NeuroScientific
BIOPHARMACEUTICALS
ASX:NSB

ASX ANNOUNCEMENT
24 DECEMBER 2021

POSITIVE OFF-TARGET SAFETY ASSESSMENT OF EMTINB

HIGHLIGHTS

- **Lead drug candidate EmtinB™ successfully completed off-target safety screening in the lead up to Phase I clinical studies**
- **Of 173 biological targets, EmtinB™ did not interact with any targets known to cause major adverse reactions and toxicities in humans**
- **ICH regulatory guidelines recommend completion of off-target screening as part of risk mitigation strategies in planning for Phase I clinical studies**
- **This safety assessment represents a major step towards commencement of first-in-human Phase I studies**

NeuroScientific Biopharmaceuticals Ltd (ASX: **NSB**) (**"NeuroScientific"** or **"the company"**) is pleased to announce positive results from recently completed off-target safety assessment of its lead drug candidate EmtinB™, involving a comprehensive *in vitro* screening program to predict drug-induced toxicities in humans prior to first-in-human Phase I clinical studies. The preclinical *in vitro* screening program was undertaken by leading contract research company Eurofins CEREP, France.

Off-target safety assessments help to identify unintended interactions between a drug and a host of biological targets that are known to cause adverse side effects and toxicities in humans (anti-targets). The key safety guidance document for drug development, The International Conference on Harmonisation Guidance for Industry (ICH) S7A, recommends completing off-target safety assessments in addition to pivotal safety studies in animals as part of risk mitigation strategies in the design and conduct of first-in-human clinical studies.[1]

Of 173 biological targets screened, EmtinB™ did not interact with any "anti-targets" (known causes of human toxicities), demonstrating the low potential for EmtinB™ to cause drug induced adverse reactions or toxicities in humans.

NeuroScientific's Managing Director and Chief Executive Officer Matt Liddelow commented: *"These positive safety results add further confidence to existing safety data for EmtinB™ in demonstrating it's low liklihood to cause any major safety issues in humans and is another major step towards achieving the landmark milestone of starting first-in-human Phase I studies in the first half of 2022. I look forward to updating the market with further progress in the New Year as we advance towards Phase I clinical studies."*

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

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[1] ICH S7A: Safety pharmacology studies for human pharmaceuticals

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.