

## SUBMISSION FOR HREC APPROVAL OF EARLY-PHASE CLINICAL TRIAL OF EMTINB™

## **HIGHLIGHTS**

- Application submitted for HREC approval to commence an early-phase clinical trial of EmtinB™
- Signals the Company is on schedule to achieve the major milestone of commencing clinical development of EmtinB™ in 1H 2022
- The early-phase clinical trial will include biomarker studies to assess proof of mechanism activity of EmtinB™ and guide efficacy outcomes in future clinical trials in patients

NeuroScientific Biopharmaceuticals Ltd (ASX: **NSB**) ("**NeuroScientific**" or "**the company**") is pleased to announce the application for an early-phase clinical trial involving lead drug candidate EmtinB™ has been submitted for Human Research Ethics Committee (HREC) approval, confirming the Company is on schedule to complete the significant milestone of commencing clinical development of EmtinB™ in 1H 2022. The timeline for approval is expected to be consistent with NeuroScientific's plans to commence the clinical trial in June 2022.

NeuroScientific's Managing Director and Chief Executive Officer Matt Liddelow commented: "I'm pleased to report that NeuroScientific has submitted a very robust data package and clinical trial plan for HREC review and we remain on schedule to achieve the major milestone of commencing clinical development of EmtinB™ during 1H 2022. Most importantly, the Company is one step closer to bringing a much-needed therapeutic option with disease-modifying potential to patients with Alzheimer's disease and Multiple Sclerosis. With the HREC review process underway and other supporting activities well-advanced, NeuroScientific has officially transitioned from being a preclinical to a clinical stage company."

The early-phase clinical trial is the initial stage of the clinical development program involving EmtinB™. An important focus of this study will involve the assessment of biomarkers in human blood samples that indicate proof of the mechanism of activity of EmtinB™ in humans and can be used to guide efficacy outcomes during future trials in patients. The importance of this data is highlighted by the high rate of attrition for drugs in Phase II clinical trials, with up to 70% failing due to lack of efficacy.¹ This clinical trial will include up to 30 healthy participants and will be undertaken by leading WA-based clinical research partner Linear Clinical Research.

A complete overview of the clinical development plan to support the neurology treatment indications for  $\mathsf{EmtinB}^{\mathsf{m}}$  will be provided in a separate announcement in the coming days.

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

-ENDS

<sup>&</sup>lt;sup>1</sup> Grignolo, A & Pretorius, S 2016 Phase III trial failures: costly but preventable. Applied Clinical Trials.

For more information please contact:

Matthew Liddelow CEO and Managing Director ml@neuroscientific.com + 61 8 6382 1805 Lucas Robinson
Investor Relations
Corporate Storytime
lucas@corporatestorytime.com
+ 61 408 228 889

## **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  $EmtinB^{TM}$ , 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 $^{TM}$ . For more information, please visit  $\underline{www.neuroscientific.com}$ 

## About EmtinB™

Emtin $B^{TM}$  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. Emtin $B^{TM}$  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  $EmtinB^{TM}$  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  $EmtinB^{TM}$  in humans.