

## US Army to Provide Additional Funding for NNZ-2566 Trial

**Thursday, 4 September 2008**: Neuren Pharmaceuticals (ASX:NEU) today announced that the Company has been informed that an additional US\$5.5 million in funding will be made available by the US Army for the Company's planned Phase II clinical trial of NNZ-2566 in traumatic brain injury (TBI). With the previously announced grant of US\$4 million to cover direct costs of the study, this results in a total commitment of approximately US\$10 million.

Neuren and the US Army intend to initiate the Phase II trial of NNZ-2566 in 200 moderate to severe TBI patients in early 2009. Results of the trial are anticipated to be released in 2010.

As the first study of NNZ-2566 in patients, the primary endpoint of the planned trial will be safety. In addition, a number of secondary endpoints will be included to assess the preliminary efficacy and biological effects of the drug. Efficacy measures will include global functional outcomes, neuropsychological and mood assessments; biological parameters will include non-convulsive seizures (measured using continuous electroencephalography—cEEG), serum-based biomarkers of brain injury and intracranial pressure.

Commenting on the announcement, Larry Glass, Neuren's Co-CEO, said: "This is a very important development for the Company, our US Army collaborators and the physicians who will participate in the trial. The increased level of support clearly reflects the Army's commitment to develop a drug for acute TBI and to continue this extraordinary relationship with Neuren. This will ensure that we have the resources to conduct the trial and that results are delivered as soon as humanly possible. If the drug proves to be safe and effective, our goal is to work with the FDA and the US Army to accelerate development and approval under Fast Track procedures."

As a result of this significant announcement Neuren has decided to extend the Share Purchase Plan (SPP) closing date to Tuesday 16 September 2008 to give participating shareholders further time to consider this announcement, and the announcement recently made by the Company concerning the out-licensing of an early-stage cancer program.

Event	New Date
The SPP Offer closes (Closing Date)	16 September 2008
Proposed share allotment	25 September 2008
Proposed ASX quotation date	26 September 2008

The updated timetable for the SPP is set out below:

Other details of the SPP are contained in the SPP Offer Document to shareholders. The SPP Offer Document contains specific information about the SPP and the Terms and Conditions upon which the Company makes the offer to shareholders. Shareholders are strongly encouraged to read the SPP Offer Document carefully and seek further assistance where necessary.

## **About Traumatic Brain Injury**

TBI is a major cause of mortality, morbidity and disability. Each year in the US alone, there are approximately 1.5 million head injuries resulting in more than 50,000 deaths, 300,000 hospital admissions and 700,000 patient treated in the emergency department. Up to 90,000 patients per year are left with permanent neurological impairment. The cost to society is estimated at more than US\$50 billion per year. TBI also is a critical concern for the military, representing a leading cause of combat deaths and one of the leading contributors to long-term disability among returning service members. The large and disproportionate effect on young people makes TBI a critically important target for development of a safe and effective therapy. There currently are no drugs approved for the treatment of acute TBI.

## About NNZ-2566

NNZ-2566 is a synthetic analogue of Glypromate<sup>®</sup>, Neuren's lead drug, which is in a Phase III trial to reduce cognitive impairment in patients undergoing cardiac surgery with cardiopulmonary bypass. Glypromate<sup>®</sup> is a naturally-occurring neuropeptide derived from Insulin-like Growth Factor 1 (IGF-1). The neuroprotective properties of NNZ-2566 are believed to derive from inhibition of inflammatory and apoptotic (cell death) processes that can result from TBI, possibly by preventing activation of microglia, part of the cellular inflammatory response to brain injury. NNZ-2566 also attenuates non-convulsive seizures that occur following brain injury. A Phase Ib safety study of NNZ-2566 was completed in late 2007 and the drug has been found to be safe and well-tolerated in normal, healthy volunteers. NNZ-2566 has been the subject of a Collaborative Research and Development Agreement with the US Army Walter Reed Army Institute of Research since 2005 to evaluate the drug as a candidate therapeutic for TBI.

## **About Neuren Pharmaceuticals**

Neuren Pharmaceuticals is a biopharmaceutical company developing novel therapeutics in the fields of brain injury, neurological diseases and conditions, and metabolic disorders including cancer. The Neuren portfolio comprises eight product families targeting markets with large unmet needs and limited competition. Neuren has three clinical-stage molecules — Glypromate<sup>®</sup>, Motiva<sup>™</sup> and NNZ-2566 — focused on a range of acute and chronic neurological conditions as well as a discovery program targeting opportunities in the neurosciences and oncology. For more information visit *www.neurenpharma.com*.

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