) application for NUZ-001, the Company's lead investigational therapy for amyotrophic lateral sclerosis (ALS), is now expected by 3 October, 2025.

The FDA's standard statutory review period for CHCRs is within 30 calendar days. This delay is not a reflection on the quality or completeness of Neurizon's submission but rather the result of broader strain in the FDA's capacity caused by agency-wide restructuring and staffing reductions under recent administrative reforms, impacting the FDA's ability to maintain timely review cycles. Similar delays have been experienced by other ALS programs, most recently by Coya Therapeutics, whose IND acceptance for COYA-302 for treating ALS was also deferred due to internal FDA workload pressures.

Dr. Michael Thurn, Managing Director and Chief Executive Officer, commented: "While this delay is extremely disappointing — particularly given the straightforward nature of the information provided in our response, we remain confident in the potential of NUZ-001 as a transformative therapy for ALS. We are committed to pursuing every possible avenue to accelerate timelines. In parallel, we are actively engaging with leading U.S. Key Opinion Leaders (KOLs) and patient advocacy groups to advocate for an expedited review, recognising the critical and urgent unmet need in ALS. Our mission remains unchanged: to deliver hope and innovative solutions to patients and families living with neurodegenerative diseases, with diligence, transparency, and unwavering focus."

"The delay follows a broader pattern in the sector, with other sponsors experiencing extended review timelines. The FDA has acknowledged persistent resourcing challenges, which have been exacerbated by organisational changes implemented under the current administration, resulting in increased review backlogs."

Neurizon remains committed to delivering innovative treatments for ALS and other neurodegenerative diseases. We appreciate the patience and ongoing support of our stakeholders as we navigate this important regulatory process. Neurizon will continue to provide timely updates as we receive further feedback and take the necessary steps to advance NUZ-001 toward regulatory approval and patient access.

-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.

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