



Neuren Initiates Oral Formulation Development for NNZ-2566

Phase II Proof of Concept Study Planned for 2011

SYDNEY, Australia, 18 November 2010: Neuren Pharmaceuticals (ASX:NEU) announced today that it has initiated development of an oral form of NNZ-2566 to treat mild traumatic brain injury (TBI) and other conditions for which an oral drug is more suitable than one administered intravenously. Initial experiments confirm that the liquid microemulsion of NNZ-2566 previously used in an animal model of stroke is an effective formulation. Based on previous pharmacokinetic (PK) studies, the Company has determined that the oral dose required to achieve the blood level being targeted in the current Phase II TBI trial will be reasonable and acceptable using the selected formulation.

On final validation of the current oral formulation, Neuren will conduct additional PK studies, "bridging" toxicology studies that will build on the substantial data generated by the IND-enabling toxicology studies with the intravenous form, and a Phase I safety/PK trial in healthy subjects. When these studies have been successfully completed, the Company plans to submit a clinical study protocol to the U.S. Army, FDA and Institutional Review Boards (IRBs) to conduct a Phase II proof of concept trial in patients with mild TBI. This Phase II trial is currently being designed in coordination with an advisory committee including academic experts and regulatory advisors and including input from U.S. Army neuroscientists. Neuren expects to submit the protocol by Q3 2011. The majority of costs for the NNZ-2566 program are covered by funding from the U.S. Army, including an additional US\$750,000 to cover the oral NNZ-2566 preclinical program.

Mild TBI is an important public health problem and therapeutic target. There are no drugs approved to treat mild TBI. There are an estimated 1.5 million head injuries that occur in the U.S. each year of which approximately 700,000 patients have mild TBI or concussion and are treated and released from the emergency department and another 80,000 with mild TBI are admitted to the hospital. Among U.S. military personnel, of the 178,876 TBIs reported between January 2000 and May 2010, 77% (137,328) were categorized as mild.ⁱ Many people who experience mild TBI have problems with mood, memory and concentration months or even years after the incident. Mild TBI represents a significant cause of disability, often affecting young, otherwise healthy individuals. It is a common sports-related injury and also occurs frequently in soldiers, often association with exposure to blast.

About NNZ-2566

NNZ-2566 is a patented, synthetic analog of the n-terminal tripeptide of IGF-1, a molecule with potent neuroprotective effects in stroke and head injury models. The principal mechanism by which NNZ-2566 appears to exert a neuroprotective effect is by limiting the expression of neuroinflammatory molecules (cytokines) following brain injury. NNZ-2566 also significantly reduces activation of microglia, a type of brain cell involved in the immune response in the central nervous system, but which can result in excessive inflammation following brain injury resulting in additional damage. NNZ-2566 also has been shown to dramatically reduce the incidence of convulsive and non-convulsive seizures in stroke and TBI models, respectively. NNZ-2566 has been in development as a treatment for TBI under a collaborative research and development agreement between Neuren and the U.S. Army since 2004. The U.S. Army has committed more than US\$18m to support the NNZ-2566 program.

About Oral NNZ-2566

Neuren has tested an oral emulsion of NNZ-2566 in an established model of stroke.ⁱⁱ Formulation as a microemulsion significantly increased bioavailability compared to a simple aqueous (water-based) formulation. Statistically significant, dose-dependent neuroprotection was observed when the drug was orally administered 3 hours following injury.

About Neuren

Neuren Pharmaceuticals is a biopharmaceutical company developing novel therapeutics in the fields of brain injury, neurological diseases and conditions, and cancer. Neuren has two clinical-stage molecules, Motiva[®] and NNZ-2566, in Phase II clinical trials largely funded by the National Health and Medical Research Council and the U.S. Army, respectively. Through its subsidiary, Perseis Therapeutics Limited, Neuren is developing monoclonal antibodies against Trefoil Factors 1 and 3, proteins produced by cancer cells that are associated with cancer spread and reduced patient survival. For more information, please visit www.neurenpharma.com.

For more information, contact:

Larry Glass, CEO Tel : +1 301 758 2987

ⁱ Testimony before the DOMESTIC POLICY SUBCOMMITTEE OF THE HOUSE OVERSIGHT AND GOVERNMENT REFORM COMMITTEE (SEPTEMBER 29, 2010).

moonshot.org/testimony/092810%20Testimony%20Terry%20Rauch%20092910.pdf

ⁱⁱ Bickerdike MJ et al. NNZ-2566: A Gly-Pro-Glu analogue with neuroprotective efficacy in a rat model of acute focal stroke. *J Neurol Sci* (2009).