NeuroScientific
BIOPHARMACEUTICALS
ASX:NSB

ASX ANNOUNCEMENT
1 JULY 2021

EMTINB™ TREATMENT SAFE AND WELL-TOLERATED IN PIVOTAL OCULAR SAFETY STUDY

HIGHLIGHTS

- **EmtinB™ successfully completed the non-clinical 4-week ocular safety and tolerance study without any reported adverse outcomes**
- **The safety study investigated low, mid and high dose groups with the high-dose cohort receiving greater than 3x the planned clinical dose**
- **The pivotal safety study was conducted in the industry recognised gold standard model for non-clinical ocular safety and tolerability**
- **Successful completion of the ocular safety study significantly advances the ocular R&D program towards starting a Phase I clinical study planned for the second half of 2021**

NeuroScientific Biopharmaceuticals Ltd (ASX: **NSB**) (**"NeuroScientific"** or **"the company"**) is pleased to announce that its lead drug candidate EmtinB™ successfully completed the 4-week ocular safety and tolerance study in non-human primates without causing any serious adverse outcomes related to treatment. The study was completed by Toxikon (Bedford, MA,USA) who are FDA audited and approved to perform non-clinical safety and toxicology studies.

The pivotal ocular study, conducted in the industry recognised gold standard model for ocular safety and tolerability, demonstrated that EmtinB administered by intravitreal injection was well tolerated across all dose groups for 28 days and there were no signs of inflammation or reporting of abnormal findings. The comprehensive safety study investigated low-dose, mid-dose, and high-dose study groups, with the high-dose group establishing a safety margin of greater than 3x the planned clinical dose.

NeuroScientific's CEO and Managing Director Matt Liddelow commented:
"NeuroScientific is pleased to report these positive safety results for EmtinB, which is a major advancement for our ocular R&D program in the lead up to starting a Phase I clinical study. Collectively, these positive results, combined with all non-clinical safety data generated to date, provide significant confidence in our progress towards developing EmtinB™ as a safe and effective treatment for ocular conditions that damage the optic nerve, such as glaucoma which is one of the leading causes of blindness globally".

Glaucoma poses a significant public health concern as it is the second leading cause of blindness after cataracts, and this blindness is usually irreversible.

By 2020, it is expected that approximately 76 million people globally will suffer from glaucoma with that number estimated to reach 111.8 million by 2040[1]

Intravitreal injection of drugs is increasingly used for the treatment of a wide variety of retinal diseases. However, adverse events and complications associated with intravitreal injection can often result in drugs been suspended from further development before reaching the market. Ophthalmologists who employ these agents for their patients always consider the potential systemic and ocular risks and benefits of intravitreal therapy and closely monitor the patients for adverse effects that may occur in the immediate or subsequent periods after administration of the drugs. It is therefore paramount for any intravitreal therapy to be extremely safe in order to achieve significant adoption and strong sales.

The company's preclinical ocular safety program is well-advanced with safety pharmacology studies due to report by August 2021. An additional ocular efficacy study, involving an ocular occlusion animal model, is set to report in the same period.

These significant safety results follow the recent announcements of the appointment of experienced drug development professional Paul Rennie as Non-executive Chairman of NeuroScientific, and partnering with Linear Clinical Research for the company's clinical development program with a Phase I study scheduled to start in the second half of 2021.

NeuroScientific's recently appointed Non-executive Chairman Paul Rennie commented: "These safety and tolerability data are very encouraging for the Company as we move towards the first-in-man studies in the 2H CY2021. No adverse reactions at the tested doses is a very important milestone for the technology. No adverse reactions in a well-established preclinical model will of course be very interesting to those pharmaceutical companies developing novel ophthalmic products."

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

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[1] Allison K et al **Epidemiology of Glaucoma: The Past, Present, and Predictions for the Future** Cureus. 2020 Nov; 12(11): e11686. Published online 2020 Nov 24. doi: 10.7759/cureus.11686

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.