Neuren completes moderate TBI Phase 1b safety trial of NNZ-2566

- **First two cohorts to support moderate TBI trial complete**
- **Phase 2 TBI trial planning on track**

Thursday 20 September 2007: Neuren Pharmaceuticals (ASX: NEU) today announced that it has completed cohorts 1 and 2 of its Phase 1b trial to test the safety, tolerability and pharmacokinetic action of NNZ-2566 as a compound to treat traumatic brain injury (TBI). The completed cohorts provide Neuren with sufficient safety data to be able to proceed with its moderate TBI Phase 2 trial, and Neuren expects to file the ethics application in the last quarter of 2007.

Each cohort in the Phase 1b study comprised seven patients – five who received drug and two who received placebo. Cohort 1 was dosed with 20 mg/kg of NNZ-2566, via 10 minute infusion, followed by 1 mg/kg/hr of NNZ-2566 for 12 hours. Cohort 2 entailed 20 mg/kg by 10 minute infusion, followed by 3 mg/kg/hr for 24 hours.

A safety report on Cohorts 1 and 2 has been submitted to the Local Ethics Committee in Australia for review and has resulted in a recommendation to proceed with dosing of Cohort 3. Cohorts 3 and 4 aim to provide higher doses and longer infusions for severe TBI, with cohorts of 20mg bolus and 3 mg/kg/hour for 48 hours, and 20mg bolus and 6 mg/kg/hour for 72 hours, respectively. The completion of Cohorts 3 and 4 will enable Neuren to proceed with a severe TBI Phase 2a trial, which is due to start in mid-2008 in the United States in conjunction with the US Army.

Development of clinical protocols for the Phase 2 trial in moderate TBI and the Phase 2 trial in severe TBI is nearing completion with approval by Neuren's clinical advisory board expected imminently. Neuren's clinical advisory board includes a number of world-renowned experts in TBI treatment and clinical trials including the former chief of neurosurgery at the Walter Reed Army Medical Center, the former chief of neurology at the Uniformed Services University of the Health Sciences (the US Department of Defense medical school), and a Professor of Neurosurgery and former Director of the Neuroscience Intensive Care Unit at Virginia Commonwealth University.

The moderate TBI trial protocol includes a comprehensive set of end points that Neuren believes provides the greatest chance of an efficacy signal. These endpoints include an assessment of cognitive performance, mood state, activities of daily living, post-concussion symptoms, global disability outcomes, and access to a novel set of brain injury biomarkers under development by a US company, Banyan Biomarkers Inc.

Mr David Clarke, Chief Executive Officer of Neuren, stated: "I am extremely pleased with the progress of our Phase 1b trial. The NNZ-2566 TBI programme is very much on track. Our partnership with the US Army and commitment to accelerating the development NNZ-2566 has enabled us to achieve our milestones with remarkable efficiency. We and they remain extremely optimistic about the promise of this critically important programme".

Clinical Appendix

The following additional information is provided in accordance with the Code of Best Practice for ASX Reporting by Life Science Companies.

Trial Title: A Phase Ib, single ascending dose, safety and pharmacokinetic study of NNZ-2566 in healthy volunteers.

Objectives: The unblinded trial aims to establish the safety of NNZ-2566 in humans. Data will also be obtained to understand the distribution of NNZ-2566 in the body to allow for the establishment of safe dosing levels for future trials. Proposed future trials will aim to test both the efficacy and safety of NNZ-2566 in patients with mild-to-moderate and severe traumatic brain injury (TBI).

Investigators:
Clinical Investigator: Dr Peter Hodsman
Project Manager: Dr Kathleen Durbin, Neuren Pharmaceuticals

Primary Objective: To establish safety, tolerability and pharmacokinetic action of NNZ-2566 in humans.

Secondary Objective: To understand the distribution of NNZ-2566 in the body to allow for the establishment of safe dosing levels for future trials.

Method: Four cohorts, each comprising seven healthy male volunteers. Starting from a very low dose the health and safety of each volunteer will be thoroughly checked before further higher dose levels are administered to other volunteers.

- **Cohort 1:** Five volunteers receive 20 mg/kg of NNZ-2566, via 10-min infusion, followed by 1 mg/kg/hr of NNZ-2566 for 12 hours. The remaining two receive placebo.
- **Cohort 2:** Five volunteers receive 20 mg/kg, 10-min infusion, followed by 3 mg/kg/hr for 24 hours. The remaining two receive placebo.
- **Cohort 3**: Five volunteers receive 20 mg/kg of NNZ-2566, via 10-min infusion, followed by 3 mg/kg/hr of NNZ-2566 for 48 hours. The remaining two receive placebo.
- **Cohort 4**: Five volunteers receive 20 mg/kg of NNZ-2566, via 10-min infusion, followed by 6 mg/kg/hr of NNZ-2566 for 72 hours. The remaining two receive placebo.

Trial Endpoints: The results of Cohorts 1 and 2 were submitted to the Local Ethics Committee in Australia for review of safety, tolerability and pharmacokinetic action of NNZ-2566. No drug-related adverse affects were noted and the trial was given approval to proceed with dosing of Cohort 3 and 4.

About Neuren Pharmaceuticals

Neuren Pharmaceuticals (ASX: NEU) is a biopharmaceutical company developing novel therapeutics in the fields of brain injury and diseases and metabolic disorders. The Neuren portfolio consists of six product families, targeting markets with large unmet needs and limited competition. Neuren has three lead candidates, Glypromate® and NNZ-2566, presently in clinical trials to treat a range of acute neurological conditions, and NNZ-2591 in preclinical development for Parkinson's and other chronic conditions. Neuren has commercial and development partnerships, including with the U.S. Army Walter Reed Army Institute of Research, Metabolic Pharmaceuticals, UCLA Medical Center and the National Trauma Research Institute in Melbourne.

For more information, please visit Neuren's website at www.neurenpharma.com

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