European Commission grants NTI164 Orphan Drug Designation for Rett Syndrome

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical company focused on paediatric neurological disorders, is pleased to announce that the European Commission has granted Orphan Drug Designation (ODD) for the Company's lead candidate, NTI164, for the treatment of Rett Syndrome.

Under the ODD framework, Neurotech may benefit from key development incentives for NTI164 in relation to Rett Syndrome, including:

- Ten years of market exclusivity in the EU, subject to obtaining marketing authorisation
- Reduced regulatory fees
- Access to EU research funding
- Dedicated protocol assistance from the EMA

The granting of ODD follows a positive opinion on NTI164 issued by the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP) (see ASX announcement 27 February 2025). These are major regulatory milestones in Neurotech's mission to bring new treatment options to patients living with rare and severe neurological conditions.

"Receiving Orphan Drug Designation from the European Commission is another powerful validation of our therapeutic approach," said Dr Anthony Filippis, CEO and Managing Director of Neurotech. "This decision further strengthens our efforts to bring NTI164 to children and families living with Rett Syndrome, a community with significant unmet need and no approved therapies in Europe."

The European designation complements Neurotech's previously granted Orphan Drug Designation by the US FDA for Rett Syndrome, positioning NTI164 for development across these major global markets.

Rett Syndrome is a rare, severe neurodevelopmental disorder that primarily affects girls. It causes a progressive loss of motor and communication skills, leading to significant lifelong challenges.

This announcement has been authorised for release by Dr Anthony Filippis, Managing Director and CEO of Neurotech International Limited.

For further information contact us via info@neurotechinternational.com

About Neurotech

Neurotech International Limited (ASX:NTI)) is a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders with a broad-spectrum oral cannabinoid drug therapy called NTI164. Neurotech has completed a Phase II/III randomised, double-blind, placebo-controlled clinical trial in Autism Spectrum Disorder (ASD) with clinically meaningful and statistically significant benefits reported across a number of clinically-validated measures and excellent safety. In addition, Neurotech has completed and reported statistically significant and clinically meaningful Phase I/II trials in ASD and Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric

Syndrome (PANS), collectively PANDAS/PANS along with Rett Syndrome. Neurotech has received human ethics committee clearance for a Phase I/II clinical trial in spastic cerebral palsy.

For more information about Neurotech please visit http://www.neurotechinternational.com.

About NTI164

NTI164 is a proprietary drug formulation derived from unique cannabis strains with a novel combination of cannabinoids including CBDA, CBC, CBDP, CBDB and CBN. Clinical studies have demonstrated a potent anti-proliferative, anti-oxidative, anti-inflammatory and neuro-protective effects in human neuronal and microglial cells. NTI164 is being developed as a therapeutic drug product for a range of neurological disorders in children where neuroinflammation is involved.