

Neurizon Therapeutics Provides Update on NUZ-001 IND Application

17th January 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 received notification from the U.S. Food and Drug Administration (FDA) that it has placed our Investigational New Drug (IND) application for NUZ-001 under clinical hold, pending further clarification and additional information. In their communication, the FDA outlined it has certain concerns about the sufficiency of information to assess the application and any risks to human subjects of the trial and with the proposed dosing regime.

The detailed FDA feedback is expected within 30 days and should provide the specific clarifications needed to progress the IND application. We are committed to thoroughly reviewing this feedback upon receipt, taking all necessary actions, and engaging in constructive dialogue with the FDA to address their feedback and provide the required information so that the FDA provides clearance to the IND.

Dr. Michael Thurn, Managing Director and Chief Executive Officer of Neurizon, commented: "While this is an unexpected development, we understand that such steps can arise during regulatory review processes. We remain confident in the potential of NUZ-001 as a transformative therapy for Amyotrophic Lateral Sclerosis (ALS), and we look forward to working closely with the FDA to address their feedback and advance our program with diligence and transparency. Our mission remains unchanged: to bring hope and innovative solutions to patients and families affected by neurodegenerative diseases."

Neurizon remains steadfast in our mission to advance innovative treatments for ALS and other neurodegenerative diseases. We have full confidence in NUZ-001's potential as a safe and effective therapy for patients with ALS and are committed to addressing the FDA's concerns diligently and comprehensively.

We appreciate the patience and support of our stakeholders as we work through this important regulatory process. Neurizon is committed to keeping all stakeholders informed as we receive additional feedback and take the necessary next steps to advance the development of NUZ-001.

-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 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.

Neurizon Investor Hub

We encourage you to utilise our Investor Hub for any enquiries regarding this announcement or other aspects concerning Neurizon.

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