NeuroScientific
BIOPHARMACEUTICALS
ASX:NSB

ASX ANNOUNCEMENT
8 February 2022

SUCCESSFUL COMPLETION OF GENOTOXICITY AND PLASMA PROTEIN BINDING STUDIES

HIGHLIGHTS

- **Lead drug candidate EmtinB™ successfully completed *in vitro* genotoxicity studies and plasma protein binding studies – key studies in finalising the neurology safety program**
- **Completion of genotoxicity studies is another significant step in developing the safety profile of EmtinB™ prior to first-in-human studies**
- **Plasma protein binding studies demonstrated that 98% of EmtinB™ in blood circulation is available for distribution to the site of action**
- **Results from final GLP toxicity studies expect to be reported in Q1 CY22**
- **An independently conducted gap analysis of the neurology safety program confirms the safety data package is suitable for approval for a Phase I clinical study**
- **First-in-human Phase I study to commence in 1H 2022**

NeuroScientific Biopharmaceuticals Ltd (ASX: **NSB**) (**"NeuroScientific"** or **"the company"**) is pleased to report positive outcomes from recently completed *in vitro* genotoxicity studies and plasma protein binding studies involving its lead drug candidate EmtinB™ in the lead up to commencement of first-in-human Phase I clinical studies in 1H 2022. Both studies were undertaken by leading contract research company Eurofins, US.

COMPLETION OF KEY STUDIES

Assessing genotoxicity is an integral part of determining the safety profile of novel drug candidates and involves a standard battery of tests designed to identify compounds that damage DNA. In accordance with regulatory guidelines for the conduct of genotoxicity studies[1], EmtinB™ was evaluated in standardised bacterial reverse mutation (Ames) and *in vitro* micronucleus tests and did not exhibit any signs of inducing genetic toxicity.

Plasma protein binding studies assess if a drug attaches to proteins within the blood, which reduces the amount of drug available to distribute into the tissues of the body to reach the site of action. It is essential to understand the plasma protein binding characteristics of a drug in order to accurately predict dosing in first-in-human clinical studies. The degree of binding of EmtinB™ to plasma proteins was evaluated in human plasma samples and the mean unbound fraction of the drug was determined to be 98%, meaning that 98% of EmtinB™ that enters the blood circulatory system is available to reach the site of action.

NeuroScientific's Managing Director and Chief Executive Officer Matt Liddelow commented: *"The positive outcomes from these studies are important for progressing our lead drug candidate EmtinB™ into first-in-human clinical studies. The genotoxicity results are another significant step in developing the safety profile of EmtinB™ prior to testing in humans and confirming the protein binding profile of EmtinB™ in human plasma is important for accurately guiding selection of the first-in-human dose."*

THE ROADMAP TO CLINICAL STUDIES

Having previously completed all necessary nonclinical safety studies for its neurology safety program, conducted in accordance with Good Laboratory Practice (GLP) standards as required, NeuroScientific is in the final stages of collating the data from nonclinical GLP toxicity studies to confirm the safety and tolerability of repeat doses of EmtinB™ in animals prior to commencement of first-in-human Phase I clinical studies. This data is expected to be reported in Q1 CY22 and represents a significant de-risking event for the commercialisation of EmtinB™ and a major milestone for the Company.

[1] International Conference on Harmonisation (ICH) S2(R1)

The safety data from all nonclinical non-GLP and GLP studies will be submitted for review by an independent Human Research Ethics Committee (HREC) for approval to commence the Phase I clinical study. The Company expects to complete this process in Q1 CY22.

Additionally, the Company recently completed an independent review process for its neurology safety program to identity any potential gaps in the safety data that may delay HREC approval, which confirmed that the current data package is suitable to gain approval to conduct a Phase I clinical study.

NeuroScientific has appointed clinical contract research company Linear Clinical Research to undertake its first-in-human Phase I study of EmtinB™ (see previous announcement from 23 June 2021) and will provide further updates in the coming weeks to confirm scheduling of the study during 1H 2022.

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

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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.