

NEUROSCIENTIFIC SUBMITS HREC APPLICATION TO COMMENCE PHASE I CLINICAL TRIAL

HIGHLIGHTS

- Application submitted for HREC approval to commence a Phase I clinical trial of EmtinB™
- The Phase I clinical trial will establish the safety profile, pharmacokinetics and pharmacodynamics of EmtinB™ in up to 88 healthy adult volunteers
- The safety data from the clinical trial is also expected to support the progression of EmtinB™ into Phase II clinical trials in patients for a range of neurodegenerative conditions in the future
- NeuroScientific recently achieved the historic milestones of HREC approval and first subject recruited for its very first clinical trial for EmtinB™, an early-phase clinical trial in healthy volunteers

NeuroScientific Biopharmaceuticals Ltd (ASX: NSB) (“NeuroScientific” or “the company”) is pleased to announce it has submitted an application for Human Research Ethics Committee (HREC) approval to commence a Phase I clinical trial of lead drug candidate EmtinB™, achieving another important milestone in the progression of EmtinB as a first-in-class treatment with disease modifying potential for Multiple sclerosis and Alzheimer’s disease.

The Phase I clinical trial is a double blind, placebo controlled, dose-escalation study designed to establish the safety profile, pharmacokinetics and pharmacodynamics of EmtinB™ in up to 88 healthy adult volunteers. The clinical trial will be a single site study undertaken by Linear Clinical Research (Nedlands, WA) and will include an initial single ascending dose (SAD) study, followed by a multiple ascending dose (MAD) study, and a separate study arm to investigate the concentrations of EmtinB™ in cerebrospinal fluid (CSF) samples. The primary endpoint of this clinical trial is the safety and tolerability of EmtinB™ versus placebo.

The Phase I clinical trial has been designed to support Phase II clinical trials of EmtinB™ for the treatment of patients with Multiple sclerosis and Alzheimer’s disease. Since this clinical trial will be conducted in healthy volunteers rather than in patients, the safety data is also expected to support the progression of EmtinB™ into Phase II clinical trials for a range of neurodegenerative conditions in the future.

NeuroScientific’s Managing Director and Chief Executive Officer Matt Liddelow commented: *“Coming off the back of the recent significant milestone of recruiting the first subject for our early-phase clinical trial, we are very excited to be submitting the HREC application for this important large-scale Phase I clinical trial of EmtinB™ that will provide human safety data to support multiple Phase II clinical trials in patients with neurodegenerative conditions, starting with Multiple sclerosis and Alzheimer’s disease.”*

NeuroScientific recently achieved the historic milestone of HREC approval to commence the Company’s very first clinical trial of EmtinB™ (see previous announcement from 7 June 2022), an early-phase clinical trial largely focused on the assessment of biomarkers in human blood samples that indicate proof of the mechanism of activity of EmtinB™ in humans, and subsequently announced the first subject recruited for the trial (see previous announcement from 30 June 2022).

This announcement is authorised by the Board of NeuroScientific Biopharmaceuticals Ltd.

-ENDS

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About NeuroScientific Biopharmaceuticals Ltd

NeuroScientific Biopharmaceuticals Limited (ASX: NSB) is a company developing peptide-based pharmaceutical drugs that target a number of neurodegenerative conditions with high unmet medical demand. The Company's product portfolio includes EmtinB™, a therapeutic peptide initially targeting Alzheimer's disease and glaucoma, as well as other Emtin peptides (EmtinAc, EmtinAn, and EmtinBn) which have demonstrated similar therapeutic potential as EmtinB™. For more information, please visit www.neuroscientific.com

About EmtinB™

EmtinB™ is a peptide-based compound that binds to surface-based cell receptors from the LDLR family, activating intracellular signalling pathways that stimulate neuroprotection, neuroregeneration and modulate neuroinflammation. EmtinB™ is modelled on a specific active domain of the complex human protein called Metallothionein-IIA, which is produced as part of the human body's innate immune response to cell injury.

Our preclinical research has established that EmtinB™ is highly specific and selective for its target receptor, safe and well tolerated at high concentrations, and is able to penetrate the blood brain barrier. A series of Phase I clinical studies will be conducted to establish the safety profile of EmtinB™ in humans.