Neurizon Therapeutics Teams Up with GenieUs Genomics to Leverage Cutting-Edge Genomic Profiling in NUZ-001 Phase 1 Trial

Neurizon partners with GenieUs for the Phase 1 trial, using genomic profiling to enhance patient stratification and deepen therapeutic insights.

SYDNEY, AUSTRALIA, November 7, 2024 /EINPresswire.com/ -- GenieUs Genomics ("GenieUs") is excited to provide advanced genomic analysis for Neurizon Therapeutics Limited's ("Neurizon"; ASX:NUZ; ASX:NUZOA) Phase 1 clinical trial of monepantel, now known as NUZ-001, marking an important step in understanding the genetic landscape of ALS patients.

Neurizon is a clinical-stage biotech company dedicated to advancing treatments for neurodegenerative diseases. Their lead ALS drug candidate NUZ-001 was recently selected for inclusion in the HEALEY ALS Platform Trial due to previously announced positive results from Phase 1 MEND study, outlining a 39% slowdown in motor function decline as measured by the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R) for all 12 patients, when compared to untreated matched controls from the Pooled Resource Open-Access ALS Clinical Trials (PRO-ACT(1)) database. This database provides a useful and validated surrogate for the survival status of past participants in ALS clinical trials with long-term follow-up.

The first patients enrolled in the Phase 1 MEND study had now entered their 25th month of continuous treatment with NUZ-001, as part of the Open Label Extension (OLE) Study. The interim results announced in August 2024 from the OLE study demonstrated that NUZ-001 reduced the rate of ALS functional decline by 43.2%, and significantly reduced the risk of death by 80.3% (HR=0.197, p=0.0059) when compared to the external historical control PRO-ACT database. This study will provide further long-term safety and efficacy data as Neurizon prepares for the Phase 2/3 HEALEY ALS Platform Trial, expected to commence in Q1 2025.

The HEALEY platform is a multi-drug evaluation across 70+ clinical sites in the United States. Selection into this prestigious trial offers independent validation of NUZ-001's potential as a treatment for ALS, accelerating its path toward FDA approval.

To better understand the genetic makeup of Phase 1 MEND and OLE patients, GenieUs will

provide genomic profiling of consenting patients, using their Deep integrated Genomic Analysis Platform (DiGAP™). These analyses aim to uncover potential genetic variants and signatures of ALS subtypes, which may serve as digital genomic biomarkers of molecular drivers of ALS in individual patients. These genomic biomarkers are expected to distinguish responders from non-responders to treatment, significantly improving our understanding of which ALS patients are likely to gain the most benefit from NUZ-001.

Dr. Sherie Ma, GenieUs Genomics' CEO said: "We are thrilled to collaborate with Neurizon on their clinical development of a potential next therapeutic for ALS. By leveraging the advanced genomic profiling capabilities of DiGAP™, we hope to provide critical insights that will help pinpoint which ALS patients stand to benefit most from NUZ-001. This partnership represents a significant step forward in ALS patient stratification, and we believe genomic profiling is the key to developing the most effective therapies for diseases with a high level of heterogeneity, such as ALS."

Dr. Michael Thurn, Neurizon's Managing Director and CEO commented: "We are excited to partner with GenieUs Genomics to incorporate their advanced genomic profiling into our clinical development program. By leveraging the precision of DiGAP™, we aim to deepen our understanding of the genetic
factors driving ALS and identify which patients may benefit the most from NUZ-001 and why. This collaboration marks an important step in making precision medicine a reality in ALS treatment, as we continue working on our mission to improve patient outcomes and bring innovative therapies to the ALS community. The average life expectancy for patients with ALS is just over 2 years from disease onset. Anything we can do to help identify patients that are more likely to respond to treatment is an admirable pursuit."

For more information, please contact: Dr. Sherie Ma, sherie@genieus.co.

About GenieUs Genomics

GenieUs Genomics' is a bioinformatics company based in Sydney, Australia. Our mission is to accelerate precision therapies for Amyotrophic Lateral Sclerosis (ALS) by decoding the genetics of neurodegeneration. Our core technology, the Deep integrated Genomic Analysis Platform - DiGAP™, is a fully automated, end-to-end platform for high-throughput whole patient genome decoding and analysis. We discover data-driven insights to enhance clinical outcomes through genome-guided patient stratification, facilitating the development of novel therapeutics in a disease characterised by a high level of heterogeneity.

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.

1 Atassi N, Berry J, Shui A, Zach N, Sherman A, Sinani E, Walker J, Katsovskiy I, Schoenfeld D, Cudkowicz M, Leitner M. The PRO-ACT database: design, initial analyses, and predictive features. Neurology. 2014 Nov 4;83(19):1719-25. doi: 10.1212/WNL.0000000000000951. Epub 2014 Oct 8. PMID: 25298304; PMCID: PMC4239834.

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