

Neurotech Files for US Orphan Drug Designation in PANDAS/PANS

Neurotech International Limited (ASX: NTI) ('Neurotech', 'NTI' or 'the Company') a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces a request for orphan drug designation (ODD) with the US Food and Drug Administration has been submitted for the use of NTI164 in children and adults diagnosed with Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS).

The FDA has authority to grant orphan drug designation to a drug or biological product to prevent, diagnose or treat a rare disease or condition. ODD qualifies sponsors for incentives including: (a) tax credits for qualified clinical trials (b) exemption from user fees and (c) potential seven years of market exclusivity after approval. The Orphan Drug Act defines a rare disease as a disease or condition that affects less than 200,000 people in the United States.

PANDAS/PANS is a rare neurological disorder predominately in children characterised by an infection-triggered autoimmune response and associated neuroinflammation which results in a sudden, dramatic change in personality, displayed as obsessive-compulsive disorder (OCD), anxiety, tics or other abnormal movements and personality changes. There are no approved therapies for PANDAS/PANS, globally. Neurotech estimates the annual market for PANDAS/PANS is worth US\$1.2 billion.¹

A response from the FDA Office of Orphan Products Development is anticipated within three months of filing.

Authority

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

Further Information

Dr Thomas Duthy
Executive Director
td@neurotechinternational.com
+61 (0) 402 493 727

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 a unique cannabis strain with low THC ($M < 0.3\%$) and a novel combination of cannabinoids including CBDA, CBC, CBDP, CBDB and CBN. NTI164 has been exclusively licenced for neurological applications globally. Pre-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 PANDAS/PANS

Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS, is a clinical diagnosis given to children who have a dramatic (typically within one day) onset of neuropsychiatric symptoms including Obsessive-Compulsive Disorder (OCD) and/or restrictive eating. Children may exhibit repetitive tic movements, become moody, irritable/aggressive and anxious and have difficulty with schoolwork. The cause of PANS is unknown in the majority of cases; however, the disorder is hypothesised to be triggered by infections, metabolic disturbances, and other inflammatory reactions. PANDAS is considered a subset of PANS.

¹ ASX Announcement 21 February 2024