# Neuren obtains further US$14 million funding from US Army

- **Most costs for the upcoming NNZ-2566 Phase 2 trial to be funded by US Army**
- **Total US Army funding represents approximately A$0.09 per share non-dilutive funding**
- **US FDA approves IND for NNZ-2566 Phase 2 trial**
- **US FDA grants "Fast Track" status**

**SYDNEY, Australia, 1 July 2009:**

Neuren Pharmaceuticals Limited (ASX: NEU) has had an extremely productive collaborative relationship with the US Army that began in 2004 when the drug NNZ-2566 was at an early pre-clinical stage. That relationship has continued as the programme has advanced into the clinic and the US Army has had significant input into the design of the forthcoming Phase 2 clinical trial of NNZ-2566 in traumatic brain injury. As a logical extension of this relationship, the US Army has now approved US$14 million in new funding for that trial. Funds will be provided via a Cooperative Agreement under which Neuren will be reimbursed for direct costs incurred in conducting the trial and in preparing for a possible pivotal trial if the results of the Phase 2 study are positive.

Together with the earlier funding award to the programme through The Geneva Foundation in January 2008, the US Army has now approved total funding for the NNZ-2566 clinical programme of US$18.7 million, representing non-dilutive funding of A$0.09 per share. A small part of the earlier funding has been used to date for clinical trial preparations including initial drug supply.

The US Army funding follows US Food and Drug Administration ("FDA") approval for the Phase 2 trial (IND opened in March). The FDA has also recently granted the trial "Fast Track" designation which accelerates the drug development review and approval process. Neuren is now in the final stages of preparing to begin the Phase 2 trial which will be conducted at up to 12 trauma centres in the US. The Company expects to begin patient enrolment in October 2009.

Commenting on the new Cooperative Agreement, Larry Glass, Neuren CEO, said "The new funding will enable Neuren to accelerate clinical development of NNZ-2566 at a pace that simply would not have been possible without the Army's continued support and at no cost to existing shareholders. The funding was peer reviewed by an independent panel of experts from the US Army, the National Institutes of Health, the Department of Veterans Affairs and leading experts in traumatic brain injury research and treatment. Their approval and the Army's support reflect the potential that NNZ-2566 holds as a potential treatment for traumatic brain injury. This is an exciting and hopeful time, not just for the Company, but also for our uniformed and civilian colleagues and collaborators in both scientific and clinical settings. We are about to begin an ambitious programme; one which we hope will impact the devastating consequences of traumatic brain injury in civilian and military populations alike."

The Cooperative Agreement is between the US Army and Neuren's wholly owned US based subsidiary. As previously announced, Neuren is seeking direct investment to the US subsidiary to support the NNZ-2566 and other programmes and will also be making a Share Purchase Plan offer to shareholders, the terms of which will be announced as soon as regulatory approvals are received.

**About the NNZ-2566 Clinical Programme**

NNZ-2566 is a synthetic analogue of Glypromate®, 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 traumatic brain injury ("TBI") by preventing activation of microglia, part of the cellular inflammatory response to brain injury. In animal models, NNZ-2566 also attenuates convulsive and non-convulsive seizures that tend to occur following brain injury. Phase 1 safety studies of NNZ-2566 were 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.

The Phase 2 clinical trial will seek to enroll a total of 260 patients with moderate to severe TBI. The drug will be administered as a standard intravenous bolus dose (rapid infusion) within 8 hours of injury followed by 72 hours of continuous infusion at one of three doses. The trial is designed as a dose-escalation study with 3 cohorts. All patients enrolled will receive a 20 mg/kg bolus. The first cohort of 30 patients will then receive 1 mg/kg/hr for 72 hours; the second cohort of 30 patients will receive 3 mg/kg/hr for 72 hours; the third cohort of 200 patients will receive 6 mg/kg/hr for 72 hours. The Data Safety Monitoring Committee will review adverse event and other safety data from 30 days of follow up on each cohort before allowing progression to the next cohort.

As the first study of NNZ-2566 in patients, the primary endpoint of the planned trial will be safety. 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. An interim analysis of safety and efficacy is planned after the first 100 patients have been enrolled and followed for 90 days. If the results of this interim analysis are positive, Neuren intends to initiate a proof of concept study in patients with mild TBI, as well.

The new Cooperative Agreement results from a proposal submitted by Neuren to a Broad Agency Announcement, a competitive funding solicitation managed by the US Army Medical Research Acquisition Activity (USAMRAA), the contracting element for the US Army Medical Research and Materiel Command (USAMRMC). The proposal was peer-reviewed by an independent panel of experts from the US Army, the National Institutes of Health (NIH), the Department of Veterans Affairs and leading experts in TBI research and treatment. The review process was coordinated by the Combat Casualty Care Research Program, one of the programs that comprise the USAMRMC and the principal proponent of the collaborative program for NNZ-2566.

**About Neuren**

Neuren Pharmaceuticals is a biopharmaceutical company developing novel therapeutics in the fields of brain injury, neurological diseases and conditions, and cancer. The Neuren portfolio comprises seven product families targeting markets with large unmet needs and limited competition. Neuren has two clinical-stage molecules — Motiva™ and NNZ-2566 — focused on a range of acute and chronic neurological conditions as well as a number of drug discovery programs focused on important targets in neurology and, through its subsidiary Perseis Therapeutics Limited, oncology. For more information, please visit www.neurenpharma.com.

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