

## **NEUROSCIENTIFIC SUCCESSFULLY COMPLETES NON-CLINICAL SAFETY PHARMACOLOGY STUDIES**

### **HIGHLIGHTS**

- **Highly encouraging results from non-clinical Safety Pharmacology studies of EmtinB with no adverse events observed**
- **Safety Pharmacology studies are critical in order to get regulatory approval to start first-in-human studies of EmtinB**
- **Approximately 48% of new therapeutic drugs in development fail to progress into human studies because of inadequate preclinical safety**
- **Phase I clinical studies of EmtinB to be initiated following the conclusion of the non-clinical safety program**

NeuroScientific Biopharmaceuticals Ltd (ASX: **NSB**) (“**NeuroScientific**” or “**the company**”) is pleased to announce that the Company’s lead drug candidate EmtinB™ has successfully completed the program of non-clinical Safety Pharmacology studies which form a key element of the safety evaluation necessary to gain regulatory approval to start Phase I clinical studies. The program was undertaken by LabCorp Inc, US to Good Laboratory (GLP) Standards and involved the core battery of studies to determine the potential for any adverse effects on the central nervous system (CNS), cardiovascular (CV) system, and respiratory system (RS).

Unacceptable safety remains one of the most important reasons for failure in preclinical and early-phase clinical studies, with 48% of drugs not progressing into Phase I clinical trials due to safety concerns<sup>1</sup>. In addition to GLP Toxicity studies, GLP Safety Pharmacology studies are pivotal studies in identifying potential adverse liabilities of a drug before progressing to testing in humans. EmtinB™ completed the program of non-clinical Safety Pharmacology studies without causing any adverse liabilities.

The Company is currently undertaking non-clinical 4-week GLP Toxicity studies in two animal species, which are the final pivotal studies of its non-clinical neurology safety program and are expected to be completed in Q4 2021.

NeuroScientific is working closely with its clinical development partner Linear Clinical Research to schedule its Phase I clinical study to initiate at the earliest date possible following conclusion of the non-clinical neurology safety program.

**NeuroScientific’s CEO and Managing Director Matt Liddelow commented:** *“We are very pleased to have completed another major determinant of safety with EmtinB™ as we finalise the remaining non-clinical studies in the lead up to starting our first-in-human Phase I clinical*

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<sup>1</sup> Informa UK 2021. Clinical development success rates and contributing factors 2011-2020.

*trial. The Company is at an incredibly exciting point in its existence as we progress towards initiating clinical studies and I look forward to providing further updates in the near future.”*

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](http://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.