# Neuren Completes Additional Phase I Safety Study for NNZ-2566 in Traumatic Brain Injury (TBI)

- **Data shows no significant difference from previously studied male patients**
- **Phase II protocol amendment will include female patients**

**SYDNEY, Australia, 16 November 2010:** Neuren Pharmaceuticals (ASX:NEU) announced today that a Phase I safety and pharmacokinetics trial of NNZ-2566 in healthy female subjects has been completed. Results of the trial indicate that NNZ-2566 appears to be safe and well-tolerated at the highest dose planned for the ongoing Phase II trial in patients with traumatic brain injury (TBI). There were no serious adverse events reported.

Adverse events reported were generally mild and the incidence of adverse events was exactly the same in patients who received drug as in those who received placebo. Further, the blood levels of NNZ-2566 in female subjects were directly comparable to those in males such that no adjustment of dose based on gender will be required for the Phase II trial. The independent Data Safety and Monitoring Committee (DSMC) have recommended that females be included in the Phase II trial. Neuren is preparing a protocol amendment for submission to the FDA and Institutional Review Boards (IRBs) to include female patients in the Phase II trial. The amendment is expected to be submitted to the U.S. Army before the end of November and to the FDA shortly thereafter. Approximately 25-30% of TBI patients admitted to hospitals are female.

Commenting on the results of the Phase I study, Larry Glass, Neuren's CEO, said: "This is an important outcome for the Company. The results of the Phase I trial confirm the safety profile of NNZ-2566 established in previously completed Phase I studies, validate our decision to utilize a buffer for drug reconstitution and justify inclusion of female patients in Phase II. We will begin enrolling female patients as soon as the protocol amendment is approved by the FDA and IRBs. This will help us meet our enrolment goals as the *INTREPID*$^{-2566}$ study progresses and ensure that women will have equal access to the potential benefits of the drug."

**About the Phase I trial**

The Phase I study, Neu-2566-HV-004, was conducted under a U.S. IND by the Nucleus Network (Assoc. Prof. Peter Hodsman, Medical Director) at the Alfred Medical Research Education Precinct Centre for Clinical Studies in Melbourne. The trial involved five cohorts of 8 patients in total with 6/8 receiving drug and 2/8 receiving placebo (saline). The total dose administered was increased from cohort to cohort following review by an independent DSMC. The highest dose was a 10 minute bolus or loading dose of 20 mg of drug per kg of body weight (mg/kg) followed by 72 hours of continuous infusion at 6 mg/kg/hr.

This Phase I study was the first safety study to employ the buffered infusion product which is being used in the Phase II TBI trial of NNZ-2566. The buffered solution significantly reduced the incidence of infusion site reactions and had no detectable effect on safety or pharmacokinetics. The incidence of infusion site reactions was the same in patients receiving drug and those receiving placebo.

**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. Studies have shown that NNZ-2566 is effective when administered both as an intravenous infusion and in oral form. 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 US$18 million to support the NNZ-2566 program.

**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 trial 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.

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