ASX Announcement

27 February 2025

Neurotech Receives Positive Opinion for Orphan Designation in Rett Syndrome for NTI164 in Europe

Neurotech International Limited (ASX: NTI) ('**Neurotech**', '**NTI**' or '**the Company**') a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces the European Medicines Agency (EMA) has issued a positive opinion on the Company's Orphan Medicinal Product Designation (OMPD) application of NTI164 for the treatment of Rett Syndrome. The Company filed for OMPD in Europe in late October 2024. Neurotech anticipates the issuance of the official decision by the European Commission in due course.

Dr Anthony Filippis, Chief Executive Officer & Managing Director of Neurotech said "*We are delighted to have received this positive opinion for orphan designation of NTI164 in Rett Syndrome for Europe. There are no approved therapies for Rett Syndrome in Europe, which remains a difficult to treat rare neurological disorder where safe and effective treatments are needed. In Europe, this represents a patient population of approximately 28,000 females. This positive opinion follows on from the US Food and Drug Administration (FDA) granting orphan designation for NTI164 in Rett Syndrome in late November 2024.*[1] *Together with the US FDA orphan designation, the positive opinion from the EMA represents an important step towards this significant regulatory milestone for the company in Europe and positions NTI164 in Rett Syndrome for both the US and European markets.*"

Sponsors who obtain orphan designation benefit from protocol assistance, a type of scientific advice specific for designated orphan medicines, and ten years' market exclusivity once the medicine is on the market. Regulatory fee reductions are also available.

Rett Syndrome is a rare genetic neurological and developmental disorder and is almost exclusively the result of a mutation(s) in the methyl CpG binding protein 2 (MECP2) gene located on the X chromosome, which is required for normal brain development and function. Rett Syndrome occurs almost exclusively in girls, with incidence of one in 10,000 female live births. The prevalence is approximately 15,000 girls and women in the US and 350,000 globally. The market is estimated at over US$2 billion annually[2].

Authority

This announcement has been authorised for release by the Board of Neurotech International Limited.

For further information contact us via info@neurotechinternational.com

[1] ASX announcement dated 26 November 2024

[2] https://www.livewiremarkets.com/wires/a-de-risked-biotech-with-4x-upside

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.

About Rett Syndrome

Rett Syndrome is a rare genetic neurological and developmental disorder and is almost exclusively the result of a mutation(s) in the methyl CpG binding protein 2 (MECP2) gene located on the X chromosome, which is required for normal brain development and function. Rett Syndrome occurs almost exclusively in girls compared to boys (mostly fatal within one year of birth), with incidence of approximately 1 in 10,000 female live births across all racial and ethnic groups worldwide. According to the Rett Syndrome Research Trust, the prevalence is approximately 15,000 girls and women in the US and 350,000 globally.

Rett syndrome is characterized by typical early normal development between 7-18 months after birth, followed by a slowing of development, loss of functional use of the hands, distinctive hand movements along with difficulty walking, communicating, irritability and seizures. There is currently no cure for Rett Syndrome and one approved therapy in the United States. Current treatments only address symptoms and provide support that may improve movement, communication and social participation into adulthood.