Neuren Initiates Phase II Trial of NNZ-2566

SYDNEY, Australia, 6 May 2010: Neuren Pharmaceuticals (ASX:NEU) announced today that its Phase II clinical trial of NNZ-2566 has been initiated. The trial, designated ***INTREPID^{2566}***, is being conducted in collaboration with the US Army which is covering the majority of direct costs associated with the study. Twelve Level I and II trauma centres in the United States are expected to participate as clinical trial sites. The University of Miami was the first site to become fully operational. The principal investigator at the University of Miami is Prof. M. Ross Bullock, MD, PhD, an internationally-recognised expert on brain injury research and clinical trials and a member of the joint Neuren-US Army Advisory Committee. The second fully operational site is Arrowhead Regional Medical Center in Colton, California. Dr. Javed Siddiqi, MD, PhD, Director of the Institute of Clinical Orthopedics and Neurosciences and a leading authority on neurosurgical intensive care, is the principal investigator at Arrowhead. Both sites are actively screening and recruiting patients for the study.

The ***INTREPID^{2566}*** trial will seek to enrol a total of 260 patients with moderate to severe brain injury. Patients will be randomised 2:1 for drug and placebo and stratified 2:1 in favour of drug versus placebo. In addition to safety, the study includes two endpoints that measure overall patient function, a wide range of neuropsychological measures and physiological assessments in the form of EEG monitoring and serum-based biomarkers. Patient enrolment is expected to take approximately 18 months. In addition to the 12 sites already committed to the study, backup sites have been identified in the event that enrolment is slower than anticipated.

While the Phase II trial is running, Neuren will undertake additional preclinical and clinical studies that are necessary to engage in a pivotal or registration trial. These include reproductive toxicology studies in animals, a cardiovascular safety study in human volunteers and a safety and pharmacokinetics study in female volunteers, the latter a requirement for enrolling women in the Phase II and subsequent trials. The reproductive toxicology studies have been initiated as has the safety and pharmacokinetics study in females which is being conducted at Nucleus Network Limited's Centre for Clinical Studies in Melbourne. The first cohort of the safety and pharmacokinetics study has been completed with no adverse events reported.

Commenting on the start-up of the Phase II trial, Larry Glass, Neuren's CEO said, "We are delighted that this critically important and ambitious trial is now off the ground. Getting to this point has required great dedication and a concerted effort on the part of the Company's staff, consultants and collaborators not to mention patience and commitment on the part of our investors, for all of which we are deeply appreciative. We are confident that the study's design and the painstaking groundwork that has been laid will pay off in the successful execution of the trial. Knowing that, between the financing announced at the end of 2009 and funding from the US Army, we have access to all of the capital resources needed to complete the study contributes significantly to our level of confidence. Most importantly, however, as this trial begins, we are hopeful that we

will be able to answer the desperate need for a drug that can make a real difference for the hundreds of thousands of people worldwide who suffer a brain injury each year."

Initiation of the trial was delayed by the need to develop a buffer system for reconstitution of the drug. In the Phase Ib study, injection site reactions occurred in some patients receiving higher doses for longer periods. These reactions were believed to result predominantly from the acidity (pH 3.7) and concentration (osmolarity) of the drug. While the reactions were not classified as serious adverse events and were not raised by the FDA as a safety issue, the Company was concerned that their appearance could make it obvious to clinical staff which patients were receiving the study drug and which were receiving placebo, with the risk of inadvertently unblinding the study. A buffer system that produces an infusion solution with normal physiologic pH and osmolarity has now been successfully developed and tested and has been provided to the clinical sites along with the drug product for use in the trial. This administration of buffered drug in humans was used in the first cohort of the safety and pharmacokinetics study noted above with no adverse events reported. Additional development work on drug manufacturing also is ongoing with a 30-35% increase in yield for clinical batches already achieved as well as a targeted reduction in impurities.

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 six 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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neuren pharmaceuticals

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 II, randomized, double-blind, placebo-controlled, dose-escalation study of NNZ-2566 in patients with traumatic brain injury (TBI).

Objectives: The trial aims to evaluate the safety and pharmacokinetics of NNZ-2566 in patients with moderate to severe TBI (GCS 4-12) when administered for a total of 72 hours commencing within 8 hours post-injury, and also provide preliminary evidence of efficacy. The study is to be performed at 12 trauma centres across the US.

Project Manager: Maggie Scott, Neuren Pharmaceuticals

Primary Objective: To obtain evidence of the safety of NNZ-2566 in TBI patients.

Secondary Objectives:

- To obtain preliminary evidence of the efficacy of NNZ-2566 compared to placebo, in modifying global outcomes.
- To obtain preliminary evidence of the efficacy of NNZ-2566 compared to placebo, in the improvement of cognitive and neuropsychological functioning.
- To obtain preliminary evidence of the efficacy of NNZ-2566 compared to placebo, in modifying the acute physiological processes in TBI, and biomarker levels.
- To determine the blood pharmacokinetics (PK) of NNZ-2566 in TBI patients (10 patients per cohort).

Method: Approximately 260 patients admitted to hospital with moderate to severe TBI (GCS 4-12). Approximately 173 moderate (GCS 9-12) and 87 severe (GCS 4-8) TBI patients will be recruited.

Cohort 1 (n=30): Thirty patients will receive either 20 mg/kg intravenous infusion of NNZ-2566 over 10 minutes immediately followed by a 1 mg/kg/h maintenance dose or placebo for 72 hours in a ratio of 2 :1.

Cohort 2 (n=30): Thirty patients will receive either 20 mg/kg intravenous infusion of NNZ-2566 over 10 minutes immediately followed by a 3 mg/kg/h maintenance dose or placebo for 72 hours in a ratio of 2 :1.

Cohort 3 (n=200): Two hundred patients will receive either a 20 mg/kg intravenous infusion of NNZ-2566 over 10 minutes immediately followed by a 6 mg/kg/h maintenance dose or placebo for 72 hours in a ratio of 2 :1.

A quota recruitment strategy will ensure that approximately 173 patients with moderate TBI will be recruited and 87 with severe TBI. Comparison with placebo treatment (n=87) will be made to determine safety and to obtain preliminary evidence of efficacy.

Trial Endpoints: The primary endpoint for the trial is safety. Secondary endpoints will assess efficacy. These include functional outcome measures (Glasgow Outcome Scale-Extended and Mayo Portland Adaptability Index), a range of neuropsychological measures, and biological

endpoints (convulsive and non-convulsive seizures, biomarkers of cellular damage and intracranial pressure).

Dose escalation criteria: The data from each cohort will be submitted to a DSMC for review of safety and pharmacokinetics. Based on the outcome of the DSMC review the Committee will recommend whether to continue to the next higher dose.