NeuroScientific
BIOPHARMACEUTICALS
ASX:NSB

ASX ANNOUNCEMENT
13 April 2022

POSITIVE SAFETY RESULTS FOR EMTINB™ SUPPORTS ADVANCEMENT TO FIRST-IN-HUMAN CLINICAL TRIAL

HIGHLIGHTS

- **EmtinB™ shown to be safe with no major adverse effects or toxicology findings reported during completion of the Preclinical Safety and Toxicology Program to support commencement of first-in-human clinical trials**
- **EmtinB™ doses of up to 100mg/kg/day shown to be well tolerated in GLP toxicology studies**
- **Safety margin of 20x the predicted human dose-range in humans exceeds the standard requirement of regulatory agencies, including the FDA**
- **NeuroScientific expects to receive HREC approval in May 2022 to enable commencement of a first-in-human clinical trial**

NeuroScientific Biopharmaceuticals Ltd (ASX: **NSB**) (**"NeuroScientific"** or **"the company"**) is pleased to report positive outcomes from its Preclinical Safety and Toxicology Program involving lead drug candidate EmtinB™, undertaken to support the commencement of first-in-human clinical trials. EmtinB™ demonstrated an impressive safety profile in multiple animal species, including pivotal GLP Toxicology studies of daily doses up to 20x above the predicted efficacious dose-range in humans, with no major adverse effects or toxicology findings attributed to EmtinB™.

NeuroScientific's Managing Director and Chief Executive Officer Matt Liddelow commented: *"We are excited to report the outstanding safety outcomes for EmtinB™ and the successful completion of the Preclinical Safety and Toxicology Program to support initiation of Phase I clinical studies for our neurology indications. This safety data provides clear validation that we have met all requirements of achieving the significant milestone of advancing our novel lead drug candidate EmtinB™ into the clinical development phase and we have been working closely with our clinical development partner Linear Clinical Research to execute on our first-in-human clinical trial in 1H 2022."*

Pivotal GLP Toxicology Data
Pivotal toxicology studies in animals are considered the most important studies in assessing the safety of drug candidates prior to testing in humans and must be completed in line with ICH guidelines[1] and compliant with 'Good Laboratory Practice' (GLP) standards to ensure the quality and integrity of the resulting data.

The safety outcomes from the GLP studies for EmtinB™ include:

- GLP toxicology studies established that doses as high as 100mg/kg/day over a period of 28-days did not result in any major safety concerns.
- No reported occurrences of organ damage or incidences of macroscopic changes in tissues to indicate damage following daily dosing for up to 28-days.
- 100% survival rate at the conclusion of the dose period across all GLP toxicology studies.
- The safety margin for the predicted dose range in humans substantially exceeds the standard requirement of regulatory agencies, such as the TGA and the FDA.

[1] International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guidance on nonclinical safety studies for the conduct of human clinical trials

Advancing EmtinB™ into first-in-human clinical trials
NeuroScientific expects to receive approval from Human Research Ethics Committee (HREC) during May 2022 allowing the Company to commence a first-in-human clinical trial for EmtinB™ during 1H 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.